State of Utah

GARY R. HERBERT
Governor

SPENCER J. COX
Lieutenant Governor

Department of
Environmental Quality

L. Scott Baird
Executive Director

DIVISION OF WASTE MANAGEMENT
AND RADIATION CONTROL
Ty L. Howard
Director

A meeting of the Waste Management and Radiation Control Board has been scheduled for
July 9, 2020 at 1:30 p.m.
This is an electronic/telephonic meeting. No Anchor Location.
All Board members and any interested persons will participate electronically/telephonically.

Join with Google Meet:
https://meet.google.com/htn-sibw-jpy

Join by phone: 1 507-881-0032
PIN: 412 749 366#

(This meeting is being held in accordance with Governor Gary Herbert's EXECUTIVE ORDER Suspending the Enforcement of Provisions of Utah Code §§ 52-4-202 and 52-4-207, and Related State Agency Orders, Rules, and Regulations, Due to Infectious Disease COVID-19 Novel Coronavirus.)

AGENDA

I. Call to Order.

II. Public Comments on Agenda Items.

III. Declarations of Conflict of Interest.

IV. Approval of Meeting Minutes for the May 14, 2020 Board meeting ..... Tab 1 (**Board Action Item**).

V. Underground Storage Tanks Update..... Tab 2

VI. Administrative Rules ..... Tab 3

A. Approval to proceed with formal rulemaking and 30-day public comment period on proposed rule changes to UAC R315-261, 262, 264, 265, 266, 268, 270, and 273 of the hazardous waste rules to incorporate federal regulatory changes promulgated by the Environmental Protection Agency (EPA) and published in the Federal Register on February 22, 2019 (84 FR 5816) (**Board Action Item**).

(Over)

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VII. Low-Level Radioactive Waste..... Tab 4

A. Energy*Solutions* request for a site-specific treatment variance from the Hazardous Waste Management Rules. Energy*Solutions* seeks authorization to receive and dispose of waste containing hazardous constituents and PCBs as Underlying Hazardous Constituents **(Board Action Item**).

VIII. Hazardous Waste Section ..... Tab 5

A. Revised proposed Stipulation and Consent Order between the Director and Tooele Army Depot South Area (Information Item Only).

B. Proposed Stipulation and Consent Order between the Director and Thermo Fluids Inc. (Information Item Only).

IX. Other Business.

A. Miscellaneous Information Items.
B. Scheduling on next Board meeting (August 13, 2020).

X. Adjourn.

In compliance with the Americans with Disabilities Act, individuals with special needs (including auxiliary communicative aids and services) should contact Larene Wyss, Office of Human Resources at (801) 536-4284, Telecommunications Relay Service 711, or by email at “lwyss@utah.gov”.

Waste Management and Radiation Control Board Electronic/Telephonic Board Meeting Minutes
May 14, 2020
1:30 p.m.

No Anchor Location. All Board members participated electronically OR telephonically. UDEQ employees and others from the general public also participated either electronically or telephonically. This meeting was held in accordance with Governor Gary Herbert's EXECUTIVE ORDER Suspending the Enforcement of Provisions of Utah Code §§ 52-4-202 and 52-4-207, Due to Infectious Disease COVID-19 Novel Coronavirus.

Board Members Participating (Electronically/Telephonically): Brett Mickelson (Chair), Dennis Riding (Vice-Chair), Richard Codell, Danielle Endres, Marc Franc, Steve McIff, Shawn Milne, Nathan Rich, Vern Rogers and Shane Whitney

Board Members Absent/Excused: Scott Baird and Jeremy Hawk

Staff Members Participating (Electronically/Telephonically): Ty Howard, Brent Everett, Thomas Ball, Jalynn Knudsen, Arlene Lovato, Rusty Lundberg, Deborah Ng, Erica Smith, Otis Willoughby

I. Call to Order.
Brett Mickelson called the meeting to order at 1:35 pm. Roll call was conducted (see above).

II. Public Comments on Agenda Items. None.

III. Declarations of Conflict of Interest. None.

IV. Approval of Meeting Minutes for the April 9, 2020 Electronic/Telephonic Board Meeting (Board Action Item).

It was moved by Nathan Rich and seconded by Richard Codell and UNANIMOUSLY CARRIED to approve the April 9, 2020 Board Meeting Minutes.

V. Underground Storage Tanks Update.

Brent Everett, Director of the Division of Environmental Response and Remediation (DERR), informed the Board that the cash balance of the Petroleum Storage Tank (PST) Trust Fund at the end of March 2020 was $16,353,246.00. The preliminary estimate for the cash balance of the PST Trust Fund for the end of April 2020 is $16,643,155.00. The PST Trust Fund is managed on a cash balance basis to ensure sufficient coverage for known claims that have been reported. The balance of the PST Trust Fund is watched closely to ensure sufficient coverage for covered releases. There were no questions or comments.

VI. Administrative Rules.

A. Approval to proceed with formal rulemaking and 30-day public comment period on proposed rule changes to UAC R315-270-42 of the hazardous waste rules to standardize language in Subsections R315-270-42(a)(1)(ii), R315-270-42(b)(2), R315-270-42(c)(2) and R315-270-42(e)(2)(iii) requiring a permitee to send notices to the facility mailing list and to appropriate units of State and local governments (Board Action Item).

Tom Ball, Planning and Technical Support Section Manager reviewed the request for the Board to approve and proceed with formal rulemaking and public comment on proposed changes to R315-270-42 of the hazardous waste rules to standardize language in Subsections R315-270-42(a)(1)(ii), R315-270-42(b)(2),

R315-270-42(c)(2) and R315-270-42(e)(2)(iii) requiring a permitee to send notices to the facility mailing list and to appropriate units of State and local governments.

Subsections R315-270-42(a)(1)(ii), R315-270-42(b)(2), R315-270-42(c)(2) and R315-270-42(e)(2)(iii) all require a permittee to send notices to the facility mailing list and to appropriate units of State and local governments. The text in each of these subsections is clear in stating the requirement. All these subsections should make reference to Subsections R315-124-10(c)(1)(ix) and (x) where the requirement is detailed. However, Subsections R315-270-42(c)(2) and (e)(2)(iii) only contain the reference to R315-124-10(c)(1)(ix).

The proposed changes correct this by adding "and (x)" to each of these references so that all four subsections contain the same basic language. Additionally, minor formatting corrections have been made throughout Section R315-270-42 to conform with the current standards for rule writing.

The proposed changes to R315-270-42 were included with the May 14, 2020 Board packet. The Board is authorized under Subsection 19-6-105(1)(c) to make rules governing generators and transporters of hazardous waste and owners and operators of hazardous waste treatment, storage and disposal facilities. The rule changes also meet existing DEQ and state rulemaking procedures.

Board approval is necessary to begin the formal rulemaking proc[illegible] by filing the appropriate documents with the Office of Administrative Rules for publishing the propose[illegible]ule c[illegible]nges in the Utah State Bulletin and conducting a public comment period.

The Director recommended the Board approve proce[illegible]ng with [illegible]rmal rulemaking and public comment by publishing in the June 1, 2020, Utah State Bulletin the p[illegible]o[illegible]d changes to UAC R315-270-42 and conducting a public comment period from June 1, 2020 to J[illegible]y 1, 2020.

It was motioned by Danielle Endres and seco[illegible]led b[illegible]is Riding and UNANIMOULSY CARRIED to approve to proceed with formal rulemaking [illegible] a 30-day public comment period on proposed rule changes to UAC R315-270-42 of th[illegible]haza[illegible]dous [illegible]aste rules to standardize language in Subsections R315-270-42(a)(1)(ii), R315-270-[illegible]2(b)(2), R315-2[illegible]0-42(c)(2) and R315-270-42(e)(2)(iii).

B. Federal Regulation Adoption [illegible]Rule Formatting Procedure (Information Item Only).

Rusty Lundberg, Depu[illegible] Director o[illegible]he Division of Waste Management and Radiation Control reviewed the documents provided in t[illegible] Executive Summary provided to the Board in their May 14, 2020 Board packet as reference material for future [illegible]ulem[illegible]ing actions to adopt federal regulation for purposes of maintaining program primacy. The docum[illegible] frames the basis for retaining certain formatting found in a federal regulation when adopting that federal regulation, in whole or in part, in a rulemaking action under consideration by the Waste Management and Radiation Control Board.

Federal law authorizes the delegation or transfer of authority to a state to administer the waste management programs (hazardous waste, solid waste, and used oil) or the radiation control programs (radioactive materials, uranium recovery byproduct material, and radioactive waste).

The Board is authorized by state statute to exercise all rulemaking authority for the waste management and radiation control programs. Accordingly, the Division serves as staff to the Board for rulemaking purposes and essentially entails preparing and formatting the rule text as well as the required rulemaking information found on the appropriate rule analysis form for the Board's consideration and action.

New federal regulations or revisions to existing federal regulations are published by the EPA or NRC in the *Federal Register*. As these agencies promulgate new regulations or changes to existing regulations, a state must also adopt equivalent regulations (rules) in order to maintain the required regulatory equivalency, compatibility, and authority. Adopting federal regulations into the Utah rules can be done by incorporation

by reference or by adding the text of the federal regulation verbatim or with text that, although not identical, meets the essential intent or objective of the federal regulation.

The Office of Administrative Rules (OAR) has compiled and published a rulewriting manual for all state rulewriting and rulemaking entities to use in drafting and formatting the text of a rule. This manual serves to provide guidance on style and formatting. Following the style and formatting of the manual provides clarity and consistency throughout the administrative code. In filing a rulemaking action with OAR, the rule is reviewed by OAR staff to ensure all filing requirements are met and all associated information is provided and meets rule and statutory requirements. The Governor's Office also reviews a rulemaking action for rule style, format, content, and consistency with gubernatorial policy.

Federal style and formatting occasionally may fail to ensure regulatory clarity and the style and formatting found in the OAR rulewriting manual may provide that added clarity. However, in general, the federal style and formatting are sufficiently clear and should be retained in order to ensure regulatory equivalency and compatibility for program primacy.
Consequently, the document addressed by this Executive Summary, as an overview for rule formatting for federal regulation adoption, provides a sufficient basis for using federal style and formatting when such style and formatting are clearly expedient and necessary for regulatory consistency for the regulated community and key program stakeholders and are required for continued program primacy from the EPA or NRC.

The Board is authorized under Section 19-3-104 of the Radiation Control Act, Sections 19-6-104 and 19-6-105 of the Solid and Hazardous Waste Act, and Section 19-6-704 of the Used Oil Management Act to make rules to meet the requirements of federal law and maintain primacy of the radioactive materials, waste, and used oil recycling programs from the federal government. Adoption of federal regulations to maintain program primacy is authorized by state statutes.

This is an informational item for the Board. The document was provided to the Board as reference material for rulemaking actions to adopt federal regulations for purposes of maintaining program primacy. The Director recommended the Board retain this document as a reference source when considering rulemaking actions to adopt federal regulations for purposes of maintaining program primacy.

VII. X-Ray Program.

A. Approval of Mammography Imaging Medical Physicists (MIMP) in accordance with UCA 19-6-104(2)(b) (Board Action Item).

Tom Ball, Planning and Technical Support Manger of the Division of Waste Management and Radiation Control, reviewed the request for the Board's approval of qualified Mammography Imaging Medical Physicists. Mr. Ball stated that individuals referred to as Mammography Imaging Medical Physicists (MIMPs) must submit an application for review of qualifications to be certified by the Board annually. These physicists perform radiation surveys and evaluate the quality control programs of the facilities in Utah providing mammography examinations.

In April 2020, eighteen (18) individuals filed applications to be recertified as a MIMP. Division staff has reviewed the applicant's qualifications and all applicants meet the requirements detailed in R313-28-140 of the Utah Administrative Code. An Executive Summary and a list of the applicants was included in the May 14, 2020 Board packet.

In accordance with Subsection 19-6-104(2)(b) of the Utah Code Annotated, the Board shall review the qualifications of, and issue certificates of approval to, individuals who: (i) survey mammography equipment; or (ii) oversee quality assurance practices at mammography facilities.

The Director of the Division of Waste Management and Radiation Control recommended the Board issue a certificate of approval effective from June 1, 2020 to May 31, 2021 for the applicants reviewed and presented to the Board.

It was moved by Dennis Riding and seconded by Danielle Endres and UNANIMOUSLY CARRIED to approve the Mammography Imaging Medical Physicists (MIMPs) in accordance with UCA 19-6-104(2)(b).

VIII. Low-Level Radioactive Waste.

A. Energy*Solutions* request for a site-specific treatment variance from the Hazardous Waste Management Rules. Energy*Solutions* seeks authorization to receive and dispose of waste requiring treatment with a PCB Underlying Constituent (Information Item Only).

Otis Willoughby, Low Level Radioactive Waste Section Manager, Low-Level Radioactive Waste Section, reviewed Energy*Solutions* request submitted on April 29, 2020, for a one time site-specific treatment variance from the Utah Hazardous Waste Management Rules to dispose of waste containing hazardous constituents and PCBs as Underlying Hazardous Constituents.

Energy*Solutions r*equests approval to dispose of waste that has been chemically treated to meet regulatory treatment standards for all contaminants except PCBs. This request is for approximately 1,000 cubic feet from Energy*Solutions* generator 9105, waste streams 9105-08 and 9105-09. The waste consists of non-liquid characteristically hazardous soils and sludges that are also contaminated with PCB remediation waste at concentrations exceeding the UTS for PCBs.

Treatment standards in R315-268-40 (40 CFR 268.40, 2015 Edition, incorporated by reference) require waste containing characteristic codes be treated to applicable UTS for their specific constituents and for all Underlying Hazardous Constituents (UHCs) listed in R315-268-48. The UTS for the PCBs UHC is 10 mg/kg. Therefore, these regulations require PCBs within waste that is characteristically hazardous be treated to less than 10 mg/kg prior to disposal. Further, the Environmental Protection Agency (EPA) has clarified the disposal of PCB remediation waste in the Toxic Substance Control Act (TSCA) regulations at 40 CFR 761. Disposal criteria for PCB remediation waste is specifically described in 40 CFR 761.61(a)(5)(i)(B)(2)(iii) as follows:

"Bulk PCB remediation wastes with a PCB concentration ≥50 ppm shall be disposed of in a hazardous waste landfill permitted by EPA under section 3004 of RCRA, or by a State authorized under section 3006 of RCRA, or a PCB disposal facility approved under this part." The MWLC is a permitted hazardous waste landfill permitted by the State of Utah. Consequently, if the PCB waste did not contain RCRA hazardous waste codes, but contained the same PCB concentrations, it could be disposed in the MWLC without additional treatment. Therefore, treatment of the PCBs within this waste stream is not required for final disposal of the waste form.

A notice for public comment was published in the Salt Lake Tribune, the Deseret News and the Tooele Transcript Bulletin on May 12, 2020. The comment period began May 13, 2020 and will end June 12, 2020.

Variances are provided for in 19-6-111 of the Utah Solid and Hazardous Waste Act. This is a one-time site-specific variance from an applicable treatment standard as allowed by R315-268.44 of the Utah Administrative Code.

The Director will provide a recommendation at the next Board meeting.

Nathan Rich questioned what techniques would be utilized for stabilization and why the treatment standards do not stabilize the PCBs, and other underlying constituents.

Mr. Orton explained the techniques and the typical stabilization process. Mr. Orton further explained that the main focus is treating the waste for the metals, but the PCBs are at such high concentrations to start with that they can not be destroyed except by incineration and the EPA does not require incineration.

IX. Election of Board Chair and Vice Chair (Board Action Item).

Mr. Mickelson informed the Board that each year a Board Chairman and Vice-Chairman must be elected. Mr. Mickelson conducted the election.

Shawn Milne nominated Brett Mickelson to continue to serve as the Board Chairman, Nathan Rich seconded the nomination. It was UNANIMOUSLY CARRIED that Brett Mickelson continue to serve as the Board Chairman.

Shane Whitney nominated Dennis Riding to continue to serve as the Board Vice-Chairman, Shawn Milne seconded the nomination. It was UNANIMOUSLY CARRIED that Dennis Riding be elected to continue to serve as the Board Vice-Chairman.

X. Other Business.

A. Miscellaneous Information Items.

Ty Howard expressed appreciation to the Board for their willingness to meet electronically during the pandemic. The hope is that in the near future, that some type of "normal" Board meeting can resume. In the meantime, he appreciates the Board's flexibility to meet electronically. It is anticipated that as the Governor outlines plans for "phased-in approach" to reopen, the Board can soon meet in person. However, the timeframe for the reopening has not been determined so the Board will continue to conduct its business electronically.

Richard Codell asked about a recent newspaper article he read regarding budget cuts that may impact the UDEQ. Mr. Howard stated that he is currently working on this matter and does anticipate some budget cuts to occur throughout the Department. Mr. Howard further stated that the Department is working with the Legislature and the Legislative Fiscal Analyst to determine exactly what cuts will be made as each Division within UDEQ will be impacted differently as each has its own distinctive funding mechanisms. Also, it is anticipated that any new projects or any new funding requests will not be granted; base-line budget cuts are anticipated as well.

B. Scheduling of next Board meeting.

The June 11, 2020 Board meeting was cancelled. The next Board meeting is scheduled for July 9, 2020 at 1:30 p.m.

XI. Adjourn.

The meeting adjourned at 2:07 p.m.

UST STATISTICAL SUMMARY

June 1, 2019 -- May 31, 2020

PROGRAM

	June	July	August	September	October	November	December	January	February	March	April	May	(+/-) OR Total
Regulated Tanks	4,084	4,083	4,098	4,093	4,092	4,089	4,081	4,090	4,108	4,113	4,116	4,130	**46**
Tanks with Certificate of Compliance	4,009	4,006	4,022	3,994	3,996	3,997	3,986	3,982	3,992	3,988	4,000	4,006	**(3)**
Tanks without COC	75	77	76	99	96	92	95	108	116	125	116	124	**49**
Cumulative Facilitlies with Registered A Operators	1,298	1,297	1,296	1,293	1,291	1,292	1,292	1,290	1,291	1,291	1,290	1,289	**96.70%**
Cumulative Facilitlies with Registered B Operators	1,298	1,297	1,296	1,293	1,291	1,292	1,292	1,290	1,290	1,291	1,290	1,290	**96.77%**
New LUST Sites	4	1	5	6	14	9	6	6	8	5	2	6	**72**
Closed LUST Sites	2	10	3	2	5	5	3	5	6	7	5	3	**56**
Cumulative Closed LUST Sites	5228	5240	5243	5245	5255	5261	5264	5270	5276	5281	5285	5291	**63**

FINANCIAL

	June	July	August	September	October	November	December	January	February	March	April	May	(+/-)
Tanks on PST Fund	2,692	2,689	2,696	2,675	2,663	2,661	2,647	2,636	2,641	2,637	2,637	2,637	**(55)**
PST Claims (Cumulative)	692	672	673	673	672	672	673	673	674	675	675	681	**(11)**
Equity Balance	-$11,876,207	-$11,102,850	-$10,785,760	-$10,680,862	-$10,323,368	-$10,502,116	-$10,575,676	-$10,309,455	-$9,997,725	-$9,765,034	-$9,475,125	-$9,022,705	**$2,853,502**
Cash Balance	$14,261,804	$15,035,161	$15,352,251	$15,457,149	$15,794,912	$15,616,114	$15,542,604	$15,808,825	$16,120,555	$16,353,246	$16,643,155	$17,095,575	**$2,833,771**
Loans	2	0	1	0	0	0	0	0	0	0	0	0	**-2**
Cumulative Loans	120	120	121	121	121	121	121	121	121	121	121	121	**1**
Cumulative Amount	$4,732,507	$4,732,507	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	$4,738,367	**$5,860**
Defaults/Amount	1	1	1	1	1	1	1	1	1	1	1	1	**0**

	June	July	August	September	October	November	December	January	February	March	April	May	TOTAL
Speed Memos	21	22	18	28	40	40	25	136	53	27	54	32	**496**
Compliance Letters	2	12	3	0	17	19	2	22	30	8	8	7	**130**
Notice of Intent to Revoke	0	0	0	0	0	0	0	1	2	0	0	0	**3**
Orders	2	1	0	0	0	4	3	0	0	0	0	0	**10**

WASTE MANAGEMENT AND RADIATION CONTROL BOARD
Executive Summary
Public Comment -- Proposed Rule Changes
UAC R315-261, R315-262, R315-264, R315-265, R315-266, R315-268, R315-270, and R315-273
July 9, 2020

What is the issue before the Board?	Approval from the Board to proceed with formal rulemaking and public comment on a proposed changes to R315-261, 262, 264, 265, 266, 268, 270, and 273 of the hazardous waste rules to incorporate federal regulatory changes promulgated by the Environmental Protection Agency (EPA) and published in the Federal Register on February 22, 2019 (84 FR 5816). A copy of the Federal Register follows this Executive Summary.
What is the historical background or context for this issue?	Under the current rules for management of hazardous waste, a small portion of pharmaceuticals are regulated as hazardous wastes when disposed. Hospitals, clinics, nursing homes, and other facilities that generate hazardous waste pharmaceuticals have experienced difficulty complying with the framework of the hazardous waste rules. To respond to these concerns and facilitate compliance among healthcare facilities, the Environmental Protection Agency (EPA) has finalized a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare facilities and reverse distributors (facilities that receive and accumulate prescription pharmaceuticals for the purpose of facilitating manufacturer credit). The rule finalized by the EPA in February of 2019 is entitled Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine, commonly called the Pharmaceutical Rule and applies to healthcare facilities that generate, accumulate, or otherwise handle hazardous waste pharmaceuticals and reverse distributors engaged in the management of prescription hazardous waste pharmaceuticals. The rule provides a new set of sector-specific standards for healthcare facilities (for both humans and animals) and reverse distributors for management of their hazardous waste pharmaceuticals in lieu of the existing hazardous waste generator regulations. The final rule amends various parts of R315 and creates R315-266-500 through R315-266-510. Healthcare facilities and reverse distributors must manage their hazardous waste pharmaceuticals under this new set of rules in lieu of operating under R315-262 as they have been. These operating standards include a prohibition on disposing of hazardous waste pharmaceuticals in the sewer, called sewering. The new rules also include a conditional exemption for hazardous waste pharmaceuticals that are also identified as controlled substances by the Drug Enforcement Administration (DEA) and are managed in accordance with DEA regulations. The new rules redefine when containers that held hazardous waste pharmaceuticals are considered empty. The new rules require healthcare facilities that are very small quantity generators (VSQGs) to comply with the sewer prohibition for their hazardous waste pharmaceuticals and allows them the

	option of complying with R315-266-500 through R315-266-510 in lieu of operating under the conditional exemption found in R315-262-14. Additionally, the final rule amends the P075 acute hazardous waste listing for nicotine and salts to indicate that U.S. Food and Drug Administration (FDA)-approved over-the counter (OTC) nicotine replacement therapies (NRTs) are not included in the listing. These rule changes became effective at the Federal level on August 21, 2019. In addition to the proposed changes detailed above, the Division, at the request of the Governor's Office, is correcting typographical and formatting errors found in the rules. The proposed changes to R315-261, 262, 264, 265, 266, 268, 270, and 273 follow this Executive Summary. Major changes associated with the Pharmaceutical Rule are highlighted in yellow.
What is the governing statutory or regulatory citation?	The Board is authorized under Subsection 19-6-105(1)(c) to make rules governing generators and transporters of hazardous waste and owners and operators of hazardous waste treatment, storage and disposal facilities. The rule changes also meet existing DEQ and state rulemaking procedures.
Is Board action required?	Yes. Board approval is necessary to begin the formal rulemaking process by filing the appropriate documents with the Office of Administrative Rules for publishing the proposed rule changes in the *Utah State Bulletin* and conducting a public comment period.
What is the Division Director's recommendation?	The Director recommends the Board approve proceeding with formal rulemaking and public comment by publishing in the August 1, 2020, *Utah State Bulletin* the proposed changes to UAC R315-261, 262, 264, 265, 266, 268, 270, and 273 and conducting a public comment period from August 1 to August 31, 2020.
Where can more information be obtained?	Please contact Tom Ball (801) 536-0251, tball@utah.gov or Rusty Lundberg (801) 536-4257, rlundberg@utah.gov.

R315. Environmental Quality, Waste Management and Radiation Control, Waste Management.
R315-261. General Requirements -- Identification and Listing of Hazardous Waste.

R315-261-4. Exclusions.

(a) Materials which are not solid wastes. The following materials are not solid wastes for the purpose of Rule R315-261:

(1)(i) Domestic sewage; and

(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, except as prohibited by Section R315-266-505 and Clean Water Act requirements at 40 CFR 403.5(b). "Domestic sewage" means untreated sanitary wastes that pass through a sewer system.

(2) Industrial wastewater discharges that are point source discharges subject to regulation under section 402 of the Clean Water Act, as amended. This exclusion applies only to the actual point source discharge. It does not exclude industrial wastewaters while they are being collected, stored or treated before discharge, nor does it exclude sludges that are generated by industrial wastewater treatment.

(3) Irrigation return flows.

(4) Source, special nuclear or by-product material as defined by the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011 et seq.

(5) Materials subjected to in-situ mining techniques which are not removed from the ground as part of the extraction process.

(6) Pulping liquors[~~, i.e.,~~] that is black liquor, that are reclaimed in a pulping liquor recovery furnace and then reused in the pulping process, unless it is accumulated speculatively as defined in Subsection R315-261-1(c).

(7) Spent sulfuric acid used to produce virgin sulfuric acid provided it is not accumulated speculatively as defined in Subsection R315-261-1(c).

(8) Secondary materials that are reclaimed and returned to the original process or processes in which they were generated where they are reused in the production process provided:

(i) Only tank storage is involved, and the entire process through completion of reclamation is closed by being entirely connected with pipes or other comparable enclosed means of conveyance;

(ii) Reclamation does not involve controlled flame combustion, such as occurs in boilers, industrial furnaces, or incinerators;

(iii) The secondary materials are never accumulated in such tanks for over twelve months without being reclaimed; and

(iv) The reclaimed material is not used to produce a fuel, or used to produce products that are used in a manner constituting disposal.

(9)(i) Spent wood preserving solutions that have been reclaimed and are reused for their original intended purpose; and

(ii) Wastewaters from the wood preserving process that have been reclaimed and are reused to treat wood.

(iii) Prior to reuse, the wood preserving wastewaters and spent wood preserving solutions described in Subsections R315-261-4(a)(9)(i) and (ii), so long as they meet [~~all of~~]the following conditions:

(A) The wood preserving wastewaters and spent wood preserving solutions are reused on-site at water borne plants in the production process for their original intended purpose;

(B) Prior to reuse, the wastewaters and spent wood preserving solutions are managed to prevent release to either land or groundwater or both;

(C) Any unit used to manage wastewaters [~~and/~~]or spent wood preserving solutions or both prior to reuse can be visually or otherwise determined to prevent such releases;

(D) Any drip pad used to manage the wastewaters [~~and/~~]or spent wood preserving solutions or both prior to reuse complies with the standards in 40 CFR 265.440 through 265.445, which are adopted and incorporated by reference, regardless of whether the plant generates a total of less than 100 kg/month of hazardous waste; and

(E) Prior to operating pursuant to this exclusion, the plant owner or operator prepares a one-time notification stating that the plant intends to claim the exclusion, giving the date on which the plant intends to begin operating under the exclusion, and containing the following language: "I have read the applicable regulation establishing an exclusion for wood preserving wastewaters and spent wood preserving solutions and understand it requires me to comply at all times with the conditions set out in the regulation." The plant shall maintain a copy of that document in its on-site records until closure of the facility. The exclusion applies so long as the plant meets [~~all~~]each of the conditions. If the plant goes out of compliance with any condition, it may apply to the Director for reinstatement. The Director may reinstate the exclusion upon finding that the plant has returned to compliance with [~~all~~]each of the conditions and that the violations are not likely to recur.

(10) EPA Hazardous Waste Nos. K060, K087, K141, K142, K143, K144, K145, K147, and K148, and any wastes from the coke by-products processes that are hazardous only because they exhibit the Toxicity Characteristic specified in Section R315-261-24, subsequent to generation, these materials are recycled to coke ovens, to the tar recovery process as a feedstock to produce coal tar, or mixed with coal tar prior to the tar's sale or refining. This exclusion is conditioned on there being no land disposal of the wastes from the point they are generated to the point they are recycled to coke ovens or tar recovery or refining processes, or mixed with coal tar.

(11) Nonwastewater splash condenser dross residue from the treatment of K061 in high temperature metals recovery units, provided it is shipped in drums, if shipped and not land disposed before recovery.

(12)(i) Oil-bearing hazardous secondary materials[~~, i.e.,~~] that is sludges, byproducts, or spent materials, that are generated at a petroleum refinery, SIC code 2911, and are inserted into the petroleum refining process, SIC code 2911-including, but not limited to, distillation, catalytic cracking, fractionation, or thermal cracking units[~~, i.e.,~~] namely cokers, unless the material is placed on the land, or speculatively accumulated before being so recycled. Materials inserted into thermal cracking units are excluded under Subsection R315-261-4(12)(i), provided that the coke product also does not exhibit a characteristic of hazardous waste. Oil-bearing hazardous secondary materials may be inserted into the [~~same~~]the

petroleum refinery where they are generated, or sent directly to another petroleum refinery and still be excluded under this provision.

Except as provided in Subsection R315-261-4(a)(12)(ii), oil-bearing hazardous secondary materials generated elsewhere in the petroleum industry[~~, i.e.,~~] namely from sources other than petroleum refineries, are not excluded under Section R315-261-4. Residuals generated from processing or recycling materials excluded under Subsection R315-261-4(a)(12)(i), where such materials as generated would have otherwise met a listing under Sections R315-261-30 through R315-261-35, are designated as F037 listed wastes [~~when~~]if disposed of or intended for disposal.

(ii) Recovered oil that is recycled in the [~~same~~]manner and with the [~~same~~]conditions as described in Subsection R315-261-4(a)(12)(i). Recovered oil is oil that has been reclaimed from secondary materials, including wastewater, generated from normal petroleum industry practices, including refining, exploration and production, bulk storage, and transportation incident thereto, SIC codes 1311, 1321, 1381, 1382, 1389, 2911, 4612, 4613, 4922, 4923, 4789, 5171, and 5172. Recovered oil does not include oil-bearing hazardous wastes listed in Sections R315-261-30 through 35; however, oil recovered from such wastes may be considered recovered oil. Recovered oil does not include used oil as defined in Subsection 19-6-703(19).

(13) Excluded scrap metal includes [~~(~~]processed scrap metal, unprocessed home scrap metal, and unprocessed prompt scrap metal[~~)~~] being recycled.

(14) Shredded circuit boards being recycled provided that they are:

(i) Stored in containers sufficient to prevent a release to the environment prior to recovery; and

(ii) Free of mercury switches, mercury relays and nickel-cadmium batteries and lithium batteries.

(15) Condensates derived from the overhead gases from kraft mill steam strippers that are used to comply with 40 CFR 63.446(e). The exemption applies only to combustion at the mill generating the condensates.

(16) Reserved.

(17) Spent materials, as defined in Section R315-261-1, other than hazardous wastes listed in Sections R315-261-30 through 35, generated within the primary mineral processing industry from which minerals, acids, cyanide, water, or other values are recovered by mineral processing or by beneficiation, provided that:

(i) The spent material is legitimately recycled to recover minerals, acids, cyanide, water or other values;

(ii) The spent material is not accumulated speculatively;

(iii) Except as provided in Subsection R315-261-4(a)(17)(iv), the spent material is stored in tanks, containers, or buildings meeting the following minimum integrity standards: a building shall be an engineered structure with a floor, walls, and a roof [~~all~~]each [~~of which are~~]being made of non-earthen materials providing structural support, except smelter buildings may have partially earthen floors provided the secondary material is stored on the non-earthen portion, and have a roof suitable for diverting rainwater away from the foundation; a tank shall be free standing, not be a surface

impoundment, as defined in Section R315-260-10, and be manufactured of a material suitable for containment of its contents; a container shall be free standing and be manufactured of a material suitable for containment of its contents. If tanks or containers contain any particulate which may be subject to wind dispersal, the owner[~~/~~] or operator shall operate these units in a manner which controls fugitive dust. Tanks, containers, and buildings shall be designed, constructed and operated to prevent significant releases to the environment of these materials.

(iv) The Director may make a site-specific determination, after public review and comment, that only solid mineral processing spent material may be placed on pads rather than tanks containers, or buildings. Solid mineral processing spent materials do not contain any free liquid. The Director shall affirm that pads are designed, constructed and operated to prevent significant releases of the secondary material into the environment. Pads shall provide the [~~same~~]degree of containment afforded by the non-RCRA tanks, containers and buildings eligible for exclusion.

(A) The Director shall also consider if storage on pads poses the potential for significant releases via groundwater, surface water, and air exposure pathways. Factors to be considered for assessing the groundwater, surface water, air exposure pathways are: The volume and physical and chemical properties of the secondary material, including its potential for migration off the pad; the potential for human or environmental exposure to hazardous constituents migrating from the pad via each exposure pathway, and the possibility and extent of harm to human and environmental receptors via each exposure pathway.

(B) Pads shall meet the following minimum standards: Be designed of non-earthen material that is compatible with the chemical nature of the mineral processing spent material, capable of withstanding physical stresses associated with placement and removal, have run on[~~/~~] and runoff controls, or both, be operated in a manner which controls fugitive dust, and have integrity assurance through inspections and maintenance programs.

(C) Before making a determination under Subsection R315-261-4(a)(17)(iv), the Director shall provide notice and the opportunity for comment to [~~all~~]each person[~~s~~] potentially interested in the determination. This can be accomplished by placing notice of this action in major local newspapers, or broadcasting notice over local radio stations.

(v) The owner or operator provides notice to the Director providing the following information: The types of materials to be recycled; the type and location of the storage units and recycling processes; and the annual quantities expected to be placed in land-based units. This notification shall be updated [~~when~~]if there is a change in the type of materials recycled or the location of the recycling process.

(vi) For purposes of Subsection R315-261-4(b)(7), mineral processing spent materials shall be the result of mineral processing and may not include any listed hazardous wastes. Listed hazardous wastes and characteristic hazardous wastes generated by non-mineral processing industries are not eligible for the conditional exclusion from the definition of solid waste.

(18) Petrochemical recovered oil from an associated organic

chemical manufacturing facility, where the oil is to be inserted into the petroleum refining process, SIC code 2911, along with normal petroleum refinery process streams, provided:

(i) The oil is hazardous only because it exhibits the characteristic of ignitability, as defined in Section R315-261-21, [~~and/~~]or toxicity for benzene or both, Section R315-261-24, waste code D018; and

(ii) The oil generated by the organic chemical manufacturing facility is not placed on the land, or speculatively accumulated before being recycled into the petroleum refining process. An "associated organic chemical manufacturing facility" is a facility where the primary SIC code is 2869, but where operations may also include SIC codes 2821, 2822, and 2865; and is physically co-located with a petroleum refinery; and where the petroleum refinery to which the oil being recycled is returned also provides hydrocarbon feedstocks to the organic chemical manufacturing facility. "Petrochemical recovered oil" is oil that has been reclaimed from secondary materials[~~, i.e.,~~] that is sludges, byproducts, or spent materials, including wastewater, from normal organic chemical manufacturing operations, as well as oil recovered from organic chemical manufacturing processes.

(19) Spent caustic solutions from petroleum refining liquid treating processes used as a feedstock to produce cresylic or naphthenic acid unless the material is placed on the land, or accumulated speculatively as defined in Subsection R315-261-1(c).

(20) Hazardous secondary materials used to make zinc fertilizers, provided that the following conditions specified are satisfied:

(i) Hazardous secondary materials used to make zinc micronutrient fertilizers shall not be accumulated speculatively, as defined in Subsection R315-261-1(c)(8).

(ii) Generators and intermediate handlers of zinc-bearing hazardous secondary materials that are to be incorporated into zinc fertilizers shall:

(A) Submit a one-time notice to the Director, which contains the name, address and EPA ID number of the generator or intermediate handler facility, provides a brief description of the secondary material that will be subject to the exclusion, and identifies when the manufacturer intends to begin managing excluded, zinc-bearing hazardous secondary materials under the conditions specified in Subsection R315-261-4(a)(20).

(B) Store the excluded secondary material in tanks, containers, or buildings that are constructed and maintained in a way that prevents releases of the secondary materials into the environment. At a minimum, any building used for this purpose shall be an engineered structure made of non-earthen materials that provide structural support, and shall have a floor, walls and a roof that prevent wind dispersal and contact with rainwater. Tanks used for this purpose shall be structurally sound and, if outdoors, shall have roofs or covers that prevent contact with wind and rain. Containers used for this purpose shall be kept closed except when it is necessary to add or remove material, and shall be in sound condition. Containers that are stored outdoors shall be managed within storage areas that:

(I) Have containment structures or systems sufficiently

impervious to contain leaks, spills and accumulated precipitation; and

(II) Provide for effective drainage and removal of leaks, spills and accumulated precipitation; and

(III) Prevent run-on into the containment system.

(C) With each off-site shipment of excluded hazardous secondary materials, provide written notice to the receiving facility that the material is subject to the conditions of Subsection R315-261-4(a)(20).

(D) Maintain at the generator's or intermediate handlers's facility for no less than three years records of [~~all~~]each shipment[~~s~~] of excluded hazardous secondary materials. For each shipment these records shall at a minimum contain the following information:

(I) Name of the transporter and date of the shipment;

(II) Name and address of the facility that received the excluded material, and documentation confirming receipt of the shipment; and

(III) Type and quantity of excluded secondary material in each shipment.

(iii) Manufacturers of zinc fertilizers or zinc fertilizer ingredients made from excluded hazardous secondary materials shall:

(A) Store excluded hazardous secondary materials in accordance with the storage requirements for generators and intermediate handlers, as specified in Subsection R315-261-4(a)(20)(ii)(B).

(B) Submit a one-time notification to the Director that, at a minimum, specifies the name, address and EPA ID number of the manufacturing facility, and identifies when the manufacturer intends to begin managing excluded, zinc-bearing hazardous secondary materials under the conditions specified in Subsection R315-261-4(a)(20).

(C) Maintain for a minimum of three years records of [~~all~~]each shipment[~~s~~] of excluded hazardous secondary materials received by the manufacturer, which shall at a minimum identify for each shipment the name and address of the generating facility, name of transporter and date the materials were received, the quantity received, and a brief description of the industrial process that generated the material.

(D) Submit to the Director an annual report that identifies the total quantities of [~~all~~]any excluded hazardous secondary materials that were used to manufacture zinc fertilizers or zinc fertilizer ingredients in the previous year, the name and address of each generating facility, and the industrial processes[~~(s)~~] from which they were generated.

(iv) Nothing in Section R315-261-4 preempts, overrides or otherwise negates the provision in Section R315-262-11, which requires any person who generates a solid waste to determine if that waste is a hazardous waste.

(v) Interim status and permitted storage units that have been used to store only zinc-bearing hazardous wastes prior to the submission of the one-time notice described in Subsection R315-261-4(a)(20)(ii)(A), and that afterward will be used only to store hazardous secondary materials excluded under Subsection R315-261-4(a)(20), are not subject to the closure requirements of Rules R315-264 and R315-265.

(21) Zinc fertilizers made from hazardous wastes, or hazardous secondary materials that are excluded under Subsection

R315-261-4(a)(20), provided that:

(i) The fertilizers meet the following contaminant limits:

(A) For metal contaminants:

TABLE

Constituent Maximum Allowable Total Concentration in Fertilizer, per Unit (1%) of Zinc ppm)

Arsenic	0.3
Cadmium	1.4
Chromium	0.6
Lead	2.8
Mercury	0.3

(B) For dioxin contaminants the fertilizer shall contain no more than eight (8) parts per trillion of dioxin, measured as toxic equivalent.

(ii) The manufacturer performs sampling and analysis of the fertilizer product to determine compliance with the contaminant limits for metals no less than every six months, and for dioxins no less than every twelve months. Testing shall also be performed [~~whenever~~]if changes occur to manufacturing processes or ingredients that could significantly affect the amounts of contaminants in the fertilizer product. The manufacturer may use any reliable analytical method to demonstrate that no constituent of concern is present in the product at concentrations above the applicable limits. It is the responsibility of the manufacturer to ensure that the sampling and analysis are unbiased, precise, and representative of the product(s) introduced into commerce.

(iii) The manufacturer maintains for no less than three years records of [~~all~~]each sampling and analyses performed for purposes of determining compliance with the requirements of Subsection R315-261-4(a)(21)(ii). Such records shall at a minimum include:

(A) The dates and times product samples were taken, and the dates the samples were analyzed;

(B) The names and qualifications of the person or persons[~~(s)~~] taking the samples;

(C) A description of the methods and equipment used to take the samples;

(D) The name and address of the laboratory facility at which analyses of the samples were performed;

(E) A description of the analytical methods used, including any cleanup and sample preparation methods; and

(F) [~~All~~]Any laboratory analytical results used to determine compliance with the contaminant limits specified in this Subsection R315-261-4(a)(21).

(22) Used cathode ray tubes (CRTs)

(i) Used, intact CRTs as defined in Section R315-260-10 are not solid wastes within the United States unless they are disposed, or unless they are speculatively accumulated as defined in Subsection R315-261-1(c)(8) by CRT collectors or glass processors.

(ii) Used, intact CRTs as defined in Section R315-260-10 are not solid wastes [~~when~~]if exported for recycling provided that they

meet the requirements of Section R315-261-40.

(iii) Used, broken CRTs as defined in Section R315-260-10 are not solid wastes provided that they meet the requirements of Section R315-261-39.

(iv) Glass removed from CRTs is not a solid waste provided that it meets the requirements of Section R315-261-39(c).

(23) Hazardous secondary material generated and legitimately reclaimed within the United States or its territories and under the control of the generator, provided that the material complies with Subsections R315-261-4(a)(23)(i) and (ii):

(i)(A) The hazardous secondary material is generated and reclaimed at the generating facility, for purposes of this definition, generating facility means [~~all~~]any contiguous property owned, leased, or otherwise controlled by the hazardous secondary material generator; or

(B) The hazardous secondary material is generated and reclaimed at different facilities, if the reclaiming facility is controlled by the generator or if both the generating facility and the reclaiming facility are controlled by a person as defined in Section R315-260-10, and if the generator provides one of the following certifications: "on behalf of (insert generator facility name), I certify that this facility will send the indicated hazardous secondary material to (insert reclaimer facility name), which is controlled by (insert generator facility name) and that (insert name of either facility) has acknowledged full responsibility for the safe management of the hazardous secondary material," or "on behalf of (insert generator facility name), I certify that this facility will send the indicated hazardous secondary material to (insert reclaimer facility name), that both facilities are under common control, and that (insert name of either facility) has acknowledged full responsibility for the safe management of the hazardous secondary material." For purposes of this paragraph, "control" means the power to direct the policies of the facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person as defined in Section R315-260-10 shall not be deemed to "control" such facilities. The generating and receiving facilities shall both maintain at their facilities for no less than three years records of hazardous secondary materials sent or received under this exclusion. In both cases, the records shall contain the name of the transporter, the date of the shipment, and the type and quantity of the hazardous secondary material shipped or received under the exclusion. These requirements may be satisfied by routine business records[~~, e.g.,~~] such as financial records, bills of lading, copies of DOT shipping papers, or electronic confirmations; or

(C) The hazardous secondary material is generated pursuant to a written contract between a tolling contractor and a toll manufacturer and is reclaimed by the tolling contractor, if the tolling contractor certifies the following: "On behalf of (insert tolling contractor name), I certify that (insert tolling contractor name) has a written contract with (insert toll manufacturer name) to manufacture (insert name of product or intermediate) which is made from specified unused materials, and that (insert tolling contractor name) will reclaim the hazardous secondary materials generated during this manufacture. On behalf of (insert tolling contractor name), I also certify that

(insert tolling contractor name) retains ownership of, and responsibility for, the hazardous secondary materials that are generated during the course of the manufacture, including any releases of hazardous secondary materials that occur during the manufacturing process". The tolling contractor shall maintain at its facility for no less than three years records of hazardous secondary materials received pursuant to its written contract with the tolling manufacturer, and the tolling manufacturer shall maintain at its facility for no less than three years records of hazardous secondary materials shipped pursuant to its written contract with the tolling contractor. In both cases, the records shall contain the name of the transporter, the date of the shipment, and the type and quantity of the hazardous secondary material shipped or received pursuant to the written contract. These requirements may be satisfied by routine business records[~~, e.g.,~~] such as financial records, bills of lading, copies of DOT shipping papers, or electronic confirmations. For purposes of Subsection R315-261-4(a)(23)(i)(C), tolling contractor means a person who arranges for the production of a product or intermediate made from specified unused materials through a written contract with a toll manufacturer. Toll manufacturer means a person who produces a product or intermediate made from specified unused materials pursuant to a written contract with a tolling contractor.

(ii)(A) The hazardous secondary material is contained as defined in Section R315-260-10. A hazardous secondary material released to the environment is discarded and a solid waste unless it is immediately recovered for the purpose of reclamation. Hazardous secondary material managed in a unit with leaks or other continuing or intermittent unpermitted releases is discarded and a solid waste.

(B) The hazardous secondary material is not speculatively accumulated, as defined in Subsection R315-261-1(c)(8).

(C) Notice is provided as required by Section R315-260-42.

(D) The material is not otherwise subject to material-specific management conditions under Subsection R315-261-4(a) [~~when~~]if reclaimed, and it is not a spent lead-acid battery, see Sections R315-266-80 and R315-273-2.

(E) Persons performing the recycling of hazardous secondary materials under this exclusion shall maintain documentation of their legitimacy determination on-site. Documentation shall be a written description of how the recycling meets [~~all~~]the three factors in Subsection R315-260-43(a) and how the factor in Subsection R315-260-43(b) was considered. Documentation shall be maintained for three years after the recycling operation has ceased.

(F) The emergency preparedness and response requirements found in Sections R315-261-400, 410, 411 and 420 are met.

(24) Hazardous secondary material that is generated and then transferred to another person for the purpose of reclamation is not a solid waste, provided that:

(i) The material is not speculatively accumulated, as defined in Subsection R315-261-1(c)(8);

(ii) The material is not handled by any person or facility other than the hazardous secondary material generator, the transporter, an intermediate facility or a reclaimer, and, while in transport, is not stored for more than 10 days at a transfer facility, as defined in Section R315-260-10, and is packaged according to applicable

Department of Transportation regulations at 49 CFR parts 173, 178, and 179 while in transport;

(iii) The material is not otherwise subject to material-specific management conditions under Subsection R315-261-4(a) [~~when~~]if reclaimed, and it is not a spent lead-acid battery, see Sections R315-266-80 and R315-273-2;

(iv) The reclamation of the material is legitimate, as specified under Section R315-260-43;

(v) The hazardous secondary material generator satisfies [~~all of~~]the following conditions:

(A) The material shall be contained as defined in Section R315-260-10. A hazardous secondary material released to the environment is discarded and a solid waste unless it is immediately recovered for the purpose of recycling. Hazardous secondary material managed in a unit with leaks or other continuing releases is discarded and a solid waste.

(B) Prior to arranging for transport of hazardous secondary materials to a reclamation facility, [~~(~~]or facilities[~~)~~], where the management of the hazardous secondary materials is not addressed under a hazardous waste part B permit or interim status standards, the hazardous secondary material generator shall make reasonable efforts to ensure that each reclaimer intends to properly and legitimately reclaim the hazardous secondary material and not discard it, and that each reclaimer will manage the hazardous secondary material in a manner that is protective of human health and the environment. If the hazardous secondary material will be passing through an intermediate facility where the management of the hazardous secondary materials is not addressed under a hazardous waste part B permit or interim status standards, the hazardous secondary material generator shall make contractual arrangements with the intermediate facility to ensure that the hazardous secondary material is sent to the reclamation facility identified by the hazardous secondary material generator, and the hazardous secondary material generator shall perform reasonable efforts to ensure that the intermediate facility will manage the hazardous secondary material in a manner that is protective of human health and the environment. Reasonable efforts shall be repeated at a minimum of every three years for the hazardous secondary material generator to claim the exclusion and to send the hazardous secondary materials to each reclaimer and any intermediate facility. In making these reasonable efforts, the generator may use any credible evidence available, including information gathered by the hazardous secondary material generator, provided by the reclaimer or either the intermediate facility, [~~and/or provided by~~]a third party, or both. The hazardous secondary material generator shall affirmatively answer [~~all of~~]the following questions for each reclamation facility and any intermediate facility:

(I) Does the available information indicate that the reclamation process is legitimate pursuant to Section R315-260-43? In answering this question, the hazardous secondary material generator can rely on their existing knowledge of the physical and chemical properties of the hazardous secondary material, as well as information from other sources including the reclamation facility and audit reports about the reclamation process.

(II) Does the publicly available information indicate that the

reclamation facility and any intermediate facility that is used by the hazardous secondary material generator notified the appropriate authorities of hazardous secondary materials reclamation activities pursuant to Section R315-260-42 and have they notified the appropriate authorities that the financial assurance condition is satisfied per Subsection R315-261-4(a)(24)(vi)(F)? In answering these questions, the hazardous secondary material generator can rely on the available information documenting the reclamation facility's and any intermediate facility's compliance with the notification requirements per Section R315-260-42, including the requirement in Subsection R315-260-42(a)(5) to notify the Director whether the reclaimer or intermediate facility has financial assurance.

(III) Does publicly available information indicate that the reclamation facility or any intermediate facility that is used by the hazardous secondary material generator has not had any formal enforcement actions taken against the facility in the previous three years for violations of Sections R315-260 through R315-268, R315-270, and R315-273 and has not been classified as a significant non-complier with Sections R315-260 through R315-268, R315-270, and R315-273? In answering this question, the hazardous secondary material generator can rely on the publicly available information from EPA or the state. If the reclamation facility or any intermediate facility that is used by the hazardous secondary material generator has had a formal enforcement action taken against the facility in the previous three years for violations of Sections R315-260 through R315-268, R315-270, and R315-273 and has been classified as a significant non-complier with Sections R315-260 through R315-268, R315-270, and R315-273, does the hazardous secondary material generator have credible evidence that the facilities will manage the hazardous secondary materials properly? In answering this question, the hazardous secondary material generator can obtain additional information from EPA, the state, or the facility itself that the facility has addressed the violations, taken remedial steps to address the violations and prevent future violations, or that the violations are not relevant to the proper management of the hazardous secondary materials.

(IV) Does the available information indicate that the reclamation facility and any intermediate facility that is used by the hazardous secondary material generator have the equipment and trained personnel to safely recycle the hazardous secondary material? In answering this question, the generator may rely on a description by the reclamation facility or by an independent third party of the equipment and trained personnel to be used to recycle the generator's hazardous secondary material.

(V) If residuals are generated from the reclamation of the excluded hazardous secondary materials, does the reclamation facility have the permits required, [~~(~~]if any[~~)~~], to manage the residuals? If not, does the reclamation facility have a contract with an appropriately permitted facility to dispose of the residuals? If not, does the hazardous secondary material generator have credible evidence that the residuals will be managed in a manner that is protective of human health and the environment? In answering these questions, the hazardous secondary material generator can rely on publicly available information from EPA or the state, or information provided by the facility itself.

(C) The hazardous secondary material generator shall maintain for a minimum of three years documentation and certification that reasonable efforts were made for each reclamation facility and, if applicable, intermediate facility where the management of the hazardous secondary materials is not addressed under a hazardous waste part B permit or interim status standards prior to transferring hazardous secondary material. Documentation and certification shall be made available upon request by the Director within 72 hours, or within a longer period of time as specified by the Director. The certification statement shall:

(I) Include the printed name and official title of an authorized representative of the hazardous secondary material generator company, the authorized representative's signature, and the date signed;

(II) Incorporate the following language: "I hereby certify in good faith and to the best of my knowledge that, prior to arranging for transport of excluded hazardous secondary materials to (insert name(s) of reclamation facility and any intermediate facility), reasonable efforts were made in accordance with Subsection R315-261-4(a)(24)(v)(B) to ensure that the hazardous secondary materials would be recycled legitimately, and otherwise managed in a manner that is protective of human health and the environment, and that such efforts were based on current and accurate information."

(D) The hazardous secondary material generator shall maintain at the generating facility for no less than three years records of [~~all~~]each off-site shipment[~~s~~] of hazardous secondary materials. For each shipment, these records shall, at a minimum, contain the following information:

(I) Name of the transporter and date of the shipment;

(II) Name and address of each reclaimer and, if applicable, the name and address of each intermediate facility to which the hazardous secondary material was sent;

(III) The type and quantity of hazardous secondary material in the shipment.

(E) The hazardous secondary material generator shall maintain at the generating facility for no less than three years confirmations of receipt from each reclaimer and, if applicable, each intermediate facility for [~~all~~]each off-site shipment[~~s~~] of hazardous secondary materials. Confirmations of receipt shall include the name and address of the reclaimer, or intermediate facility, the type and quantity of the hazardous secondary materials received and the date which the hazardous secondary materials were received. This requirement may be satisfied by routine business records[~~, e.g.,~~] such as financial records, bills of lading, copies of DOT shipping papers, or electronic confirmations of receipt;

(F) The hazardous secondary material generator shall comply with the emergency preparedness and response conditions in Sections R315-261-400, 410, 411, and 420.

(vi) Reclaimers of hazardous secondary material excluded from regulation under this exclusion and intermediate facilities as defined in Section R315-260-10 satisfy [~~all of~~]the following conditions:

(A) The reclaimer and intermediate facility shall maintain at its facility for no less than three years records of [~~all~~]each shipment[~~s~~] of hazardous secondary materials that were received at the facility and, if applicable, for [~~all~~]each shipment[~~s~~] of

hazardous secondary materials that were received and subsequently sent off-site from the facility for further reclamation. For each shipment, these records shall at a minimum contain the following information:

(I) Name of the transporter and date of the shipment;

(II) Name and address of the hazardous secondary material generator and, if applicable, the name and address of the reclaimer or intermediate facility which the hazardous secondary materials were received from;

(III) The type and quantity of hazardous secondary material in the shipment; and

(IV) For hazardous secondary materials that, after being received by the reclaimer or intermediate facility, were subsequently transferred off-site for further reclamation, the name and address of the, subsequent, reclaimer and, if applicable, the name and address of each intermediate facility to which the hazardous secondary material was sent.

(B) The intermediate facility shall send the hazardous secondary material to the reclaimer, or reclaimers[~~(s)~~] designated by the hazardous secondary materials generator.

(C) The reclaimer and intermediate facility shall send to the hazardous secondary material generator confirmations of receipt for [~~all~~]each off-site shipment[~~s~~] of hazardous secondary materials. Confirmations of receipt shall include the name and address of the reclaimer, or intermediate facility, the type and quantity of the hazardous secondary materials received and the date which the hazardous secondary materials were received. This requirement may be satisfied by routine business records[~~, e.g.,~~] such as financial records, bills of lading, copies of DOT shipping papers, or electronic confirmations of receipt.

(D) The reclaimer and intermediate facility shall manage the hazardous secondary material in a manner that is at least as protective as that employed for analogous raw material and shall be contained. An "analogous raw material" is a raw material for which a hazardous secondary material is a substitute and serves the [~~same~~]function and has similar physical and chemical properties as the hazardous secondary material.

(E) Any residuals that are generated from reclamation processes shall be managed in a manner that is protective of human health and the environment. If any residuals exhibit a hazardous characteristic according to Sections R315-261-20 through 24, or if they themselves are specifically listed in Sections R315-261-30 through 35, such residuals are hazardous wastes and shall be managed in accordance with the applicable requirements of Rules R315-260 through R315-266, R315-268, and R315-270.

(F) The reclaimer and intermediate facility have financial assurance as required under Sections R315-261-140 through 151,

(vii) In addition, [~~all~~]each person[~~s~~] claiming the exclusion under Subsection R315-261-4(a)(24) provide notification as required under Section R315-260-42.

(25) Hazardous secondary material that is exported from the United States and reclaimed at a reclamation facility located in a foreign country is not a solid waste, provided that the hazardous secondary material generator complies with the applicable

requirements of Subsection R315-261-4(a)(24)(i)-(v), excepting Subsection R315-261-4(a)(24)(v)(B)(2) for foreign reclaimers and foreign intermediate facilities, and that the hazardous secondary material generator also complies with the following requirements:

(i) Notify EPA of an intended export before the hazardous secondary material is scheduled to leave the United States. A complete notification shall be submitted at least sixty days before the initial shipment is intended to be shipped off-site. This notification may cover export activities extending over a twelve month or lesser period. The notification shall be in writing, signed by the hazardous secondary material generator, and include the following information:

(A) Name, mailing address, telephone number and EPA ID number, if applicable, of the hazardous secondary material generator;

(B) A description of the hazardous secondary material and the EPA hazardous waste number that would apply if the hazardous secondary material was managed as hazardous waste and the U.S. DOT proper shipping name, hazard class and ID number, UN/NA, for each hazardous secondary material as identified in 49 CFR parts 171 through 177;

(C) The estimated frequency or rate at which the hazardous secondary material is to be exported and the period of time over which the hazardous secondary material is to be exported;

(D) The estimated total quantity of hazardous secondary material;

(E) [~~All~~]Each point[~~s~~] of entry to and departure from each foreign country through which the hazardous secondary material will pass;

(F) A description of the means by which each shipment of the hazardous secondary material will be transported, for example mode of transportation vehicle including air, highway, rail and water, and types of containers including drums, boxes and tanks;

(G) A description of the manner in which the hazardous secondary material will be reclaimed in the country of import;

(H) The name and address of the reclaimer, any intermediate facility and any alternate reclaimer and intermediate facilities; and

(I) The name of any countries of transit through which the hazardous secondary material will be sent and a description of the approximate length of time it will remain in such countries and the nature of its handling while there, for purposes of this section, the terms "EPA Acknowledgement of Consent", "country of import" and "country of transit" are used as defined in [~~40 CFR~~]Section R315-262[~~.~~]-81 with the exception that the terms in Section R315-261-4 refer to hazardous secondary materials, rather than hazardous waste:

(ii) Notifications shall be submitted electronically using EPA's Waste Import Export Tracking System, WIETS, or its successor system.

(iii) Except for changes to the telephone number in Subsection R315-261-4(a)(25)(i)(A) and decreases in the quantity of hazardous secondary material indicated pursuant to Subsection R315-261-4(a)(25)(i)(D), [~~when~~]if the conditions specified on the original notification change, including any exceedance of the estimate of the quantity of hazardous secondary material specified in the original notification, the hazardous secondary material generator

shall provide EPA with a written renotification of the change. The shipment cannot take place until consent of the country of import to the changes, except for changes to Subsection R315-261-4(a)(25)(i)(I) and in the ports of entry to and departure from countries of transit pursuant to Subsection R315-261-4(a)(25)(i)(E), has been obtained and the hazardous secondary material generator receives from EPA an EPA Acknowledgment of Consent reflecting the country of import's consent to the changes.

(iv) Upon request by EPA, the hazardous secondary material generator shall furnish to EPA any additional information which a country of import requests in order to respond to a notification.

(v) EPA will provide a complete notification to the country of import and any countries of transit. A notification is complete when EPA receives a notification which EPA determines satisfies the requirements of Subsection R315-261-4(a)(25)(i). Where a claim of confidentiality is asserted with respect to any notification information required by Subsection R315-261-4(a)(25)(i), EPA may find the notification not complete until any such claim is resolved in accordance with 40 CFR 260.2.

(vi) The export of hazardous secondary material under Subsection R315-261-4(a)(25) is prohibited unless the country of import consents to the intended export. [~~When~~]If the country of import consents in writing to the receipt of the hazardous secondary material, EPA will send an EPA Acknowledgment of Consent to the hazardous secondary material generator. Where the country of import objects to receipt of the hazardous secondary material or withdraws a prior consent, EPA will notify the hazardous secondary material generator in writing. EPA will also notify the hazardous secondary material generator of any responses from countries of transit.

(vii) For exports to OECD Member countries, the receiving country may respond to the notification using tacit consent. If no objection has been lodged by any country of import or countries of transit to a notification provided pursuant to Subsection R315-261-4(a)(25)(i) within thirty days after the date of issuance of the acknowledgement of receipt of notification by the competent authority of the country of import, the transboundary movement may commence. In such cases, EPA will send an EPA Acknowledgment of Consent to inform the hazardous secondary material generator that the country of import and any relevant countries of transit have not objected to the shipment, and are thus presumed to have consented tacitly. Tacit consent expires one calendar year after the close of the thirty-[–]day period; renotification and renewal of [~~all~~]each consent[~~s~~] is required for exports after that date.

(viii) A copy of the EPA Acknowledgment of Consent shall accompany the shipment. The shipment shall conform to the terms of the EPA Acknowledgment of Consent.

(ix) If a shipment cannot be delivered for any reason to the reclaimer, intermediate facility or the alternate reclaimer or alternate intermediate facility, the hazardous secondary material generator shall re-notify EPA of a change in the conditions of the original notification to allow shipment to a new reclaimer in accordance with Subsection R315-261-4(a)(25)(iii) and obtain another EPA Acknowledgment of Consent.

(x) Hazardous secondary material generators shall keep a copy

of each notification of intent to export and each EPA Acknowledgment of Consent for a period of three years following receipt of the EPA Acknowledgment of Consent. They may satisfy this recordkeeping requirement by retaining electronically submitted notifications or electronically generated Acknowledgements in their account on EPA's Waste Import Export Tracking System, WIETS, or its successor system, provided that such copies are readily available for viewing and production if requested by any EPA or authorized state inspector. No hazardous secondary material generator may be held liable for the inability to produce a notification or Acknowledgement for inspection under Subsection R315-261-4(a)(25) if they can demonstrate that the inability to produce such copies are due exclusively to technical difficulty with EPA's Waste Import Export Tracking System, WIETS, or its successor system for which the hazardous secondary material generator bears no responsibility.

(xi) Hazardous secondary material generators shall file with the Administrator no later than March 1 of each year, a report summarizing the types, quantities, frequency and ultimate destination of [~~all~~]each hazardous secondary material[~~s~~] exported during the previous calendar year. Annual reports shall be submitted electronically using EPA's Waste Import Export Tracking System, WIETS, or its successor system. Such reports shall include the following information:

(A) Name, mailing and site address, and EPA ID number, if applicable, of the hazardous secondary material generator;

(B) The calendar year covered by the report;

(C) The name and site address of each reclaimer and intermediate facility;

(D) By reclaimer and intermediate facility, for each hazardous secondary material exported, a description of the hazardous secondary material and the EPA hazardous waste number that would apply if the hazardous secondary material was managed as hazardous waste, the DOT hazard class, the name and U.S. EPA ID number, where applicable, for each transporter used, the total amount of hazardous secondary material shipped and the number of shipments pursuant to each notification;

(E) A certification signed by the hazardous secondary material generator which states: "I certify under penalty of law that I have personally examined and am familiar with the information submitted in this and [~~all~~]each attached document[~~s~~], and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information including the possibility of fine and imprisonment."

(xii) [~~All~~]Each person[~~s~~] claiming an exclusion under Subsection R315-261-4(a)(25) shall provide notification as required by Section R315-260-42.

(26) Solvent-contaminated wipes that are sent for cleaning and reuse are not solid wastes from the point of generation, provided that

(i) The solvent-contaminated wipes, when accumulated, stored, and transported, are contained in non-leaking, closed containers that are labeled "Excluded Solvent-Contaminated Wipes." The containers

shall be able to contain free liquids, should free liquids occur. During accumulation, a container is considered closed [~~when~~]if there is complete contact between the fitted lid and the rim, except when it is necessary to add or remove solvent-contaminated wipes. When the container is full, or when the solvent-contaminated wipes are no longer being accumulated, or when the container is being transported, the container shall be sealed with [~~all~~]the lids properly and securely affixed to the container and [~~all~~]any openings tightly bound or closed sufficiently to prevent leaks and emissions;

(ii) The solvent-contaminated wipes may be accumulated by the generator for up to 180 days from the start date of accumulation for each container prior to being sent for cleaning;

(iii) At the point of being sent for cleaning on-site or at the point of being transported off-site for cleaning, the solvent-contaminated wipes shall contain no free liquids as defined in Section R315-260-10.

(iv) Free liquids removed from the solvent-contaminated wipes or from the container holding the wipes shall be managed according to the applicable [~~regulations~~]rules found in Rules R315-260 through R315-266, R315-268, R315-270, and R315-273;

(v) Generators shall maintain at their site the following documentation:

(A) Name and address of the laundry or dry cleaner that is receiving the solvent-contaminated wipes;

(B) Documentation that the 180-day accumulation time limit in Subsection R315-261-4(a)(26)(ii) is being met;

(C) Description of the process the generator is using to ensure the solvent-contaminated wipes contain no free liquids at the point of being laundered or dry cleaned on-site or at the point of being transported off-site for laundering or dry cleaning;

(vi) The solvent-contaminated wipes are sent to a laundry or dry cleaner whose discharge, if any, is regulated under sections 301 and 402 or section 307 of the Clean Water Act.

(27) Hazardous secondary material that is generated and then transferred to another person for the purpose of remanufacturing is not a solid waste, provided that:

(i) The hazardous secondary material consists of one or more of the following spent solvents: Toluene, xylenes, ethylbenzene, 1,2,4-trimethylbenzene, chlorobenzene, n-hexane, cyclohexane, methyl tert-butyl ether, acetonitrile, chloroform, chloromethane, dichloromethane, methyl isobutyl ketone, N,N-dimethylformamide, tetrahydrofuran, n-butyl alcohol, ethanol, [~~and/~~]or methanol;

(ii) The hazardous secondary material originated from using one or more of the solvents listed in Subsection R315-261-4(a)(27)(i) in a commercial grade for reacting, extracting, purifying, or blending chemicals, or for rinsing out the process lines associated with these functions; in the pharmaceutical manufacturing, NAICS 325412; basic organic chemical manufacturing, NAICS 325199; plastics and resins manufacturing, NAICS 325211; and[~~/or~~] the paints and coatings manufacturing sectors, NAICS 325510.

(iii) The hazardous secondary material generator sends the hazardous secondary material spent solvents listed in Subsection R315-261-4(a)(27)(i) to a remanufacturer in the pharmaceutical manufacturing, NAICS 325412; basic organic chemical manufacturing,

NAICS 325199; plastics and resins manufacturing, NAICS 325211; [~~and/~~]or the paints and coatings manufacturing sectors, NAICS 325510.

(iv) After remanufacturing one or more of the solvents listed in Subsection R315-261-4(a)(27)(i), the use of the remanufactured solvent shall be limited to reacting, extracting, purifying, or blending chemicals, or for rinsing out the process lines associated with these functions, in the pharmaceutical manufacturing, NAICS 325412; basic organic chemical manufacturing, NAICS 325199; plastics and resins manufacturing, NAICS 325211; and the paints and coatings manufacturing sectors, NAICS 325510; or to using them as ingredients in a product. These allowed uses correspond to chemical functional uses enumerated under the Chemical Data Reporting Rule of the Toxic Substances Control Act, 40 CFR parts 704, 710-711, including Industrial Function Codes U015, solvents consumed in a reaction to produce other chemicals, and U030, solvents become part of the mixture;

(v) After remanufacturing one or more of the solvents listed in Subsection R315-261-4(a)(27)(i), the use of the remanufactured solvent does not involve cleaning or degreasing oil, grease, or similar material from textiles, glassware, metal surfaces, or other articles. [~~(~~]These disallowed continuing uses correspond to chemical functional uses in Industrial Function Code U029 under the Chemical Data Reporting Rule of the Toxics Substances Control Act.[~~)~~]; and

(vi) Both the hazardous secondary material generator and the remanufacturer shall:

(A) Notify the Director and update the notification every two years per Section R315-260-42;

(B) Develop and maintain an up-to-date remanufacturing plan which identifies:

(I) The name, address and EPA ID number of the generator[~~(~~]s[~~)~~] and the remanufacturer[~~(~~]s[~~)~~],

(II) The types and estimated annual volumes of spent solvents to be remanufactured,

(III) The processes and industry sectors that generate the spent solvents,

(IV) The specific uses and industry sectors for the remanufactured solvents, and

(V) A certification from the remanufacturer stating "on behalf of (insert remanufacturer facility name), I certify that this facility is a remanufacturer under pharmaceutical manufacturing, NAICS 325412; basic organic chemical manufacturing, NAICS 325199; plastics and resins manufacturing, NAICS 325211; and/or the paints and coatings manufacturing sectors, NAICS 325510; and will accept the spent solvent(s) for the sole purpose of remanufacturing into commercial-grade solvent(s) that will be used for reacting, extracting, purifying, or blending chemicals, or for rinsing out the process lines associated with these functions, or for use as product ingredient(s). I also certify that the remanufacturing equipment, vents, and tanks are equipped with and are operating air emission controls in compliance with the appropriate Clean Air Act regulations under 40 CFR part 60, part 61 or part 63, or, absent such Clean Air Act standards for the particular operation or piece of equipment covered by the remanufacturing exclusion, are in compliance with the appropriate standards in Sections R315-261-1030 through 1035, 1050 through 1064 and 1080 through 1089";

(C) Maintain records of shipments and confirmations of receipts for a period of three years from the dates of the shipments;

(D) Prior to remanufacturing, store the hazardous spent solvents in tanks or containers that meet technical standards found in Sections R315-261-17- through 179 and 190 through 200, with the tanks and containers being labeled or otherwise having an immediately available record of the material being stored;

(E) During remanufacturing, and during storage of the hazardous secondary materials prior to remanufacturing, the remanufacturer certifies that the remanufacturing equipment, vents, and tanks are equipped with and are operating air emission controls in compliance with the appropriate Clean Air Act regulations under 40 CFR part 60, part 61 or part 63; or, absent such Clean Air Act standards for the particular operation or piece of equipment covered by the remanufacturing exclusion, are in compliance with the appropriate standards in Sections R315-261-1030 through 1035, 1050 through 1064 and 1080 through 1089; and

(F) Meet the requirements prohibiting speculative accumulation per Subsection R315-261-1(c)(8).

(b) Solid wastes which are not hazardous wastes. The following solid wastes are not hazardous wastes:

(1) Household waste, including household waste that has been collected, transported, stored, treated, disposed, recovered[~~, e.g.,~~] such as refuse-derived fuel, or reused. "Household waste" means any material, including garbage, trash and sanitary wastes in septic tanks, derived from households, including single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds and day-use recreation areas. A resource recovery facility managing municipal solid waste shall not be deemed to be treating, storing, disposing of, or otherwise managing hazardous wastes for the purposes of regulation under this subtitle, if such facility:

(i) Receives and burns only

(A) Household waste, from single and multiple dwellings, hotels, motels, and other residential sources, and

(B) Solid waste from commercial or industrial sources that does not contain hazardous waste; and

(ii) Such facility does not accept hazardous wastes and the owner or operator of such facility has established contractual requirements or other appropriate notification or inspection procedures to assure that hazardous wastes are not received at or burned in such facility.

(2) Solid wastes generated by any of the following and which are returned to the soils as fertilizers:

(i) The growing and harvesting of agricultural crops.

(ii) The raising of animals, including animal manures.

(3) Mining overburden returned to the mine site.

(4)(i) Fly ash waste, bottom ash waste, slag waste, and flue gas emission control waste generated primarily from the combustion of coal or other fossil fuels, except as provided by Section R315-266-112 for facilities that burn or process hazardous waste.

(ii) The following wastes generated primarily from processes that support the combustion of coal or other fossil fuels that are co-disposed with the wastes in Subsection R315-261-4(b)(4)(i), except

as provided by Section R315-266-112 for facilities that burn or process hazardous waste:

(A) Coal pile run-off. For purposes of Subsection R315-261-4(b)(4), coal pile run-off means any precipitation that drains off coal piles.

(B) Boiler cleaning solutions. For purposes of Subsection R315-261-4(b)(4), boiler cleaning solutions means water solutions and chemical solutions used to clean the fire-side and water-side of the boiler.

(C) Boiler blowdown. For purposes of Subsection R315-261-4(b)(4), boiler blowdown means water purged from boilers used to generate steam.

(D) Process water treatment and demineralizer regeneration wastes. For purposes of Subsection R315-261-4(b)(4), process water treatment and demineralizer regeneration wastes means sludges, rinses, and spent resins generated from processes to remove dissolved gases, suspended solids, and dissolved chemical salts from combustion system process water.

(E) Cooling tower blowdown. For purposes of Subsection R315-261-4(b)(4), cooling tower blowdown means water purged from a closed cycle cooling system. Closed cycle cooling systems include cooling towers, cooling ponds, or spray canals.

(F) Air heater and precipitator washes. For purposes of Subsection R315-261-4(b)(4), air heater and precipitator washes means wastes from cleaning air preheaters and electrostatic precipitators.

(G) Effluents from floor and yard drains and sumps. For purposes of Subsection R315-261-4(b)(4), effluents from floor and yard drains and sumps means wastewaters, such as wash water, collected by or from floor drains, equipment drains, and sumps located inside the power plant building; and wastewaters, such as rain runoff, collected by yard drains and sumps located outside the power plant building.

(H) Wastewater treatment sludges. For purposes of Subsection R315-261-4(b)(4), wastewater treatment sludges refers to sludges generated from the treatment of wastewaters specified in Subsections R315-261-4(b)(4)(ii)(A) through (F).

(5) Drilling fluids, produced waters, and other wastes associated with the exploration, development, or production of crude oil, natural gas or geothermal energy.

(6)(i) Wastes which fail the test for the Toxicity Characteristic because chromium is present or are listed in Sections R315-261-30 through R316-261-35 due to the presence of chromium, which do not fail the test for the Toxicity Characteristic for any other constituent or are not listed due to the presence of any other constituent, and which do not fail the test for any other characteristic, if it is shown by a waste generator or by waste generators that:

(A) The chromium in the waste is exclusively, or nearly exclusively, trivalent chromium; and

(B) The waste is generated from an industrial process which uses trivalent chromium exclusively, [~~(~~]or nearly exclusively[~~)~~], and the process does not generate hexavalent chromium; and

(C) The waste is typically and frequently managed in non-oxidizing environments.

(ii) Specific wastes which meet the standard in Subsections R315-261-4(b)(6)(i)(A), (B), and (C), so long as they do not fail the test for the toxicity characteristic for any other constituent, and do not exhibit any other characteristic, are:

(A) Chrome, [~~(~~]blue[~~)~~], trimmings generated by the following subcategories of the leather tanning and finishing industry; hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; retan/wet finish; no beamhouse; through-the-blue; and shearling.

(B) Chrome, [~~(~~]blue[~~)~~], shavings generated by the following subcategories of the leather tanning and finishing industry: Hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; retan/wet finish; no beamhouse; through-the-blue; and shearling.

(C) Buffing dust generated by the following subcategories of the leather tanning and finishing industry; hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; retan/wet finish; no beamhouse; through-the-blue.

(D) Sewer screenings generated by the following subcategories of the leather tanning and finishing industry: Hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; retan/wet finish; no beamhouse; through-the-blue; and shearling.

(E) Wastewater treatment sludges generated by the following subcategories of the leather tanning and finishing industry: Hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; retan/wet finish; no beamhouse; through-the-blue; and shearling.

(F) Wastewater treatment sludges generated by the following subcategories of the leather tanning and finishing industry: Hair pulp/chrome tan/retan/wet finish; hair save/chrome tan/retan/wet finish; and through-the-blue.

(G) Waste scrap leather from the leather tanning industry, the shoe manufacturing industry, and other leather product manufacturing industries.

(H) Wastewater treatment sludges from the production of TiO2 pigment using chromium-bearing ores by the chloride process.

(7) Solid waste from the extraction, beneficiation, and processing of ores and minerals, including coal, phosphate rock, and overburden from the mining of uranium ore, except as provided by Section R315-266-112 for facilities that burn or process hazardous waste.

(i) For purposes of Subsection R315-261-4(b)(7) beneficiation of ores and minerals is restricted to the following activities; crushing; grinding; washing; dissolution; crystallization; filtration; sorting; sizing; drying; sintering; pelletizing; briquetting; calcining to remove water, [~~and/or~~]carbon dioxide, or both; roasting, autoclaving, [~~and/or~~]chlorination, or both in preparation for leaching, [~~(~~]except where the roasting, [~~(and/~~]or autoclaving, [~~and/~~]or chlorination[~~)~~][~~/~~] or leaching, or any combination of these, sequence produces a final or intermediate product that does not undergo further beneficiation or processing[~~)~~]; gravity concentration; magnetic separation; electrostatic separation; flotation; ion exchange; solvent extraction; electrowinning; precipitation; amalgamation; and heap, dump, vat,

tank, and in situ leaching.

(ii) For the purposes of Subsection R315-261-4(b)(7), solid waste from the processing of ores and minerals includes only the following wastes as generated:

(A) Slag from primary copper processing;

(B) Slag from primary lead processing;

(C) Red and brown muds from bauxite refining;

(D) Phosphogypsum from phosphoric acid production;

(E) Slag from elemental phosphorus production;

(F) Gasifier ash from coal gasification;

(G) Process wastewater from coal gasification;

(H) Calcium sulfate wastewater treatment plant sludge from primary copper processing;

(I) Slag tailings from primary copper processing;

(J) Fluorogypsum from hydrofluoric acid production;

(K) Process wastewater from hydrofluoric acid production;

(L) Air pollution control dust[~~/~~] or sludge from iron blast furnaces;

(M) Iron blast furnace slag;

(N) Treated residue from roasting[~~/~~] or leaching of chrome ore;

(O) Process wastewater from primary magnesium processing by the anhydrous process;

(P) Process wastewater from phosphoric acid production;

(Q) Basic oxygen furnace and open hearth furnace air pollution control dust[~~/~~] or sludge from carbon steel production;

(R) Basic oxygen furnace and open hearth furnace slag from carbon steel production;

(S) Chloride process waste solids from titanium tetrachloride production;

(T) Slag from primary zinc processing.

(iii) A residue derived from co-processing mineral processing secondary materials with normal beneficiation raw materials or with normal mineral processing raw materials remains excluded under Subsection R315-261-4(b) if the owner or operator:

(A) Processes at least 50 percent by weight normal beneficiation raw materials or normal mineral processing raw materials; and,

(B) Legitimately reclaims the secondary mineral processing materials.

(8) Cement kiln dust waste, except as provided by Section R315-266-112 for facilities that burn or process hazardous waste.

(9) Solid waste which consists of discarded arsenical-treated wood or wood products which fails the test for the Toxicity Characteristic for Hazardous Waste Codes D004 through D017 and which is not a hazardous waste for any other reason if the waste is generated by persons who utilize the arsenical-treated wood and wood products for these materials' intended end use.

(10) Petroleum-contaminated media and debris that fail the test for the Toxicity Characteristic of Section R315-261-24, Hazardous Waste Codes D018 through D043 only, and are subject to the corrective action [~~regulations~~]rules under Section R[~~315-~~]311-202-1 which adopts 40 CFR 280 by reference.

(11) Injected groundwater that is hazardous only because it exhibits the Toxicity Characteristic, Hazardous Waste Codes D018 through D043 only, in Section R315-261-24 that is reinjected through

an underground injection well pursuant to free phase hydrocarbon recovery operations undertaken at petroleum refineries, petroleum marketing terminals, petroleum bulk plants, petroleum pipelines, and petroleum transportation spill sites until January 25, 1993. This extension applies to recovery operations in existence, or for which contracts have been issued, on or before March 25, 1991. For groundwater returned through infiltration galleries from such operations at petroleum refineries, marketing terminals, and bulk plants, until October 2, 1991. New operations involving injection wells, beginning after March 25, 1991, will qualify for this compliance date extension, until January 25, 1993, only if:

(i) Operations are performed pursuant to a written state agreement that includes a provision to assess the groundwater and the need for further remediation once the free phase recovery is completed; and

(ii) A copy of the written agreement has been submitted to: Waste Identification Branch (5304), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460 and the Division of Waste Management and Radiation Control, PO Box 144880, Salt Lake City, UT 84114-4880.

(12) Used chlorofluorocarbon refrigerants from totally enclosed heat transfer equipment, including mobile air conditioning systems, mobile refrigeration, and commercial and industrial air conditioning and refrigeration systems that use chlorofluorocarbons as the heat transfer fluid in a refrigeration cycle, provided the refrigerant is reclaimed for further use.

(13) Non-terne plated used oil filters that are not mixed with wastes listed in Sections R315-261-30 through R315-261-35 if these oil filters have been gravity hot-drained using one of the following methods:

(i) Puncturing the filter anti-drain back valve or the filter dome end and hot-draining;

(ii) Hot-draining and crushing;

(iii) Dismantling and hot-draining; or

(iv) Any other equivalent hot-draining method that will remove used oil.

(14) Used oil re-refining distillation bottoms that are used as feedstock to manufacture asphalt products.

(15) Leachate or gas condensate collected from landfills where certain solid wastes have been disposed, provided that:

(i) The solid wastes disposed would meet one or more of the listing descriptions for Hazardous Waste Codes K169, K170, K171, K172, K174, K175, K176, K177, K178 and K181 if these wastes had been generated after the effective date of the listing;

(ii) The solid wastes described in Subsection R315-261-4(b)(15)(i) were disposed prior to the effective date of the listing;

(iii) The leachate or gas condensate do not exhibit any characteristic of hazardous waste nor are derived from any other listed hazardous waste;

(iv) Discharge of the leachate or gas condensate, including leachate or gas condensate transferred from the landfill to a POTW by truck, rail, or dedicated pipe, is subject to regulation under sections 307(b) or 402 of the Clean Water Act.

(v) As of February 13, 2001, leachate or gas condensate derived from K169-K172 is no longer exempt if it is stored or managed in a surface impoundment prior to discharge. As of November 21, 2003, leachate or gas condensate derived from K176, K177, and K178 is no longer exempt if it is stored or managed in a surface impoundment prior to discharge. After February 26, 2007, leachate or gas condensate derived from K181 will no longer be exempt if it is stored or managed in a surface impoundment prior to discharge. There is one exception: if the surface impoundment is used to temporarily store leachate or gas condensate in response to an emergency situation[~~, e.g.,~~] such as shutdown of wastewater treatment system, provided the impoundment has a double liner, and provided the leachate or gas condensate is removed from the impoundment and continues to be managed in compliance with the conditions of Subsection R315-261-4(b)(15)(v) after the emergency ends.

(16) Reserved

(17) Reserved

(18) Solvent-contaminated wipes, except for wipes that are hazardous waste due to the presence of trichloroethylene, that are sent for disposal are not hazardous wastes from the point of generation provided that

(i) The solvent-contaminated wipes, when accumulated, stored, and transported, are contained in non-leaking, closed containers that are labeled "Excluded Solvent-Contaminated Wipes." The containers shall be able to contain free liquids, should free liquids occur. During accumulation, a container is considered closed [~~when~~]if there is complete contact between the fitted lid and the rim, except when it is necessary to add or remove solvent-contaminated wipes. When the container is full, or when the solvent-contaminated wipes are no longer being accumulated, or when the container is being transported, the container shall be sealed with [~~all~~]the lids properly and securely affixed to the container and [~~all~~]any openings tightly bound or closed sufficiently to prevent leaks and emissions;

(ii) The solvent-contaminated wipes may be accumulated by the generator for up to 180 days from the start date of accumulation for each container prior to being sent for disposal;

(iii) At the point of being transported for disposal, the solvent-contaminated wipes shall contain no free liquids as defined in Section R315-260-10.

(iv) Free liquids removed from the solvent-contaminated wipes or from the container holding the wipes shall be managed according to the applicable [~~regulations~~]rules found in Rules R315-260 through R315-266, R315-268, R315-270, and R315-273;

(v) Generators shall maintain at their site the following documentation:

(A) Name and address of the landfill or combustor that is receiving the solvent-contaminated wipes;

(B) Documentation that the 180 day accumulation time limit in Subsection R315-261-4(b)(18)(ii) is being met;

(C) Description of the process the generator is using to ensure solvent-contaminated wipes contain no free liquids at the point of being transported for disposal;

(vi) The solvent-contaminated wipes are sent for disposal

(A) To a solid waste landfill that:

(I) is regulated under R315-301 through R315-320

(II) is a Class I or V Landfill; and

(III) has a composite liner; or

(B) To a hazardous waste landfill regulated under Rules R315-260 through R315-266, R315-268, and R315-270; or

(C) To a municipal waste combustor or other combustion facility regulated under section 129 of the Clean Air Act or to a hazardous waste combustor, boiler, or industrial furnace regulated under Rule R315-264, Rule R315-265, or Sections R315-266-100 through R315-266-112.

(c) Hazardous wastes which are exempted from certain [~~regulations~~]rules. A hazardous waste which is generated in a product or raw material storage tank, a product or raw material transport vehicle or vessel, a product or raw material pipeline, or in a manufacturing process unit or an associated non-waste-treatment-manufacturing unit, is not subject to regulation under Rules R315-262 through R315-265, R315-268, R315-270, and R315-124 or to the notification requirements of section 3010 of RCRA until it exits the unit in which it was generated, unless the unit is a surface impoundment, or unless the hazardous waste remains in the unit more than 90 days after the unit ceases to be operated for manufacturing, or for storage or transportation of product or raw materials.

(d)(1) Samples. Except as provided in Subsections R315-261-4(d)(2) and (4), a sample of solid waste or a sample of water, soil, or air, which is collected for the sole purpose of testing to determine its characteristics or composition, is not subject to any requirements of Rules R315-261 through R315-266, R315-268 or R315-270 or R315-124 or to the notification requirements of Section 3010 of RCRA, [~~when~~]if:

(i) The sample is being transported to a laboratory for the purpose of testing; or

(ii) The sample is being transported back to the sample collector after testing; or

(iii) The sample is being stored by the sample collector before transport to a laboratory for testing; or

(iv) The sample is being stored in a laboratory before testing; or

(v) The sample is being stored in a laboratory after testing but before it is returned to the sample collector; or

(vi) The sample is being stored temporarily in the laboratory after testing for a specific purpose, [~~(~~]for example, until conclusion of a court case or enforcement action where further testing of the sample may be necessary[~~)~~].

(2) In order to qualify for the exemption in Subsections R315-261-4(d)(1) (i) and (ii), a sample collector shipping samples to a laboratory and a laboratory returning samples to a sample collector shall:

(i) Comply with U.S. Department of Transportation (DOT), U.S. Postal Service (USPS), or any other applicable shipping requirements; or

(ii) Comply with the following requirements if the sample collector determines that DOT, USPS, or other shipping requirements do not apply to the shipment of the sample:

(A) Assure that the following information accompanies the sample:

(I) The sample collector's name, mailing address, and telephone number;

(II) The laboratory's name, mailing address, and telephone number;

(III) The quantity of the sample;

(IV) The date of shipment; and

(V) A description of the sample.

(B) Package the sample so that it does not leak, spill, or vaporize from its packaging.

(3) This exemption does not apply if the laboratory determines that the waste is hazardous but the laboratory is no longer meeting any of the conditions stated in Subsection R315-261-4(d)(1).

(4) In order to qualify for the exemption in Subsections R315-261-4(d)(1)(i) and (ii), the mass of a sample that will be exported to a foreign laboratory or that will be imported to a U.S. laboratory from a foreign source [~~must~~]shall additionally not exceed 25 kg.

(e)(1) Treatability Study Samples. Except as provided in Subsections R315-261-4(e)(2) and (4), persons who generate or collect samples for the purpose of conducting treatability studies as defined in Section R315-260-10, are not subject to any requirement of Rules R315-261 through 263 or to the notification requirements of Section 3010 of RCRA, nor are such samples included in the quantity determinations of Section R315-261-5 and Subsection R315-262-34(d) [~~when~~]if:

(i) The sample is being collected and prepared for transportation by the generator or sample collector; or

(ii) The sample is being accumulated or stored by the generator or sample collector prior to transportation to a laboratory or testing facility; or

(iii) The sample is being transported to the laboratory or testing facility for the purpose of conducting a treatability study.

(2) The exemption in Subsection R315-261-4(e)(1) is applicable to samples of hazardous waste being collected and shipped for the purpose of conducting treatability studies provided that:

(i) The generator or sample collector uses, [~~(~~]in "treatability studies"[~~)~~], no more than 10,000 kg of media contaminated with non-acute hazardous waste, 1000 kg of non-acute hazardous waste other than contaminated media, 1 kg of acute hazardous waste, 2500 kg of media contaminated with acute hazardous waste for each process being evaluated for each generated waste stream; and

(ii) The mass of each sample shipment does not exceed 10,000 kg; the 10,000 kg quantity may be [~~all~~] media contaminated with non-acute hazardous waste, or may include 2500 kg of media contaminated with acute hazardous waste, 1000 kg of hazardous waste, and 1 kg of acute hazardous waste; and

(iii) The sample shall be packaged so that it will not leak, spill, or vaporize from its packaging during shipment and the requirements of Subsections R315-261-4(e)(2)(iii)(A) or (B) are met.

(A) The transportation of each sample shipment complies with U.S. Department of Transportation (DOT), U.S. Postal Service (USPS), or any other applicable shipping requirements; or

(B) If the DOT, USPS, or other shipping requirements do not apply to the shipment of the sample, the following information shall accompany the sample:

(I) The name, mailing address, and telephone number of the originator of the sample;

(II) The name, address, and telephone number of the facility that will perform the treatability study;

(III) The quantity of the sample;

(IV) The date of shipment; and

(V) A description of the sample, including its EPA Hazardous Waste Number.

(iv) The sample is shipped to a laboratory or testing facility which is exempt under Subsection R315-261-4(f) or has an appropriate RCRA permit or interim status.

(v) The generator or sample collector maintains the following records for a period ending three years after completion of the treatability study:

(A) Copies of the shipping documents;

(B) A copy of the contract with the facility conducting the treatability study;

(C) Documentation showing:

(I) The amount of waste shipped under this exemption;

(II) The name, address, and EPA identification number of the laboratory or testing facility that received the waste;

(III) The date the shipment was made; and

(IV) Whether or not unused samples and residues were returned to the generator.

(vi) The generator reports the information required under Subsection R315-261-4(e)(2)(v)(C) in its biennial report.

(3) The Director may grant requests on a case-by-case basis for up to an additional two years for treatability studies involving bioremediation. The Director may grant requests on a case-by-case basis for quantity limits in excess of those specified in Subsections R315-261-4(e)(2)(i) and (ii) and Subsection R315-261-4(f)(4), for up to an additional 5000 kg of media contaminated with non-acute hazardous waste, 500 kg of non-acute hazardous waste, 2500 kg of media contaminated with acute hazardous waste and 1 kg of acute hazardous waste:

(i) In response to requests for authorization to ship, store and conduct treatability studies on additional quantities in advance of commencing treatability studies. Factors to be considered in reviewing such requests include the nature of the technology; the type of process, [~~e.g., ~~]batch versus continuous; size of the unit undergoing testing, particularly in relation to scale-up considerations; the time[~~/~~] or quantity of material required to reach steady state operating conditions; or test design considerations such as mass balance calculations.

(ii) In response to requests for authorization to ship, store and conduct treatability studies on additional quantities after initiation or completion of initial treatability studies, [~~when~~]if: There has been an equipment or mechanical failure during the conduct of a treatability study; there is a need to verify the results of a previously conducted treatability study; there is a need to study and analyze alternative techniques within a previously evaluated

treatment process; or there is a need to do further evaluation of an ongoing treatability study to determine final specifications for treatment.

(iii) The additional quantities and timeframes allowed in Subsections R315-261-4(e)(3)(i) and (ii) are subject to [~~all the provisions in~~]Subsections R315-261-4(e)(1) and R315-261-4(e)(2)(iii) through R315-261-4(e)(2)(vi). The generator or sample collector shall apply to the Director and provide in writing the following information:

(A) The reason why the generator or sample collector requires additional time or quantity of sample for treatability study evaluation and the additional time or quantity needed;

(B) Documentation accounting for [~~all~~]any samples of hazardous waste from the waste stream which have been sent for or undergone treatability studies including the date each previous sample from the waste stream was shipped, the quantity of each previous shipment, the laboratory or testing facility to which it was shipped, what treatability study processes were conducted on each sample shipped, and the available results on each treatability study;

(C) A description of the technical modifications or change in specifications which will be evaluated and the expected results;

(D) If such further study is being required due to equipment or mechanical failure, the applicant shall include information regarding the reason for the failure or breakdown and also include what procedures or equipment improvements have been made to protect against further breakdowns; and

(E) Such other information that the Director considers necessary.

(4) In order to qualify for the exemption in Subsection R315-261-4(e)(1)(i), the mass of a sample that will be exported to a foreign laboratory or testing facility or that will be imported to a U.S. laboratory or testing facility from a foreign source [~~must~~]shall additionally no exceed 25 kg.

(f) Samples Undergoing Treatability Studies at Laboratories and Testing Facilities. Samples undergoing treatability studies and the laboratory or testing facility conducting such treatability studies, to the extent such facilities are not otherwise subject to RCRA requirements, are not subject to any requirement of Rules R315-261 through R315-266, R315-268, and R315-270, or to the notification requirements of Section 3010 of RCRA provided that the conditions of Subsection R315-261-4(f)(1) through (11) are met. A mobile treatment unit (MTU) may qualify as a testing facility subject to Subsections R315-261-4(f)(1) through (11). Where a group of MTUs are located at [~~the same~~]a site, the limitations specified in Subsections R315-261-4(f)(1) through (11) apply to the entire group of MTUs collectively as if the group were one MTU.

(1) No less than 45 days before conducting treatability studies, the facility notifies the Director, in writing that it intends to conduct treatability studies under Subsection R315-261-4(f).

(2) The laboratory or testing facility conducting the treatability study has an EPA identification number.

(3) No more than a total of 10,000 kg of "as received" media contaminated with non-acute hazardous waste, 2500 kg of media contaminated with acute hazardous waste or 250 kg of other "as

received" hazardous waste is subject to initiation of treatment in [~~all~~]treatability studies in any single day. "As received" waste refers to the waste as received in the shipment from the generator or sample collector.

(4) The quantity of "as received" hazardous waste stored at the facility for the purpose of evaluation in treatability studies does not exceed 10,000 kg, the total of which can include 10,000 kg of media contaminated with non-acute hazardous waste, 2500 kg of media contaminated with acute hazardous waste, 1000 kg of non-acute hazardous wastes other than contaminated media, and 1 kg of acute hazardous waste. This quantity limitation does not include treatment materials, including nonhazardous solid waste, added to "as received" hazardous waste.

(5) No more than 90 days have elapsed since the treatability study for the sample was completed, or no more than one year, two years for treatability studies involving bioremediation, have elapsed since the generator or sample collector shipped the sample to the laboratory or testing facility, whichever date first occurs. Up to 500 kg of treated material from a particular waste stream from treatability studies may be archived for future evaluation up to five years from the date of initial receipt. Quantities of materials archived are counted against the total storage limit for the facility.

(6) The treatability study does not involve the placement of hazardous waste on the land or open burning of hazardous waste.

(7) The facility maintains records for three years following completion of each study that show compliance with the treatment rate limits and the storage time and quantity limits. The following specific information shall be included for each treatability study conducted:

(i) The name, address, and EPA identification number of the generator or sample collector of each waste sample;

(ii) The date the shipment was received;

(iii) The quantity of waste accepted;

(iv) The quantity of "as received" waste in storage each day;

(v) The date the treatment study was initiated and the amount of "as received" waste introduced to treatment each day;

(vi) The date the treatability study was concluded;

(vii) The date any unused sample or residues generated from the treatability study were returned to the generator or sample collector or, if sent to a designated facility, the name of the facility and the EPA identification number.

(8) The facility keeps, on-site, a copy of the treatability study contract and [~~all~~]any shipping papers associated with the transport of treatability study samples to and from the facility for a period ending three years from the completion date of each treatability study.

(9) The facility prepares and submits a report to the Director, by March 15 of each year, that includes the following information for the previous calendar year:

(i) The name, address, and EPA identification number of the facility conducting the treatability studies;

(ii) The types, [~~(~~]by process[~~)~~], of treatability studies conducted;

(iii) The names and addresses of persons for whom studies have

been conducted, including their EPA identification numbers;

(iv) The total quantity of waste in storage each day;

(v) The quantity and types of waste subjected to treatability studies;

(vi) When each treatability study was conducted;

(vii) The final disposition of residues and unused sample from each treatability study.

(10) The facility determines whether any unused sample or residues generated by the treatability study are hazardous waste under Section R315-261-3 and, if so, are subject to Rules R315-261 through R315-268 and R315-270, unless the residues and unused samples are returned to the sample originator under the Subsection R3315-261-4(e) exemption.

(11) The facility notifies the Director, by letter when the facility is no longer planning to conduct any treatability studies at the site.

(g) Dredged material that is not a hazardous waste. Dredged material that is subject to the requirements of a permit that has been issued under 404 of the Federal Water Pollution Control Act, [~~(~~]33 U.S.C. 1344[~~)~~], or section 103 of the Marine Protection, Research, and Sanctuaries Act of 1972, [~~(~~]33 U.S.C. 1413[~~)~~], is not a hazardous waste. For Subsection R315-261-4(g), the following definitions apply:

(1) The term dredged material has the [~~same~~]meaning as defined in 40 CFR 232.2;

(2) The term permit means:

(i) A permit issued by the U.S. Army Corps of Engineers (Corps) or an approved State under section 404 of the Federal Water Pollution Control Act, [~~(~~]33 U.S.C. 1344[~~)~~];

(ii) A permit issued by the Corps under section 103 of the Marine Protection, Research, and Sanctuaries Act of 1972, [~~(~~]33 U.S.C. 1413[~~)~~]; or

(iii) In the case of Corps civil works projects, the administrative equivalent of the permits referred to in Subsections R315-261-4(g)(2)(i) and (ii), as provided for in Corps regulations.

(h) Carbon dioxide stream injected for geologic sequestration. Carbon dioxide streams that are captured and transported for purposes of injection into an underground injection well subject to the requirements for Class VI Underground Injection Control wells, including the requirements in Rule R317-7, are not a hazardous waste, provided the following conditions are met:

(1) Transportation of the carbon dioxide stream shall be in compliance with U.S. Department of Transportation requirements, including the pipeline safety laws, 49 U.S.C. 60101 et seq. and regulations, 49 CFR Parts 190-199, of the U.S. Department of Transportation, and pipeline safety regulations adopted and administered by a state authority pursuant to a certification under 49 U.S.C. 60105, as applicable.

(2) Injection of the carbon dioxide stream shall be in compliance with the applicable requirements for Class VI Underground Injection Control wells, including the applicable requirements in Rule R317-7;

(3) No hazardous wastes shall be mixed with, or otherwise co-injected with, the carbon dioxide stream; and

(4)(i) Any generator of a carbon dioxide stream, who claims that a carbon dioxide stream is excluded under Subsection R315-261-4(h), shall have an authorized representative, as defined in Section R315-260-10, sign a certification statement worded as follows: I certify under penalty of law that the carbon dioxide stream that I am claiming to be excluded under Subsection R315-261.4(h) has not been mixed with hazardous wastes, and I have transported the carbon dioxide stream in compliance with, or have contracted with a pipeline operator or transporter to transport the carbon dioxide stream in compliance with, Department of Transportation requirements, including the pipeline safety laws, 49 U.S.C. 60101 et seq., and regulations, 49 CFR Parts 190-199, of the U.S. Department of Transportation, and the pipeline safety regulations adopted and administered by a state authority pursuant to a certification under 49 U.S.C. 60105, as applicable, for injection into a well subject to the requirements for the Class VI Underground Injection Control Program of Rule R317-7.

(ii) Any Class VI Underground Injection Control well owner or operator, who claims that a carbon dioxide stream is excluded under Subsection R315-261-4(h), shall have an authorized representative, as defined in Section R315-260-10, sign a certification statement worded as follows: I certify under penalty of law that the carbon dioxide stream that I am claiming to be excluded under Subsection R315-261-4(h) has not been mixed with, or otherwise co-injected with, hazardous waste at the Underground Injection Control (UIC) Class VI permitted facility, and that injection of the carbon dioxide stream is in compliance with the applicable requirements for UIC Class VI wells, including the applicable requirements in Rule R317-7.

(iii) The signed certification statement shall be kept on-site for no less than three years, and shall be made available within 72 hours of a written request from the Director. The signed certification statement shall be renewed every year that the exclusion is claimed, by having an authorized representative, as defined in Section R315-260-10, annually prepare and sign a new copy of the certification statement within one year of the date of the previous statement. The signed certification statement shall also be readily accessible on the facility's publicly-available Web site, if such Web site exists, as a public notification with the title of "Carbon Dioxide Stream Certification" at the time the exclusion is claimed.

(i) Reserved

(j)(1) Airbag waste at the airbag waste handler or during transport to an airbag waste collection facility or designated facility is not subject to regulation under Rules R315-262 through 268, R315-270 or R315-124, and is not subject to the notification requirements of section 3010 of RCRA provided that:

(i) The airbag waste is accumulated in a quantity of no more than 250 airbag modules or airbag inflators, for no longer than 180 days;

(ii) The airbag waste is packaged in a container designed to address the risk posed by the airbag waste and labeled "Airbag Waste -- Do Not Reuse;"

(iii) The airbag waste is sent directly to either

(A) An airbag waste collection facility in the United States under the control of a vehicle manufacturer or their authorized representative, or under the control of an authorized party

administering a remedy program in response to a recall under the National Highway Traffic Safety Administration, or

(B) A designated facility as defined in Section R315-260-10;

(iv) The transport of the airbag waste complies with [~~all~~]applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 during transit;

(v) The airbag waste handler maintains at the handler facility for no less than three years records of [~~all~~]each off-site shipment[~~s~~] of airbag waste and [~~all~~]each confirmation[~~s~~] of receipt from the receiving facility. For each shipment, these records [~~must~~]shall, at a minimum, contain the name of the transporter and date of the shipment; name and address of receiving facility; and the type and quantity of airbag waste, [~~i.e.~~]that is, airbag modules or airbag inflators, in the shipment. Confirmations of receipt [~~must~~]shall include the name and address of the receiving facility; the type and quantity of the airbag waste, [~~i.e.~~]that is, airbag modules and airbag inflators, received; and the date which it was received. Shipping records and confirmations of receipt [~~must~~]shall be made available for inspection and may be satisfied by routine business records[~~, e.g.,~~] such as electronic or paper financial records, bills of lading, copies of DOT shipping papers, or electronic confirmations of receipt.

(2) Once the airbag waste arrives at an airbag waste collection facility or designated facility, it becomes subject to [~~all~~]applicable hazardous waste [~~regulations~~]rules, and the facility receiving airbag waste is considered the hazardous waste generator for the purposes of the hazardous waste [~~regulations~~]rules and [~~must~~]shall comply with the requirements of Rule R315-262.

(3) Reuse in vehicles of defective airbag modules or defective airbag inflators subject to a recall under the National Highway Traffic Safety Administration is considered sham recycling and prohibited under Subsection R315-261-2(g).

R315-261-6. Requirements for Recyclable Materials.

(a)(1) Hazardous wastes that are recycled are subject to the requirements for generators, transporters, and storage facilities of Subsections R315-261-6(b) and (c), except for the materials listed in Subsections R315-261-6(a)(2) and (a)(3). Hazardous wastes that are recycled shall be known as "recyclable materials."

(2) The following recyclable materials are not subject to the requirements of Section R315-261-6 but are regulated under Sections R315-266-20 through R315-266-23, Section R315-266-70, Section R315-266-80, Sections R315-266-100 through R315-266-112[~~, Sections R315-266-200 through 206, and Sections R315-266-210, 220, 225, 230,235, 240, 245, 250, 255, 260, 310, 315, 320, 325, 330, 335, 340, 345,350, 355, and 360~~] and [~~all applicable provisions in~~]Rules R315-268, R315-270, and R315-124.

(i) Recyclable materials used in a manner constituting disposal, Sections R315-266-20 through 23;

(ii) Hazardous wastes burned, as defined in Subsection R315-266-100(a), in boilers and industrial furnaces that are not regulated under Sections R315-264-340 through 345, 347 and 351; Sections R315-370, 373, 375, 377, and 381 through 383; and Section R315-266-100 through 112;

(iii) Recyclable materials from which precious metals are

reclaimed, Section R315-266-70;

(iv) Spent lead-acid batteries that are being reclaimed, Section R315-266-80.

(3) The following recyclable materials are not subject to regulation under Rules R315-262 through R315-268, R315-270, and R315-124, and are not subject to the notification requirements of section 3010 of RCRA:

(i) Industrial ethyl alcohol that is reclaimed except that exports and imports of such recyclable materials [~~must~~]shall comply with the requirements of Sections R315-262-80 through R315-262-84.

(ii) Scrap metal that is not excluded under Subsection R315-261-4(a)(13);

(iii) Fuels produced from the refining of oil-bearing hazardous waste along with normal process streams at a petroleum refining facility if such wastes result from normal petroleum refining, production, and transportation practices, this exemption does not apply to fuels produced from oil recovered from oil-bearing hazardous waste, where such recovered oil is already excluded under Subsection R315-261-4(a)(12);

(iv)(A) Hazardous waste fuel produced from oil-bearing hazardous wastes from petroleum refining, production, or transportation practices, or produced from oil reclaimed from such hazardous wastes, where such hazardous wastes are reintroduced into a process that does not use distillation or does not produce products from crude oil so long as the resulting fuel meets the used oil specification under Subsection R315-15-1.2(c) and so long as no other hazardous wastes are used to produce the hazardous waste fuel;

(B) Hazardous waste fuel produced from oil-bearing hazardous waste from petroleum refining production, and transportation practices, where such hazardous wastes are reintroduced into a refining process after a point at which contaminants are removed, so long as the fuel meets the used oil fuel specification under Subsection R315-15-1.2(c); and

(C) Oil reclaimed from oil-bearing hazardous wastes from petroleum refining, production, and transportation practices, which reclaimed oil is burned as a fuel without reintroduction to a refining process, so long as the reclaimed oil meets the used oil fuel specification under Subsection R315-15-1.2(c).

(4) Used oil that is recycled and is also a hazardous waste solely because it exhibits a hazardous characteristic is not subject to the requirements of Rules R315-260 through 268, but is regulated under Rule R315-15. Used oil that is recycled includes any used oil which is reused, following its original use, for any purpose, including the purpose for which the oil was originally used. Such term includes, but is not limited to, oil which is re-refined, reclaimed, burned for energy recovery, or reprocessed.

(5) Hazardous waste that is exported or imported for purpose of recovery is subject to the requirements of Sections R315-262-80 through 84.

(b) Generators and transporters of recyclable materials are subject to the applicable requirements of Rules R315-262 and 263 and the notification requirements under section 3010 of RCRA, except as provided in Subsection R315-261-6(a).

(c)(1) Owners and operators of facilities that store recyclable

materials before they are recycled are regulated under [~~all applicable provisions of~~]Rules R315-264 and R315-265, and under Rules R315-266, R315-268, R315-270, and R315-124 and the notification requirements under section 3010 of RCRA, except as provided in Subsection R315-261-6(a). The recycling process itself is exempt from regulation except as provided in Subsection R315-261-6(d).

(2) Owners or operators of facilities that recycle recyclable materials without storing them before they are recycled are subject to the following requirements, except as provided in R315-261-6(a):

(i) Notification requirements under section 3010 of RCRA;

(ii) Sections R315-265-71 and 72 dealing with the use of the manifest and manifest discrepancies;

(iii) Subsection R315-261-6(d); and

(iv) Section R315-265-75, addressing biennial reporting requirements.

(d) Owners or operators of facilities subject to permitting requirements under Section 19-6-108 with hazardous waste management units that recycle hazardous wastes are subject to the requirements of Sections R315-264-1030 through 1036; and Sections R315-264-1050 through 1065; [~~40 CFR~~]Sections R315-265[~~.~~]-1030 through R315-265-1035[~~, which are adopted and incorporated by reference~~]; or 40 CFR 265.1050 through 1064, which are adopted and incorporated by reference.

R315-261-7. Residues of Hazardous Waste in Empty Containers.

(a)(1) Any hazardous waste remaining in either: an empty container; or an inner liner removed from an empty container, as defined in Subsection R315-261-7(b), is not subject to regulation under Rules R315-261 through R315-266, R315-268, R315-270 or R315-124 or to the notification requirements of section 3010 of RCRA.

(2) Any hazardous waste in either a container that is not empty or an inner liner removed from a container that is not empty, as defined in Subsection R315-261-7(b), is subject to regulation under Rules R315-261 through R315-266, R315-268, R315-270, and R315-124 and to the notification requirements of section 3010 of RCRA.

(b)(1) A container or an inner liner removed from a container that has held any hazardous waste, except a waste that is a compressed gas or that is identified as an acute hazardous waste listed in Section R315-261-31 or Subsection R315-261-33(e) is empty if:

(i) [~~All~~]The wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container[~~, e.g.,~~] such as pouring, pumping, and aspirating, and

(ii) No more than 2.5 centimeters, one inch, of residue remain on the bottom of the container or inner liner, or

(iii)(A) No more than three percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or

(B) No more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.

(2) A container that has held a hazardous waste that is a compressed gas is empty [~~when~~]if the pressure in the container approaches atmospheric.

(3) A container or an inner liner removed from a container that

has held an acute hazardous waste listed in Section R315-261-31 or Subsection R315-261-33(e) is empty if:

(i) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

(c) Containers of hazardous waste pharmaceuticals are subject to Section R315-266-507 for determining if they are considered empty, in lieu of Section R315-261-7, except as provided by Subsections R315-266-507(c) and R315-266-507(d).

R315-261-33. Lists of Hazardous Wastes - Discarded Commercial Chemical Products, Off-Specification Species, Container Residues, and Spill Residues Thereof.

The following materials or items are hazardous wastes if [~~and when~~]they are discarded or intended to be discarded as described in Subsection R315-261-2(a)(2)(i), [~~when~~]if they are mixed with waste oil or used oil or other material and applied to the land for dust suppression or road treatment, [~~when~~]if they are otherwise applied to the land in lieu of their original intended use or [~~when~~]if they are contained in products that are applied to the land in lieu of their original intended use, or [~~when~~]if, in lieu of their original intended use, they are produced for use as, or a component of, a fuel, distributed for use as a fuel, or burned as a fuel.

(a) Any commercial chemical product, or manufacturing chemical intermediate having the generic name listed in Subsections R315-261-33(e) or (f).

(b) Any off-specification commercial chemical product or manufacturing chemical intermediate which, if it met specifications, would have the generic name listed in Subsection R315-261-33(e) or (f).

(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in Subsection R315-261-33(e) or R315-261-33(f), unless the container is empty as defined in Subsection R315-261-7(b) or Section R315-266-507. Unless the residue is being beneficially used or reused, or legitimately recycled or reclaimed; or being accumulated, stored, transported or treated prior to such use, re-use, recycling or reclamation, the Director considers the residue to be intended for discard, and thus, a hazardous waste. An example of a legitimate re-use of the residue would be where the residue remains in the container and the container is used to hold the [~~same~~]commercial chemical product or manufacturing chemical intermediate it previously held. An example of the discard of the residue would be where the drum is sent to a drum reconditioner who reconditions the drum but discards the residue.

(d) Any residue or contaminated soil, water or other debris resulting from the cleanup of a spill into or on any land or water

of any commercial chemical product or manufacturing chemical intermediate having the generic name listed in Subsection R315-261-33(e) or (f), or any residue or contaminated soil, water or other debris resulting from the cleanup of a spill, into or on any land or water, of any off-specification chemical product and manufacturing chemical intermediate which, if it met specifications, would have the generic name listed in Subsection R315-261-33(e) or (f). The phrase "commercial chemical product or manufacturing chemical intermediate having the generic name listed in..." refers to a chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and [~~all~~]each formulation[~~s~~] in which the chemical is the sole active ingredient. It does not refer to a material, such as a manufacturing process waste, that contains any of the substances listed in Subsection R315-261-33(e) or (f). Where a manufacturing process waste is deemed to be a hazardous waste because it contains a substance listed in Subsection R315-261-33(e) or (f), such waste shall be listed in either Sections R315-261-31 or 32 or shall be identified as a hazardous waste by the characteristics set forth in Sections R315-261-20 through 24.

(e) The commercial chemical products, manufacturing chemical intermediates or off-specification commercial chemical products or manufacturing chemical intermediates referred to in Subsections R315-261-33(a) through (d), are identified as acute hazardous wastes (H). For the convenience of the regulated community the primary hazardous properties of these materials have been indicated by the letters T (Toxicity), and R (Reactivity). Absence of a letter indicates that the compound only is listed for acute toxicity. Wastes are first listed in alphabetical order by substance and then listed again in numerical order by Hazardous Waste Number. These wastes and their corresponding EPA Hazardous Waste Numbers are:

TABLE

Hazardous waste No.	Chemical abstracts No.	Substance
P023	107-20-0	Acetaldehyde, chloro-
P002	591-08-2	Acetamide, N-(aminothioxomethyl)-
P057	640-19-7	Acetamide, 2-fluoro-
P058	62-74-8	Acetic acid, fluoro-, sodium salt
P002	591-08-2	1-Acetyl-2-thiourea
P003	107-02-8	Acrolein
P070	116-06-3	Aldicarb
P203	1646-88-4	Aldicarb sulfone.
P004	309-00-2	Aldrin
P005	107-18-6	Allyl alcohol
P006	20859-73-8	Aluminum phosphide (R,T)
P007	2763-96-4	5-(Aminomethyl)-3-isoxazolol
P008	504-24-5	4-Aminopyridine
P009	131-74-8	Ammonium picrate (R)
P119	7803-55-6	Ammonium vanadate

P099	506-61-6	Argentate(1-), bis(cyano-C)-, potassium
P010	7778-39-4	Arsenic acid H3 AsO4
P012	1327-53-3	Arsenic oxide As2 O3
P011	1303-28-2	Arsenic oxide As2 O5
P011	1303-28-2	Arsenic pentoxide
P012	1327-53-3	Arsenic trioxide
P038	692-42-2	Arsine, diethyl-
P036	696-28-6	Arsonous dichloride, phenyl-
P054	151-56-4	Aziridine
P067	75-55-8	Aziridine, 2-methyl-
P013	542-62-1	Barium cyanide
P024	106-47-8	Benzenamine, 4-chloro-
P077	100-01-6	Benzenamine, 4-nitro-
P028	100-44-7	Benzene, (chloromethyl)-
P042	51-43-4	1,2-Benzenediol, 4-(1-hydroxy-2-(methylamino)ethyl)-, (R)-
P046	122-09-8	Benzeneethanamine, alpha,alpha-dimethyl-
P014	108-98-5	Benzenethiol
P127	1563-66-2	7-Benzofuranol, 2,3-dihydro-2,2-dimethyl-,methylcarbamate.
P188	57-64-7	Benzoic acid, 2-hydroxy-, compd. with (3aS-cis)-1,2,3,3a,8,8a-hexahydro-1,3a,8-trimethylpyrrolo(2,3-b)indol-5-ylmethylcarbamate ester (1:1).
P001	(1)81-81-2	2H-1-Benzopyran-2-one, 4-hydroxy-3-(3-oxo-1-phenylbutyl)-, and salts, [~~when~~]<u>if</u> present at concentrations greater than 0.3%
P028	100-44-7	Benzyl chloride
P015	7440-41-7	Beryllium powder
P017	598-31-2	Bromoacetone
P018	357-57-3	Brucine
P045	39196-18-4	2-Butanone, 3,3-dimethyl-1-(methylthio)-, O-methylamino)carbonyl) oxime
P021	592-01-8	Calcium cyanide
P021	592-01-8	Calcium cyanide Ca(CN)2
P189	55285-14-8	Carbamic acid, ((dibutylamino)-thio)methyl-, 2,3-dihydro-2,2-dimethyl- 7-benzofuranyl ester.
P191	644-64-4	Carbamic acid, dimethyl-, 1-((dimethyl-amino)carbonyl)-5-methyl-1H- pyrazol-3-yl ester.
P192	119-38-0	Carbamic acid, dimethyl-, 3-methyl-1- (1-methylethyl)-1H-pyrazol-5-yl ester.
P190	1129-41-5	Carbamic acid, methyl-, 3-methylphenyl ester.
P127	1563-66-2	Carbofuran.
P022	75-15-0	Carbon disulfide
P095	75-44-5	Carbonic dichloride

P189	55285-14-8	Carbosulfan.
P023	107-20-0	Chloroacetaldehyde
P024	106-47-8	p-Chloroaniline
P026	5344-82-1	1-(o-Chlorophenyl)thiourea
P027	542-76-7	3-Chloropropionitrile
P029	544-92-3	Copper cyanide
P029	544-92-3	Copper cyanide Cu(CN)
P202	64-00-6	m-Cumenyl methylcarbamate.
P030		Cyanides (soluble cyanide salts), not otherwise specified
P031	460-19-5	Cyanogen
P033	506-77-4	Cyanogen chloride
P033	506-77-4	Cyanogen chloride (CN)Cl
P034	131-89-5	2-Cyclohexyl-4,6-dinitrophenol
P016	542-88-1	Dichloromethyl ether
P036	696-28-6	Dichlorophenylarsine
P037	60-57-1	Dieldrin
P038	692-42-2	Diethylarsine
P041	311-45-5	Diethyl-p-nitrophenyl phosphate
P040	297-97-2	O,O-Diethyl O-pyrazinyl phosphorothioate
P043	55-91-4	Diisopropylfluorophosphate (DFP)
P004	309-00-2	1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexa- chloro- 1,4,4a,5,8,8a,- hexahydro-, (1alpha, 4alpha, 4abeta, 5alpha,8alpha,8abeta)-
P060	465-73-6	1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexa- chloro- 1,4,4a,5,8,8ahexahydro-, (1alpha, 4alpha, 4abeta, 5beta, 8beta,8abeta)-
P037	60-57-1	2,7:3,6-Dimethanonaphth(2,3-b)oxirene, 3,4,5,6,9,9-hexachloro- 1a,2,2a,3,6,6a,7,7a-octahydro-, (1aalpha, 2beta, 2aalpha, 3beta, 6beta, 6aalpha,7beta, 7aalpha)-
P051	(1)72-20-8	2,7:3,6-Dimethanonaphth (2,3-b)oxirene, 3,4,5,6,9,9- hexachloro- 1a,2,2a,3,6,6a,7,7a- octahydro-, (1aalpha, 2beta, 2abeta, 3alpha, 6alpha, 6abeta, 7beta, 7aalpha)-, and metabolites
P044	60-51-5	Dimethoate
P046	122-09-8	alpha,alpha-Dimethylphenethylamine
P191	644-64-4	Dimetilan.
P047	(1)534-52-1	4,6-Dinitro-o-cresol, and salts
P048	51-28-5	2,4-Dinitrophenol
P020	88-85-7	Dinoseb
P085	152-16-9	Diphosphoramide, octamethyl-
P111	107-49-3	Diphosphoric acid, tetraethyl ester
P039	298-04-4	Disulfoton
P049	541-53-7	Dithiobiuret
P185	26419-73-8	1,3-Dithiolane-2-carboxaldehyde, 2,4-dimethyl-, O- ((methylamino)-

		carbonyl)oxime.
P050	115-29-7	Endosulfan
P088	145-73-3	Endothall
P051	72-20-8	Endrin
P051	72-20-8	Endrin, and metabolites
P042	51-43-4	Epinephrine
P031	460-19-5	Ethanedinitrile
P194	23135-22-0	Ethanimidothioic acid, 2-(dimethylamino)-N-(((methylamino) carbonyl)oxy)-2-oxo-, methyl ester.
P066	16752-77-5	Ethanimidothioic acid, N-(((methylamino)carbonyl)oxy)-, methyl ester
P101	107-12-0	Ethyl cyanide
P054	151-56-4	Ethyleneimine
P097	52-85-7	Famphur
P056	7782-41-4	Fluorine
P057	640-19-7	Fluoroacetamide
P058	62-74-8	Fluoroacetic acid, sodium salt
P198	23422-53-9	Formetanate hydrochloride.
P197	17702-57-7	Formparanate.
P065	628-86-4	Fulminic acid, mercury(2+) salt (R,T)
P059	76-44-8	Heptachlor
P062	757-58-4	Hexaethyl tetraphosphate
P116	79-19-6	Hydrazinecarbothioamide
P068	60-34-4	Hydrazine, methyl-
P063	74-90-8	Hydrocyanic acid
P063	74-90-8	Hydrogen cyanide
P096	7803-51-2	Hydrogen phosphide
P060	465-73-6	Isodrin
P192	119-38-0	Isolan.
P202	64-00-6	3-Isopropylphenyl N-methylcarbamate.
P007	2763-96-4	3(2H)-Isoxazolone, 5-(aminomethyl)-
P196	15339-36-3	Manganese, bis(dimethylcarbamodithioato-S,S')-,
P196	15339-36-3	Manganese dimethyldithiocarbamate.
P092	62-38-4	Mercury, (acetato-O)phenyl-
P065	628-86-4	Mercury fulminate (R,T)
P082	62-75-9	Methanamine, N-methyl-N-nitroso-
P064	624-83-9	Methane, isocyanato-
P016	542-88-1	Methane, oxybis(chloro-
P112	509-14-8	Methane, tetranitro- (R)
P118	75-70-7	Methanethiol, trichloro-
P198	23422-53-9	Methanimidamide, N,N-dimethyl-N'-(3-(((methylamino)-carbonyl)oxy)phenyl)-, monohydrochloride.
P197	17702-57-7	Methanimidamide, N,N-dimethyl-N'-(2-methyl-4-(((methylamino)carbonyl)oxy)phenyl)-
P050	115-29-7	6,9-Methano-2,4,3-benzodioxathiepin, 6,7,8,9,10,10- hexachloro-1,5,5a,6,9,9a-hexahydro-, 3-oxide
P059	76-44-8	4,7-Methano-1H-indene, 1,4,5,6,7,8,8-

		heptachloro- 3a,4,7,7a-tetrahydro-
P199	2032-65-7	Methiocarb.
P066	16752-77-5	Methomyl
P068	60-34-4	Methyl hydrazine
P064	624-83-9	Methyl isocyanate
P069	75-86-5	2-Methyllactonitrile
P071	298-00-0	Methyl parathion
P190	1129-41-5	Metolcarb.
P128	315-8-4	Mexacarbate.
P072	86-88-4	alpha-Naphthylthiourea
P073	13463-39-3	Nickel carbonyl
P073	13463-39-3	Nickel carbonyl Ni(CO)4, (T-4)-
P074	557-19-7	Nickel cyanide
P074	557-19-7	Nickel cyanide Ni(CN)2
P075	(1)54-11-5	Nicotine, and salts, this listing does not include patches, gums and lozenges that are FDA approved over-the-counter nicotine replacement therapies
P076	10102-43-9	Nitric oxide
P077	100-01-6	p-Nitroaniline
P078	10102-44-0	Nitrogen dioxide
P076	10102-43-9	Nitrogen oxide NO
P078	10102-44-0	Nitrogen oxide NO2
P081	55-63-0	Nitroglycerine (R)
P082	62-75-9	N-Nitrosodimethylamine
P084	4549-40-0	N-Nitrosomethylvinylamine
P085	152-16-9	Octamethylpyrophosphoramide
P087	20816-12-0	Osmium oxide OsO4, (T-4)-
P087	20816-12-0	Osmium tetroxide
P088	145-73-3	7-Oxabicyclo(2.2.1)heptane-2,3-dicarboxylic acid
P194	23135-22-0	Oxamyl.
P089	56-38-2	Parathion
P034	131-89-5	Phenol, 2-cyclohexyl-4,6-dinitro-
P048	51-28-5	Phenol, 2,4-dinitro-
P047	(1)534-52-1	Phenol, 2-methyl-4,6-dinitro-, and salts
P020	88-85-7	Phenol, 2-(1-methylpropyl)-4,6-dinitro-
P009	131-74-8	Phenol, 2,4,6-trinitro-, ammonium salt (R)
P128	315-18-4	Phenol, 4-(dimethylamino)-3,5-dimethyl-, methylcarbamate (ester).
P199	2032-65-7	Phenol, (3,5-dimethyl-4-(methylthio)-, methylcarbamate
P202	64-00-6	Phenol, 3-(1-methylethyl)-, methyl carbamate.
P201	2631-37-0	Phenol, 3-methyl-5-(1-methylethyl)-, methyl carbamate.
P092	62-38-4	Phenylmercury acetate
P093	103-85-5	Phenylthiourea
P094	298-02-2	Phorate
P095	75-44-5	Phosgene

P096	7803-51-2	Phosphine
P041	311-45-5	Phosphoric acid, diethyl 4-nitrophenyl ester
P039	298-04-4	Phosphorodithioic acid, O,O-diethyl S-(2- (ethylthio)ethyl) ester
P094	298-02-2	Phosphorodithioic acid, O,O-diethyl S-((ethylthio)methyl) ester
P044	60-51-5	Phosphorodithioic acid, O,O-dimethyl S-(2- (methylamino)-2-oxoethyl) ester
P043	55-91-4	Phosphorofluoridic acid, bis(1-methylethyl) ester
P089	56-38-2	Phosphorothioic acid, O,O-diethyl O-(4-nitrophenyl) ester
P040	297-97-2	Phosphorothioic acid, O,O-diethyl O-pyrazinyl ester
P097	52-85-7	Phosphorothioic acid, O-(4-((dimethylamino)sulfonyl)phenyl) O,O-dimethyl ester
P071	298-00-0	Phosphorothioic acid, O,O,-dimethyl O-(4-nitrophenyl) ester
P204	57-47-6	Physostigmine.
P188	57-64-7	Physostigmine salicylate.
P110	78-00-2	Plumbane, tetraethyl-
P098	151-50-8	Potassium cyanide
P098	151-50-8	Potassium cyanide K(CN)
P099	506-61-6	Potassium silver cyanide
P201	2631-37-0	Promecarb
P070	116-06-3	Propanal, 2-methyl-2-(methylthio)-, O-((methylamino)carbonyl)oxime
P203	1646-88-4	Propanal, 2-methyl-2-(methyl-sulfonyl)-, O- ((methylamino)carbonyl) oxime.
P101	107-12-0	Propanenitrile
P027	542-76-7	Propanenitrile, 3-chloro-
P069	75-86-5	Propanenitrile, 2-hydroxy-2-methyl-
P081	55-63-0	1,2,3-Propanetriol, trinitrate (R)
P017	598-31-2	2-Propanone, 1-bromo-
P102	107-19-7	Propargyl alcohol
P003	107-02-8	2-Propenal
P005	107-18-6	2-Propen-1-ol
P067	75-55-8	1,2-Propylenimine
P102	107-19-7	2-Propyn-1-ol
P008	504-24-5	4-Pyridinamine
P075	(1)54-11-5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, and salts, this listing does not include patches, gums and lozenges that are FDA approved over-the-counter nicotine replacement therapies
P204	57-47-6	Pyrrolo(2,3-b)indol-5-ol, 1,2,3,3a,8,8a-hexahydro-1,3a,8-trimethyl-, methylcarbamate (ester), (3aS-cis)-.
P114	12039-52-0	Selenious acid, dithallium(1+) salt
P103	630-10-4	Selenourea

P104	506-64-9	Silver cyanide
P104	506-64-9	Silver cyanide Ag(CN)
P105	26628-22-8	Sodium azide
P106	143-33-9	Sodium cyanide
P106	143-33-9	Sodium cyanide Na(CN)
P108	(1)57-24-9	Strychnidin-10-one, and salts
P018	357-57-3	Strychnidin-10-one, 2,3-dimethoxy-
P108	(1)57-24-9	Strychnine, and salts
P115	7446-18-6	Sulfuric acid, dithallium(1+) salt
P109	3689-24-5	Tetraethyldithiopyrophosphate
P110	78-00-2	Tetraethyl lead
P111	107-49-3	Tetraethyl pyrophosphate
P112	509-14-8	Tetranitromethane (R)
P062	757-58-4	Tetraphosphoric acid, hexaethyl ester
P113	1314-32-5	Thallic oxide
P113	1314-32-5	Thallium oxide Tl2 O3
P114	12039-52-0	Thallium(I) selenite
P115	7446-18-6	Thallium(I) sulfate
P109	3689-24-5	Thiodiphosphoric acid, tetraethyl ester
P045	39196-18-4	Thiofanox
P049	541-53-7	Thioimidodicarbonic diamide ((H2 N)C(S))2 NH
P014	108-98-5	Thiophenol
P116	79-19-6	Thiosemicarbazide
P026	5344-82-1	Thiourea, (2-chlorophenyl)-
P072	86-88-4	Thiourea, 1-naphthalenyl-
P093	103-85-5	Thiourea, phenyl-
P185	26419-73-8	Tirpate.
P123	8001-35-2	Toxaphene
P118	75-70-7	Trichloromethanethiol
P119	7803-55-6	Vanadic acid, ammonium salt
P120	1314-62-1	Vanadium oxide V2 O5
P120	1314-62-1	Vanadium pentoxide
P084	4549-40-0	Vinylamine, N-methyl-N-nitroso-
P001	(1)81-81-2	Warfarin, and salts, [~~when~~]if present at concentrations greater than 0.3%
P205	137-30-4	Zinc, bis(dimethylcarbamodithioato-S,S')-,
P121	557-21-1	Zinc cyanide
P121	557-21-1	Zinc cyanide Zn(CN)2
P122	1314-84-7	Zinc phosphide Zn3 P2, [~~when~~]if present at concentrations greater than 10% (R,T)
P205	137-30-4	Ziram.
P001	(1)81-81-2	2H-1-Benzopyran-2-one, 4-hydroxy-3-(3-oxo-1-phenylbutyl)-, and salts, [~~when~~]if present at concentrations greater than 0.3%
P001	(1)81-81-2	Warfarin, and salts, [~~when~~]if present at concentrations greater than 0.3%
P002	591-08-2	Acetamide, -(aminothioxomethyl)-
P002	591-08-2	1-Acetyl-2-thiourea
P003	107-02-8	Acrolein
P003	107-02-8	2-Propenal

P004	309-00-2	Aldrin
P004	309-00-2	1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexa-chloro-1,4,4a,5,8,8a,- hexahydro-, (1alpha, 4alpha, 4abeta, 5alpha, 8alpha,8abeta)-
P005	107-18-6	Allyl alcohol
P005	107-18-6	2-Propen-1-ol
P006	20859-73-8	Aluminum phosphide (R,T)
P007	2763-96-4	5-(Aminomethyl)-3-isoxazolol
P007	2763-96-4	3(2H)-Isoxazolone, 5-(aminomethyl)-
P008	504-24-5	4-Aminopyridine
P008	504-24-5	4-Pyridinamine
P009	131-74-8	Ammonium picrate (R)
P009	131-74-8	Phenol, 2,4,6-trinitro-, ammonium salt (R)
P010	7778-39-4	Arsenic acid H3 AsO4
P011	1303-28-2	Arsenic oxide As2 O5
P011	1303-28-2	Arsenic pentoxide
P012	1327-53-3	Arsenic oxide As2 O3
P012	1327-53-3	Arsenic trioxide
P013	542-62-1	Barium cyanide
P014	108-98-5	Benzenethiol
P014	108-98-5	Thiophenol
P015	7440-41-7	Beryllium powder
P016	542-88-1	Dichloromethyl ether
P016	542-88-1	Methane, oxybis(chloro-
P017	598-31-2	Bromoacetone
P017	598-31-2	2-Propanone, 1-bromo-
P018	357-57-3	Brucine
P018	357-57-3	Strychnidin-10-one, 2,3-dimethoxy-
P020	88-85-7	Dinoseb
P020	88-85-7	Phenol, 2-(1-methylpropyl)-4,6-dinitro-
P021	592-01-8	Calcium cyanide
P021	592-01-8	Calcium cyanide Ca(CN)2
P022	75-15-0	Carbon disulfide
P023	107-20-0	Acetaldehyde, chloro-
P023	107-20-0	Chloroacetaldehyde
P024	106-47-8	Benzenamine, 4-chloro-
P024	106-47-8	p-Chloroaniline
P026	5344-82-1	1-(o-Chlorophenyl)thiourea
P026	5344-82-1	Thiourea, (2-chlorophenyl)-
P027	542-76-7	3-Chloropropionitrile
P027	542-76-7	Propanenitrile, 3-chloro-
P028	100-44-7	Benzene, (chloromethyl)-
P028	100-44-7	Benzyl chloride
P029	544-92-3	Copper cyanide
P029	544-92-3	Copper cyanide Cu(CN)
P030		Cyanides (soluble cyanide salts), not otherwise specified
P031	460-19-5	Cyanogen
P031	460-19-5	Ethanedinitrile
P033	506-77-4	Cyanogen chloride

P033	506-77-4	Cyanogen chloride (CN)Cl
P034	131-89-5	2-Cyclohexyl-4,6-dinitrophenol
P034	131-89-5	Phenol, 2-cyclohexyl-4,6-dinitro-
P036	696-28-6	Arsonous dichloride, phenyl-
P036	696-28-6	Dichlorophenylarsine
P037	60-57-1	Dieldrin
P037	60-57-1	2,7:3,6-Dimethanonaphth(2,3-b)oxirene, 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-, (1aalpha, 2beta, 2aalpha, 3beta, 6beta,6aalpha,7beta, 7aalpha)-
P038	692-42-2	Arsine, diethyl-
P038	692-42-2	Diethylarsine
P039	298-04-4	Disulfoton
P039	298-04-4	Phosphorodithioic acid, O,O-diethyl S-(2- (ethylthio)ethyl) ester
P040	297-97-2	O,O-Diethyl O-pyrazinyl phosphorothioate
P040	297-97-2	Phosphorothioic acid, O,O-diethyl O-pyrazinyl ester
P041	311-45-5	Diethyl-p-nitrophenyl phosphate
P041	311-45-5	Phosphoric acid, diethyl 4-nitrophenyl ester
P042	51-43-4	1,2-Benzenediol, 4-(1-hydroxy-2-(methylamino)ethyl)-, (R)-
P042	51-43-4	Epinephrine
P043	55-91-4	Diisopropylfluorophosphate (DFP)
P043	55-91-4	Phosphorofluoridic acid, bis(1-methylethyl) ester
P044	60-51-5	Dimethoate
P044	60-51-5	Phosphorodithioic acid, O,O-dimethyl S-(2-(methyl amino)-2-oxoethyl) ester
P045	39196-18-4	2-Butanone, 3,3-dimethyl-1-(methylthio)-, O-((methylamino)carbonyl) oxime
P045	39196-18-4	Thiofanox
P046	122-09-8	Benzeneethanamine, alpha,alpha-dimethyl-
P046	122-09-8	alpha,alpha-Dimethylphenethylamine
P047	(1)534-52-1	4,6-Dinitro-o-cresol, and salts
P047	(1)534-52-1	Phenol, 2-methyl-4,6-dinitro-, and salts
P048	51-28-5	2,4-Dinitrophenol
P048	51-28-5	Phenol, 2,4-dinitro-
P049	541-53-7	Dithiobiuret
P049	541-53-7	Thioimidodicarbonic diamide ((H2 N)C(S))2 NH
P050	115-29-7	Endosulfan
P050	115-29-7	6,9-Methano-2,4,3-benzodioxathiepin, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-, 3-oxide
P051	(1)72-20-8	2,7:3,6-Dimethanonaphth (2,3-b)oxirene, 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-,

		(1aalpha, 2beta,2abeta, 3alpha, 6alpha, 6abeta,7beta, 7aalpha)-, and metabolites
P051	72-20-8	Endrin
P051	72-20-8	Endrin, and metabolites
P054	151-56-4	Aziridine
P054	151-56-4	Ethyleneimine
P056	7782-41-4	Fluorine
P057	640-19-7	Acetamide, 2-fluoro-
P057	640-19-7	Fluoroacetamide
P058	62-74-8	Acetic acid, fluoro-, sodium salt
P058	62-74-8	Fluoroacetic acid, sodium salt
P059	76-44-8	Heptachlor
P059	76-44-8	4,7-Methano-1H-indene, 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-
P060	465-73-6	1,4,5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexa-chloro-1,4,4a,5,8,8a-hexahydro-, (1alpha, 4alpha,4abeta,5beta, 8beta,8abeta)-
P060	465-73-6	Isodrin
P062	757-58-4	Hexaethyl tetraphosphate
P062	757-58-4	Tetraphosphoric acid, hexaethyl ester
P063	74-90-8	Hydrocyanic acid
P063	74-90-8	Hydrogen cyanide
P064	624-83-9	Methane, isocyanato-
P064	624-83-9	Methyl isocyanate
P065	628-86-4	Fulminic acid, mercury(2+) salt (R,T)
P065	628-86-4	Mercury fulminate (R,T)
P066	16752-77-5	Ethanimidothioic acid, N-(((methylamino)carbonyl)oxy)-, methyl ester
P066	16752-77-5	Methomyl
P067	75-55-8	Aziridine, 2-methyl-
P067	75-55-8	1,2-Propylenimine
P068	60-34-4	Hydrazine, methyl-
P068	60-34-4	Methyl hydrazine
P069	75-86-5	2-Methyllactonitrile
P069	75-86-5	Propanenitrile, 2-hydroxy-2-methyl-
P070	116-06-3	Aldicarb
P070	116-06-3	Propanal, 2-methyl-2-(methylthio)-, O-((methylamino)carbonyl)oxime
P071	298-00-0	Methyl parathion
P071	298-00-0	Phosphorothioic acid, O,O,-dimethyl O-(4-nitrophenyl) ester
P072	86-88-4	alpha-Naphthylthiourea
P072	86-88-4	Thiourea, 1-naphthalenyl-
P073	13463-39-3	Nickel carbonyl
P073	13463-39-3	Nickel carbonyl Ni(CO)4, (T-4)-
P074	557-19-7	Nickel cyanide
P074	557-19-7	Nickel cyanide Ni(CN)2
P075	(1)54-11-5	Nicotine, and salts, this listing does not include patches, gums and lozenges that are FDA approved over-the-counter nicotine replacement therapies

P075	(1)54-11-5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, S)-, and salts, this listing does not include patches, gums and lozenges that are FDA approved over-the-counter nicotine replacement therapies
P076	10102-43-9	Nitric oxide
P076	10102-43-9	Nitrogen oxide NO
P077	100-01-6	Benzenamine, 4-nitro-
P077	100-01-6	p-Nitroaniline
P078	10102-44-0	Nitrogen dioxide
P078	10102-44-0	Nitrogen oxide NO2
P081	55-63-0	Nitroglycerine (R)
P081	55-63-0	1,2,3-Propanetriol, trinitrate (R)
P082	62-75-9	Methanamine, -methyl-N-nitroso-
P082	62-75-9	N-Nitrosodimethylamine
P084	4549-40-0	N-Nitrosomethylvinylamine
P084	4549-40-0	Vinylamine, -methyl-N-nitroso-
P085	152-16-9	Diphosphoramide, octamethyl-
P085	152-16-9	Octamethylpyrophosphoramide
P087	20816-12-0	Osmium oxide OsO4, (T-4)-
P087	20816-12-0	Osmium tetroxide
P088	145-73-3	Endothall
P088	145-73-3	7-Oxabicyclo(2.2.1)heptane-2,3-dicarboxylic acid
P089	56-38-2	Parathion
P089	56-38-2	Phosphorothioic acid, O,O-diethyl O-(4-nitrophenyl) ester
P092	62-38-4	Mercury, (acetato-O)phenyl-
P092	62-38-4	Phenylmercury acetate
P093	103-85-5	Phenylthiourea
P093	103-85-5	Thiourea, phenyl-
P094	298-02-2	Phorate
P094	298-02-2	Phosphorodithioic acid, O,O-diethyl S-((ethylthio)methyl) ester
P095	75-44-5	Carbonic dichloride
P095	75-44-5	Phosgene
P096	7803-51-2	Hydrogen phosphide
P096	7803-51-2	Phosphine
P097	52-85-7	Famphur
P097	52-85-7	Phosphorothioic acid, O-(4-((dimethylamino)sulfonyl)phenyl) O,O-dimethyl ester
P098	151-50-8	Potassium cyanide
P098	151-50-8	Potassium cyanide K(CN)
P099	506-61-6	Argentate(1-), bis(cyano-C)-, potassium
P099	506-61-6	Potassium silver cyanide
P101	107-12-0	Ethyl cyanide
P101	107-12-0	Propanenitrile
P102	107-19-7	Propargyl alcohol
P102	107-19-7	2-Propyn-1-ol
P103	630-10-4	Selenourea
P104	506-64-9	Silver cyanide
P104	506-64-9	Silver cyanide Ag(CN)

P105	26628-22-8	Sodium azide
P106	143-33-9	Sodium cyanide
P106	143-33-9	Sodium cyanide Na(CN)
P108	(1)157-24-9	Strychnidin-10-one, and salts
P108	(1)157-24-9	Strychnine, and salts
P109	3689-24-5	Tetraethyldithiopyrophosphate
P109	3689-24-5	Thiodiphosphoric acid, tetraethyl ester
P110	78-00-2	Plumbane, tetraethyl-
P110	78-00-2	Tetraethyl lead
P111	107-49-3	Diphosphoric acid, tetraethyl ester
P111	107-49-3	Tetraethyl pyrophosphate
P112	509-14-8	Methane, tetranitro-(R)
P112	509-14-8	Tetranitromethane (R)
P113	1314-32-5	Thallic oxide
P113	1314-32-5	Thallium oxide Tl2 O3
P114	12039-52-0	Selenious acid, dithallium(1+) salt
P114	12039-52-0	Tetraethyldithiopyrophosphate
P115	7446-18-6	Thiodiphosphoric acid, tetraethyl ester
P115	7446-18-6	Plumbane, tetraethyl-
P116	79-19-6	Tetraethyl lead
P116	79-19-6	Thiosemicarbazide
P118	75-70-7	Methanethiol, trichloro-
P118	75-70-7	Trichloromethanethiol
P119	7803-55-6	Ammonium vanadate
P119	7803-55-6	Vanadic acid, ammonium salt
P120	1314-62-1	Vanadium oxide V2O5
P120	1314-62-1	Vanadium pentoxide
P121	557-21-1	Zinc cyanide
P121	557-21-1	Zinc cyanide Zn(CN)2
P122	1314-84-7	Zinc phosphide Zn3 P2, [~~when~~]if present at concentrations greater than 10% (R,T)
P123	8001-35-2	Toxaphene
P127	1563-66-2	7-Benzofuranol, 2,3-dihydro-2,2-dimethyl-, methylcarbamate.
P127	1563-66-2	Carbofuran
P128	315-8-4	Mexacarbate
P128	315-18-4	Phenol, 4-(dimethylamino)-3,5-dimethyl-, methylcarbamate (ester)
P185	26419-73-8	1,3-Dithiolane-2-carboxaldehyde, 2,4-dimethyl-, O-((methylamino)-carbonyl)oxime.
P185	26419-73-8	Tirpate
P188	57-64-7	Benzoic acid, 2-hydroxy-, compd. with (3aS-cis)-1,2,3,3a,8,8a-hexahydro-1,3a,8-trimethylpyrrolo(2,3-b)indol-5-yl methylcarbamate ester (1:1)
P188	57-64-7	Physostigmine salicylate
P189	55285-14-8	Carbamic acid, ((dibutylamino)-thio)methyl-, 2,3-dihydro-2,2-dimethyl-7-benzofuranyl ester
P189	55285-14-8	Carbosulfan

P190	1129-41-5	Carbamic acid, methyl-, 3-methylphenyl ester
P190	1129-41-5	Metolcarb
P191	644-64-4	Carbamic acid, dimethyl-, 1-((dimethyl-amino)carbonyl)-5-methyl-1H-pyrazol-3-yl ester
P191	644-64-4	Dimetilan
P192	119-38-0	Carbamic acid, dimethyl-, 3-methyl-1-(1-methylethyl)-1H-pyrazol-5-yl ester
P192	119-38-0	Isolan
P194	23135-22-0	Ethanimidthioic acid, 2-(dimethylamino)-N- (((methylamino) carbonyl)oxy)-2-oxo-, methyl ester
P194	23135-22-0	Oxamyl
P196	15339-36-3	Manganese, bis(dimethylcarbamodithioato-S,S')-,
P196	15339-36-3	Manganese dimethyldithiocarbamate
P197	17702-57-7	Formparanate
P197	17702-57-7	Methanimidamide, N,N-dimethyl-N'-(2-methyl-4-(((methylamino)carbonyl)oxy)phenyl)-
P198	23422-53-9	Formetanate hydrochloride
P198	23422-53-9	Methanimidamide, N,N-dimethyl-N'-(3-(((methylamino)-carbonyl)oxy)phenyl)-monohydrochloride
P199	2032-65-7	Methiocarb
P199	2032-65-7	Phenol, (3,5-dimethyl-4-(methylthio)-, methylcarbamate
P201	2631-37-0	Phenol, 3-methyl-5-(1-methylethyl)-, methyl carbamate
P201	2631-37-0	Promecarb
P202	64-00-6	m-Cumenyl methylcarbamate
P202	64-00-6	3-Isopropylphenyl N-methylcarbamate
P202	64-00-6	Phenol, 3-(1-methylethyl)-, methyl carbamate
P203	1646-88-4	Aldicarb sulfone
P203	1646-88-4	Propanal, 2-methyl-2-(methyl-sulfonyl)-, O- ((methylamino)carbonyl) oxime
P204	57-47-6	Physostigmine
P204	57-47-6	Pyrrolo(2,3-b)indol-5-ol, 1,2,3,3a,8,8a-hexahydro-1,3a,8-trimethyl-, methylcarbamate (ester), (3aS-cis)-
P205	137-30-4	Zinc, bis(dimethylcarbamodithioato-S,S')-,
P205	137-30-4	Ziram
P999		Nerve, Military, and Chemical Agents' [~~(i.e.~~]that is, CX, GA, GB, GD, H, HD, HL, HN-1, HN-2, HN-3, HT, L, T, and VX.[~~)~~]

Note (1) CAS Number given for parent compound only.

(f) The commercial chemical products, manufacturing chemical intermediates, or off-specification commercial chemical products referred to in Subsections R315-261-33(a) through (d), are identified as toxic wastes (T), unless otherwise designated. For the convenience of the regulated community, the primary hazardous properties of these materials have been indicated by the letters T (Toxicity), R (Reactivity), I (Ignitability) and C (Corrosivity). Absence of a letter indicates that the compound is only listed for toxicity. Wastes are first listed in alphabetical order by substance and then listed again in numerical order by Hazardous Waste Number. These wastes and their corresponding EPA Hazardous Waste Numbers are:

TABLE

Hazardous waste No.	Chemical abstracts No.	Substance
U394	30558-43-1	A2213.
U001	75-07-0	Acetaldehyde (I)
U034	75-87-6	Acetaldehyde, trichloro-
U187	62-44-2	Acetamide, N-(4-ethoxyphenyl)-
U005	53-96-3	Acetamide, N-9H-fluoren-2-yl-
U240 (1)	94-75-7	Acetic acid, (2,4-dichlorophenoxy)-, salts and esters
U112	141-78-6	Acetic acid ethyl ester (I)
U144	301-04-2	Acetic acid, lead(2+) salt
U214	563-68-8	Acetic acid, thallium(1+) salt
see F027	93-76-5	Acetic acid, (2,4,5-trichlorophenoxy)-
U002	67-64-1	Acetone (I)
U003	75-05-8	Acetonitrile (I,T)
U004	98-86-2	Acetophenone
U005	53-96-3	2-Acetylaminofluorene
U006	75-36-5	Acetyl chloride (C,R,T)
U007	79-06-1	Acrylamide
U008	79-10-7	Acrylic acid (I)
U009	107-13-1	Acrylonitrile
U011	61-82-5	Amitrole
U012	62-53-3	Aniline (I,T)
U136	75-60-5	Arsinic acid, dimethyl-
U014	492-80-8	Auramine
U015	115-02-6	Azaserine
U010	50-07-7	Azirino(2',3':3,4)pyrrolo(1,2-a)indole-4,7-dione, 6-amino-8-(((aminocarbonyl)oxy) methyl)-1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methyl-, (1aS-(1aalpha, 8beta, 8aalpha,8balpha))-
U280	101-27-9	Barban.
U278	22781-23-3	Bendiocarb.
U364	22961-82-6	Bendiocarb phenol.
U271	17804-35-2	Benomyl.
U157	56-49-5	Benz(j)aceanthrylene, 1,2-dihydro-3-methyl-

U016	225-51-4	Benz(c)acridine
U017	98-87-3	Benzal chloride
U192	23950-58-5	Benzamide, 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)-
U018	56-55-3	Benz(a)anthracene
U094	57-97-6	Benz(a)anthracene, 7,12-dimethyl-
U012	62-53-3	Benzenamine (I,T)
U014	492-80-8	Benzenamine, 4,4'-carbonimidoylbis(N,N-dimethyl-
U049	3165-93-3	Benzenamine, 4-chloro-2-methyl-, hydrochloride
U093	60-11-7	Benzenamine, N,N-dimethyl-4-(phenylazo)-
U328	95-53-4	Benzenamine, 2-methyl-
U353	106-49-0	Benzenamine, 4-methyl-
U158	101-14-4	Benzenamine, 4,4'-methylenebis(2-chloro-
U222	636-21-5	Benzenamine, 2-methyl-, hydrochloride
U181	99-55-8	Benzenamine, 2-methyl-5-nitro-
U019	71-43-2	Benzene (I,T)
U038	510-15-6	Benzeneacetic acid, 4-chloro-alpha-(4-chlorophenyl)-alpha-hydroxy-, ethyl ester
U030	101-55-3	Benzene, 1-bromo-4-phenoxy-
U035	305-03-3	Benzenebutanoic acid, 4-(bis(2-chloroethyl)amino)-
U037	108-90-7	Benzene, chloro-
U221	25376-45-8	Benzenediamine, ar-methyl-
U028	117-81-7	1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester
U069	84-74-2	1,2-Benzenedicarboxylic acid, dibutyl ester
U088	84-66-2	1,2-Benzenedicarboxylic acid, diethyl ester
U102	131-11-3	1,2-Benzenedicarboxylic acid, dimethyl ester
U107	117-84-0	1,2-Benzenedicarboxylic acid, dioctyl ester
U070	95-50-1	Benzene, 1,2-dichloro-
U071	541-73-1	Benzene, 1,3-dichloro-
U072	106-46-7	Benzene, 1,4-dichloro-
U060	72-54-8	Benzene, 1,1'-(2,2-dichloroethylidene) bis(4-chloro-
U017	98-87-3	Benzene, (dichloromethyl)-
U223	26471-62-5	Benzene, 1,3-diisocyanatomethyl- (R,T)
U239	1330-20-7	Benzene, dimethyl- (I)
U201	108-46-3	1,3-Benzenediol
U127	118-74-1	Benzene, hexachloro-
U056	110-82-7	Benzene, hexahydro- (I)
U220	108-88-3	Benzene, methyl-
U105	121-14-2	Benzene, 1-methyl-2,4-dinitro-
U106	606-20-2	Benzene, 2-methyl-1,3-dinitro-
U055	98-82-8	Benzene, (1-methylethyl)- (I)
U169	98-95-3	Benzene, nitro-

U183	608-93-5	Benzene, pentachloro-
U185	82-68-8	Benzene, pentachloronitro-
U020	98-09-9	Benzenesulfonic acid chloride (C,R)
U020	98-09-9	Benzenesulfonyl chloride (C,R)
U207	95-94-3	Benzene, 1,2,4,5-tetrachloro-
U061	50-29-3	Benzene, 1,1'-(2,2,2-trichloroethylidene) bis(4-chloro-
U247	72-43-5	Benzene, 1,1'-(2,2,2-trichloroethylidene) bis(4- methoxy-
U023	98-07-7	Benzene, (trichloromethyl)-
U234	99-35-4	Benzene, 1,3,5-trinitro-
U021	92-87-5	Benzidine
U278	22781-23-3	1,3-Benzodioxol-4-ol, 2,2-dimethyl-, methyl carbamate.
U364	22961-82-6	1,3-Benzodioxol-4-ol, 2,2-dimethyl-,
U203	94-59-7	1,3-Benzodioxole, 5-(2-propenyl)-
U141	120-58-1	1,3-Benzodioxole, 5-(1-propenyl)-
U367	1563-38-8	7-Benzofuranol, 2,3-dihydro-2,2-dimethyl-
U090	94-58-6	1,3-Benzodioxole, 5-propyl-
U064	189-55-9	Benzo(rst)pentaphene
U248	(1)81-81-2	2H-1-Benzopyran-2-one, 4-hydroxy-3-(3-oxo-1-phenyl-butyl)-, and salts, [~~when~~]if present at concentrations of 0.3% or less
U022	50-32-8	Benzo(a)pyrene
U197	106-51-4	p-Benzoquinone
U023	98-07-7	Benzotrichloride (C,R,T)
U085	1464-53-5	2,2'-Bioxirane
U021	92-87-5	(1,1'-Biphenyl)-4,4'-diamine
U073	91-94-1	(1,1'-Biphenyl)-4,4'-diamine, 3,3'-dichloro-
U091	119-90-4	(1,1'-Biphenyl)-4,4'-diamine, 3,3'-dimethoxy-
U095	119-93-7	(1,1'-Biphenyl)-4,4'-diamine, 3,3'-dimethyl-
U225	75-25-2	Bromoform
U030	101-55-3	4-Bromophenyl phenyl ether
U128	87-68-3	1,3-Butadiene, 1,1,2,3,4,4-hexachloro-
U172	924-16-3	1-Butanamine, N-butyl-N-nitroso-
U031	71-36-3	1-Butanol (I)
U159	78-93-3	2-Butanone (I,T)
U160	1338-23-4	2-Butanone, peroxide (R,T)
U053	4170-30-3	2-Butenal
U074	764-41-0	2-Butene, 1,4-dichloro- (I,T)
U143	303-34-4	2-Butenoic acid, 2-methyl-, 7-((2,3-dihydroxy- 2-(1-methoxyethyl)-3-methyl-1-oxobutoxy)methyl)- 2,3,5,7a-tetrahydro-1H-pyrrolizin-1-yl ester, (1S- (1alpha(Z),7(2S*,3R*),7aalpha))-
U031	71-36-3	n-Butyl alcohol (I)
U136	75-60-5	Cacodylic acid
U032	13765-19-0	Calcium chromate

U372	10605-21-7	Carbamic acid, 1H-benzimidazol-2-yl, methyl ester.
U271	17804-35-2	Carbamic acid, (1-((butylamino)carbonyl)-1H-benzimidazol-2-yl)-, methyl ester.
U280	101-27-9	Carbamic acid, (3-chlorophenyl)-, 4-chloro-2-butynyl ester.
U238	51-79-6	Carbamic acid, ethyl ester
U178	615-53-2	Carbamic acid, methylnitroso-, ethyl ester
U373	122-42-9	Carbamic acid, phenyl-, 1-methylethyl ester.
U409	23564-05-8	Carbamic acid, (1,2-phenylenebis(iminocarbonothioyl))bis-, dimethyl ester.
U097	79-44-7	Carbamic chloride, dimethyl-
U389	2303-17-5	Carbamothioic acid, bis(1-methylethyl)-, S-(2,3,3-trichloro-2-propenyl) ester.
U387	52888-80-9	Carbamothioic acid, dipropyl-, S-(phenylmethyl) ester.
U114	(1)111-54-6	Carbamodithioic acid, 1,2-ethanediylbis-, salts and esters
U062	2303-16-4	Carbamothioic acid, bis(1-methylethyl)-, S- (2,3-dichloro-2-propenyl) ester
U279	63-25-2	Carbaryl.
U372	10605-21-7	Carbendazim.
U367	1563-38-8	Carbofuran phenol.
U215	6533-73-9	Carbonic acid, dithallium(1+) salt
U033	353-50-4	Carbonic difluoride
U156	79-22-1	Carbonochloridic acid, methyl ester (I,T)
U033	353-50-4	Carbon oxyfluoride (R,T)
U211	56-23-5	Carbon tetrachloride
U034	75-87-6	Chloral
U035	305-03-3	Chlorambucil
U036	57-74-9	Chlordane, alpha and gamma isomers
U026	494-03-1	Chlornaphazin
U037	108-90-7	Chlorobenzene
U038	510-15-6	Chlorobenzilate
U039	59-50-7	p-Chloro-m-cresol
U042	110-75-8	2-Chloroethyl vinyl ether
U044	67-66-3	Chloroform
U046	107-30-2	Chloromethyl methyl ether
U047	91-58-7	beta-Chloronaphthalene
U048	95-57-8	o-Chlorophenol
U049	3165-93-3	4-Chloro-o-toluidine, hydrochloride
U032	13765-19-0	Chromic acid H2 CrO4, calcium salt
U050	218-01-9	Chrysene
U051		Creosote
U052	1319-77-3	Cresol (Cresylic acid)
U053	4170-30-3	Crotonaldehyde

U055	98-82-8	Cumene (I)
U246	506-68-3	Cyanogen bromide (CN)Br
U197	106-51-4	2,5-Cyclohexadiene-1,4-dione
U056	110-82-7	Cyclohexane (I)
U129	58-89-9	Cyclohexane, 1,2,3,4,5,6-hexachloro-, (1alpha,2alpha,3beta,4alpha, 5alpha, 6beta)-
U057	108-94-1	Cyclohexanone (I)
U130	77-47-4	1,3-Cyclopentadiene, 1,2,3,4,5,5-hexachloro-
U058	50-18-0	Cyclophosphamide
U240	(1)94-75-7	2,4-D, salts and esters
U059	20830-81-3	Daunomycin
U060	72-54-8	DDD
U061	50-29-3	DDT
U062	2303-16-4	Diallate
U063	53-70-3	Dibenz(a,h)anthracene
U064	189-55-9	Dibenzo(a,i)pyrene
U066	96-12-8	1,2-Dibromo-3-chloropropane
U069	84-74-2	Dibutyl phthalate
U070	95-50-1	o-Dichlorobenzene
U071	541-73-1	m-Dichlorobenzene
U072	106-46-7	p-Dichlorobenzene
U073	91-94-1	3,3'-Dichlorobenzidine
U074	764-41-0	1,4-Dichloro-2-butene (I,T)
U075	75-71-8	Dichlorodifluoromethane
U078	75-35-4	1,1-Dichloroethylene
U079	156-60-5	1,2-Dichloroethylene
U025	111-44-4	Dichloroethyl ether
U027	108-60-1	Dichloroisopropyl ether
U024	111-91-1	Dichloromethoxy ethane
U081	120-83-2	2,4-Dichlorophenol
U082	87-65-0	2,6-Dichlorophenol
U084	542-75-6	1,3-Dichloropropene
U085	1464-53-5	1,2:3,4-Diepoxybutane (I,T)
U108	123-91-1	1,4-Diethyleneoxide
U028	117-81-7	Diethylhexyl phthalate
U395	5952-26-1	Diethylene glycol, dicarbamate.
U086	1615-80-1	N,N'-Diethylhydrazine
U087	3288-58-2	O,O-Diethyl S-methyl dithiophosphate
U088	84-66-2	Diethyl phthalate
U089	56-53-1	Diethylstilbesterol
U090	94-58-6	Dihydrosafrole
U091	119-90-4	3,3'-Dimethoxybenzidine
U092	124-40-3	Dimethylamine (I)
U093	60-11-7	p-Dimethylaminoazobenzene
U094	57-97-6	7,12-Dimethylbenz(a)anthracene
U095	119-93-7	3,3'-Dimethylbenzidine
U096	80-15-9	alpha,alpha-Dimethylbenzylhydroperoxide (R)
U097	79-44-7	Dimethylcarbamoyl chloride
U098	57-14-7	1,1-Dimethylhydrazine
U099	540-73-8	1,2-Dimethylhydrazine
U101	105-67-9	2,4-Dimethylphenol

U102	131-11-3	Dimethyl phthalate
U103	77-78-1	Dimethyl sulfate
U105	121-14-2	2,4-Dinitrotoluene
U106	606-20-2	2,6-Dinitrotoluene
U107	117-84-0	Di-n-octyl phthalate
U108	123-91-1	1,4-Dioxane
U109	122-66-7	1,2-Diphenylhydrazine
U110	142-84-7	Dipropylamine (I)
U111	621-64-7	Di-n-propylnitrosamine
U041	106-89-8	Epichlorohydrin
U001	75-07-0	Ethanal (I)
U404	121-44-8	Ethanamine, N,N-diethyl-
U174	55-18-5	Ethanamine, N-ethyl-N-nitroso-
U155	91-80-5	1,2-Ethanediamine, N,N-dimethyl-N'-2-pyridinyl-N'-(2-thienylmethyl)-
U067	106-93-4	Ethane, 1,2-dibromo-
U076	75-34-3	Ethane, 1,1-dichloro-
U077	107-06-2	Ethane, 1,2-dichloro-
U131	67-72-1	Ethane, hexachloro-
U024	111-91-1	Ethane, 1,1'-(methylenebis(oxy))bis(2-chloro-
U117	60-29-7	Ethane, 1,1'-oxybis-(I)
U025	111-44-4	Ethane, 1,1'-oxybis(2-chloro-
U184	76-01-7	Ethane, pentachloro-
U208	630-20-6	Ethane, 1,1,1,2-tetrachloro-
U209	79-34-5	Ethane, 1,1,2,2-tetrachloro-
U218	62-55-5	Ethanethioamide
U226	71-55-6	Ethane, 1,1,1-trichloro-
U227	79-00-5	Ethane, 1,1,2-trichloro-
U410	59669-26-0	Ethanimidothioic acid, N,N'-(thiobis((methylimino)carbonyloxy))bis-, dimethyl ester
U394	30558-43-1	Ethanimidothioic acid, 2-(dimethylamino)-N-hydroxy-2-oxo-, methyl ester.
U359	110-80-5	Ethanol, 2-ethoxy-
U173	1116-54-7	Ethanol, 2,2'-(nitrosoimino)bis-
U395	5952-26-1	Ethanol, 2,2'-oxybis-, dicarbamate.
U004	98-86-2	Ethanone, 1-phenyl-
U043	75-01-4	Ethene, chloro-
U042	110-75-8	Ethene, (2-chloroethoxy)-
U078	75-35-4	Ethene, 1,1-dichloro-
U079	156-60-5	Ethene, 1,2-dichloro-, (E)-
U210	127-18-4	Ethene, tetrachloro-
U228	79-01-6	Ethene, trichloro-
U112	141-78-6	Ethyl acetate (I)
U113	140-88-5	Ethyl acrylate (I)
U238	51-79-6	Ethyl carbamate (urethane)
U117	60-29-7	Ethyl ether (I)
U114	(1)111-54-6	Ethylenebisdithiocarbamic acid, salts and esters
U067	106-93-4	Ethylene dibromide
U077	107-06-2	Ethylene dichloride
U359	110-80-5	Ethylene glycol monoethyl ether

U115	75-21-8	Ethylene oxide (I,T)
U116	96-45-7	Ethylenethiourea
U076	75-34-3	Ethylidene dichloride
U118	97-63-2	Ethyl methacrylate
U119	62-50-0	Ethyl methanesulfonate
U120	206-44-0	Fluoranthene
U122	50-00-0	Formaldehyde
U123	64-18-6	Formic acid (C,T)
U124	110-00-9	Furan (I)
U125	98-01-1	2-Furancarboxaldehyde (I)
U147	108-31-6	2,5-Furandione
U213	109-99-9	Furan, tetrahydro-(I)
U125	98-01-1	Furfural (I)
U124	110-00-9	Furfuran (I)
U206	18883-66-4	Glucopyranose, 2-deoxy-2-(3-methyl-3-nitrosoureido)-, D-
U206	18883-66-4	D-Glucose, 2-deoxy-2-(((methylnitrosoamino)-carbonyl)amino)-
U126	765-34-4	Glycidylaldehyde
U163	70-25-7	Guanidine, N-methyl-N'-nitro-N-nitroso-
U127	118-74-1	Hexachlorobenzene
U128	87-68-3	Hexachlorobutadiene
U130	77-47-4	Hexachlorocyclopentadiene
U131	67-72-1	Hexachloroethane
U132	70-30-4	Hexachlorophene
U243	1888-71-7	Hexachloropropene
U133	302-01-2	Hydrazine (R,T)
U086	1615-80-1	Hydrazine, 1,2-diethyl-
U098	57-14-7	Hydrazine, 1,1-dimethyl-
U099	540-73-8	Hydrazine, 1,2-dimethyl-
U109	122-66-7	Hydrazine, 1,2-diphenyl-
U134	7664-39-3	Hydrofluoric acid (C,T)
U134	7664-39-3	Hydrogen fluoride (C,T)
U135	7783-06-4	Hydrogen sulfide
U135	7783-06-4	Hydrogen sulfide H2 S
U096	80-15-9	Hydroperoxide, 1-methyl-1-phenylethyl-(R)
U116	96-45-7	2-Imidazolidinethione
U137	193-39-5	Indeno(1,2,3-cd)pyrene
U190	85-44-9	1,3-Isobenzofurandione
U140	78-83-1	Isobutyl alcohol (I,T)
U141	120-58-1	Isosafrole
U142	143-50-0	Kepone
U143	303-34-4	Lasiocarpine
U144	301-04-2	Lead acetate
U146	1335-32-6	Lead, bis(acetato-O)tetrahydroxytri-
U145	7446-27-7	Lead phosphate
U146	1335-32-6	Lead subacetate
U129	58-89-9	Lindane
U163	70-25-7	MNNG
U147	108-31-6	Maleic anhydride
U148	123-33-1	Maleic hydrazide

U149	109-77-3	Malononitrile
U150	148-82-3	Melphalan
U151	7439-97-6	Mercury
U152	126-98-7	Methacrylonitrile (I, T)
U092	124-40-3	Methanamine, N-methyl- (I)
U029	74-83-9	Methane, bromo-
U045	74-87-3	Methane, chloro- (I, T)
U046	107-30-2	Methane, chloromethoxy-
U068	74-95-3	Methane, dibromo-
U080	75-09-2	Methane, dichloro-
U075	75-71-8	Methane, dichlorodifluoro-
U138	74-88-4	Methane, iodo-
U119	62-50-0	Methanesulfonic acid, ethyl ester
U211	56-23-5	Methane, tetrachloro-
U153	74-93-1	Methanethiol (I, T)
U225	75-25-2	Methane, tribromo-
U044	67-66-3	Methane, trichloro-
U121	75-69-4	Methane, trichlorofluoro-
U036	57-74-9	4,7-Methano-1H-indene, 1,2,4,5,6,7,8,8-octachloro-2,3,3a,4,7,7a-hexahydro-
U154	67-56-1	Methanol (I)
U155	91-80-5	Methapyrilene
U142	143-50-0	1,3,4-Metheno-2H-cyclobuta(cd)pentalen-2-one, 1,1a,3,3a,4,5,5,5a,5b,6-decachlorooctahydro-
U247	72-43-5	Methoxychlor
U154	67-56-1	Methyl alcohol (I)
U029	74-83-9	Methyl bromide
U186	504-60-9	1-Methylbutadiene (I)
U045	74-87-3	Methyl chloride (I,T)
U156	79-22-1	Methyl chlorocarbonate (I,T)
U226	71-55-6	Methyl chloroform
U157	56-49-5	3-Methylcholanthrene
U158	101-14-4	4,4'-Methylenebis(2-chloroaniline)
U068	74-95-3	Methylene bromide
U080	75-09-2	Methylene chloride
U159	78-93-3	Methyl ethyl ketone (MEK) (I,T)
U160	1338-23-4	Methyl ethyl ketone peroxide (R,T)
U138	74-88-4	Methyl iodide
U161	108-10-1	Methyl isobutyl ketone (I)
U162	80-62-6	Methyl methacrylate (I,T)
U161	108-10-1	4-Methyl-2-pentanone (I)
U164	56-04-2	Methylthiouracil
U010	50-07-7	Mitomycin C
U059	20830-81-3	5,12-Naphthacenedione, 8-acetyl-10-((3-amino-2,3,6-trideoxy)-alpha-L-lyxo-hexopyranosyl)oxy)-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-, (8S-cis)-
U167	134-32-7	1-Naphthalenamine
U168	91-59-8	2-Naphthalenamine
U026	494-03-1	Naphthalenamine, N,N'-bis(2-

		chloroethyl)-
U165	91-20-3	Naphthalene
U047	91-58-7	Naphthalene, 2-chloro-
U166	130-15-4	1,4-Naphthalenedione
U236	72-57-1	2,7-Naphthalenedisulfonic acid, 3,3'-((3,3'- dimethyl(1,1'-biphenyl)-4,4'-diyl)bis(azo)bis(5-amino-4-hydroxy)-, tetrasodium salt
U279	63-25-2	1-Naphthalenol, methylcarbamate.
U166	130-15-4	1,4-Naphthoquinone
U167	134-32-7	alpha-Naphthylamine
U168	91-59-8	beta-Naphthylamine
U217	10102-45-1	Nitric acid, thallium(1+) salt
U169	98-95-3	Nitrobenzene (I,T)
U170	100-02-7	p-Nitrophenol
U171	79-46-9	2-Nitropropane (I,T)
U172	924-16-3	N-Nitrosodi-n-butylamine
U173	1116-54-7	N-Nitrosodiethanolamine
U174	55-18-5	N-Nitrosodiethylamine
U176	759-73-9	N-Nitroso-N-ethylurea
U177	684-93-5	N-Nitroso-N-methylurea
U178	615-53-2	N-Nitroso-N-methylurethane
U179	100-75-4	N-Nitrosopiperidine
U180	930-55-2	N-Nitrosopyrrolidine
U181	99-55-8	5-Nitro-o-toluidine
U193	1120-71-4	1,2-Oxathiolane, 2,2-dioxide
U058	50-18-0	2H-1,3,2-Oxazaphosphorin-2-amine, N,N-bis(2-chloroethyl)tetrahydro-, 2-oxide
U115	75-21-8	Oxirane (I,T)
U126	765-34-4	Oxiranecarboxyaldehyde
U041	106-89-8	Oxirane, (chloromethyl)-
U182	123-63-7	Paraldehyde
U183	608-93-5	Pentachlorobenzene
U184	76-01-7	Pentachloroethane
U185	82-68-8	Pentachloronitrobenzene (PCNB)
See F027	87-86-5	Pentachlorophenol
U161	108-10-1	Pentanol, 4-methyl-
U186	504-60-9	1,3-Pentadiene (I)
U187	62-44-2	Phenacetin
U188	108-95-2	Phenol
U048	95-57-8	Phenol, 2-chloro-
U039	59-50-7	Phenol, 4-chloro-3-methyl-
U081	120-83-2	Phenol, 2,4-dichloro-
U082	87-65-0	Phenol, 2,6-dichloro-
U089	56-53-1	Phenol, 4,4'-(1,2-diethyl-1,2-ethenediyl)bis-, (E)-
U101	105-67-9	Phenol, 2,4-dimethyl-
U052	1319-77-3	Phenol, methyl-
U132	70-30-4	Phenol, 2,2'-methylenebis(3,4,6-trichloro-
U411	114-26-1	Phenol, 2-(1-methylethoxy)-, methylcarbamate.
U170	100-02-7	Phenol, 4-nitro-
See F027	87-86-5	Phenol, pentachloro-

See F027	58-90-2	Phenol, 2,3,4,6-tetrachloro-
See F027	95-95-4	Phenol, 2,4,5-trichloro-
See F027	88-06-2	Phenol, 2,4,6-trichloro-
U150	148-82-3	L-Phenylalanine, 4-(bis(2-chloroethyl)amino)-
U145	7446-27-7	Phosphoric acid, lead(2+) salt (2:3)
U087	3288-58-2	Phosphorodithioic acid, O,O-diethyl S-methyl ester
U189	1314-80-3	Phosphorus sulfide (R)
U190	85-44-9	Phthalic anhydride
U191	109-06-8	2-Picoline
U179	100-75-4	Piperidine, 1-nitroso-
U192	23950-58-5	Pronamide
U194	107-10-8	1-Propanamine (I,T)
U111	621-64-7	1-Propanamine, N-nitroso-N-propyl-
U110	142-84-7	1-Propanamine, N-propyl- (I)
U066	96-12-8	Propane, 1,2-dibromo-3-chloro-
U083	78-87-5	Propane, 1,2-dichloro-
U149	109-77-3	Propanedinitrile
U171	79-46-9	Propane, 2-nitro- (I,T)
U027	108-60-1	Propane, 2,2'-oxybis(2-chloro-
U193	1120-71-4	1,3-Propane sultone
See F027	93-72-1	Propanoic acid, 2-(2,4,5-trichlorophenoxy)-
U235	126-72-7	1-Propanol, 2,3-dibromo-, phosphate (3:1)
U140	78-83-1	1-Propanol, 2-methyl- (I,T)
U002	67-64-1	2-Propanone (I)
U007	79-06-1	2-Propenamide
U084	542-75-6	1-Propene, 1,3-dichloro-
U243	1888-71-7	1-Propene, 1,1,2,3,3,3-hexachloro-
U009	107-13-1	2-Propenenitrile
U152	126-98-7	2-Propenenitrile, 2-methyl- (I,T)
U008	79-10-7	2-Propenoic acid (I)
U113	140-88-5	2-Propenoic acid, ethyl ester (I)
U118	97-63-2	2-Propenoic acid, 2-methyl-, ethyl ester
U162	80-62-6	2-Propenoic acid, 2-methyl-, methyl ester (I,T)
U373	122-42-9	Propham.
U411	114-26-1	Propoxur.
U387	52888-80-9	Prosulfocarb.
U194	107-10-8	n-Propylamine (I,T)
U083	78-87-5	Propylene dichloride
U148	123-33-1	3,6-Pyridazinedione, 1,2-dihydro-
U196	110-86-1	Pyridine
U191	109-06-8	Pyridine, 2-methyl-
U237	66-75-1	2,4-(1H,3H)-Pyrimidinedione, 5-(bis(2-chloroethyl)amino)-
U164	56-04-2	4(1H)-Pyrimidinone, 2,3-dihydro-6-methyl-2-thioxo-
U180	930-55-2	Pyrrolidine, 1-nitroso-
U200	50-55-5	Reserpine

U201	108-46-3	Resorcinol
U203	94-59-7	Safrole
U204	7783-00-8	Selenious acid
U204	7783-00-8	Selenium dioxide
U205	7488-56-4	Selenium sulfide
U205	7488-56-4	Selenium sulfide SeS2 (R,T)
U015	115-02-6	L-Serine, diazoacetate (ester)
See F027	93-72-1	Silvex (2,4,5-TP)
U206	18883-66-4	Streptozotocin
U103	77-78-1	Sulfuric acid, dimethyl ester
U189	1314-80-3	Sulfur phosphide (R)
See F027	93-76-5	2,4,5-T
U207	95-94-3	1,2,4,5-Tetrachlorobenzene
U208	630-20-6	1,1,1,2-Tetrachloroethane
U209	79-34-5	1,1,2,2-Tetrachloroethane
U210	127-18-4	Tetrachloroethylene
See F027	58-90-2	2,3,4,6-Tetrachlorophenol
U213	109-99-9	Tetrahydrofuran (I)
U214	563-68-8	Thallium(I) acetate
U215	6533-73-9	Thallium(I) carbonate
U216	7791-12-0	Thallium(I) chloride
U216	7791-12-0	thallium chloride TlCl
U217	10102-45-1	Thallium(I) nitrate
U218	62-55-5	Thioacetamide
U410	59669-26-0	Thiodicarb.
U153	74-93-1	Thiomethanol (I,T)
U244	137-26-8	Thioperoxydicarbonic diamide ((H2 N)C(S))2 S2, tetramethyl-
U409	23564-05-8	Thiophanate-methyl.
U219	62-56-6	Thiourea
U244	137-26-8	Thiram
U220	108-88-3	Toluene
U221	25376-45-8	Toluenediamine
U223	26471-62-5	Toluene diisocyanate (R,T)
U328	95-53-4	o-Toluidine
U353	106-49-0	p-Toluidine
U222	636-21-5	o-Toluidine hydrochloride
U389	2303-17-5	Triallate.
U011	61-82-5	1H-1,2,4-Triazol-3-amine
U226	71-55-6	1,1,1-Trichloroethane
U227	79-00-5	1,1,2-Trichloroethane
U228	79-01-6	Trichloroethylene
U121	75-69-4	Trichloromonofluoromethane
See F027	95-95-4	2,4,5-Trichlorophenol
See F027	88-06-2	2,4,6-Trichlorophenol
U404	121-44-8	Triethylamine.
U234	99-35-4	1,3,5-Trinitrobenzene (R,T)
U182	123-63-7	1,3,5-Trioxane, 2,4,6-trimethyl-
U235	126-72-7	Tris(2,3-dibromopropyl) phosphate
U236	72-57-1	Trypan blue
U237	66-75-1	Uracil shallard
U176	759-73-9	Urea, N-ethyl-N-nitroso-
U177	684-93-5	Urea, N-methyl-N-nitroso-
U043	75-01-4	Vinyl chloride

U248	(1)81-81-2	Warfarin, and salts, [~~when~~]if present at concentrations of 0.3% or less
U239	1330-20-7	Xylene (I)
U200	50-55-5	Yohimban-16-carboxylic acid, 11,17-dimethoxy-18-((3,4,5-trimethoxybenzoyl) oxy)-, methyl ester, (3beta,16beta, 17alpha,18beta, 20alpha)-
U249	1314-84-7	Zinc phosphide Zn3 P2, [~~when~~]if present at concentrations of 10% or less
U001	75-07-0	Acetaldehyde (I)
U001	75-07-0	Ethanal (I)
U002	67-64-1	Acetone (I)
U002	67-64-1	2-Propanone (I)
U003	75-05-8	Acetonitrile (I,T)
U004	98-86-2	Acetophenone
U004	98-86-2	Ethanone, 1-phenyl-
U005	53-96-3	Acetamide, -9H-fluoren-2-yl-
U005	53-96-3	2-Acetylaminofluorene
U006	75-36-5	Acetyl chloride (C,R,T)
U007	79-06-1	Acrylamide
U007	79-06-1	2-Propenamide
U008	79-10-7	Acrylic acid (I)
U008	79-10-7	2-Propenoic acid (I)
U009	107-13-1	Acrylonitrile
U009	107-13-1	2-Propenenitrile
U010	50-07-7	Azirino(2',3':3,4)pyrrolo(1,2-a)indole-4,7-dione, 6-amino-8-(((aminocarbonyl) oxy)methyl)-1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methyl-, (1aS-(1aalpha, 8beta, 8aalpha,8balpha))-
U010	50-07-7	Mitomycin C
U011	61-82-5	Amitrole
U011	61-82-5	1H-1,2,4-Triazol-3-amine
U012	62-53-3	Aniline (I,T)
U012	62-53-3	Benzenamine (I,T)
U014	492-80-8	Auramine
U014	492-80-8	Benzenamine, 4,4'-carbonimidoylbis(N,N-dimethyl-
U015	115-02-6	Azaserine
U015	115-02-6	L-Serine, diazoacetate (ester)
U016	225-51-4	Benz(c)acridine
U017	98-87-3	Benzal chloride
U017	98-87-3	Benzene, (dichloromethyl)-
U018	56-55-3	Benz(a)anthracene
U019	71-43-2	Benzene (I,T)
U020	98-09-9	Benzenesulfonic acid chloride (C,R)
U020	98-09-9	Benzenesulfonyl chloride (C,R)
U021	92-87-5	Benzidine
U021	92-87-5	(1,1'-Biphenyl)-4,4'-diamine
U022	50-32-8	Benzo(a)pyrene
U023	98-07-7	Benzene, (trichloromethyl)-
U023	98-07-7	Benzotrichloride (C,R,T)

U024	111-91-1	Dichloromethoxy ethane
U024	111-91-1	Ethane, 1,1'-(methylenebis(oxy))bis(2-chloro-
U025	111-44-4	Dichloroethyl ether
U025	111-44-4	Ethane, 1,1'-oxybis(2-chloro-
U026	494-03-1	Chlornaphazin
U026	494-03-1	Naphthalenamine, N,N'-bis(2-chloroethyl)-
U027	108-60-1	Dichloroisopropyl ether
U027	108-60-1	Propane, 2,2'-oxybis(2-chloro-
U028	117-81-7	1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester
U028	117-81-7	Diethylhexyl phthalate
U029	74-83-9	Methane, bromo-
U029	74-83-9	Methyl bromide
U030	101-55-3	Benzene, 1-bromo-4-phenoxy-
U030	101-55-3	4-Bromophenyl phenyl ether
U031	71-36-3	1-Butanol (I)
U031	71-36-3	n-Butyl alcohol (I)
U032	13765-19-0	Calcium chromate
U032	13765-19-0	Chromic acid H2 CrO4, calcium salt
U033	353-50-4	Carbonic difluoride
U033	353-50-4	Carbon oxyfluoride (R,T)
U034	75-87-6	Acetaldehyde, trichloro-
U034	75-87-6	Chloral
U035	305-03-3	Benzenebutanoic acid, 4-(bis(2-chloroethyl)amino)-
U035	305-03-3	Chlorambucil
U036	57-74-9	Chlordane, alpha and gamma isomers
U036	57-74-9	4,7-Methano-1H-indene, 1,2,4,5,6,7,8,8-octachloro-2,3,3a,4,7,7a-hexahydro-
U037	108-90-7	Benzene, chloro-
U037	108-90-7	Chlorobenzene
U038	510-15-6	Benzeneacetic acid, 4-chloro-alpha-(4-chlorophenyl)-alpha-hydroxy-, ethyl ester
U038	510-15-6	Chlorobenzilate
U039	59-50-7	p-Chloro-m-cresol
U039	59-50-7	Phenol, 4-chloro-3-methyl-
U041	106-89-8	Epichlorohydrin
U041	106-89-8	Oxirane, (chloromethyl)-
U042	110-75-8	2-Chloroethyl vinyl ether
U042	110-75-8	Ethene, (2-chloroethoxy)-
U043	75-01-4	Ethene, chloro-
U043	75-01-4	Vinyl chloride
U044	67-66-3	Chloroform
U044	67-66-3	Methane, trichloro-
U045	74-87-3	Methane, chloro- (I,T)
U045	74-87-3	Methyl chloride (I,T)
U046	107-30-2	Chloromethyl methyl ether
U046	107-30-2	Methane, chloromethoxy-
U047	91-58-7	beta-Chloronaphthalene
U047	91-58-7	Naphthalene, 2-chloro-

U048	95-57-8	o-Chlorophenol
U048	95-57-8	Phenol, 2-chloro-
U049	3165-93-3	Benzenamine, 4-chloro-2-methyl-, hydrochloride
U049	3165-93-3	4-Chloro-o-toluidine, hydrochloride
U050	218-01-9	Chrysene
U051		Creosote
U052	1319-77-3	Cresol (Cresylic acid)
U052	1319-77-3	Phenol, methyl-
U053	4170-30-3	2-Butenal
U053	4170-30-3	Crotonaldehyde
U055	98-82-8	Benzene, (1-methylethyl)-(I)
U055	98-82-8	Cumene (I)
U056	110-82-7	Benzene, hexahydro-(I)
U056	110-82-7	Cyclohexane (I)
U057	108-94-1	Cyclohexanone (I)
U058	50-18-0	Cyclophosphamide
U058	50-18-0	2H-1,3,2-Oxazaphosphorin-2-amine, N,N-bis(2-chloroethyl)tetrahydro-, 2-oxide
U059	20830-81-3	Daunomycin
U059	20830-81-3	5,12-Naphthacenedione, 8-acetyl-10-((3-amino-2,3,6-trideoxy)-alpha-L-lyxo-hexopyranosyl)oxy)-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-, (8S-cis)-
U060	72-54-8	Benzene, 1,1'-(2,2-dichloroethylidene)bis(4-chloro-
U060	72-54-8	DDD
U061	50-29-3	Benzene, 1,1'-(2,2,2-trichloroethylidene)bis(4-chloro-
U061	50-29-3	DDT
U062	2303-16-4	Carbamothioic acid, bis(1-methylethyl)-, S- (2,3-di chloro-2-propenyl) ester
U062	2303-16-4	Diallate
U063	53-70-3	Dibenz(a,h)anthracene
U064	189-55-9	Benzo(rst)pentaphene
U064	189-55-9	Dibenzo(a,i)pyrene
U066	96-12-8	1,2-Dibromo-3-chloropropane
U066	96-12-8	Propane, 1,2-dibromo-3-chloro-
U067	106-93-4	Ethane, 1,2-dibromo-
U067	106-93-4	Ethylene dibromide
U068	74-95-3	Methane, dibromo-
U068	74-95-3	Methylene bromide
U069	84-74-2	1,2-Benzenedicarboxylic acid, dibutyl ester
U069	84-74-2	Dibutyl phthalate
U070	95-50-1	Benzene, 1,2-dichloro-
U070	95-50-1	o-Dichlorobenzene
U071	541-73-1	Benzene, 1,3-dichloro-
U071	541-73-1	m-Dichlorobenzene
U072	106-46-7	Benzene, 1,4-dichloro-
U072	106-46-7	p-Dichlorobenzene

U073	91-94-1	(1,1'-Biphenyl)-4,4'-diamine, 3,3'-dichloro-
U073	91-94-1	3,3'-Dichlorobenzidine
U074	764-41-0	2-Butene, 1,4-dichloro-(I,T)
U074	764-41-0	1,4-Dichloro-2-butene (I,T)
U075	75-71-8	Dichlorodifluoromethane
U075	75-71-8	Methane, dichlorodifluoro-
U076	75-34-3	Ethane, 1,1-dichloro-
U076	75-34-3	Ethylidene dichloride
U077	107-06-2	Ethane, 1,2-dichloro-
U077	107-06-2	Ethylene dichloride
U078	75-35-4	1,1-Dichloroethylene
U078	75-35-4	Ethene, 1,1-dichloro-
U079	156-60-5	1,2-Dichloroethylene
U079	156-60-5	Ethene, 1,2-dichloro-, (E)-
U080	75-09-2	Methane, dichloro-
U080	75-09-2	Methylene chloride
U081	120-83-2	2,4-Dichlorophenol
U081	120-83-2	Phenol, 2,4-dichloro-
U082	87-65-0	2,6-Dichlorophenol
U082	87-65-0	Phenol, 2,6-dichloro-
U083	78-87-5	Propane, 1,2-dichloro-
U083	78-87-5	Propylene dichloride
U084	542-75-6	1,3-Dichloropropene
U084	542-75-6	1-Propene, 1,3-dichloro-
U085	1464-53-5	2,2'-Bioxirane
U085	1464-53-5	1,2:3,4-Diepoxybutane (I,T)
U086	1615-80-1	N,N'-Diethylhydrazine
U086	1615-80-1	Hydrazine, 1,2-diethyl-
U087	3288-58-2	O,O-Diethyl S-methyl dithiophosphate
U087	3288-58-2	Phosphorodithioic acid, O,O-diethyl S-methyl ester
U088	84-66-2	1,2-Benzenedicarboxylic acid, diethyl ester
U088	84-66-2	Diethyl phthalate
U089	56-53-1	Diethylstilbesterol
U089	56-53-1	Phenol, 4,4'-(1,2-diethyl-1,2-ethenediyl)bis-, (E)-
U090	94-58-6	1,3-Benzodioxole, 5-propyl-
U090	94-58-6	Dihydrosafrole
U091	119-90-4	(1,1'-Biphenyl)-4,4'-diamine, 3,3'-dimethoxy-
U091	119-90-4	3,3'-Dimethoxybenzidine
U092	124-40-3	Dimethylamine (I)
U092	124-40-3	Methanamine, -methyl-(I)
U093	60-11-7	Benzenamine, N,N-dimethyl-4-(phenylazo)-
U093	60-11-7	p-Dimethylaminoazobenzene
U094	57-97-6	Benz(a)anthracene, 7,12-dimethyl-
U094	57-97-6	7,12-Dimethylbenz(a)anthracene
U095	119-93-7	(1,1'-Biphenyl)-4,4'-diamine, 3,3'-dimethyl-
U095	119-93-7	3,3'-Dimethylbenzidine
U096	80-15-9	alpha,alpha-

		Dimethylbenzylhydroperoxide (R)
U096	80-15-9	Hydroperoxide, 1-methyl-1-phenylethyl- (R)
U097	79-44-7	Carbamic chloride, dimethyl-
U097	79-44-7	Dimethylcarbamoyl chloride
U098	57-14-7	1,1-Dimethylhydrazine
U098	57-14-7	Hydrazine, 1,1-dimethyl-
U099	540-73-8	1,2-Dimethylhydrazine
U099	540-73-8	Hydrazine, 1,2-dimethyl-
U101	105-67-9	2,4-Dimethylphenol
U101	105-67-9	Phenol, 2,4-dimethyl-
U102	131-11-3	1,2-Benzenedicarboxylic acid, dimethyl ester
U102	131-11-3	Dimethyl phthalate
U103	77-78-1	Dimethyl sulfate
U103	77-78-1	Sulfuric acid, dimethyl ester
U105	121-14-2	Benzene, 1-methyl-2,4-dinitro-
U105	121-14-2	2,4-Dinitrotoluene
U106	606-20-2	Benzene, 2-methyl-1,3-dinitro-
U106	606-20-2	2,6-Dinitrotoluene
U107	117-84-0	1,2-Benzenedicarboxylic acid, dioctyl ester
U107	117-84-0	Di-n-octyl phthalate
U108	123-91-1	1,4-Diethyleneoxide
U108	123-91-1	1,4-Dioxane
U109	122-66-7	1,2-Diphenylhydrazine
U109	122-66-7	Hydrazine, 1,2-diphenyl-
U110	142-84-7	Dipropylamine (I)
U110	142-84-7	1-Propanamine, N-propyl-(I)
U111	621-64-7	Di-n-propylnitrosamine
U111	621-64-7	1-Propanamine, N-nitroso-N-propyl-
U112	141-78-6	Acetic acid ethyl ester (I)
U112	141-78-6	Ethyl acetate (I)
U113	140-88-5	Ethyl acrylate (I)
U113	140-88-5	2-Propenoic acid, ethyl ester (I)
U114	(1)111-54-6	Carbamodithioic acid, 1,2-ethanediylbis-, salts and esters
U114	(1)111-54-6	Ethylenebisdithiocarbamic acid, salts and esters
U115	75-21-8	Ethylene oxide (I,T)
U115	75-21-8	Oxirane (I,T)
U116	96-45-7	Ethylenethiourea
U116	96-45-7	2-Imidazolidinethione
U117	60-29-7	Ethane, 1,1'-oxybis-(I)
U117	60-29-7	Ethyl ether (I)
U118	97-63-2	Ethyl methacrylate
U118	97-63-2	2-Propenoic acid, 2-methyl-, ethyl ester
U119	62-50-0	Ethyl methanesulfonate
U119	62-50-0	Methanesulfonic acid, ethyl ester
U120	206-44-0	Fluoranthene
U121	75-69-4	Methane, trichlorofluoro-
U121	75-69-4	Trichloromonofluoromethane
U122	50-00-0	Formaldehyde

U123	64-18-6	Formic acid (C,T)
U124	110-00-9	Furan (I)
U124	110-00-9	Furfuran (I)
U125	98-01-1	2-Furancarboxaldehyde (I)
U125	98-01-1	Furfural (I)
U126	765-34-4	Glycidylaldehyde
U126	765-34-4	Oxiranecarboxyaldehyde
U127	118-74-1	Benzene, hexachloro-
U127	118-74-1	Hexachlorobenzene
U128	87-68-3	1,3-Butadiene, 1,1,2,3,4,4-hexachloro-
U128	87-68-3	Hexachlorobutadiene
U129	58-89-9	Cyclohexane, 1,2,3,4,5,6-hexachloro-, (1alpha,2alpha,3beta,4alpha,5alpha, 6beta)-
U129	58-89-9	Lindane
U130	77-47-4	1,3-Cyclopentadiene, 1,2,3,4,5,5-hexachloro-
U130	77-47-4	Hexachlorocyclopentadiene
U131	67-72-1	Ethane, hexachloro-
U131	67-72-1	Hexachloroethane
U132	70-30-4	Hexachlorophene
U132	70-30-4	Phenol, 2,2'-methylenebis(3,4,6-trichloro-
U133	302-01-2	Hydrazine (R,T)
U134	7664-39-3	Hydrofluoric acid (C,T)
U134	7664-39-3	Hydrogen fluoride (C,T)
U135	7783-06-4	Hydrogen sulfide
U135	7783-06-4	Hydrogen sulfide H2S
U136	75-60-5	Arsinic acid, dimethyl-
U136	75-60-5	Cacodylic acid
U137	193-39-5	Indeno(1,2,3-cd)pyrene
U138	74-88-4	Methane, iodo-
U138	74-88-4	Methyl iodide
U140	78-83-1	Isobutyl alcohol (I,T)
U140	78-83-1	1-Propanol, 2-methyl- (I,T)
U141	120-58-1	1,3-Benzodioxole, 5-(1-propenyl)-
U141	120-58-1	Isosafrole
U142	143-50-0	Kepone
U142	143-50-0	1,3,4-Metheno-2H-cyclobuta(cd)pentalen-2-one, 1,1a,3,3a,4,5,5,5a,5b,6-decachlorooctahydro-
U143	303-34-4	2-Butenoic acid, 2-methyl-, 7-((2,3-dihydroxy-2-(1-methoxyethyl)-3-methyl-1-oxobutoxy)methyl)-2,3,5,7a-tetrahydro-1H-pyrrolizin-1-yl ester, (1S- (1alpha(Z),7(2S*,3R*), 7aalpha))-
U143	303-34-4	Lasiocarpine
U144	301-04-2	Acetic acid, lead(2+) salt
U144	301-04-2	Lead acetate
U145	7446-27-7	Lead phosphate
U145	7446-27-7	Phosphoric acid, lead(2+) salt (2:3)
U146	1335-32-6	Lead, bis(acetato-O)tetrahydroxytri-

U146	1335-32-6	Lead subacetate
U147	108-31-6	2,5-Furandione
U147	108-31-6	Maleic anhydride
U148	123-33-1	Maleic hydrazide
U148	123-33-1	3,6-Pyridazinedione, 1,2-dihydro-
U149	109-77-3	Malononitrile
U149	109-77-3	Propanedinitrile
U150	148-82-3	Melphalan
U150	148-82-3	L-Phenylalanine, 4-(bis(2-chloroethyl)amino)-
U151	7439-97-6	Mercury
U152	126-98-7	Methacrylonitrile (I,T)
U152	126-98-7	2-Propenenitrile, 2-methyl- (I,T)
U153	74-93-1	Methanethiol (I,T)
U153	74-93-1	Thiomethanol (I,T)
U154	67-56-1	Methanol (I)
U154	67-56-1	Methyl alcohol (I)
U155	91-80-5	1,2-Ethanediamine, N,N-dimethyl-N'-2-pyridinyl-N'-(2-thienylmethyl)-
U155	91-80-5	Methapyrilene
U156	79-22-1	Carbonochloridic acid, methyl ester (I,T)
U156	79-22-1	Methyl chlorocarbonate (I,T)
U157	56-49-5	Benz(j)aceanthrylene, 1,2-dihydro-3-methyl-
U157	56-49-5	3-Methylcholanthrene
U158	101-14-4	Benzenamine, 4,4'-methylenebis(2-chloro-
U158	101-14-4	4,4'-Methylenebis(2-chloroaniline)
U159	78-93-3	2-Butanone (I,T)
U159	78-93-3	Methyl ethyl ketone (MEK) (I,T)
U160	1338-23-4	2-Butanone, peroxide (R,T)
U160	1338-23-4	Methyl ethyl ketone peroxide (R,T)
U161	108-10-1	Methyl isobutyl ketone (I)
U161	108-10-1	4-Methyl-2-pentanone (I)
U161	108-10-1	Pentanol, 4-methyl-
U162	80-62-6	Methyl methacrylate (I,T)
U162	80-62-6	2-Propenoic acid, 2-methyl-, methyl ester (I,T)
U163	70-25-7	Guanidine, -methyl-N'-nitro-N-nitroso-
U163	70-25-7	MNNG
U164	56-04-2	Methylthiouracil
U164	56-04-2	4(1H)-Pyrimidinone, 2,3-dihydro-6-methyl-2-thioxo-
U165	91-20-3	Naphthalene
U166	130-15-4	1,4-Naphthalenedione
U166	130-15-4	1,4-Naphthoquinone
U167	134-32-7	1-Naphthalenamine
U167	134-32-7	alpha-Naphthylamine
U168	91-59-8	2-Naphthalenamine
U168	91-59-8	beta-Naphthylamine
U169	98-95-3	Benzene, nitro-
U169	98-95-3	Nitrobenzene (I,T)
U170	100-02-7	p-Nitrophenol

U170	100-02-7	Phenol, 4-nitro-
U171	79-46-9	2-Nitropropane (I,T)
U171	79-46-9	Propane, 2-nitro- (I,T)
U172	924-16-3	1-Butanamine, N-butyl-N-nitroso-
U172	924-16-3	N-Nitrosodi-n-butylamine
U173	1116-54-7	Ethanol, 2,2'-(nitrosoimino)bis-
U173	1116-54-7	N-Nitrosodiethanolamine
U174	55-18-5	Ethanamine, -ethyl-N-nitroso-
U174	55-18-5	N-Nitrosodiethylamine
U176	759-73-9	N-Nitroso-N-ethylurea
U176	759-73-9	Urea, N-ethyl-N-nitroso-
U177	684-93-5	N-Nitroso-N-methylurea
U177	684-93-5	Urea, N-methyl-N-nitroso-
U178	615-53-2	Carbamic acid, methylnitroso-, ethyl ester
U178	615-53-2	N-Nitroso-N-methylurethane
U179	100-75-4	N-Nitrosopiperidine
U179	100-75-4	Piperidine, 1-nitroso-
U180	930-55-2	N-Nitrosopyrrolidine
U180	930-55-2	Pyrrolidine, 1-nitroso-
U181	99-55-8	Benzenamine, 2-methyl-5-nitro-
U181	99-55-8	5-Nitro-o-toluidine
U182	123-63-7	1,3,5-Trioxane, 2,4,6-trimethyl-
U182	123-63-7	Paraldehyde
U183	608-93-5	Benzene, pentachloro-
U183	608-93-5	Pentachlorobenzene
U184	76-01-7	Ethane, pentachloro-
U184	76-01-7	Pentachloroethane
U185	82-68-8	Benzene, pentachloronitro-
U185	82-68-8	Pentachloronitrobenzene (PCNB)
U186	504-60-9	1-Methylbutadiene (I)
U186	504-60-9	1,3-Pentadiene (I)
U187	62-44-2	Acetamide, -(4-ethoxyphenyl)-
U187	62-44-2	Phenacetin
U188	108-95-2	Phenol
U189	1314-80-3	Phosphorus sulfide (R)
U189	1314-80-3	Sulfur phosphide (R)
U190	85-44-9	1,3-Isobenzofurandione
U190	85-44-9	Phthalic anhydride
U191	109-06-8	2-Picoline
U191	109-06-8	Pyridine, 2-methyl-
U192	23950-58-5	Benzamide, 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)-
U192	23950-58-5	Pronamide
U193	1120-71-4	1,2-Oxathiolane, 2,2-dioxide
U193	1120-71-4	1,3-Propane sultone
U194	107-10-8	1-Propanamine (I,T)
U194	107-10-8	n-Propylamine (I,T)
U196	110-86-1	Pyridine
U197	106-51-4	p-Benzoquinone
U197	106-51-4	2,5-Cyclohexadiene-1,4-dione
U200	50-55-5	Reserpine
U200	50-55-5	Yohimban-16-carboxylic acid, 11,17-dimethoxy-18-((3,4,5-

		trimethoxybenzoyl)oxy)-, methyl ester,(3beta,16beta,17alpha,18beta, 20alpha)-
U201	108-46-3	1,3-Benzenediol
U201	108-46-3	Resorcinol
U203	94-59-7	1,3-Benzodioxole, 5-(2-propenyl)-
U203	94-59-7	Safrole
U204	7783-00-8	Selenious acid
U204	7783-00-8	Selenium dioxide
U205	7488-56-4	Selenium sulfide
U205	7488-56-4	Selenium sulfide SeS2 (R,T)
U206	18883-66-4	Glucopyranose, 2-deoxy-2-(3-methyl-3-nitrosoureido)-, D-
U206	18883-66-4	D-Glucose, 2-deoxy-2-(((methylnitrosoamino)-carbonyl)amino)-
U206	18883-66-4	Streptozotocin
U207	95-94-3	Benzene, 1,2,4,5-tetrachloro-
U207	95-94-3	1,2,4,5-Tetrachlorobenzene
U208	630-20-6	Ethane, 1,1,1,2-tetrachloro-
U208	630-20-6	1,1,1,2-Tetrachloroethane
U209	79-34-5	Ethane, 1,1,2,2-tetrachloro-
U209	79-34-5	1,1,2,2-Tetrachloroethane
U210	127-18-4	Ethene, tetrachloro-
U210	127-18-4	Tetrachloroethylene
U211	56-23-5	Carbon tetrachloride
U211	56-23-5	Methane, tetrachloro-
U213	109-99-9	Furan, tetrahydro-(I)
U213	109-99-9	Tetrahydrofuran (I)
U214	563-68-8	Acetic acid, thallium(1+) salt
U214	563-68-8	Thallium(I) acetate
U215	6533-73-9	Carbonic acid, dithallium(1+) salt
U215	6533-73-9	Thallium(I) carbonate
U216	7791-12-0	Thallium(I) chloride
U216	7791-12-0	Thallium chloride TlCl
U217	10102-45-1	Nitric acid, thallium(1+) salt
U217	10102-45-1	Thallium(I) nitrate
U218	62-55-5	Ethanethioamide
U218	62-55-5	Thioacetamide
U219	62-56-6	Thiourea
U220	108-88-3	Benzene, methyl-
U220	108-88-3	Toluene
U221	25376-45-8	Benzenediamine, ar-methyl-
U221	25376-45-8	Toluenediamine
U222	636-21-5	Benzenamine, 2-methyl-, hydrochloride
U222	636-21-5	o-Toluidine hydrochloride
U223	26471-62-5	Benzene, 1,3-diisocyanatomethyl- (R,T)
U223	26471-62-5	Toluene diisocyanate (R,T)
U225	75-25-2	Bromoform
U225	75-25-2	Methane, tribromo-
U226	71-55-6	Ethane, 1,1,1-trichloro-
U226	71-55-6	Methyl chloroform
U226	71-55-6	1,1,1-Trichloroethane
U227	79-00-5	Ethane, 1,1,2-trichloro-

U227	79-00-5	1,1,2-Trichloroethane
U228	79-01-6	Ethene, trichloro-
U228	79-01-6	Trichloroethylene
U234	99-35-4	Benzene, 1,3,5-trinitro-
U234	99-35-4	1,3,5-Trinitrobenzene (R,T)
U235	126-72-7	1-Propanol, 2,3-dibromo-, phosphate (3:1)
U235	126-72-7	Tris(2,3-dibromopropyl) phosphate
U236	72-57-1	2,7-Naphthalenedisulfonic acid, 3,3'-((3,3'-dimethyl(1,1'-biphenyl)-4,4'-diyl)bis(azo)bis(5-amino-4-hydroxy)-, tetrasodium salt
U236	72-57-1	Trypan blue
U237	66-75-1	2,4-(1H,3H)-Pyrimidinedione, 5-(bis(2-chloroethyl)amino)-
U237	66-75-1	Uracil shallard
U238	51-79-6	Carbamic acid, ethyl ester
U238	51-79-6	Ethyl carbamate (urethane)
U239	1330-20-7	Benzene, dimethyl- (I,T)
U239	1330-20-7	Xylene (I)
U240	(1)94-75-7	Acetic acid, (2,4-dichlorophenoxy)-, salts and esters
U240	(1)94-75-7	2,4-D, salts and esters
U243	1888-71-7	Hexachloropropene
U243	1888-71-7	1-Propene, 1,1,2,3,3,3-hexachloro-
U244	137-26-8	Thioperoxydicarbonic diamide ((H2N)C(S))2 S2, tetramethyl-
U244	137-26-8	Thiram
U246	506-68-3	Cyanogen bromide (CN)Br
U247	72-43-5	Benzene, 1,1'-(2,2,2-trichloroethylidene)bis(4- methoxy-
U247	72-43-5	Methoxychlor
U248	(1)81-81-2	2H-1-Benzopyran-2-one, 4-hydroxy-3-(3-oxo-1-phenyl-butyl)-, and salts, [~~when~~]if present at concentrations of 0.3% or less
U248	(1)81-81-2	Warfarin, and salts, [~~when~~]if present at concentrations of 0.3% or less
U249	1314-84-7	Zinc phosphide Zn3 P2, [~~when~~]if present at concentrations of 10% or less
U271	17804-35-2	Benomyl
U271	17804-35-2	Carbamic acid, (1-((butylamino)carbonyl)-1H-benzimidazol-2-yl)-, methyl ester
U278	22781-23-3	Bendiocarb
U278	22781-23-3	1,3-Benzodioxol-4-ol, 2,2-dimethyl-, methyl carbamate
U279	63-25-2	Carbaryl
U279	63-25-2	1-Naphthalenol, methylcarbamate
U280	101-27-9	Barban
U280	101-27-9	Carbamic acid, (3-chlorophenyl)-, 4-chloro-2-butynyl ester
U328	95-53-4	Benzenamine, 2-methyl-
U328	95-53-4	o-Toluidine

U353	106-49-0	Benzenamine, 4-methyl-
U353	106-49-0	p-Toluidine
U359	110-80-5	Ethanol, 2-ethoxy-
U359	110-80-5	Ethylene glycol monoethyl ether
U364	22961-82-6	Bendiocarb phenol
U364	22961-82-6	1,3-Benzodioxol-4-ol, 2,2-dimethyl-,
U367	1563-38-8	7-Benzofuranol, 2,3-dihydro-2,2-dimethyl-
U367	1563-38-8	Carbofuran phenol
U372	10605-21-7	Carbamic acid, 1H-benzimidazol-2-yl, methyl ester
U372	10605-21-7	Carbendazim
U373	122-42-9	Carbamic acid, phenyl-, 1-methylethyl ester
U373	122-42-9	Propham
U387	52888-80-9	Carbamothioic acid, dipropyl-, S-(phenylmethyl) ester
U387	52888-80-9	Prosulfocarb
U389	2303-17-5	Carbamothioic acid, bis(1-methylethyl)-, S- (2,3,3-trichloro-2-propenyl) ester
U389	2303-17-5	Triallate
U394	30558-43-1	A2213
U394	30558-43-1	Ethanimidothioic acid, 2-(dimethylamino)-N-hydroxy-2-oxo-, methyl ester
U395	5952-26-1	Diethylene glycol, dicarbamate
U395	5952-26-1	Ethanol, 2,2'-oxybis-, dicarbamate
U404	121-44-8	Ethanamine, N,N-diethyl-
U404	121-44-8	Triethylamine
U409	23564-05-8	Carbamic acid, (1,2-phenylenebis (iminocarbonothioyl))bis-, dimethyl ester
U409	23564-05-8	Thiophanate-methyl
U410	59669-26-0	Ethanimidothioic acid, N,N'-(thiobis((methylimino)carbonyloxy)) bis-, dimethyl ester
U410	59669-26-0	Thiodicarb
U411	114-26-1	Phenol, 2-(1-methylethoxy)-, methylcarbamate
U411	114-26-1	Propoxur
See F027	93-76-5	Acetic acid, (2,4,5-trichlorophenoxy)-
See F027	7-86-5	Pentachlorophenol
See F027	87-86-5	Phenol, pentachloro-
See F027	58-90-2	Phenol, 2,3,4,6-tetrachloro-
See F027	95-95-4	Phenol, 2,4,5-trichloro-
See F027	88-06-2	Phenol, 2,4,6-trichloro-
See F027	93-72-1	Propanoic acid, 2-(2,4,5-trichlorophenoxy)-
See F027	93-72-1	Silvex (2,4,5-TP)
See F027	93-76-5	2,4,5-T
See F027	58-90-2	2,3,4,6-Tetrachlorophenol
See F027	95-95-4	2,4,5-Trichlorophenol
See F027	88-06-2	2,4,6-Trichlorophenol

KEY: hazardous waste
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Authorizing, and Implemented or Interpreted Law: 19-6-105; 19-6-106

R315. Environmental Quality, Waste Management and Radiation Control, Waste Management.
R315-262. Hazardous Waste Generator Requirements.

R315-262-10. General -- Purpose, Scope, and Applicability.

(a) The [~~regulations~~]rules in Rule R315-262 establish standards for generators of hazardous waste as defined by Section R315-260-10.

(1) A person who generates a hazardous waste as defined by Rule R315-261 is subject to [~~all~~]the applicable independent requirements in the sections listed below:

(i) Independent requirements of a very small quantity generator.

(A) Subsections R315-262-11(a) through R315-262-11(d) Hazardous waste determination and recordkeeping; and

(B) Section R315-262-13 Generator category determination.

(ii) Independent requirements of a small quantity generator.

(A) Section R315-262-11 Hazardous waste determination and recordkeeping;

(B) Section R315-262-13 Generator category determination;

(C) Section R315-262-18 EPA identification numbers and re-notification for small quantity generators and large quantity generators;

(D) Sections R315-262-20 through R315-262-27--Manifest requirements applicable to small and large quantity generators;

(E) Sections R315-262-30 through R315-262-34--Pre-transport requirements applicable to small and large quantity generators;

(F) Section R315-262-40 Recordkeeping;

(G) Section R315-262-44 Recordkeeping for small quantity generators; and

(H) Sections R315-262-80 through R315-262-84--Transboundary movements of hazardous waste for recovery or disposal.

(iii) Independent requirements of a large quantity generator.

(A) Section R315-262-11 Hazardous waste determination and recordkeeping;

(B) Section R315-262-13 Generator category determination;

(C) Section R315-262-18 EPA identification numbers and re-notification for small quantity generators and large quantity generators;

(D) Sections R315-262-20 through R315-262-27--Manifest requirements applicable to small and large quantity generators;

(E) Sections R315-262-30 through R315-262-34--Pre-transport requirements applicable to small and large quantity generators;

(F) Sections R315-262-40 through R315-262-44--Recordkeeping and reporting applicable to small and large quantity generators, except Section R315-262-44; and

(G) Sections R315-262-80 through R315-262-84--Transboundary movements of hazardous waste for recovery or disposal.

(2) A generator that accumulates hazardous waste on site is a person that stores hazardous waste; such generator is subject to the applicable requirements of Rule R315-124, R315-264 through R315-266, R315-270 and section 3010 of RCRA, unless it is one of the following:

(i) A very small quantity generator that meets the conditions for exemption in Section R315-262-14;

(ii) A small quantity generator that meets the conditions for exemption in Sections R315-262-15 and R315-262-16; or

(iii) A large quantity generator that meets the conditions for exemption in Sections R315-262-15 and R315-262-17.

(3) A generator shall not transport, offer its hazardous waste for transport, or otherwise cause its hazardous waste to be sent to a facility that is not a designated facility, as defined in Section R315-260-10, or not otherwise authorized to receive the generator's hazardous waste.

(b) Determining generator category. A generator shall use Section R315-262-13 to determine which provisions of Rule R315-262 are applicable to the generator based on the

quantity of hazardous waste generated per calendar month.

(c) Reserved.

(d) Any person who exports or imports hazardous wastes shall comply with Section R315-262-18 and Sections R315-262-80 through R315-262-84.

(e) Any person who imports hazardous waste into the United States shall comply with the standards applicable to generators established in Rule R315-262.

(f) A farmer who generates waste pesticides which are hazardous waste and who complies with [~~all of~~]the requirements of Section R315-262-70 is not required to comply with other standards in Rule R315-262 or Rules R315-[—]270, R315-264, R315-265, or R315-268 with respect to such pesticides.

(1) A generator's violation of an independent requirement is subject to penalty and injunctive relief under Sections 19-6-112 and 19-6-113.

(2) A generator's noncompliance with a condition for exemption in Rule R315-262 is not subject to penalty or injunctive relief under Sections 19-6-112 and 19-6-113 as a violation of a Rule R315-262 condition for exemption. Noncompliance by any generator with an applicable condition for exemption from storage permit and operations requirements means that the facility is a storage facility operating without an exemption from the permit, interim status, and operations requirements in Rules R315-124, R315-264 through R315-266, and R315-270, and the notification requirements of section 3010 of RCRA. Without an exemption, any violations of such storage requirements are subject to penalty and injunctive relief under Sections 19-6-112 and 19-6-113.

(h) An owner or operator who initiates a shipment of hazardous waste from a treatment, storage, or disposal facility shall comply with the generator standards established in Rule R315-262.

Note 1: [~~The provisions of~~]Section R315-262-34 [~~are~~]is applicable to the on-site accumulation of hazardous waste by generators. Therefore, [~~the provisions of~~]Section R315-262-34 only appl[~~y~~]ies to owners or operators who are shipping hazardous waste which they generated at that facility.

Note 2: A generator who treats, stores, or disposes of hazardous waste on-site shall comply with the applicable standards and permit requirements set forth in Rules R315-264, R315-265, R315-266, R315-268, and R315-270.

(i) Reserved.

(j) Reserved.

(k) Reserved.

(l) The laboratories owned by an eligible academic entity that chooses to be subject to the requirements of Sections R315-262-200 through R315-262-216 are not subject to, for purposes of Subsection R315-262-10(l), the terms "laboratory" and "eligible academic entity" shall have the meaning as defined in Section R315-262-200:

(1) The independent requirements of Section R315-262-11 or the [~~regulations~~]rules in Section R315-262-15 for large quantity generators and small quantity generators, except as provided in Sections R315-262-200 through R315-262-216, and

(2) The conditions of Section R315-262-14, for very small quantity generators, except as provided in Sections R315-262-200 through R315-262-216.

(m) Generators of lamps, as defined in Section R315-273-9, using a drum-top crusher, as defined in Section R315-273-9, shall meet the requirements of Subsection R315-273-13(d)(3), except for the registration requirement; and Subsections R315-273-13(d)(4) and R315-273-13(d)(5).

(n) Reverse distributors, as defined in Section R315-266-500, are subject to Sections R315-266-500 through R315-266-510 for the management of hazardous waste pharmaceuticals in lieu of Rule R315-262.

(o) Each healthcare facility, as defined in Section R315-266-500, shall determine whether it is subject to Sections R315-266-500 through R315-266-510 for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month, including both hazardous waste pharmaceuticals and non-pharmaceutical

hazardous waste. A healthcare facility that generates more than 100 kg, 220 pounds, of hazardous waste per calendar month, or more than 1 kg, 2.2 pounds, of acute hazardous waste per calendar month, or more than 100 kg, 220 pounds, per calendar month of any residue or contaminated soil, water, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in Section R315-261-31 or Subsection R315-261-33(e), is subject to Sections R315-266-500 through R315-266-510 for the management of hazardous waste pharmaceuticals in lieu of Rule R315-262. A healthcare facility that is a very small quantity generator when counting its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to Section R315-262-14 and is not subject to Sections R315-266-500 through R315-266-510, except for Sections R315-266-505 and R315-266-507 and the optional provisions of Section R315-266-504.

Note: A generator who treats, stores, or disposes of hazardous waste on-site shall comply with the applicable standards and permit requirements set forth in Rules R315-264, R315-265, R315-266, R315-268, and R315-270.

R315-262-13. General -- Generator Category Determination.

A generator shall determine its generator category. A generator's category is based on the amount of hazardous waste generated each month and may change from month to month. This section sets forth procedures to determine whether a generator is a very small quantity generator, a small quantity generator, or a large quantity generator for a particular month, as defined in Section R315-260-10.

(a) Generators of either acute hazardous waste or non-acute hazardous waste. A generator who either generates acute hazardous waste or non-acute hazardous waste in a calendar month shall determine its generator category for that month by doing the following:

(1) Counting the total amount of hazardous waste generated in the calendar month;

(2) Subtracting from the total any amounts of waste exempt from counting as described in Subsections R315-262-13(c) and R315-262-13(d); and

(3) Determining the resulting generator category for the hazardous waste generated using Table 1 below.

(b) Generators of both acute and non-acute hazardous wastes. A generator who generates both acute hazardous waste and non-acute hazardous waste in [~~the same~~]a calendar month shall determine its generator category for that month by doing the following:

(1) Counting separately the total amount of acute hazardous waste and the total amount of non-acute hazardous waste generated in the calendar month;

(2) Subtracting from each total any amounts of waste exempt from counting as described in Subsections R315-262-13(c) and (d);

(3) Determining separately the resulting generator categories for the quantities of acute and non-acute hazardous waste generated using Table 1 below; and

(4) Comparing the resulting generator categories from Subsection R315-262-13(b)(3) and applying the more stringent generator category to the accumulation and management of both non-acute hazardous waste and acute hazardous waste generated for that month.

TABLE 1 to Section R315-262-13

Generator Categories Based on
Quantity of Waste Generated in a Calendar Month

Quantity of acute hazardous waste generated	Quantity of non-acute hazardous waste	Quantity of residues from a cleanup of acute	Generator category

in a calendar month	generated in a calendar month	hazardous waste generated in a calendar month	
>1kg	Any amount	Any amount	Large quantity generator
Any amount	> or = 1,000kg	Any amount	Large quantity generator
Any amount	Any Amount	>100kg	Large quantity generator
< or = 1 kg	>100 kg and < 1,000 kg	< or = 100 kg	Small quantity Generator
< or = 1 kg	< or = 100 kg	< or = 100 kg	Very small quantity generator

(c) When making the monthly quantity-based determinations required by Rule R315-262, the generator shall include [~~all~~]each hazardous waste that it generates, except hazardous waste that:

(1) Is exempt from regulation under Subsections R315-261-4(c) through R315-261-4(f), R315-261-6(a)(3), R315-261-7(a)(1), or Section R315-261-8;

(2) Is managed immediately upon generation only in on-site elementary neutralization units, wastewater treatment units, or totally enclosed treatment facilities as defined in Section R315-260-10;

(3) Is recycled, without prior storage or accumulation, only in an on-site process subject to regulation under Subsection R315-261-6(c)(2);

(4) Is used oil managed under the requirements of Subsection R315-261-6(a)(4) and Section R315-15;

(5) Is spent lead-acid batteries managed under the requirements of Section R315-266-80;

(6) Is universal waste managed under Section R315-261-9 and Rule R315-273;

(7) Is a hazardous waste that is an unused commercial chemical product, listed in Sections R315-261-30 through R315-261-35 or exhibiting one or more characteristics in Sections R315-261-20 through R315-261-24, that is generated solely as a result of a laboratory clean-out conducted at an eligible academic entity pursuant to Section R315-262-213. For purposes of this provision, the term eligible academic entity shall have the meaning as defined in Section R315-262-200; or

(8) Is managed as part of an episodic event in compliance with the conditions of Sections R315-262-230 through R315-262-233.

(9) Is a hazardous waste pharmaceutical, as defined in Section R315-266-500, that is subject to or managed in accordance with Sections R315-266-500 through R315-266-510 or is a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under Section R315-266-506.

(d) In determining the quantity of hazardous waste generated in a calendar month, a generator need not include:

(1) Hazardous waste [~~when~~]if it is removed from on-site accumulation, so long as the hazardous waste was previously counted once;

(2) Hazardous waste generated by on-site treatment, [~~(~~]including reclamation[~~)~~], of the generator's hazardous waste, so long as the hazardous waste that is treated was previously counted once; and

(3) Hazardous waste spent materials that are generated, reclaimed, and subsequently reused on site, so long as such spent materials have been previously counted

once.

(e) Based on the generator category as determined under Section R315-262-13, the generator shall meet the applicable independent requirements listed in Section R315-262-10. A generator's category also determines which of the provisions of Sections R315-262-14, R315-262-15, R315-262-16 or R315-262-17 shall be met to obtain an exemption from the storage facility permit, interim status, and operating requirements when accumulating hazardous waste.

(f) Mixing hazardous wastes with solid wastes

(1) Very small quantity generator wastes.

(i) Hazardous wastes generated by a very small quantity generator may be mixed with solid wastes. Very small quantity generators may mix [~~a portion or all of~~]its hazardous waste with solid waste and remain subject to Section R315-262-14 even though the resultant mixture exceeds the quantity limits identified in the definition of very small quantity generator at Section R315-260-10, unless the mixture exhibits one or more of the characteristics of hazardous waste identified in Sections R315-261-20 through R315-261-24.

(ii) If the resulting mixture exhibits a characteristic of hazardous waste, this resultant mixture is a newly-generated hazardous waste. The very small quantity generator shall count both the resultant mixture amount plus the other hazardous waste generated in the calendar month to determine whether the total quantity exceeds the very small quantity generator calendar month quantity limits identified in the definition of generator categories found in Section R315-260-10. If so, to remain exempt from the permitting, interim status, and operating standards, the very small quantity generator shall meet the conditions for exemption applicable to either a small quantity generator or a large quantity generator. The very small quantity generator shall also comply with the applicable independent requirements for either a small quantity generator or a large quantity generator.

(iii) If a very small quantity generator's wastes are mixed with used oil, the mixture is subject to Rule R315-15. Any material produced from such a mixture by processing, blending, or other treatment is also regulated under Rule R315-15.

(2) Small quantity generator and large quantity generator wastes.

(i) Hazardous wastes generated by a small quantity generator or large quantity generator may be mixed with solid waste. These mixtures are subject to the following: the mixture rule in Subsections R315-261-3(a)(2)(iv), R315-261-3(b)(2) and R315-261-3(b)(3), and R315-261-3(g)(2)(i); the prohibition of dilution rule at Subsection R315-268-3(a); the land disposal restriction requirements of Section R315-268-40 if a characteristic hazardous waste is mixed with a solid waste so that it no longer exhibits the hazardous characteristic; and the hazardous waste determination requirement at Section R315-262-11.

(ii) If the resulting mixture is found to be a hazardous waste, this resultant mixture is a newly-generated hazardous waste. A small quantity generator shall count both the resultant mixture amount plus the other hazardous waste generated in the calendar month to determine whether the total quantity exceeds the small quantity generator calendar monthly quantity limits identified in the definition of generator categories found in Section R315-260-10. If so, to remain exempt from the permitting, interim status, and operating standards, the small quantity generator shall meet the conditions for exemption applicable to a large quantity generator. The small quantity generator shall also comply with the applicable independent requirements for a large quantity generator.

R315-262-14. General -- Conditions For Exemption for a Very Small Quantity Generator.

(a) Provided that the very small quantity generator meets [~~all~~]the conditions for exemption listed in Section R315-262-14, hazardous waste generated by the very small quantity generator is not subject to the requirements of Rules R315-124, R315-262,

[(]except Sections R315-262-10 through R315-262-14[)], through R315-268[.] and R315-270, and the notification requirements of section 3010 of RCRA and the very small quantity generator may accumulate hazardous waste on site without complying with such requirements. The conditions for exemption are as follows:

(1) In a calendar month the very small quantity generator generates less than or equal to the amounts specified in the definition of ''very small quantity generator'' in Section R315-260-10;

(2) The very small quantity generator complies with Subsections R315-262-11(a) through R315-262-11(d);

(3) If the very small quantity generator accumulates at any time greater than 1 kilogram, [(]2.2 lbs[)], of acute hazardous waste or 100 kilograms, [(]220 lbs[)], of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in Section R315-261-31 or Subsection R315-261-33(e), [all]the quantities of that acute hazardous waste are subject to the following additional conditions for exemption:

(i) Such waste is held on site for no more than 90 days beginning on the date when the accumulated wastes exceed the amounts provided in Subsection R315-262-14(a)(3); and

(ii) The conditions for exemption in Subsections R315-262-17(a) through R315-262-17(g).

(4) If the very small quantity generator accumulates at any time 1,000 kilograms, [(]2,200 lbs[)], or greater of non-acute hazardous waste, [all]the quantities of that hazardous waste are subject to the following additional conditions for exemption:

(i) Such waste is held on site for no more than 180 days, or 270 days, if applicable, beginning on the date when the accumulated waste exceed the amounts provided in Subsection R315-262-14(a)(4);

(ii) The quantity of waste accumulated on site never exceeds 6,000 kilograms, [(]13,200 lbs[)]; and

(iii) The conditions for exemption in Subsections R315-262-16(b)(2) through R315-262-16(f).

(5) A very small quantity generator that accumulates hazardous waste in amounts less than or equal to the limits in Subsections R315-262-14(a)(3) and R315-262-14(a)(4) shall either treat or dispose of its hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage, or disposal facility, either of which, if located in the U.S., is:

(i) Permitted under Rule R315-270;

(ii) In interim status under Rules R315-265 and R315-270;

(iii) Authorized to manage hazardous waste by a state with a hazardous waste management program approved under 40 CFR 271;

(iv) Permitted, licensed, or registered by a state to manage municipal solid waste and, if managed in a municipal solid waste landfill is subject to Rules R315-301 through R315-320;

(v) Permitted, licensed, or registered by a state to manage non-municipal non-hazardous waste and, if managed in a non-municipal non-hazardous waste disposal unit, is subject to the requirements in Rules R315-301 through R315-320 or 40 CFR 257.5 through 257.30;

(vi) A facility which:

(A) Beneficially uses or reuses, or legitimately recycles or reclaims its waste; or

(B) Treats its waste prior to beneficial use or reuse, or legitimate recycling or reclamation;

(vii) For universal waste managed under Rule R315-273, a universal waste handler or destination facility subject to the requirements of Rule R315-273;

(viii) A large quantity generator under the control of the same person as the

very small quantity generator, provided the following conditions are met:

(A) The very small quantity generator and the large quantity generator are under the control of the same person as defined in Section R315-260-10. "Control,'' for the purposes of Subsection R315-262-14(a)(5)(viii), means the power to direct the policies of the generator, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate generator facilities on behalf of a different person as defined in Section R315-260-10 shall not be deemed to "control'' such generators.

(B) The very small quantity generator marks its container[~~(~~]s[~~)~~] of hazardous waste with:

(1) The words ``Hazardous Waste'' and

(2) An indication of the hazards of the contents, examples include, but are not limited to:

(I) the applicable hazardous waste characteristic[~~(~~]s[~~)~~], [~~i.e.,~~]ignitable, corrosive, reactive, toxic;

(II) hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E, labeling, or subpart F, placarding;

(III) a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or

(IV) a chemical hazard label consistent with the National Fire Protection Association code 704.

(ix) [~~Reserved~~]A reverse distributor, as defined in Section R315-266-500, if the hazardous waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical generated by a healthcare facility, as defined in Section R315-266-500.

(x) [~~Reserved~~]A healthcare facility, as defined in Section R315-266-500, that meets the conditions in Subsections R315-266-502(l) and R315-266-503(b), as applicable, to accept non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.

(xi) For airbag waste, an airbag waste collection facility or a designated facility subject to the requirements of Subsection R315-261-4(j).

(b) The placement of bulk or non-containerized liquid hazardous waste or hazardous waste containing free liquids, [~~(~~]whether or not sorbents have been added[~~)~~], in any landfill is prohibited.

(c) A very small quantity generator experiencing an episodic event may generate and accumulate hazardous waste in accordance with Sections R315-262-230 through R315-262-233 in lieu of Sections R315-262-15, R315-262-16, and R315-262-17.

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R315. Environmental Quality, Waste Management and Radiation Control, Waste Management.
R315-264. Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities.
R315-264-1. General -- Purpose, Scope and Applicability.

(a) The purpose of Rule R315-264 is to establish minimum State of Utah standards which define the acceptable management of hazardous waste.

(b) The standards in Rule R315-264 apply to owners and operators of [~~all~~]facilities which treat, store, or dispose of hazardous waste, except as specifically provided otherwise in Rules R315-264 or R315-261.

(c) Reserved

(d) The requirements of Rule R315-264 apply to a person disposing of hazardous waste by means of underground injection subject to a permit issued under an Underground Injection Control (UIC) program approved or promulgated under the Safe Drinking Water Act only to the extent they are required by 40 CFR 144.14. Rule R315-264 applies to the above-ground treatment or storage of hazardous waste before it is injected underground.

(e) The requirements of Rule R315-264 apply to the owner or operator of a POTW which treats, stores, or disposes of hazardous waste only to the extent they are included in a RCRA permit by rule granted to such a person under Rule R315-270.

(f) Reserved

(g) The requirements of Rule R315-264 do not apply to:

(1) The owner or operator of a facility permitted under Rules R315-301 through R315-320 to manage municipal or industrial solid waste, if the only hazardous waste the facility treats, stores, or disposes of is excluded from regulation under Rule R315-264 by Section R315-262-14;

(2) The owner or operator of a facility managing recyclable materials described in Subsections R315-261-6(a)(2), R315-261-6(a)(3), and R315-261-6(a)(4), except to the extent they are referred to in Rule R315-15 or Sections R315-266-20 through R315-266-23, R315-266-70, R315-266-80, or R315-266-100 through R315-266-112.

(3) A generator accumulating waste on site in compliance with Section R315-262-14, R315-262-15, R315-262-16, or R315-262-17;

(4) A farmer disposing of waste pesticides from his own use in compliance with Section R315-262-70; or

(5) The owner or operator of a totally enclosed treatment facility, as defined in Section R315-260-10.

(6) The owner or operator of an elementary neutralization unit or a wastewater treatment unit as defined in Section R315-260-10, provided that if the owner or operator is diluting hazardous ignitable (D001) wastes, other than the D001 High TOC Subcategory defined in Section R315-268-40, or reactive (D003) waste, to remove the characteristic before land disposal, the owner[~~/~~] or operator shall comply with the requirements set out in Subsection R315-264-17(b).

(7) Reserved

(8)(i) Except as provided in Subsection R315-264-1(g)(8)(ii), a person engaged in treatment or containment activities during immediate response to any of the following situations:

(A) A discharge of a hazardous waste;

(B) An imminent and substantial threat of a discharge of hazardous waste;

(C) A discharge of a material which, [~~when~~]if discharged, becomes a hazardous waste.

(ii) An owner or operator of a facility otherwise regulated by Rule R315-264 shall comply with [~~all~~]the applicable requirements of Sections R315-264-30 through R315-264-35, R315-264-37 and R315-264-50 through R315-264-56.

(iii) Any person who is covered by Subsection R315-264-1(g)(8)(i) and who continues or initiates hazardous waste treatment or containment activities after the immediate response is over is subject to [~~all~~]the applicable requirements of Rule R315-

264 and 40 CFR 122 and 123 and Rule R315-124 for those activities.

(iv) In the case of an explosives or munitions emergency response, if a Federal, State, Tribal or local official acting within the scope of his or her official responsibilities, or an explosives or munitions emergency response specialist, determines that immediate removal of the material or waste is necessary to protect human health or the environment, that official or specialist may authorize the removal of the material or waste by transporters who do not have EPA identification numbers and without the preparation of a manifest. In the case of emergencies involving military munitions, the responding military emergency response specialist's organizational unit shall retain records for three years identifying the dates of the response, the responsible persons responding, the type and description of material addressed, and its disposition.

(9) A transporter storing manifested shipments of hazardous waste in containers meeting the requirements of Section R315-262-30 at a transfer facility for a period of ten days or less.

(10) The addition of absorbent material to waste in a container, as defined in Section R315-260-10, or the addition of waste to absorbent material in a container, provided that these actions occur at the time waste is first placed in the container; and Subsections R315-264-17(b), R315-264-171, and R315-264-172 are complied with.

(11) Universal waste handlers and universal waste transporters, as defined in Section R315-260-10, handling the wastes listed below. These handlers are subject to regulation under Rule R315-273, [~~when~~]if handling the below listed universal wastes.

(i) Batteries as described in Section R315-273-2;

(ii) Pesticides as described in Section R315-273-3;

(iii) Mercury-containing equipment as described in Section R315-273-4;

(iv) Lamps as described in Section R315-273-5;

(v) Antifreeze as described in Subsection R315-272-6(a); and

(vi) Aerosol cans as described in Subsection R315-273-6(b).

(12) Reserved

(13) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in Section R315-266-500. Reverse distributors are subject to regulation under Sections R315-266-500 through R315-266-510 in lieu of Rule R315-264 for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(h) The requirements of Rule R315-264 apply to owners or operators of [~~all~~]facilities which treat, store, or dispose of hazardous wastes referred to in Rule R315-268.

(i) Reserved

(j) The requirements of Sections R315-264-10 through R315-264-19, R315-264-30 through R315-264-37, R315-264-50 through R315-264-56, and R315-264-101 do not apply to remediation waste management sites. However, some remediation waste management sites may be a part of a facility that is subject to a traditional hazardous waste permit because the facility is also treating, storing or disposing of hazardous wastes that are not remediation wastes. In these cases, Sections R315-264-10 through R315-264-19, R315-264-30 through R315-264-37, R315-264-50 through R315-264-56, and R315-264-101 do apply to the facility subject to the traditional hazardous waste permit. Instead of the requirements of Sections R315-264-10 through R315-264-19, R315-264-30 through R315-264-37, and R315-264-50 through R315-264-56, owners or operators of remediation waste management sites shall:

(1) Obtain an EPA identification number by applying to the [~~Administrator~~]Director using EPA Form 8700-12;

(2) Obtain a detailed chemical and physical analysis of a representative sample of the hazardous remediation wastes to be managed at the site. At a minimum, the analysis shall contain [~~all of~~]the information which shall be known to treat, store or dispose of the waste according to Rules R315-264 and R315-268, and shall be kept accurate

and up to date;

(3) Prevent people who are unaware of the danger from entering, and minimize the possibility for unauthorized people or livestock to enter onto the active portion of the remediation waste management site, unless the owner or operator can demonstrate to the Director that:

(i) Physical contact with the waste, structures, or equipment within the active portion of the remediation waste management site shall not injure people or livestock who may enter the active portion of the remediation waste management site; and

(ii) Disturbance of the waste or equipment by people or livestock who enter onto the active portion of the remediation waste management site, shall not cause a violation of the requirements of Rule R315-264;

(4) Inspect the remediation waste management site for malfunctions, deterioration, operator errors, and discharges that may be causing, or may lead to, a release of hazardous waste constituents to the environment, or a threat to human health. The owner or operator shall conduct these inspections often enough to identify problems in time to correct them before they harm human health or the environment, and shall remedy the problem before it leads to a human health or environmental hazard. Where a hazard is imminent or has already occurred, the owner[~~/~~] or operator shall take remedial action immediately;

(5) Provide personnel with classroom or on-the-job training on how to perform their duties in a way that ensures the remediation waste management site complies with the requirements of Rule R315-264, and on how to respond effectively to emergencies;

(6) Take precautions to prevent accidental ignition or reaction of ignitable or reactive waste, and prevent threats to human health and the environment from ignitable, reactive and incompatible waste;

(7) For remediation waste management sites subject to regulation under Sections R315-264-170 through R315-264-179, R315-264-190 through R315-264-200, R315-264-220 through R315-264-232, R315-264-250 through R315-264-259, R315-264-270 [~~T~~]through R315-264-283, R315-264-300 through R315-264-317, R315-264-340 through R315-264-351, and R315-264-600 through R315-264-603, the owner[~~/~~] or operator shall design, construct, operate, and maintain a unit within a 100-year floodplain to prevent washout of any hazardous waste by a 100-year flood, unless the owner[~~/~~] or operator can meet the demonstration of Subsection R315-264-18(b);

(8) Not place any non-containerized or bulk liquid hazardous waste in any salt dome formation, salt bed formation, underground mine or cave;

(9) Develop and maintain a construction quality assurance program for [~~all~~]each surface impoundment[~~s~~], waste pile[~~s~~] and landfill unit[~~s~~] that are required to comply with Subsections R315-264-221(c) and R315-264-221(d), R315-264-251(c) and R315-264-251(d), and R315-264-301(c) and R315-264-301(d) at the remediation waste management site, according to the requirements of Section R315-264-19;

(10) Develop and maintain procedures to prevent accidents and a contingency and emergency plan to control accidents that occur. These procedures shall address proper design, construction, maintenance, and operation of remediation waste management units at the site. The goal of the plan shall be to minimize the possibility of, and the hazards from a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water that could threaten human health or the environment. The plan shall explain specifically how to treat, store and dispose of the hazardous remediation waste in question, and shall be implemented immediately whenever a fire, explosion, or release of hazardous waste or hazardous waste constituents which could threaten human health or the environment;

(11) Designate at least one employee, either on the facility premises or on call, [~~(~~]that is, available to respond to an emergency by reaching the facility quickly[~~)~~], to coordinate [~~all~~]emergency response measures. This emergency coordinator shall be thoroughly familiar with [~~all aspects of~~]the facility's contingency plan, [~~all~~

]operations and activities at the facility, the location and characteristics of waste handled, the location of [~~all~~]the records within the facility, and the facility layout. In addition, this person shall have the authority to commit the resources needed to carry out the contingency plan;

(12) Develop, maintain and implement a plan to meet the requirements in Subsections R315-264-1(j)(2) through R315-264-1(j)(6) and R315-264-1(j)(9) through R315-264-1(j)(10); and

(13) Maintain records documenting compliance with Subsections R315-264-1(j)(1) through R315-264-1(j)(12).

KEY: hazardous waste, TSD facilities
Date of Enactment or Last Substantive Amendment: April 13, 2020
Authorizing, and Implemented or Interpreted Law: 19-6-105; 19-6-106

R315. Environmental Quality, Waste Management and Radiation Control, Waste Management.
R315-265. Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities.
R315-265-1. Incorporation, General -- Purpose, Scope, and Applicability.

40 CFR 265.270 through 265.282, 265.300 through 265.316, 265.340 through 265.352, 265.370 through 265.383, 265.400 through 265.406, 265.430, 265.440 through 265.445, 265.1050 through 265.1064, 265.1100 through 265.1102, 265.1200 through 265.1202, 265.1300 through 265.1316 and Appendices I and III through VI of 40 CFR 265, 2015 edition, as amended by 81 FR 85827, are adopted and incorporated by reference except that "Director" is substituted for [~~all~~]references to "Regional Administrator", and for [~~all~~]references to "EPA" or "Environmental Protection Agency" except for references to "EPA identification number" and where EPA is used in reference to actions under Subsection R315-268-42(b) and in Subsection R315-265-71(a)(3).

(a) The purpose of Rule R315-265 is to establish minimum standards that define the acceptable management of hazardous waste during the period of interim status and until certification of final closure or, if the facility is subject to post-closure requirements, until post-closure responsibilities are fulfilled.

(b) Except as provided in Subsection R315-265-1080(b), the standards of Rule R315-265, and of Sections R315-264-552, R315-264-553, and R315-264-554, apply to owners and operators of facilities that treat, store or dispose of hazardous waste who have fully complied with the requirements for interim status under section 3005(e) of RCRA and Section R315-270-10 until either a permit is issued under Rule R315-270 or until applicable Rule R315-265 closure and post-closure responsibilities are fulfilled, and to those owners and operators of facilities in existence on November 19, 1980 who have failed to provide timely notification as required by section 3010(a) of RCRA, failed to file Part A of the permit application as required by Subsections R315-270-10 (e) and R315-270-10(g), or both. These standards apply to [~~all~~]treatment, storage and disposal of hazardous waste at these facilities after the effective date of these [~~regulations~~]rules, except as specifically provided otherwise in Rule R315-265 or Rule R315-261.

Comment: As stated in section 3005(a) of RCRA, after the effective date of regulations under that section, [~~i.e., ~~]that is Rules R315-270 and R315-124, the treatment, storage and disposal of hazardous waste is prohibited except in accordance with a permit. Section 3005(e) of RCRA provides for the continued operation of an existing facility that meets certain conditions, until final administrative disposition of the owner's and operator's permit application is made.

(c) The requirements of Rule R315-265 do not apply to:

(1) A person disposing of hazardous waste by means of ocean disposal subject to a permit issued under the Marine Protection, Research, and Sanctuaries Act;

Comment: These Rule R315-265 [~~regulations~~]rules do apply to the treatment or storage of hazardous waste before it is loaded onto an ocean vessel for incineration or disposal at sea, as provided in Subsection R315-265-1(b).

(2) Reserved

(3) The owner or operator of a POTW which treats, stores, or disposes of hazardous waste;

Comment: The owner or operator of a facility under Subsections R315-265-1(c)(1) through R315-265-1(c)(3) is subject to the requirements of Rule R315-264 to the extent they are included in a permit by rule granted to such a person under 40 CFR 122, or are required by 40 CFR 144.14.

(4) Reserved

(5) The owner or operator of a facility permitted under Rules R315-301 through R315-320 to manage municipal or industrial solid waste, if the only hazardous waste the facility treats, stores, or disposes of is excluded from regulation under Rule R315-265 by Section R315-262-14;

(6) The owner or operator of a facility managing recyclable materials described in Subsections R315-261-6(a)(2), R315-261-6(a)(3), and R315-261-6(a)(4), except to the extent they are referred to in Rule R315-[~~279~~]15 or Sections R315-266-20 through R315-266-23, R315-266-70, R315-266-80, or R315-266-100 through R315-266-112.

(7) A generator accumulating waste on site in compliance with applicable conditions for exemption in Sections R315-262-14 through R315-262-17 and Sections R315-262-200 through R315-262-216 and R315-262-230 through R315-262-233, except to the extent the requirements of Rule R315-265 are included in those sections;

(8) A farmer disposing of waste pesticides from his own use in compliance with Section R315-262-70; or

(9) The owner or operator of a totally enclosed treatment facility, as defined in Section R315-260-10.

(10) The owner or operator of an elementary neutralization unit or a wastewater treatment unit as defined in Section R315-260-10, provided that if the owner or operator is diluting hazardous ignitable (D001) wastes, [~~(~~]other than the D001 High TOC Subcategory defined in Section R315-268-40, Table Treatment Standards for Hazardous Wastes[~~)~~], or reactive (D003) waste, to remove the characteristic before land disposal, the owner[~~/~~] or operator shall comply with the requirements set out in Subsection R315-265-17(b).

(11)(i) Except as provided in Subsection R315-265-1(c)(11)(ii), a person engaged in treatment or containment activities during immediate response to any of the following situations:

(A) A discharge of a hazardous waste;

(B) An imminent and substantial threat of a discharge of a hazardous waste;

(C) A discharge of a material which, [~~when~~]if discharged, becomes a hazardous waste.

(ii) An owner or operator of a facility otherwise regulated by this Rule R315-265 shall comply with [~~all~~]the applicable requirements of Sections R315-265-30 through R315-265-37 and Sections R315-265-50 through R315-265-56.

(iii) Any person who is covered by Subsection R315-265-1(c)(11)(i) and who continues or initiates hazardous waste treatment or containment activities after the immediate response is over is subject to [~~all~~]the applicable requirements of [~~this~~]Rule R315-265 and Rule R315-124 for those activities.

(12) A transporter storing manifested shipments of hazardous waste in containers meeting the requirements of Section R315-262-30 at a transfer facility for a period of ten days or less.

(13) The addition of absorbent material to waste in a container, as defined in Section R315-260-10, or the addition of waste to the absorbent material in a container provided that these actions occur at the time waste is first placed in the containers; and Subsection R315-265-17(b), Sections R315-265-171, and R315-265-172 are complied with.

(14) Universal waste handlers and universal waste transporters, as defined in Section R315-260-10, handling the wastes listed below. These handlers are subject to regulation under Rule R315-273, [~~when~~]if handling the below listed universal wastes.

(i) Batteries as described in Section R315-273-2;

(ii) Pesticides as described in Section R315-273-3;

(iii) Mercury-containing equipment as described in Section R315-273-4; and

(iv) Lamps as described in Section R315-273-5;

(v) Antifreeze as described in Subsection R315-273-6(a); and

(vi) Aerosol cans as described in Subsection R315-273-6(b).

(15) Reserved

(16) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in Section R315-266-500. Reverse distributors are subject to regulation under Sections R315-266-500 through R315-266-510 in lieu of Rule R315-265 for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(d) The following hazardous wastes shall not be managed at facilities subject to regulation under Rule R315-265.

(1) EPA Hazardous Waste Nos. F[~~0~~]020, F[~~0~~]021, F[~~0~~]022, F[~~0~~]023, F[~~0~~]026, or F[~~0~~]027 unless:

(i) The wastewater treatment sludge is generated in a surface impoundment as part of the plant's wastewater treatment system;

(ii) The waste is stored in tanks or containers;

(iii) The waste is stored or treated in waste piles that meet the requirements of Subsection R315-264-250(c) as well as [~~all~~]other applicable requirements of Sections R315-265-250 through R315-265-260;

(iv) The waste is burned in incinerators that are certified pursuant to the standards and procedures in 40 CFR 265.352, which is adopted by reference; or

(v) The waste is burned in facilities that thermally treat the waste in a device other than an incinerator and that are certified pursuant to the standards and procedures in 40 CFR 265.383, which is adopted by reference.

(e) The requirements of Rule R315-265 apply to owners or operators of [~~all~~]facilities which treat, store or dispose of hazardous waste referred to in Rule R315-268, and the Rule R315-268 standards are considered material conditions or requirements of the Rule R315-265 interim status standards.

KEY: hazardous waste, TSD facilities, interim status
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Authorizing, and Implemented or Interpreted Law: 19-6-105; 19-6-106

R315. Environmental Quality, Waste Management and Radiation Control, Waste Management.
R315-266. Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities.

R315-266-500. Hazardous Waste Pharmaceuticals – Definitions for Sections R315-266-500 through R315-266-510.

(a) The following definitions apply to Sections R315-266-500 through R315-266-510:

(1) "Evaluated hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with Subsection R315-266-510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

(2) "Hazardous waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in Section R315-261-2, and exhibits one or more characteristics identified in Sections R315-261-20 through R315-261-24 or is listed in Sections R315-261-30 through R315-261-35. A pharmaceutical is not a solid waste, as defined in Section R315-261-2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used or reused, for example, lawfully donated for its intended purpose, or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in Section R315-261-2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used or reused, for example, lawfully redistributed for its intended purpose, or reclaimed.

(3) "Healthcare facility" means any person that is lawfully authorized to:

(i) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(ii) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

(4) "Household waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in Section R315-261-2, but is excluded from being a hazardous waste under Subsection R315-261-4(b)(1).

(5) "Long-term care facility" means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to,

hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

(6) "Non-creditable hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used or reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

(7) Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in Section R315-261-2, and is not listed in Sections R315-261-30 through R315-261-35, and does not exhibit a characteristic identified in Sections R315-261-20 through R315-261-24.

(8) "Non-pharmaceutical hazardous waste" means a solid waste, as defined in Section R315-261-2, that is listed in Sections R315-261-30 through R315-261-35, or exhibits one or more characteristics identified in Sections R315-261-20 through R315-261-24, but is not a pharmaceutical, as defined in Section R315-266-500.

(9) "Pharmaceutical" means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system, such as electronic cigarette or vaping pen; or any liquid nicotine, e-liquid, packaged for retail sale for use in electronic nicotine delivery systems, such as pre-filled cartridges or vials. This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

(10) "Potentially creditable hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is:

(i) In original manufacturer packaging, except pharmaceuticals that were subject to a recall;

(ii) Undispensed; and

(iii) Unexpired or less than one-year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

(11) "Reverse distributor" means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including

forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

R315-266-501. Hazardous Waste Pharmaceuticals – Applicability.

(a) A healthcare facility that is a very small quantity generator when counting its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to Section R315-262-14 and is not subject to Sections R315-266-500 through R315-266-510, except for Sections R315-266-505 and R315-266-507 and the optional provisions of Section R315-266-504.

(b) A healthcare facility that is a very small quantity generator when counting its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with Subsection R315-266-501(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with Section R315-262-14 and the optional provisions of Section R315-266-504.

(c) A healthcare facility or reverse distributor remains subject to the applicable hazardous waste rules with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in Subsection R315-266-501(a), a healthcare facility is subject to the following in lieu of Rules R315-262 through R315-265:

(1) Sections R315-266-502 and R315-266-505 through R315-266-508 with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals; and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

(2) Subsections R315-266-502(a), R315-266-503, R315-266-505 through R315-266-507 and R315-266-509 with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to Sections R315-266-505 through R315-266-510 in lieu of Rules R315-262 through R315-265 with respect to the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors, that is pharmaceutical manufacturers and reverse logistics centers, are not subject to Sections R315-266-500 through R315-266-510. Other generators are subject to Rule R315-262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) The following are not subject to Rules R315-260 through R315-273, except as specified:

(1) Pharmaceuticals that are not solid waste, as defined by Section R315-261-2, because they are legitimately used or reused, for example, lawfully donated for their intended purpose, or reclaimed.

(2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by Section

R315-261-2, because they have a reasonable expectation of being legitimately used or reused, for example, lawfully redistributed for their intended purpose, or reclaimed.

(3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 subpart C. Sections R315-266-500 through R315-266-510 do apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. Sections R315-266-500 through R315-266-510 do apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(5) Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded or a decision is made to discard the pharmaceuticals or both.

(6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. Sections R315-266-500 through R315-266-510 do apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

(7) Household waste pharmaceuticals, including those that have been collected by an authorized collector, as defined by the Drug Enforcement Administration, provided the authorized collector complies with the conditional exemption in Subsections R315-266-506(a)(2) and R315-266-506(b).

R315-266-502. Hazardous Waste Pharmaceuticals – Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals.

(a) Notification and withdrawal from Sections R315-266-500 through R315-266-510 for healthcare facilities managing hazardous waste pharmaceuticals.

(1) Notification. A healthcare facility shall notify the Director, using the Site Identification Form, EPA Form 8700-12, that it is a healthcare facility operating under Sections R315-266-500 through R315-266-510. A healthcare facility is not required to fill out Box 10.B., Waste Codes for Federally Regulated Hazardous Waste, of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility shall submit a separate notification, Site Identification Form, for each site or EPA identification number.

(i) A healthcare facility that already has an EPA identification number shall notify the Director, using the Site Identification Form, EPA Form 8700-12, that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective

date of Sections R315-266-500 through R315-266-510, or within 60 days of becoming subject to Sections R315-266-500 through R315-266-510.

(ii) A healthcare facility that does not have an EPA identification number shall obtain one by notifying the Director, using the Site Identification Form, EPA Form 8700-12, that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of Sections R315-266-500 through R315-266-510, or within 60 days of becoming subject to Sections R315-266-500 through R315-266-510.

(iii) A healthcare facility shall keep a copy of its notification on file for as long as the healthcare facility is subject to Sections R315-266-500 through R315-266-510.

(2) Withdrawal. A healthcare facility that operated under Sections R315-266-500 through R315-266-510 but is no longer subject to Sections R315-266-500 through R315-266-510, because it is a very small quantity generator under Section R315-262-14, and elects to withdraw from Sections R315-266-500 through R315-266-510, shall notify the Director using the Site Identification Form, EPA Form 8700-12, that it is no longer operating under Sections R315-266-500 through R315-266-510. A healthcare facility is not required to fill out Box 10.B., Waste Codes for Federally Regulated Hazardous Waste, of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility shall submit a separate notification, Site Identification Form, for each EPA identification number.

(i) A healthcare facility shall submit the Site Identification Form notifying that it is withdrawing from Sections R315-266-500 through R315-266-510 before it begins operating under the conditional exemption of Section R315-262-14.

(ii) A healthcare facility shall keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility shall ensure that any personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) Hazardous waste determination for non-creditable pharmaceuticals. A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical shall determine whether that pharmaceutical is a hazardous waste pharmaceutical, for example, it exhibits a characteristic identified in Sections R315-261-20 through R315-261-24 or is listed in Sections R315-261-30 through R315-261-35, in order to determine whether the waste is subject to Sections R315-266-500 through R315-266-510. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under Sections R315-266-500 through R315-266-510.

(d) Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.

(1) A healthcare facility shall place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound,

compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals shall manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility shall keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in a container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of Subsection R315-268-3(c) shall be accumulated in separate containers and labeled with applicable hazardous waste numbers, in other words the hazardous waste codes.

(e) Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility shall label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals".

(f) Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.

(1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site shall demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) Land disposal restrictions for non-creditable hazardous waste pharmaceuticals. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of Rule R315-268. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals shall comply with the land disposal restrictions in accordance with Subsection R315-268-7(a) requirements, except that it is not required to identify the hazardous waste numbers, in other words the hazardous waste codes, on the land disposal restrictions notification.

(h) Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals. A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of Section R315-264-72 or R315-265-72 may accumulate the returned non-creditable hazardous waste pharmaceuticals on site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with Subsections R315-266-502(d) and R315-266-502(e). Upon receipt of the returned shipment, the healthcare facility shall:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of Subsection R315-266-508(a).

(i) Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals.

(1) Biennial reporting by healthcare facilities. Healthcare facilities are not subject to biennial reporting requirements under Section R315-262-41, with respect to non-creditable hazardous waste pharmaceuticals managed under Sections R315-266-500 through R315-266-510.

(2) Exception reporting by healthcare facilities for a missing copy of the manifest.

(i) For shipments from a healthcare facility to a designated facility:

(A) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility shall submit:

(I) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Director; and

(II) A handwritten or typed note on the manifest itself, or

on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) Reserved.

(ii) For shipments rejected by the designated facility and shipped to an alternate facility.

(A) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility, using appropriate manifest procedures, with the signature of the owner or operator of the alternate facility, within 60 days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility shall submit:

(I) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Director; and

(II) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) Reserved.

(3) Additional reports. The Director may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals

(1) A healthcare facility shall keep a copy of each manifest signed in accordance with Subsection R315-262-23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy shall be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility shall keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility shall keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determinations consistent with Subsection R315-262-11(f), for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages its non-creditable non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(4) The periods of retention referred to in Section R315-266-502 are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Director.

(5) Records shall be readily available upon request by an inspector.

(k) Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility shall immediately contain any spills of non-creditable hazardous waste

pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of Sections R315-266-500 through R315-266-510.

(l) Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under Section R315-262-14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in Section R315-260-10, as the very small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site, "control," for the purposes of Section R315-266-502, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person as defined in Section R315-260-10 shall not be deemed to "control" such healthcare facilities, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under Sections R315-266-500 through R315-266-510 for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with Sections R315-266-500 through R315-266-510; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

R315-266-503. Hazardous Waste Pharmaceuticals – Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals.

(a) Hazardous waste determination for potentially creditable pharmaceuticals. A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical shall determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical, for example, it is listed in Sections R315-261-30 through R315-261-35 or exhibits a characteristic identified in Sections R315-261-20 through R315-261-24. A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under Sections R315-266-500 through R315-266-510.

(b) Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under Section R315-262-14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in

Section R315-260-10, as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under Sections R315-266-500 through R315-266-510 for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with Sections R315-266-500 through R315-266-510; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

(c) Prohibition. Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) Biennial Reporting by healthcare facilities. Healthcare facilities are not subject to biennial reporting requirements under Section R315-262-41 with respect to potentially creditable hazardous waste pharmaceuticals managed under Sections R315-266-500 through R315-266-510.

(e) Recordkeeping by healthcare facilities.

(1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor shall keep the following records, paper or electronic, for each shipment of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(i) The confirmation of delivery; and

(ii) The shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(2) The periods of retention referred to in Section R315-266-503 are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Director.

(3) Records shall be readily available upon request by an inspector.

(f) Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility shall immediately contain any spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with Sections R315-266-500 through R315-266-510.

R315-266-504. Hazardous Waste Pharmaceuticals – Healthcare Facilities that are Very Small Quantity Generators for both Hazardous Waste Pharmaceuticals and Non-Pharmaceutical Hazardous Waste.

(a) Potentially creditable hazardous waste pharmaceuticals. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) Off-site collection of hazardous waste pharmaceuticals

generated by a healthcare facility that is a very small quantity generator. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) The receiving healthcare facility meets the conditions in Subsections R315-266-502(l) and R315-266-503(b), as applicable, or

(2) The very small quantity generator healthcare facility meets the conditions in Subsection R315-262-14(a)(5)(viii) and the receiving large quantity generator meets the conditions in Subsection R315-262-17(f).

(c) Long-term care facilities that are very small quantity generators. A long-term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals, excluding contaminated personal protective equipment or clean-up materials, in an on-site collection receptacle of an authorized collector, as defined by the Drug Enforcement Administration, that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with applicable Drug Enforcement Administration regulations for controlled substances.

(d) Long-term care facilities with 20 beds or fewer. A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to Section R315-262-14 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and not subject to Sections R315-266-500 through R315-266-510, except for Sections R315-266-505 and R315-266-507 and the other optional provisions of Section R315-266-504. The Director has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in Section R315-260-10. A long-term care facility with more than 20 beds that operates as a very small quantity generator under Section R315-262-14 shall demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by Section R315-260-10.

R315-266-505. Hazardous Waste Pharmaceuticals – Prohibition of Sewering Hazardous Waste Pharmaceuticals.

Healthcare facilities, including very small quantity generators operating under Section R315-262-14 in lieu of Sections R315-266-500 through R315-266-510, and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).

R315-266-506. Hazardous Waste Pharmaceuticals – Conditional Exemptions for Hazardous Waste Pharmaceuticals that are also Controlled Substances and Household Waste Pharmaceuticals Collected in a Take-Back Event or Program.

(a) Conditional exemptions. Provided the conditions of

Subsection R315-266-506(b) are met, the following are exempt from Rules R315-262 through R315-273:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308; and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector, as defined by the Drug Enforcement Administration, registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user, as defined by the Drug Enforcement Administration.

(b) Conditions for exemption. The hazardous waste pharmaceuticals shall be:

(1) Managed in compliance with the sewer prohibition of Section R315-266-505; and

(2) Collected, stored, transported, and disposed of in compliance with applicable Drug Enforcement Administration regulations for controlled substances; and

(3) Destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(i) A permitted large municipal waste combustor, subject to 40 CFR part 62 subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR part 60 subparts Eb for new large municipal waste combustors; or

(ii) A permitted small municipal waste combustor, subject to 40 CFR part 62 subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR part 60 subparts AAAA for new small municipal waste combustors; or

(iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62 subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60 subpart Ec for new hospital, medical and infectious waste incinerators; or

(iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62 subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR part 60 subpart CCCC for new commercial and industrial solid waste incinerators; or

(v) A permitted hazardous waste combustor subject to 40 CFR part 63 subpart EEE.

R315-266-507. Hazardous Waste Pharmaceuticals – Residues of Hazardous Waste Pharmaceuticals in Empty Containers.

(a) Stock, dispensing and unit-dose containers. A stock bottle, dispensing bottle, vial, or ampule, not to exceed 1 liter or 10,000 pills; or a unit-dose container, such as a unit-dose packet, cup, wrapper, blister pack, or delivery device, is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) Syringes. A syringe is considered empty and the residues

are not regulated as hazardous waste under Sections R315-266-500 through R315-266-510 provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe shall be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under Sections R315-266-500 through R315-266-510 and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) Intravenous (IV) bags. An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag shall be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under Sections R315-266-500 through R315-266-510, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in Subsection R315-261-7(b)(1).

(d) Other containers, including delivery devices. Hazardous waste pharmaceuticals remaining in any other type of unused, partially administered, or fully administered containers shall be managed as non-creditable hazardous waste pharmaceuticals under Sections R315-266-500 through R315-266-510, unless the container held non-acute hazardous waste pharmaceuticals and is empty as defined in Subsection R315-261-7(b)(1) or R315-261-7(b)(2). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

R315-266-508. Hazardous Waste Pharmaceuticals – Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor.

(a) Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility shall ship non-creditable hazardous waste pharmaceuticals and a reverse distributor shall ship evaluated hazardous waste pharmaceuticals off-site to a designated facility, that is, a permitted or interim status treatment, storage, or disposal facility, in compliance with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) Packaging. Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) Labeling. Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172 subpart E.

(iii) Marking.

(A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation (DOT) regulations on hazardous materials under 49 CFR part 172 subpart D.

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found,

contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.
Healthcare Facility's or Reverse distributor's Name and Address _____.
Healthcare Facility's or Reverse distributor's EPA Identification Number_____.
Manifest Tracking Number _____.

(C) Lab packs that will be incinerated in compliance with Subsection R315-268-42(c) are not required to be marked with EPA Hazardous Waste Numbers, except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Numbers.

(iv) Placarding. Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172 subpart F.

(2) The manifest requirements of Sections R315-262-20 through R315-262-27, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list each applicable hazardous waste number, in other words, hazardous waste codes, in Item 13 of EPA Form 8700-22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals shall write either the word "PHARMS" or "PHRM" in Item 13 of EPA Form 8700-22.

(b) Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to Sections R315-262-80 through R315-262-89.

(c) Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to Sections R315-262-80 through R315-262-89. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off site.

R315-266-509. Hazardous Waste Pharmaceuticals – Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor.

(a) Shipping potentially creditable hazardous waste pharmaceuticals. A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor shall comply with applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8. For purposes of the Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the U.S. Environmental Protection Agency specified in Rule R315-262. Because

a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

(b) Delivery confirmation. Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor shall provide confirmation, paper or electronic, to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) Procedures for if delivery confirmation is not received within 35 days. If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment shall contact the carrier and the intended recipient, in other word the reverse distributor, promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) Exporting potentially creditable hazardous waste pharmaceuticals. A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination shall comply with the applicable sections of Sections R315-262-80 through R315-262-89, except the manifesting requirement of Subsection R315-262-83(c), in addition to Subsections R315-266-509(a) through R315-266-509(c).

(e) Importing potentially creditable hazardous waste pharmaceuticals. Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to Subsections R315-266-509(a) through R315-266-509(c) in lieu of Sections R315-262-80 through R315-262-89. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to the applicable requirements of Sections R315-266-500 through R315-266-510.

R315-266-510. Hazardous Waste Pharmaceuticals – Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals at Reverse Distributors.

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that it complies with the following conditions:

(a) Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(1) Notification. A reverse distributor shall notify the Director, using the Site Identification Form, EPA Form 8700-12, that it is a reverse distributor operating under Sections R315-266-500 through R315-266-510.

(i) A reverse distributor that already has an EPA identification number shall notify the Director, using the Site Identification Form, EPA Form 8700-12, that it is a reverse distributor, as defined in Section R315-266-500, within 60 days of the effective date of Sections R315-266-500 through R315-266-510, or within 60 days of becoming subject to Sections R315-266-500 through R315-266-510.

(ii) A reverse distributor that does not have an EPA identification number shall obtain one by notifying the Director, using the Site Identification Form, EPA Form 8700-12, that it is a reverse distributor, as defined in Section R315-266-500, within 60 days of the effective date of Sections R315-266-500 through R315-266-510, or within 60 days of becoming subject to Sections R315-266-500 through R315-266-510.

(2) Inventory by the reverse distributor. A reverse distributor shall maintain a current inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on site.

(i) A reverse distributor shall inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of each waste arriving at the reverse distributor.

(ii) The inventory shall include the identity, for example, name or national drug code, and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(iii) If the reverse distributor already meets the inventory requirements of Subsection R315-266-510(a)(2) because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory pursuant to Section R315-266-510.

(3) Evaluation by a reverse distributor that is not a manufacturer. A reverse distributor that is not a pharmaceutical manufacturer shall evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical" and shall be managed in accordance with Subsection R315-266-510(b).

(ii) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and shall be managed in accordance with Subsection R315-266-501(c).

(4) Evaluation by a reverse distributor that is a manufacturer. A reverse distributor that is a pharmaceutical manufacturer shall evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility and following the evaluation shall manage the evaluated hazardous waste pharmaceuticals in accordance with Subsection R315-266-501(c).

(5) Maximum accumulation time for hazardous waste

pharmaceuticals at a reverse distributor.

(i) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 calendar days or less. The 180 days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to any hazardous waste pharmaceuticals accumulated on site, regardless of whether they are destined for another reverse distributor, that is potentially creditable hazardous waste pharmaceuticals, or a permitted or interim status treatment, storage, or disposal facility, that is evaluated hazardous waste pharmaceuticals.

(ii) Aging pharmaceuticals. Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date, in other words, aging in a holding morgue, can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with Subsection R315-266-510(a) and the container labeling and management standards in Subsections R315-266-510(c)(4)(i) through R315-266-510(c)(4)(vi).

(6) Security at the reverse distributor facility. A reverse distributor shall prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(A) A 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) A means to control entry, such as keycard access.

(ii) If the reverse distributor already meets the security requirements of Subsection R315-266-510(a)(6) because of other regulatory requirements, such as Drug Enforcement Administration or State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to Section R315-266-510.

(7) Contingency plan and emergency procedures at a reverse distributor. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site shall prepare a contingency plan and comply with the other requirements of Sections R315-262-250 through R315-262-265.

(8) Closure of a reverse distributor. If closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor shall comply with Subsections R315-262-17(a)(8)(ii) and R315-262-17(a)(8)(iii).

(9) Reporting by a reverse distributor.

(i) Unauthorized waste report. A reverse distributor shall submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive, for example, non-pharmaceutical hazardous waste, regulated medical waste. The reverse distributor shall prepare and submit an unauthorized waste report to the Director within 45 calendar days after the unauthorized waste arrives at the reverse distributor and shall send a copy of the unauthorized waste report to the healthcare

facility, or other entity, that sent the unauthorized waste. The reverse distributor shall manage the unauthorized waste in accordance with applicable rules. The unauthorized waste report shall be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the reverse distributor;

(B) The date the reverse distributor received the unauthorized waste;

(C) The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(D) A description and the quantity of each unauthorized waste the reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) Additional reports. The Director may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(10) Recordkeeping by reverse distributors. A reverse distributor shall keep the following records, paper or electronic, readily available upon request by an inspector. The periods of retention referred to in Section R315-266-510 are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Director.

(i) A copy of its notification on file for as long as the facility is subject to Sections R315-266-500 through R315-266-510;

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date the shipment arrives at the reverse distributor; and

(iii) A copy of its current inventory for as long as the facility is subject to Sections R315-266-500 through R315-266-510.

(b) Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor. A reverse distributor that does not have a permit or interim status shall comply with the following conditions, in addition to the requirements in Subsection R315-266-510(a), for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility shall send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow Subsection R315-266-510(c) for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor

shall send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow Subsection R315-266-510(c) for evaluated hazardous waste pharmaceuticals.

(3) A reverse distributor shall ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with Section R315-266-509.

(4) Recordkeeping by reverse distributors. A reverse distributor shall keep the following records, paper or electronic, readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment. The periods of retention referred to in Section R315-266-510 are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Director.

(i) The confirmation of delivery; and

(ii) The DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(c) Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals. A reverse distributor that does not have a permit or interim status shall comply with the following conditions, in addition to the requirements of Subsection R315-266-510(a), for the management of evaluated hazardous waste pharmaceuticals:

(1) Accumulation area at the reverse distributor. A reverse distributor shall designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) Inspections of on-site accumulation area. A reverse distributor shall inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) Personnel training at a reverse distributor. Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of Subsection R315-262-17(a)(7).

(4) Labeling and management of containers at on-site accumulation areas. A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area shall:

(i) Label the containers with the words, "hazardous waste pharmaceuticals";

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are

considered to meet the closed container standard;

(v) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of Subsection R315-268-3(c), for example, arsenic trioxide (P012), in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) Hazardous waste numbers. Prior to shipping evaluated hazardous waste pharmaceuticals off site, each container shall be marked with the applicable hazardous waste numbers, in other words hazardous waste codes. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Numbers.

(6) Shipments. A reverse distributor shall ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in Subsections R315-266-508(a) or R315-266-508(b).

(7) Procedures for a reverse distributor for managing rejected shipments. A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of Section R315-264-72 or R315-265-72, may accumulate the returned evaluated hazardous waste pharmaceuticals on site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with Subsections R315-266-510(a) and R315-266-510(c). Upon receipt of the returned shipment, the reverse distributor shall:

(i) Sign either:

(A) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(iv) Within 90 days of receipt of the rejected shipment,

transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of Subsection R315-266-508(a) or R315-266-508(b).

(8) Land disposal restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of Rule R315-268. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site shall comply with the land disposal restrictions in accordance with the requirements of Subsection R315-268-7(a).

(9) Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals.

(i) Biennial reporting by a reverse distributor. A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site shall prepare and submit a single copy of a biennial report to the Director by March 1 of each even numbered year in accordance with Section R315-262-41.

(ii) Exception reporting by a reverse distributor for a missing copy of the manifest.

(A) For shipments from a reverse distributor to a designated facility.

(I) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor shall contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(II) A reverse distributor shall submit an exception report to the Director if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report shall include:

(1) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

(2) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B) For shipments rejected by the designated facility and shipped to an alternate facility.

(I) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter shall contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(II) A reverse distributor shall submit an Exception Report to the Director if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 days of the date the evaluated hazardous waste pharmaceuticals

were accepted by the initial transporter. The 45-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The Exception Report shall include:

(1) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(2) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals.

(i) A reverse distributor shall keep a log, written or electronic, of the inspections of the on-site accumulation area, required by Subsection R315-266-510(c)(2). This log shall be retained as a record for at least three years from the date of the inspection.

(ii) A reverse distributor shall keep a copy of each manifest signed in accordance with Subsection R315-262-23(a) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy shall be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A reverse distributor shall keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A reverse distributor shall keep a copy of each exception report for at least three years from the submission of the report.

(v) A reverse distributor shall keep records to document personnel training, in accordance with Subsection R315-262-17(a)(7)(iv).

(vi) Records shall be readily available upon request by an inspector. The periods of retention referred to in Section R315-266-510 are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Director.

(d) When a reverse distributor shall have a permit. A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of Rules R315-264, and R315-265, and the permit requirements of Rule R315-270, if the reverse distributor:

(1) Does not meet the conditions of Section R315-266-510;

(2) Accepts manifested hazardous waste from off site; or

(3) Treats or disposes of hazardous waste pharmaceuticals on site.

R315-266-[~~203~~]600. Appendix I to Rule R315-266 -- Tier I and Tier II Feed Rate and Emissions Screening Limits for Metals.

Appendix I of 40 CFR 266, 2015 edition, is adopted and incorporated by reference.

R315-266-[~~204~~]601. Appendix II to Rule R315-266 -- Tier I Feed Rate Screening Limits for Total Chlorine.

Table

Terrain-adjusted effective stack height (m)	Noncomplex Terrain Urban (g/hr)	Noncomplex Terrain Rural (g/hr)	Complex Terrain (g/hr)
4	8.2E+01	4.2E+01	1.9E+01
6	9.1E+01	4.8E+01	2.8E+01
8	1.0E+02	5.3E+01	4.1E+01
10	1.2E+02	6.2E+01	5.8E+01
12	1.3E+02	7.7E+01	7.2E+01
14	1.5E+02	9.1E+01	9.1E+01
16	1.7E+02	1.2E+02	1.1E+02
18	1.9E+02	1.4E+02	1.2E+02
20	2.1E+02	1.8E+02	1.3E+02
22	2.4E+02	2.3E+02	1.4E+02
24	2.7E+02	2.9E+02	1.6E+02
26	3.1E+02	3.7E+02	1.7E+02
28	3.5E+02	4.7E+02	1.9E+02
30	3.9E+02	5.8E+02	2.1E+02
35	5.3E+02	9.6E+02	2.6E+02
40	6.2E+02	1.4E+03	3.3E+02
45	8.2E+02	2.0E+03	4.0E+02
50	1.1E+03	2.6E+03	4.8E+02
55	1.3E+03	3.5E+03	6.2E+02
60	1.6E+03	4.6E+03	7.7E+02
65	2.0E+03	6.2E+03	9.1E+02
70	2.3E+03	7.2E+03	1.1E+03
75	2.5E+03	8.6E+03	1.2E+03
80	2.9E+03	1.0E+04	1.3E+03
85	3.3E+03	1.2E+04	1.4E+03
90	3.7E+03	1.4E+04	1.6E+03
95	4.2E+03	1.7E+04	1.8E+03
100	4.8E+03	2.1E+04	2.0E+03
105	5.3E+03	2.4E+04	2.3E+03
110	6.2E+03	2.9E+04	2.5E+03
115	7.2E+03	3.5E+04	2.8E+03
120	8.2E+03	4.1E+04	3.2E+03

R315-266-[~~205~~]602. Appendix III to Rule R315-266 -- Tier II Emission Rate Screening Limits for Free Chlorine and Hydrogen Chloride.

Appendix III of 40 CFR 266, 2015 edition, is adopted and incorporated by reference.

R315-266-[~~206~~]603. Appendix IV to Rule R315-266 -- Reference Air Concentrations*.

Table

Constituent	CAS No.	RAC (ug/m^3)
Acetaldehyde	75-07-0	10
Acetonitrile	75-05-8	10
Acetophenone	98-86-2	100

Acrolein	107-02-8	20
Aldicarb	116-06-3	1
Aluminum Phosphide	20859-73-8	0.3
Allyl Alcohol	107-18-6	5
Antimony	7440-36-0	0.3
Barium	7440-39-3	50
Barium Cyanide	542-62-1	50
Bromomethane	74-83-9	0.8
Calcium Cyanide	592-01-8	30
Carbon Disulfide	75-15-0	200
Chloral	75-87-6	2
Chlorine (free)		0.4
2-Chloro-1,3-butadiene	126-99-8	3
Chromium III	16065-83-1	1000
Copper Cyanide	544-92-3	5
Cresols	1319-77-3	50
Cumene	98-82-8	1
Cyanide (free)	57-12-15	20
Cyanogen	460-19-5	30
Cyanogen Bromide	506-68-3	80
Di-n-butyl Phthalate	84-74-2	100
o-Dichlorobenzene	95-50-1	10
p-Dichlorobenzene	106-46-7	10
Dichlorodifluoromethane	75-71-8	200
2,4-Dichlorophenol	120-83-2	3
Diethyl Phthalate	84-66-2	800
Dimethoate	60-51-5	0.8
2,4-Dinitrophenol	51-28-5	2
Dinoseb	88-85-7	0.9
Diphenylamine	122-39-4	20
Endosulfan	115-29-1	0.05
Endrin	72-20-8	0.3
Fluorine	7782-41-4	50
Formic Acid	64-18-6	2000
Glycidyaldehyde	765-34-4	0.3
Hexachlorocyclopentadiene	77-47-4	5
Hexachlorophene	70-30-4	0.3
Hydrocyanic Acid	74-90-8	20
Hydrogen Chloride	7647-01-1	7
Hydrogen Sulfide	7783-06-4	3
Isobutyl Alcohol	78-83-1	300
Lead	7439-92-1	0.09
Maleic Anhydride	108-31-6	100
Mercury	7439-97-6	0.3
Methacrylonitrile	126-98-7	0.1
Methomyl	16752-77-5	20
Methoxychlor	72-43-5	50
Methyl Chlorocarbonate	79-22-1	1000
Methyl Ethyl Ketone	78-93-3	80
Methyl Parathion	298-00-0	0.3
Nickel Cyanide	557-19-7	20
Nitric Oxide	10102-43-9	100
Nitrobenzene	98-95-3	0.8
Pentachlorobenzene	608-93-5	0.8

Pentachlorophenol	87-86-5	30
Phenol	108-95-2	30
M-Phenylenediamine	108-45-2	5
Phenylmercuric Acetate	62-38-4	0.075
Phosphine	7803-51-2	0.3
Phthalic Anhydride	85-44-9	2000
Potassium Cyanide	151-50-8	50
Potassium Silver Cyanide	506-61-6	200
Pyridine	110-86-1	1
Selenious Acid	7783-60-8	3
Selenourea	630-10-4	5
Silver	7440-22-4	3
Silver Cyanide	506-64-9	100
Sodium Cyanide	143-33-9	30
Strychnine	57-24-9	0.3
1,2,4,5-Tetrachlorobenzene	95-94-3	0.3
2,3,4,6-Tetrachlorophenol	58-90-2	30
Tetraethyl Lead	78-00-2	0.0001
Tetrahydrofuran	109-99-9	10
Thallic Oxide	1314-32-5	0.3
Thallium	7440-28-0	0.5
Thallium (I) Acetate	563-68-8	0.5
Thallium (I) Carbonate	6533-73-9	0.3
Thallium (I) Chloride	7791-12-0	0.3
Thallium (I) Nitrate	10102-45-1	0.5
Thallium Selenite	12039-52-0	0.5
Thallium (I) Sulfate	7446-18-6	0.075
Thiram	137-26-8	5
Toluene	108-88-3	300
1,2,4-Trichlorobenzene	120-82-1	20
Trichloromonofluoromethane	75-69-4	300
2,4,5-Trichlorophenol	95-95-4	100
Vanadium Pentoxide	1314-62-1	20
Warfarin	81-81-2	0.3
Xylenes	1330-20-7	80
Zinc Cyanide	557-21-1	50
Zinc Phosphide	1314-84-7	0.3

*The RAC for other appendix VIII Rule R315-261 constituents not listed herein or in appendix V of Rule R315-266 is 0.1 ug/m^3.

R315-266-[~~207~~]604. Appendix V to Rule R315-266 -- Risk Specific Doses.

Table

Constituent	CAS No.	Unit risk (m3/microg)	RsD (microg/m3)
Acrylamide	79-06-1	1.3E[+]-03	7.7E[+]-03
Acrylonitrile	107-13-1	6.8E[+]-05	1.5E[+]-01
Aldrin	309-00-2	4.9E[+]-03	2.0E[+]-03
Aniline	62-53-3	7.4E[+]-06	1.4E+00

Arsenic	7440-38-2	4.3E[+]-03	2.3E[+]-03
Benz(a)anthracene	56-55-3	8.9E[+]-04	1.1E[+]-02
Benzene	71-43-2	8.3E[+]-06	1.2E+00
Benzidine	92-87-5	6.7E[+]-02	1.5E[+]-04
Benzo(a)pyrene	50-32-8	3.3E[+]-03	3.0E[+]-03
Beryllium	7440-41-7	2.4E[+]-03	4.2E[+]-03
Bis(2-chloroethyl) ether	111-44-4	3.3E[+]-04	3.0E[+]-02
Bis(chloromethyl)ether	542-88-1	6.2E[+]-02	1.6E[+]-04
Bis(2-ethylhexyl) -phthalate	117-81-7	2.4E[+]-07	4.2E+01
1,3-Butadiene	106-99-0	2.8E[+]-04	3.6E[+]-02
Cadmium	7440-43-9	1.8E[+]-03	5.6E[+]-03
Carbon Tetrachloride	56-23-5	1.5E[+]-05	6.7E[+]-01
Chlordane	57-74-9	3.7E[+]-04	2.7E[+]-02
Chloroform	67-66-3	2.3E[+]-05	4.3E[+]-01
Chloromethane	74-87-3	3.6E[+]-06	2.8E+00
Chromium VI	7440-47-3	1.2E[+]-02	8.3E[+]-04
DDT	50-29-3	9.7E[+]-05	1.0E[+]-01
Dibenz(a,h)anthracene	53-70-3	1.4E[+]-02	7.1E[+]-04
1,2-Dibromo-3 -chloropropane	96-12-8	6.3E[+]-03	1.6E[+]-03
1,2-Dibromoethane	106-93-4	2.2E[+]-04	4.5E[+]-02
1,1-Dichloroethane	75-34-3	2.6E[+]-05	3.8E[+]-01
1,2-Dichloroethane	107-06-2	2.6E[+]-05	3.8E[+]-01
1,1-Dichloroethylene	75-35-4	5.0E[+]-05	2.0E[+]-01
1,3-Dichloropropene	542-75-6	3.5E[+]-01	2.9E[+]-05
Dieldrin	60-57-1	4.6E[+]-03	2.2E[+]-03
Diethylstilbestrol	56-53-1	1.4E[+]-01	7.1E[+]-05
Dimethylnitrosamine	62-75-9	1.4E[+]-02	7.1E[+]-04
2,4-Dinitrotoluene	121-14-2	8.8E[+]-05	1.1E[+]-01
1,2-Diphenylhydrazine	122-66-7	2.2E[+]-04	4.5E[+]-02
1,4-Dioxane	123-91-1	1.4E[+]-06	7.1E+00
Epichlorohydrin	106-89-8	1.2E[+]-06	8.3E+00
Ethylene Oxide	75-21-8	1.0E[+]-04	1.0E[+]-01
Ethylene Dibromide	106-93-4	2.2E[+]-04	4.5E[+]-02
Formaldehyde	50-00-0	1.3E[+]-05	7.7E[+]-01
Heptachlor	76-44-8	1.3E[+]-03	7.7E[+]-03
Heptachlor Epoxide	1024-57-3	2.6E[+]-03	3.8E[+]-03
Hexachlorobenzene	118-74-1	4.9E[+]-04	2.0E[+]-02
Hexachlorobutadiene	87-68-3	2.0E[+]-05	5.0E[+]-01
Alpha-hexachloro -cyclohexane	319-84-6	1.8E[+]-03	5.6E[+]-03
Beta-hexachloro	319-85-7	5.3E[+]-04	1.9E[+]-02

-cyclohexane			
Gamma-hexachloro -cyclohexane	58-89-9	3.8E[+]-04	2.6E[+]-02
Hexachlorocyclo -hexane, Technical		5.1E[+]-04	2.0E[+]-02
Hexachlorodibenzo- p-dioxin (1,2 Mixture)		1.3E+0	7.7E[+]-06
Hexachloroethane	67-72-1	4.0E[+]-06	2.5E+00
Hydrazine	302-01-2	2.9E[+]-03	3.4E[+]-03
Hydrazine Sulfate	302-01-2	2.9E[+]-03	3.4E[+]-03
3-Methylcholanthrene	56-49-5	2.7E[+]-03	3.7E[+]-03
Methyl Hydrazine	60-34-4	3.1E[+]-04	3.2E[+]-02
Methylene Chloride	75-09-2	4.1E[+]-06	2.4E+00
4,4'-Methylene-bis-2 -chloroaniline	101-14-4	4.7E[+]-05	2.1E[+]-01
Nickel	7440-02-0	2.4E[+]-04	4.2E[+]-02
Nickel Refinery Dust	7440-02-0	2.4E[+]-04	4.2E[+]-02
Nickel Subsulfide	12035-72-2	4.8E[+]-04	2.1E[+]-02
2-Nitropropane	79-46-9	2.7E[+]-02	3.7E[+]-04
N-Nitroso-n-butylamine	924-16-3	1.6E[+]-03	6.3E[+]-03
N-Nitroso-n-methylurea	684-93-5	8.6E[+]-02	1.2E[+]-04
N-Nitrosodiethylamine	55-18-5	4.3E[+]-02	2.3E[+]-04
N-Nitrosopyrrolidine	930-55-2	6.1E[+]-04	1.6E[+]-02
Pentachloronitrobenzene	82-68-8	7.3E[+]-05	1.4E[+]-01
PCBs	1336-36-3	1.2E[+]-03	8.3E[+]-03
Pronamide	23950-58-5	4.6E[+]-06	2.2E+00
Reserpine	50-55-5	3.0E[+]-03	3.3E[+]-03
2,3,7,8-Tetrachloro -dibenzo-p-dioxin	1746-01-6	4.5E+01	2.2E[+]-07
1,1,2,2- Tetrachloroethane	79-34-5	5.8E[+]-05	1.7E[+]-01
Tetrachloroethylene	127-18-4	4.8E[+]-07	2.1E+01
Thiourea	62-56-6	5.5E[+]-04	1.8E[+]-02
1,1,2-Trichloroethane	79-00-5	1.6E[+]-05	6.3E[+]-01
Trichloroethylene	79-01-6	1.3E[+]-06	7.7E+00
2,4,6-Trichlorophenol	88-06-2	5.7E[+]-06	1.8E+00
Toxaphene	8001-35-2	3.2E[+]-04	3.1E[+]-02
Vinyl Chloride	75-01-4	7.1E[+]-06	1.4E+00

R315-266-[~~208~~]605. Appendix VI to Rule R315-266 -- Stack Plume Rise.

Appendix VI of 40 CFR 266, 2015 edition, is adopted and incorporated by reference.

R315-266-[~~209~~]606. Appendix VII to Rule R315-266 -- Health-Based Limits for Exclusion of Waste-Derived Residues.

Table

Metals -- TCLP Extract Concentration Limits.

Constituent	CAS No.	Concentration limits (mg/L)
Antimony	7440-36-0	1xE+00
Arsenic	7440-38-2	5xE+00
Barium	7440-39-3	1xE+02
Beryllium	7440-41-7	7xE[-]-03
Cadmium	7440-43-9	1xE+00
Chromium	7440-47-3	5xE+00
Lead	7439-92-1	5xE+00
Mercury	7439-97-6	2xE[-]-01
Nickel	7440-02-0	7xE+01
Selenium	7782-49-2	1xE+00
Silver	7440-22-4	5xE+00
Thallium	7440-28-0	7xE+00

Nonmetals -- Residue Concentration Limits

Constituent	CAS No.	Concentration limits for residues (mg/kg)
Acetonitrile	75-05-8	2xE[-]-01
Acetophenone	98-86-2	4xE+00
Acrolein	107-02-8	5xE[-]-01
Acrylamide	79-06-1	2xE[-]-04
Acrylonitrile	107-13-1	7xE[-]-04
Aldrin	309-00-2	2xE[-]-05
Allyl alcohol	107-18-6	2xE[-]-01
Aluminum phosphide	20859-73-8	1xE[-]-02
Aniline	62-53-3	6xE[-]-02
Barium cyanide	542-62-1	1xE+00
Benz(a)anthracene	56-55-3	1xE[-]-04
Benzene	71-43-2	5xE[-]-03
Benzidine	92-87-5	1xE[-]-06
Bis(2-chloroethyl) ether	111-44-4	3xE[-]-04
Bis(chloroethyl) ether	542-88-1	2xE[-]-06
Bis(2-ethylhexyl) phthalate	117-81-7	3xE+01
Bromoform	75-25-2	7xE[-]-01
Calcium cyanide	592-01-8	1xE[-]-06
Carbon disulfide	75-15-0	4xE+00
Carbon tetrachloride	56-23-5	5xE[-]-03
Chlordane	57-74-9	3xE[-]-04
Chlorobenzene	108-90-7	1xE+00

Chloroform	67-66-3	6xE[ł]_02
Copper cyanide	544-92-3	2xE[ł]_01
Cresols (Cresylic acid)	1319-77-3	2xE+00
Cyanogen	460-19-5	1xE+00
DDT	50-29-3	1xE[ł]_03
Dibenz(a, h)-anthracene	53-70-3	7xE[ł]_06
1,2-Dibromo-3 -chloropropane	96-12-8	2xE[ł]_05
p-Dichlorobenzene	106-46-7	7.5xE[ł]_02
Dichlorodifluoromethane	75-71-8	7xE+00
1,1-Dichloroethylene	75-35-4	5xE[ł]_03
2,4-Dichlorophenol	120-83-2	1xE[ł]_01
1,3-Dichloropropene	542-75-6	1xE[ł]_03
Dieldrin	60-57-1	2xE[ł]_05
Diethyl phthalate	84-66-2	3xE+01
Diethylstilbesterol	56-53-1	7xE[ł]_07
Dimethoate	60-51-5	3xE[ł]_02
2,4-Dinitrotoluene	121-14-2	5xE[ł]_04
Diphenylamine	122-39-4	9xE[ł]_01
1,2-Diphenylhydrazine	122-66-7	5xE[ł]_04
Endosulfan	115-29-7	2xE[ł]_03
Endrin	72-20-8	2xE[ł]_04
Epichlorohydrin	106-89-8	4xE[ł]_02
Ethylene dibromide	106-93-4	4xE[ł]_07
Ethylene oxide	75-21-8	3xE[ł]_04
Fluorine	7782-41-4	4xE+00
Formic acid	64-18-6	7xE+01
Heptachlor	76-44-8	8xE[ł]_05
Heptachlor epoxide	1024-57-3	4xE[ł]_05
Hexachlorobenzene	118-74-1	2xE[ł]_04
Hexachlorobutadiene	87-68-3	5xE[ł]_03
Hexachlorocyclopentadiene	77-47-4	2xE[ł]_01
Hexachlorodibenzo-p -dioxins	19408-74-3	6xE[ł]_08
Hexachloroethane	67-72-1	3xE[ł]_02
Hydrazine	302-01-1	1xE[ł]_04
Hydrogen cyanide	74-90-8	7xE[ł]_05
Hydrogen sulfide	7783-06-4	1xE[ł]_06
Isobutyl alcohol	78-83-1	1xE+01
Methomyl	16752-77-5	1xE+00
Methoxychlor	72-43-5	1xE[ł]_01
3-Methylcholanthrene	56-49-5	4xE[ł]_05
4,4'-Methylenebis (2-chloroaniline)	101-14-4	2xE[ł]_03

Methylene chloride	75-09-2	5xE[-]-02
Methyl ethyl ketone (MEK)	78-93-3	2xE+00
Methyl hydrazine	60-34-4	3xE[-]-04
Methyl parathion	298-00-0	2xE[-]-02
Naphthalene	91-20-3	1xE+01
Nickel cyanide	557-19-7	7xE[-]-01
Nitric oxide	10102-43-9	4xE+00
Nitrobenzene	98-95-3	2xE[-]-02
N-Nitrosodi-n-butylamine	924-16-3	6xE[-]-05
N-Nitrosodiethylamine	55-18-5	2xE[-]-06
N-Nitroso-N-methylurea	684-93-5	1xE[-]-07
N-Nitrosopyrrolidine	930-55-2	2xE[-]-04
Pentachlorobenzene	608-93-5	3xE[-]-02
Pentachloronitrobenzene (PCNB)	82-68-8	1xE[-]-01
Pentachlorophenol	87-86-5	1xE+00
Phenol	108-95-2	1xE+00
Phenylmercury acetate	62-38-4	3xE[-]-03
Phosphine	7803-51-2	1xE[-]-02
Polychlorinated biphenyls, N.O.S	1336-36-3	5xE[-]-05
Potassium cyanide	151-50-8	2xE+00
Potassium silver cyanide	506-61-6	7xE+00
Pronamide	23950-58-5	3xE+00
Pyridine	110-86-1	4xE[-]-02
Reserpine	50-55-5	3xE[-]-05
Selenourea	630-10-4	2xE[-]-01
Silver cyanide	506-64-9	4xE+00
Sodium cyanide	143-33-9	1xE+00
Strychnine	57-24-9	1xE[-]-02
1,2,4,5-Tetrachlorobenzene	95-94-3	1xE[-]-02
1,1,2,2-tetrachloroethane	79-34-5	2xE[-]-03
Tetrachloroethylene	127-18-4	7xE[-]-01
2,3,4,6-Tetrachlorophenol	58-90-2	1xE[-]-02
Tetraethyl lead	78-00-2	4xE[-]-06
Thiourea	62-56-6	2xE[-]-04
Toluene	108-88-3	1xE+01
Toxaphene	8001-35-2	5xE[-]-03
1,1,2-Trichloroethane	79-00-5	6xE[-]-03
Trichloroethylene	79-01-6	5xE[-]-03
Trichloromonofluoromethane	75-69-4	1xE+01
2,4,5-Trichlorophenol	95-95-4	4xE+00
2,4,6-Trichlorophenol	88-06-2	4xE+00

Vanadium pentoxide	1314-62-1	7xE[+]-01
Vinyl chloride	75-01-4	2xE[+]-03

*Note 1: The health-based concentration limits for appendix VIII Rule R315-261 constituents for which a health-based concentration is not provided below is 2xE[+]-06 mg/kg.

Note 2: The levels specified in this appendix and the default level of 0.002 micrograms per kilogram or the level of detection for constituents as identified in Note 1 of this appendix are administratively stayed under the condition, for those constituents specified in Subsection R315-266-112(b)(1), that the owner or operator complies with alternative levels defined as the land disposal restriction limits specified in Section R315-268-43 for F[~~0~~]039 nonwastewaters. See Subsection R315-266-112(b)(2)(i).

R315-266-[~~210~~]607. Appendix VIII to Rule R315-266 -- Organic Compounds for Which Residues Shall Be Analyzed.

Table

Volatiles

Benzene
Toluene
Carbon tetrachloride
Chloroform
Methylene chloride
Trichloroethylene
Tetra chloroethylene
1,1,1-Trichloroethane
Chlorobenzene
cis-1,4-Dichloro-2-butene
Bromochloromethane
Bromodichloromethane
Bromoform
Bromomethane
Methylene bromide
Methyl ethyl ketone

Semivolatiles

Bis(2-ethylhexyl)phthalate
Naphthalene
Phenol
Diethyl phthalate
Butyl benzyl phthalate
2,4-Dimethylphenol
o-Dichlorobenzene
m-Dichlorobenzene
p-Dichlorobenzene

Hexachlorobenzene
2,4,6-Trichlorophenol
Fluoranthene
o-Nitrophenol
1,2,4-Trichlorobenzene
o-Chlorophenol
Pentachlorophenol
Pyrene
Dimethyl phthalate
Mononitrobenzene
2,6-Toluene diisocyanate
Polychlorinated dibenzo-p-dioxins(1)
Polychlorinated dibenzo-furans(1)

(1) Analyses for polychlorinated dibenzo-p-dioxins and polychlorinated dibenzo-furans are required only for residues collected from areas downstream of the combustion chamber, e.g., ductwork, boiler tubes, heat exchange surfaces, air pollution control devices, etc.

Note to Appendix VIII: Analysis is not required for those compounds that do not have an established F039 nonwastewater concentration limit.

R315-266-[~~211~~]608. Appendix IX to Rule R315-266 -- Methods Manual for Compliance With the BIF Regulations.

Appendix IX of 40 CFR 266, 2015 edition, is adopted and incorporated by reference.

R315-266-[~~212~~]609. Appendix XI to Rule R315-266 -- Lead-Bearing Materials That May Be Processed in Exempt Lead Smelters.

A. Exempt Lead-Bearing Materials [~~When~~]If Generated or Originally Produced By Lead-Associated Industries(1)

Acid dump[~~/~~] or fill solids
Sump mud
Materials from laboratory analyses
Acid filters
Baghouse bags
Clothing, e.g., coveralls, aprons, shoes, hats, gloves
Sweepings
Air filter bags and cartridges
Respiratory cartridge filters
Shop abrasives
Stacking boards
Waste shipping containers, e.g., cartons, bags, drums, cardboard
Paper hand towels
Wiping rags and sponges
Contaminated pallets
Water treatment sludges, filter cakes, residues, and solids
Emission control dusts, sludges, filter cakes, residues, and solids from lead-associated industries, e.g., K069 and D008 wastes
Spent grids, posts, and separators
Spent batteries
Lead oxide and lead oxide residues

Lead plates and groups
Spent battery cases, covers, and vents
Pasting belts
Water filter media
Cheesecloth from pasting rollers
Pasting additive bags
Asphalt paving materials

B. Exempt Lead-Bearing Materials [~~When~~]If Generated or Originally Produced By Any Industry

Charging jumpers and clips
Platen abrasive
Fluff from lead wire and cable casings
Lead-based pigments and compounding pigment dust

(1) Lead-associated industries are lead smelters, lead-acid battery manufacturing, and lead chemical manufacturing, e.g., manufacturing of lead oxide or other lead compounds.

R315-266-[~~213~~]610. Appendix XII to Rule R315-266 -- Nickel or Chromium-Bearing Materials That May Be Processed in Exempt Nickel-Chromium Recovery Furnaces.

A. Exempt Nickel or Chromium-Bearing Materials [~~when~~]if Generated by Manufacturers or Users of Nickel, Chromium, or Iron

Baghouse bags
Raney nickel catalyst
Floor sweepings
Air filters
Electroplating bath filters
Wastewater filter media
Wood pallets
Disposable clothing (coveralls, aprons, hats, and gloves)
Laboratory samples and spent chemicals
Shipping containers and plastic liners from containers or vehicles used to transport nickel or chromium-containing wastes
Respirator cartridge filters
Paper hand towels

B. Exempt Nickel or Chromium-Bearing Materials [~~when~~]if Generated by Any Industry

Electroplating wastewater treatment sludges (F006)
Solutions containing Nickel, [~~and/or~~]chromium[~~-containing solutions~~] or both
Nickel, chromium, and iron catalysts
Nickel-cadmium and nickel-iron batteries
Filter cake from wet scrubber system water treatment plants in the specialty steel industry(1)
Filter cake from nickel-chromium alloy pickling operations(1)

(1) If a hazardous waste under an authorized State program.

R315-266-[~~214~~]611. Appendix XIII to Rule R315-266 -- Mercury Bearing Wastes That May Be Processed in Exempt Mercury Recovery Units.

These are exempt mercury-bearing materials with less than 500 ppm of Rule R315-261, appendix VIII organic constituents [~~when~~]if generated by manufacturers or users of mercury or mercury products.

1. Activated carbon
2. Decomposer graphite

3. Wood
4. Paper
5. Protective clothing
6. Sweepings
7. Respiratory cartridge filters
8. Cleanup articles
9. Plastic bags and other contaminated containers
10. Laboratory and process control samples
11. K106 and other wastewater treatment plant sludge and filter cake
12. Mercury cell sump and tank sludge
13. Mercury cell process solids
14. Recoverable levels of mercury contained in soil

KEY: hazardous waste
Date of Enactment or Last Substantive Amendment: October 15, 2019
Authorizing, and Implemented or Interpreted Law: 19-6-105; 19-6-106

R315. Environmental Quality, Waste Management and Radiation Control, Waste Management.
R315-268. Land Disposal Restrictions.

R315-268-7. Land Disposal Restrictions -- Testing, Tracking, and Recordkeeping Requirements for Generators, Reverse Distributors, Treaters, and Disposal Facilities.

(a) Requirements for generators and reverse distributors:

(1) A generator of hazardous waste shall determine if the waste has to be treated before it can be land disposed. This is done by determining if the hazardous waste meets the treatment standards in Sections R315-268-40, R315-268-45, or R315-268-49. This determination can be made concurrently with the hazardous waste determination required in Section R315-262-11, in either of two ways: testing the waste or using knowledge of the waste. If the generator tests the waste, testing would normally determine the total concentration of hazardous constituents, or the concentration of hazardous constituents in an extract of the waste obtained using test method 1311 in "Test Methods of Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846, incorporated by reference, see Section R315-260-11, depending on whether the treatment standard for the waste is expressed as a total concentration or concentration of hazardous constituent in the waste's extract. Alternatively, the generator shall send the waste to a hazardous waste treatment facility permitted under Section 19-6-108, where the waste treatment facility shall comply with the requirements of Section R315-264-13 and Subsection R315-268-7(b). In addition, [~~some~~]certain hazardous wastes shall be treated by particular treatment methods before they can be land disposed and [~~some~~]soils [~~are~~]contaminated by such hazardous wastes. These treatment standards are also found in Section R315-268-40[~~,~~] and are described in detail in Section R315-268-42, Table 1. These wastes, and soils contaminated with such wastes, do not need to be tested, however, if they are in a waste mixture, other wastes with concentration level treatment standards would have to be tested. If a generator determines they are managing a waste or soil contaminated with a waste, that displays a hazardous characteristic of ignitability, corrosivity, reactivity, or toxicity, they shall comply with the special requirements of Section R315-268-9 in addition to any applicable requirements in Section R315-268-7.

(2) If the waste or contaminated soil does not meet the treatment standards, or if the generator chooses not to make the determination of whether [~~his~~]the waste shall be treated, with the initial shipment of waste to each treatment or storage facility, the generator shall send a one-time written notice to each treatment or storage facility receiving the waste, and place a copy in the file. The notice shall include the information in column "268-7(a)(2)" of the Generator Paperwork Requirements Table in Subsection R315-268-7(a)(4). Alternatively, if the generator chooses not to make the determination of whether the waste shall be treated, the notification shall include the EPA Hazardous Waste Numbers and Manifest Number of the first shipment and shall state "This hazardous waste may or may not be subject to the LDR treatment standards. The treatment facility shall make the determination." No further notification is necessary until such

time that the waste or facility change, in which case a new notification shall be sent and a copy placed in the generator's file.

(3) If the waste or contaminated soil meets the treatment standard at the original point of generation:

(i) With the initial shipment of waste to each treatment, storage, or disposal facility, the generator shall send a one-time written notice to each treatment, storage, or disposal facility receiving the waste, and place a copy in the file. The notice shall include the information indicated in column "268-7(a)(3)" of the Generator Paperwork Requirements Table in Subsection R315-268-7(a)(4) and the following certification statement, signed by an authorized representative:

I certify under penalty of law that I personally have examined and am familiar with the waste through analysis and testing or through knowledge of the waste to support this certification that the waste complies with the treatment standards specified in Sections R315-268-40 through R315-268-49. I believe that the information I submitted is true, accurate, and complete. I am aware that there are significant penalties for submitting a false certification, including the possibility of a fine and imprisonment.

(ii) For contaminated soil, with the initial shipment of wastes to each treatment, storage, or disposal facility, the generator shall send a one-time written notice to each facility receiving the waste and place a copy in the file. The notice shall include the information in column "268-7(a)(3)" of the Generator Paperwork Requirements Table in Subsection R315-268-7(a)(4).

(iii) If the waste changes, the generator shall send a new notice and certification to the receiving facility[~~,~~] and place a copy in their files. Generators of hazardous debris excluded from the definition of hazardous waste under Subsection R315-261-3(f) are not subject to these requirements.

(4) For reporting, tracking, and recordkeeping if[~~when~~] exceptions allow certain wastes or contaminated soil that do not meet the treatment standards to be land disposed: There are certain exemptions from the requirement that hazardous wastes or contaminated soil meet treatment standards before they can be land disposed. These include, but are not limited to case-by-case extensions under Section R315-268-5, disposal in a no-migration unit under Section R315-268-6, or a national capacity variance or case-by-case capacity variance under Sections R315-268-20 through R315-268-39. If a generator's waste is so exempt, then with the initial shipment of waste, the generator shall send a one-time written notice to each land disposal facility receiving the waste. The notice shall include the information indicated in column "268-7(a)(4)" of the Generator Paperwork Requirements Table below. If the waste changes, the generator shall send a new notice to the receiving facility, and place a copy in their files.

TABLE 1

Generator Paperwork Requirements

Required information	268-7 (a)(2)	268-7 (a)(3)	268-7 (a)(4)	268-7 (a)(9)

1. EPA Hazardous Waste Numbers and Manifest Number of first shipment	X	X	X	X
2. Statement: this waste is not prohibited from land disposal			X	
3. The waste is subject to the LDRs. The constituents of concern for F001-F005, and F039, and underlying hazardous constituents in characteristic wastes, unless the waste will be treated and monitored for [~~all~~]each constituent[~~s~~]. If [~~all~~]each Constituent[~~s~~] will be treated and monitored, there is no need to put each of them[~~all~~] on the LDR notice	X	X		
4. The notice shall include the applicable wastewater[~~/~~] or nonwastewater category (see Section R315-268-2(d)[~~–~~] and R315-268-2(f)) and subdivisions made within a waste code based on waste-specific criteria, [~~(~~]such as D003 reactive cyanide[~~)~~]	X	X		
5. Waste analysis data, [~~when~~]if available	X	X	X	
6. Date the waste is subject to the prohibition			X	
7. For hazardous debris, [~~when~~]if treating with the alternative treatment technologies provided by Section R315-268-45: the contaminants subject to treatment, as described in Section R315-268-45(b); and an indication that these contaminants are being treated to comply with Section R315-268-45	X			X
8. For contaminated soil subject to LDRs as provided in [~~S~~]Subsection R315-268-49(a), the constituents subject to treatment as described in [~~S~~]Subsection R315-268-49(d), and the following statement: "This contaminated soil, does/does not, contain listed hazardous waste and, does/does not, exhibit a characteristic of hazardous waste and, is subject to/complies with, the soil treatment standards as	X	X		

provided by [~~S~~]Subsection R315-268-49(c) or the universal treatment standards"		
9. A certification is needed, see applicable section for exact wording	X	X

(5) If a generator is managing and treating prohibited waste or contaminated soil in tanks, containers, or containment buildings regulated under Sections R315-262-15, R315-262-16, and R315-262-17 to meet applicable LDR treatment standards found at Section R315-268-40, the generator shall develop and follow a written waste analysis plan which describes the procedures it will carry out to comply with the treatment standards. Generators treating hazardous debris under the alternative treatment standards of Table 1 to Section R315-268-45, however, are not subject to these waste analysis requirements. The plan [~~must~~]shall be kept on site in the generator's records, and the following requirements [~~must~~]shall be met:

(i) The waste analysis plan shall be based on a detailed chemical and physical analysis of a representative sample of the prohibited waste(s) being treated, and contain [~~all~~]the information necessary to treat the waste[~~(~~]s[~~)~~] in accordance with the requirements of Rule R315-268, including the selected testing frequency.

(ii) Such plan shall be kept in the facility's on-site files and made available to inspectors.

(iii) Wastes shipped off-site pursuant to Subsection R315-268-7(a) shall comply with the notification requirements of Subsection R315-268-7(a)(3).

(6) If a generator determines that the waste or contaminated soil is restricted based solely on his knowledge of the waste, [~~all~~]the supporting data used to make this determination shall be retained on-site in the generator's files. If a generator determines that the waste is restricted based on testing this waste or an extract developed using the test method 1311 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846, as referenced in Section R315-260-11, and [~~all~~]the waste analysis data shall be retained on-site in the generator's files.

(7) If a generator determines that he is managing a prohibited waste that is excluded from the definition of hazardous or solid waste or is exempted from regulation under Sections R315-261-2 through R315-261-6 subsequent to the point of generation, including deactivated characteristic hazardous wastes managed in wastewater treatment systems subject to the Clean Water Act (CWA) as specified at Subsection R315-261-4(a)(2) or that are CWA-equivalent, or are managed in an underground injection well regulated by the SDWA, he shall place a one-time notice describing such generation, subsequent exclusion from the definition of hazardous or solid waste or exemption from regulation under Sections R315-261-2 through R315-261-6, and the disposition of the waste, in the facility's on-site files.

(8) Generators shall retain on-site a copy of [~~all~~]the notices, certifications, waste analysis data, and other documentation produced pursuant to Section R315-268-7 for at least three years from the date that the waste that is the subject of such documentation was last sent to on-site or off-site treatment, storage, or disposal. The

three[-]-year record retention period is automatically extended during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Director. The requirements of Subsection R315-268-7(a) apply to solid wastes even [~~when~~]if the hazardous characteristic is removed prior to disposal, or [~~when~~]if the waste is excluded from the definition of hazardous or solid waste under Sections R315-261-2 through R315-261-6, or exempted from hazardous waste regulation, subsequent to the point of generation.

(9) If a generator is managing a lab pack containing hazardous wastes and wishes to use the alternative treatment standard for lab packs found at Subsection R315-268-42(c):

(i) With the initial shipment of waste to a treatment facility, the generator shall submit a notice that provides the information in column "268-7(a)(9)" in the Generator Paperwork Requirements Table of Subsection R315-268-7(a)(4), and the following certification. The certification, which shall be signed by an authorized representative and shall be placed in the generator's files, shall say the following:

I certify under penalty of law that I personally have examined and am familiar with the waste and that the lab pack contains only wastes that have not been excluded under [~~a~~]Appendix IV to Rule R315-268 and that this lab pack will be sent to a combustion facility in compliance with the alternative treatment standards for lab packs at Subsection R315-268-42(c). I am aware that there are significant penalties for submitting a false certification, including the possibility of fine or imprisonment.

(ii) No further notification is necessary until such time that the wastes in the lab pack change, or the receiving facility changes, in which case a new notice and certification shall be sent and a copy placed in the generator's file.

(iii) If the lab pack contains characteristic hazardous wastes, D001-D043 excluding D009, underlying hazardous constituents, as defined in Subsection R315-268-2(i) need not be determined.

(iv) The generator shall also comply with the requirements in Subsections R315-268-7(a)(6) and R315-268-7(a)(7).

(10) Small quantity generators with tolling agreements pursuant to Subsection R315-262-20(e) shall comply with the applicable notification and certification requirements of Subsection R315-268-7(a) for the initial shipment of the waste subject to the agreement. Such generators shall retain on-site a copy of the notification and certification, together with the tolling agreement, for at least three years after termination or expiration of the agreement. The three-year record retention period is automatically extended during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Director.

(b) Treatment facilities shall test their wastes according to the frequency specified in their waste analysis plans as required by Section R315-264-13, for permitted TSDs, or [~~40 CFR 265.13, which is adopted by reference~~]Section R315-265-13, for interim status facilities. Such testing shall be performed as provided in Subsections R315-268-7(b)(1), R315-268-7(b)(2) and R315-268-7(b)(3).

(1) For wastes or contaminated soil with treatment standards expressed in the waste extract, [~~(~~]TCLP[~~)~~], the owner or operator of the treatment facility shall test an extract of the treatment

residues, using test method 1311, the Toxicity Characteristic Leaching Procedure, described in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846 as incorporated by reference in Section R315-260-11, to assure that the treatment residues extract meet the applicable treatment standards.

(2) For wastes or contaminated soil with treatment standards expressed as concentrations in the waste, the owner or operator of the treatment facility shall test the treatment residues, not an extract of such residues, to assure that they meet the applicable treatment standards.

(3) A one-time notice shall be sent with the initial shipment of waste or contaminated soil to the land disposal facility. A copy of the notice shall be placed in the treatment facility's file.

(i) No further notification is necessary until such time that the waste or receiving facility change, in which case a new notice shall be sent and a copy placed in the treatment facility's file.

(ii) The one-time notice shall include these requirements:

TABLE 2

Treatment Facility Paperwork Requirements

Required information	268-7(b)
1. EPA Hazardous Waste Numbers and Manifest Number of first shipment	X
2. The waste is subject to the LDRs. The constituents of concern for F001-F005, and F039, and underlying hazardous constituents in characteristic wastes, unless the waste will be treated and monitored for [~~all~~]each constituent[~~s~~]. If [~~all~~]each constituent[~~s~~] will be treated and monitored, there is no need to put each of them[~~ all~~] on the LDR notice.	X
3. The notice shall include the applicable Wastewater[~~/~~] or nonwastewater category, see Subsections R315-268-2(d) and R315-268-2(f))[~~—~~] and subdivisions made within a waste code based on waste-specific criteria, such as D003 reactive cyanide	X
4. Waste analysis data, [~~when~~]if available	X
5. For contaminated soil subject to LDRs as provided in Subsection R315-268-49(a), the constituents subject to treatment as described in Subsection R315-268-49(d) and the following statement, "this contaminated soil, does/does not, exhibit a characteristic of hazardous waste and, is subject to/complies with, the soil treatment standards as provided by Subsection R315-268-49(c)".	X
6. A certification is needed, see applicable section for exact wording	X

(4) The treatment facility shall submit a one-time certification signed by an authorized representative with the initial shipment of waste or treatment residue of a restricted waste to the

land disposal facility. The certification shall state:

I certify under penalty of law that I have personally examined and am familiar with the treatment technology and operation of the treatment process used to support this certification. Based on my inquiry of those individuals immediately responsible for obtaining this information, I believe that the treatment process has been operated and maintained properly so as to comply with the treatment standards specified in Section R315-268-40 without impermissible dilution of the prohibited waste. I am aware there are significant penalties for submitting a false certification, including the possibility of fine and imprisonment.

A certification is also necessary for contaminated soil and it shall state:

I certify under penalty of law that I have personally examined and am familiar with the treatment technology and operation of the treatment process used to support this certification and believe that it has been maintained and operated properly so as to comply with treatment standards specified in Section R315-268-49 without impermissible dilution of the prohibited wastes. I am aware there are significant penalties for submitting a false certification, including the possibility of fine and imprisonment.

(i) A copy of the certification shall be placed in the treatment facility's on-site files. If the waste or treatment residue changes, or the receiving facility changes, a new certification shall be sent to the receiving facility, and a copy placed in the file.

(ii) Debris excluded from the definition of hazardous waste under Subsection R315-261-3(f)[~~, i.e.,~~] that is debris treated by an extraction or destruction technology provided by Table 1, Section R315-268-45, and debris that the Director has determined does not contain hazardous waste, however, is subject to the notification and certification requirements of Subsection R315-268-7(d) rather than the certification requirements of Subsection R315-268-7(b).

(iii) For wastes with organic constituents having treatment standards expressed as concentration levels, if compliance with the treatment standards is based in whole or in part on the analytical detection limit alternative specified in Subsection R315-268-40(d), the certification, signed by an authorized representative, shall state the following:

I certify under penalty of law that I have personally examined and am familiar with the treatment technology and operation of the treatment process used to support this certification. Based on my inquiry of those individuals immediately responsible for obtaining this information, I believe that the nonwastewater organic constituents have been treated by combustion units as specified in Section R315-268-42, Table 1. I have been unable to detect the nonwastewater organic constituents, despite having used best good-faith efforts to analyze for such constituents. I am aware there are significant penalties for submitting a false certification, including the possibility of fine and imprisonment.

(iv) For characteristic wastes that are subject to the treatment standards in Section R315-268-40, other than those expressed as a method of treatment, or Section R315-268-49, and that contain underlying hazardous constituents as defined in Subsection R315-268-2(i); if these wastes are treated on-site to remove the

hazardous characteristic; and are then sent off-site for treatment of underlying hazardous constituents, the certification shall state the following:

I certify under penalty of law that the waste has been treated in accordance with the requirements of Section R315-268-40 or R315-268-49 to remove the hazardous characteristic. This decharacterized waste contains underlying hazardous constituents that require further treatment to meet treatment standards. I am aware that there are significant penalties for submitting a false certification, including the possibility of fine and imprisonment.

(v) For characteristic wastes that contain underlying hazardous constituents as defined Subsection R315-268-2(i) that are treated on-site to remove the hazardous characteristic to treat underlying hazardous constituents to levels in Section R315-268-48 Universal Treatment Standards, the certification shall state the following:

I certify under penalty of law that the waste has been treated in accordance with the requirements of Section R315-268-40 to remove the hazardous characteristic and that underlying hazardous constituents, as defined in Subsection R315-268-2(i) have been treated on-site to meet the Section R315-268-48 Universal Treatment Standards. I am aware that there are significant penalties for submitting a false certification, including the possibility of fine and imprisonment.

(5) If the waste or treatment residue will be further managed at a different treatment, storage, or disposal facility, the treatment, storage, or disposal facility sending the waste or treatment residue off-site shall comply with the notice and certification requirements applicable to generators under Section R315-268-7.

(6) Where the wastes are recyclable materials used in a manner constituting disposal subject to [~~the provisions of~~]Subsection R315-266-20(b) regarding treatment standards and prohibition levels, the owner or operator of a treatment facility,[~~i.e.~~]that is[~~,~~] the recycler, shall, for the initial shipment of waste, prepare a one-time certification described in Subsection R315-268-7(b)(4), and a one-time notice which includes the information in Subsection R315-268-7(b)(3), except the manifest number. The certification and notification shall be placed in the facility's on-site files. If the waste or the receiving facility changes, a new certification and notification shall be prepared and placed in the on-site files. In addition, the recycling facility shall also keep records of the name and location of each entity receiving the hazardous waste-derived product.

(c) Except where the owner or operator is disposing of any waste that is a recyclable material used in a manner constituting disposal pursuant to Subsection R315-266-20(b), the owner or operator of any land disposal facility disposing any waste subject to restrictions under Rule R315-268 shall:

(1) Have copies of the notice and certifications specified in Subsection R315-268-7(a) or R315-268-7(b).

(2) Test the waste, or an extract of the waste or treatment residue developed using test method 1311, the Toxicity Characteristic Leaching Procedure, described in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846 as

incorporated by reference in Section R315-260-11, to assure that the wastes or treatment residues are in compliance with the applicable treatment standards set forth in Sections R315-268-40 through R315-268-49. Such testing shall be performed according to the frequency specified in the facility's waste analysis plan as required by Section R315-264-13 or R315-265-13[~~40 CFR 265.13, which is adopted by reference~~].

(d) Generators or treaters who first claim that hazardous debris is excluded from the definition of hazardous waste under Subsection R315-261-3(f)[~~, i.e.,~~] that is debris treated by an extraction or destruction technology provided by Table 1, Section R315-268-45, and debris that the Director has determined does not contain hazardous waste, are subject to the following notification and certification requirements:

(1) A one-time notification, including the following information, shall be submitted to the Director:

(i) The name and address of the Subtitle D facility receiving the treated debris;

(ii) A description of the hazardous debris as initially generated, including the applicable EPA Hazardous Waste Number[~~(~~]s[~~)~~]; and

(iii) For debris excluded under Subsection R315-261-3(f)(1), the technology from Table 1, Section R315-268-45, used to treat the debris.

(2) The notification shall be updated if the debris is shipped to a different facility, and, for debris excluded under Subsection R315-261-2(f)(1), if a different type of debris is treated or if a different technology is used to treat the debris.

(3) For debris excluded under Subsection R315-261-3(f)(1), the owner or operator of the treatment facility shall document and certify compliance with the treatment standards of Table 1, Section R315-268-45, as follows:

(i) Records shall be kept of [~~all~~]each inspection[~~s~~], evaluation[~~s~~], and analyses of treated debris that are made to determine compliance with the treatment standards;

(ii) Records shall be kept of any data or information the treater obtains during treatment of the debris that identifies key operating parameters of the treatment unit; and

(iii) For each shipment of treated debris, a certification of compliance with the treatment standards shall be signed by an authorized representative and placed in the facility's files. The certification shall state the following: "I certify under penalty of law that the debris has been treated in accordance with the requirements of Section R315-268-45. I am aware that there are significant penalties for making a false certification, including the possibility of fine and imprisonment."

(e) Generators and treaters who first receive from the Director a determination that a given contaminated soil subject to LDRs as provided in Subsection R315-268-49(a) no longer contains a listed hazardous waste and generators and treaters who first determine that a contaminated soil subject to LDRs as provided in Subsection R315-268-49(a) no longer exhibits a characteristic of hazardous waste shall:

(1) Prepare a one-time only documentation of these

determinations including [~~all~~]supporting information; and[~~,~~]

(2) Maintain that information in the facility files and other records for a minimum of three years.

R315-268-50. Land Disposal Restrictions -- Prohibitions on Storage of Restricted Wastes.

(a) Except as provided in Section R315-268-50, the storage of hazardous wastes restricted from land disposal under Sections R315-268-20 through R315-268-39 is prohibited, unless the following conditions are met:

(1) A generator stores such wastes in tanks, containers, or containment buildings on-site solely for the purpose of the accumulation of such quantities of hazardous waste as necessary to facilitate proper recovery, treatment, or disposal and the generator complies with the requirements in Sections R315-262-16 and R315-262-17, and Rules R315-264 and R315-265.

(2) An owner[~~/~~] or operator of a hazardous waste treatment, storage, or disposal facility stores such wastes in tanks, containers, or containment buildings solely for the purpose of the accumulation of such quantities of hazardous waste as necessary to facilitate proper recovery, treatment, or disposal and:

(i) Each container is clearly marked to identify its contents and with:

(A) The words "Hazardous Waste";

(B) The applicable EPA hazardous waste number[~~(~~]s[~~)~~], EPA hazardous waste codes, in Sections R315-261-20 through R315-261-24 and R315-261-30 through R315-261-35; or use a nationally recognized electronic system, such as bar coding, to identify the EPA hazardous waste number[~~(~~]s[~~)~~];

(C) An indication of the hazards of the contents, examples include:

(I) the applicable hazardous waste characteristic[~~(~~]s[~~)~~], [~~i.e., ~~]ignitable, corrosive, reactive, toxic;

(II) hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E, labeling, or subpart F, placarding;

(III) a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or

(IV) a chemical hazard label consistent with the National Fire Protection Association code 704; and

(D) The date each period of accumulation begins;

(ii) Each tank is clearly marked with a description of its contents, the quantity of each hazardous waste received, and the date each period of accumulation begins, or such information for each tank is recorded and maintained in the operating record at that facility. Regardless of whether the tank itself is marked, an owner[~~/~~] or operator shall comply with the operating record requirements specified in Section R315-264-73 or R315-265-73[~~40 CFR 265.73, which are adopted by reference~~].

(3) A transporter stores manifested shipments of such wastes at a transfer facility for 10 days or less.

(4) A healthcare facility accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities

of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the applicable requirements in Sections R315-266-500 through R315-266-503.

(5) A reverse distributor accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the reverse distributor complies with Section R315-266-510.

(b) An owner[~~/~~] or operator of a treatment, storage or disposal facility may store such wastes for up to one year unless the Director can demonstrate that such storage was not solely for the purpose of accumulation of such quantities of hazardous waste as are necessary to facilitate proper recovery, treatment, or disposal.

(c) An owner[~~/~~] or operator of a treatment, storage or disposal facility may store such wastes beyond one year; however, the owner[~~/~~] or operator bears the burden of proving that such storage was solely for the purpose of accumulation of such quantities of hazardous waste as are necessary to facilitate proper recovery, treatment, or disposal.

(d) If a generator's waste is exempt from a prohibition on the type of land disposal utilized for the waste, for example, because of an approved case-by-case extension under Section R315-268-5, an approved Section R315-268-6 petition, or a national capacity variance under Sections R315-268-20 through R315-268-39, the prohibition in Subsection R315-268-50(a) does not apply during the period of such exemption.

(e) The prohibition in Subsection R315-268-50(a) does not apply to hazardous wastes that meet the treatment standards specified under Sections R315-268-41, R315-268-42, and R315-268-43 or the treatment standards specified under the variance in Section R315-268-44, or, where treatment standards have not been specified, is in compliance with the applicable prohibitions specified in Section R315-268-32 or RCRA section 3004.

(f) Liquid hazardous wastes containing polychlorinated biphenyls (PCBs) at concentrations greater than or equal to 50 ppm shall be stored at a facility that meets the requirements of 40 CFR 761.65(b) and shall be removed from storage and treated or disposed as required by Rule R315-268 within one year of the date when such wastes are first placed into storage. [~~The provisions of~~]Subsection R315-268-50(c) does not apply to such PCB wastes prohibited under Section R315-268-32.

(g) The prohibition and requirements in Section R315-268-50 do not apply to hazardous remediation wastes stored in a staging pile approved pursuant to Section R315-264-554.

KEY: hazardous waste, land disposal restrictions
Date of Enactment or Last Substantive Amendment: August 31, 2017
Authorizing, and Implemented or Interpreted Law: 19-6-105; 19-6-106

R315. Environmental Quality, Waste Management and Radiation Control, Waste Management.
R315-270. Hazardous Waste Permit Program.
R315-270-1. Hazardous Waste Permit Program -- Purpose and Scope of These Rules.

(a) No person shall own, construct, modify, or operate any facility for the purpose of treating, storing, or disposing of hazardous waste without first submitting, and receiving the approval of the Director for, a hazardous waste permit for that facility. However, any person owning or operating a facility on or before November 19, 1980, who has given timely notification as required by section 3010 of the Resource Conservation and Recovery Act (RCRA) of 1976, 42 U.S.C., section 6921, et seq., and who has submitted a proposed hazardous waste permit as required by Section R315-270-1 and Section 19-6-108 for that facility, may continue to operate that facility without violating Section R315-270-1 until such time as the permit is approved or disapproved pursuant to Section R315-270-1.

(b)(1) The Director shall review each proposed hazardous waste permit application to determine whether the application will be in accord with [~~the provisions of~~]Rules R315-260 through R315-266, R315-268, R315-270, and R315-273, and Section 19-6-108 and, on that basis, shall approve or disapprove the application within the applicable time period specified in Section 19-6-108. If, after the receipt of plans, specifications, or other information required under Rule R315-270 and Section 19-6-108 and within the applicable time period of Section 19-6-108, the Director determines that the proposed construction, installation or establishment or any part of it will not be in accord with the requirements of Rule R315-270 or other applicable rules, he shall issue an order prohibiting the construction, installation or establishment of the proposal in whole or in part. The date of submission shall be deemed to be the date [~~of~~]that [~~all~~]the required information is provided to the Director as required by Rule R315-270.

(2) Any permit application which does not meet the requirements of Rules R315-260 through R315-266, R315-268, R315-270, and R315-273 shall be disapproved within the applicable time period specified in Section 19-6-108. If within the applicable time period specified in Section 19-6-108 the Director fails to approve or disapprove the permit application or to request the submission of any additional information or modification to the application, the application shall not be deemed approved but the applicant may petition the Director for a decision or seek judicial relief requiring a decision of approval or disapproval.

(3) An application for approval of a hazardous waste permit consists of two parts, part A and part B. For an existing facility, the requirement is satisfied by submitting only part A of the application until the date the Director sets for each individual facility for submitting part B of the application, which date shall be in no case less than six months after the Director gives notice to a particular facility that it shall submit part B of the application.

(c) Scope of the hazardous waste permit requirement. Section 19-6-108 requires a permit for the "treatment," "storage," and "disposal" of any "hazardous waste" as identified or listed in Rule R315-261. The terms "treatment," "storage," "disposal," and

"hazardous waste" are defined in Section R315-270-2. Owners and operators of hazardous waste management units shall have permits during the active life, including the closure period, of the unit. Owners and operators of surface impoundments, landfills, land treatment units, and waste pile units that received waste after July 26, 1982, or that certified closure, [~~according to 40 CFR 265.115, which is adopted by reference~~]in accordance with Section R315-265-115, after January 26, 1983, shall have post-closure permits, unless they demonstrate closure by removal or decontamination as provided under Subsections R315-270-1(c)(5) and R315-270-1(c)(6), or obtain an enforceable document in lieu of a post-closure permit, as provided under Subsection R315-270-1(c)(7). If a post-closure permit is required, the permit shall address applicable Rule R315-264 groundwater monitoring, unsaturated zone monitoring, corrective action, and post-closure care requirements. The denial of a permit for the active life of a hazardous waste management facility or unit does not affect the requirement to obtain a post-closure permit under Section R315-270-1.

(1) Specific inclusions. Owners and operators of certain facilities require hazardous waste permits as well as permits under other programs for certain aspects of the facility operation. Hazardous waste permits are required for:

(i) Injection wells that dispose of hazardous waste, and associated surface facilities that treat, store or dispose of hazardous waste. However, the owner and operator with a Utah or Federal UIC permit, shall be deemed to have a "permit by rule" for the injection well itself if they comply with the requirements of Subsection R315-270-60(b).

(ii) Treatment, storage, or disposal of hazardous waste at facilities requiring an NPDES permit. However, the owner and operator of a publicly owned treatment works receiving hazardous waste shall be deemed to have a "permit by rule" for that waste if they comply with the requirements of Section R315-270-60(c).

(2) Specific exclusions and exemptions. The following persons are among those who are not required to obtain a hazardous waste permit:

(i) Generators who accumulate hazardous waste on-site in compliance with [~~all of~~]the conditions for exemption provided in Sections R315-262-14, R315-262-15, R315-262-16, and R315-262-17.

(ii) Farmers who dispose of hazardous waste pesticides from their own use as provided in Section R315-262-70[~~:~~].

(iii) Persons who own or operate facilities solely for the treatment, storage or disposal of hazardous waste excluded from regulation[~~s~~] under Rule R315-270 by Section R315-261-4 or Section R315-262-14, very small quantity generator exemption.

(iv) Owners or operators of totally enclosed treatment facilities as defined in Section R315-260-10.

(v) Owners and operators of elementary neutralization units or wastewater treatment units as defined in Section R315-260-10.

(vi) Transporters storing manifested shipments of hazardous waste in containers meeting the requirements of Section R315-262-30 at a transfer facility for a period of ten days or less.

(vii) Persons adding absorbent material to waste in a container, as defined in Section R315-260-10, and persons adding waste to absorbent material in a container, provided that these actions occur

at the time waste is first placed in the container; and Subsection R315-264-17(b) and Sections R315-264-171, and 172 are complied with.

(viii) Universal waste handlers and universal waste transporters, as defined in Section R315-260-10, managing the wastes listed below. These handlers are subject to regulation under Rule R315-273.

(A) Batteries as described in Section R315-273-2;

(B) Pesticides as described in Section R315-273-3;

(C) Mercury-containing equipment as described in Section R315-273-4; and

(D) Lamps as described in Section R315-273-5.

(ix) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in Section R315-266-500. Reverse distributors are subject to regulation under Sections R315-266-500 through R315-266-510 for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(3) Further exclusions.

(i) A person is not required to obtain a permit for treatment or containment activities taken during immediate response to any of the following situations:

(A) A discharge of a hazardous waste;

(B) An imminent and substantial threat of a discharge of hazardous waste;

(C) A discharge of a material which, [~~when~~]if discharged, becomes a hazardous waste.

(ii) Any person who continues or initiates hazardous waste treatment or containment activities after the immediate response is over is subject to [~~all~~]the applicable requirements of Rule R315-270 for those activities.

(iii) In the case of emergency responses involving military munitions, the responding military emergency response specialist's organizational unit shall retain records for three years identifying the dates of the response, the responsible persons responding, the type and description of material addressed, and its disposition.

(4) Permits for less than an entire facility. The Director may issue or deny a permit for one or more units at a facility without simultaneously issuing or denying a permit to [~~all~~]each of the units at the facility. The interim status of any unit for which a permit has not been issued or denied is not affected by the issuance or denial of a permit to any other unit at the facility.

(5) Closure by removal. Owners[~~/~~] or operators of surface impoundments, land treatment units, and waste piles closing by removal or decontamination under Rule R315-265 standards shall obtain a post-closure permit unless they can demonstrate to the Director that the closure met the standards for closure by removal or decontamination in Section R315-264-228, Subsection R315-264-280(e), or Section R315-264-258, respectively. The demonstration may be made in the following ways:

(i) If the owner[~~/~~] or operator has submitted a part B application for a post-closure permit, the owner[~~/~~] or operator may request a determination, based on information contained in the application, that Rule R315-264 closure by removal standards were

met. If the Director believes that Rule R315-264 standards were met, [~~T~~]the Director shall notify the public of this proposed decision, allow for public comment, and reach a final determination according to the procedures in Subsection R315-270-1(c)(6).

(ii) If the owner[~~/~~] or operator has not submitted a part B application for a post-closure permit, the owner[~~/~~] or operator may petition the Director for a determination that a post-closure permit is not required because the closure met the applicable Rule R315-264 closure standards.

(A) The petition shall include data demonstrating that closure by removal or decontamination standards of Rule R315-264 were met.

(B) The Director shall approve or deny the petition according to the procedures outlined in Subsection R315-270-1(c)(6).

(6) Procedures for closure equivalency determination.

(i) If a facility owner[~~/~~] or operator seeks an equivalency demonstration under Subsection R315-270-1(c)(5), the Director shall provide the public, through a newspaper notice, the opportunity to submit written comments on the information submitted by the owner[~~/~~] or operator within 30 days from the date of the notice. The Director shall also, in response to a request or at the Director's discretion, hold a public hearing whenever such a hearing might clarify one or more issues concerning the equivalence of the Rule R315-265 closure to a Rule R315-264 closure. The Director shall give public notice of the hearing at least 30 days before it occurs. Public notice of the hearing may be given at the same time as notice of the opportunity for the public to submit written comments, and the two notices may be combined.

(ii) The Director shall determine whether the Rule R315-265 closure met the Rule R315-264 closure by removal or decontamination requirements within 90 days of its receipt. If the Director finds that the closure did not meet the applicable Rule R315-264 standards, the Director shall provide the owner[~~/~~] or operator with a written statement of the reasons why the closure failed to meet Rule R315-264 standards. The owner[~~/~~] or operator may submit additional information in support of an equivalency demonstration within 30 days after receiving such written statement. The Director shall review any additional information submitted and make a final determination within 60 days.

(iii) If the Director determines that the facility did not close in accordance with Rule R315-264 closure by removal standards, the facility is subject to post-closure permitting requirements.

(7) Enforceable documents for post-closure care. At the discretion of the Director, an owner or operator may obtain, in lieu of a post-closure permit, an enforceable document imposing the requirements of Section R315-265-121[~~40 CFR 265.121, which is adopted by reference~~]. "Enforceable document" means an order, a permit, or other document issued by the Director including, but not limited to, a corrective action order issued by EPA under section 3008(h), a CERCLA remedial action, or a closure or post-closure permit.

KEY: hazardous waste
Date of Enactment or Last Substantive Amendment: August 31, 2017
Authorizing, and Implemented or Interpreted Law: 19-6-105; 19-6-106

R315. Environmental Quality, Waste Management and Radiation Control, Waste Management.
R315-273. Standards for Universal Waste Management.

R315-273-80. Standards for Universal Waste Management, Petitions to Include Other Wastes Under Rule R315-273 -- General.

(a) Except as provided in Subsection R315-273-80(e), [~~A~~]any person seeking to add a hazardous waste or a category of hazardous waste to Rule R315-273 may petition for a [~~regulatory~~]rule amendment under Sections R315-273-80 and R315-273-81 and Sections R315-260-20 and R315-260-23.

(b) To be successful, the petitioner shall demonstrate to the satisfaction of the Board that regulation under the universal waste [~~regulations~~]rules of Rule R315-273 is: appropriate for the waste or category of waste; will improve management practices for the waste or category of waste; and will improve implementation of the hazardous waste program. The petition shall include the information required by Subsection R315-260-20(b). The petition should also address as many of the factors listed in Section R315-273-81 as are appropriate for the waste or waste category addressed in the petition.

(c) The Board shall evaluate petitions using the factors listed in Section R315-273-81. The Board shall grant or deny a petition using the factors listed in Section R315-273-81. The decision shall be based on the weight of evidence showing that regulation under Rule R315-273 is appropriate for the waste or category of waste, shall improve management practices for the waste or category of waste, and shall improve implementation of the hazardous waste program.

(d) The Board may request additional information needed to evaluate the merits of the petition.

(e) Hazardous waste pharmaceuticals are regulated by Sections R315-266-500 through R315-266-510 and may not be added as a category of hazardous waste for management under Rule R315-273.

KEY: hazardous waste, universal waste
Date of Enactment or Last Substantive Amendment: October 15, 2019
Authorizing, and Implemented or Interpreted Law: 19-6-105; 19-6-106

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261, 262, 264, 265, 266, 268, 270, and 273

[EPA–HQ–RCRA–2007–0932; FRL–9988–26–OLEM]

RIN 2050–AG39

Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Some pharmaceuticals are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. This final rule adds regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. Healthcare facilities (for both humans and animals) and reverse distributors will manage their hazardous waste pharmaceuticals under this new set of sector-specific standards in lieu of the existing hazardous waste generator regulations. Among other things, these new regulations prohibit the disposal of hazardous waste pharmaceuticals down the drain and eliminates the dual regulation of RCRA hazardous waste pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances. The new rules also maintain the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical take-back programs and events, while ensuring their proper disposal. The new rules codify Environmental Protection Agency (EPA)'s prior policy on the regulatory status of nonprescription pharmaceuticals going through reverse logistics. Additionally, EPA is excluding certain U.S. Food and Drug Administration (FDA) approved over-the-counter (OTC) nicotine replacement therapies (NRTs) from regulation as hazardous waste and is establishing a policy on the regulatory status of unsold retail items that are not pharmaceuticals and are managed via reverse logistics, fulfilling the commitment we made in the Retail Strategy of September 2016.

DATES: This final rule is effective on August 21, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–RCRA–2007–0932. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kristin Fitzgerald, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 308–8286; email address: *Fitzgerald.Kristin@epa.gov*, or Brian Knieser, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 347–8769; email address: *Knieser.Brian@epa.gov.* Also see the EPA's website at *https://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste.*

SUPPLEMENTARY INFORMATION:

Table of Contents

The information presented in this preamble is organized as follows:

I. General Information

A. Does this action apply to me?

This final rule applies to healthcare facilities that generate, accumulate, or otherwise handle hazardous waste pharmaceuticals and reverse distributors engaged in the management of prescription hazardous waste pharmaceuticals. The list of North American Industry Classification System (NAICS) codes for the potentially affected entities, other than RCRA transfer, storage, and disposal facilities (TSDFs), are presented in Table 1. More detailed information on the potentially affected entities is presented in sections VII and IX of this preamble and the Regulatory Impact Analysis (RIA) which is available in the docket for this final rule.[1]

TABLE 1—NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE: HEALTHCARE FACILITIES AND REVERSE DISTRIBUTORS

NAICS codes	Description of NAICS code
4242	Drug Wholesalers.
44511	Supermarkets and Other Grocery (except convenience) Stores.
44611	Pharmacies and Drug Stores.
452311	Warehouse Clubs and Supercenters.
54194	Veterinary Services.
6211	Physicians' Offices.
6212	Dentists' Offices.
6213	Other Health Practitioners (e.g., chiropractors).
6214	Outpatient Care Centers.
6219	Other Ambulatory Health Care Services.
622	Hospitals.

[1] EPA–HQ–RCRA–2007–0932.

TABLE 1—NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE: HEALTHCARE FACILITIES AND REVERSE DISTRIBUTORS—Continued

NAICS codes	Description of NAICS code
6231	Nursing Care Facilities (e.g., assisted living facilities, nursing homes).
623311	Continuing Care Retirement Communities (e.g., assisted living facilities with on-site nursing facilities).
Various NAICS	Reverse Distributors.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities potentially impacted by this action. This table lists examples of the types of entities EPA knows could potentially be affected by this action. Other types of entities not listed could also be affected. To determine whether your entity, company, business, organization, etc., is affected by this action, you should examine the applicability criteria in this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this document.

B. What action is the Agency taking?

On September 25, 2015, EPA proposed new regulations under part 266 subpart P for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors.[2] This final rule promulgates part 266 subpart P. However, in response to public comments, we have made a number of changes to the proposed rulemaking. The comments and the changes are discussed in detail below. When this final rule becomes effective in their states, a process that is explained in section XX of this preamble, healthcare facilities and reverse distributors must manage their hazardous waste pharmaceuticals under this new set of regulations in part 266 subpart P in lieu of operating under part 262 as they have been. These operating standards include a prohibition on the sewering of hazardous waste pharmaceuticals. Part 266 subpart P also includes a conditional exemption for hazardous waste pharmaceuticals that are also identified as controlled substances by the Drug Enforcement Administration (DEA). Further, subpart P redefines when containers that held hazardous waste pharmaceuticals are considered ''RCRA empty.'' Healthcare facilities that are very small quantity generators (VSQGs) must comply with the sewer prohibition for their hazardous waste pharmaceuticals under part 266 subpart P and have the option of complying with the entire subpart in lieu of operating under the conditional exemption of § 262.14.

EPA is also taking two actions in addition to promulgating part 266 subpart P. First, this final rule amends the P075 acute hazardous waste listing for nicotine and salts to indicate that U.S. Food and Drug Administration (FDA)-approved over-the counter (OTC) nicotine replacement therapies (NRTs) are not included in the listing. Second, the preamble to this final rule also establishes EPA's policy on the regulatory status of unsold retail items, including nonprescription pharmaceuticals, managed at reverse logistics centers, fulfilling the commitment we made in the Retail Strategy of September 2016.

Although the proposed rulemaking sought comment on ideas for how to expand the universe of pharmaceuticals that are hazardous waste, this final rule does not add pharmaceuticals to the hazardous waste listings or expand the hazardous waste characteristics to include additional pharmaceuticals. At the time of proposal, we indicated that any action to expand the universe of hazardous waste pharmaceuticals would be part of a separate, future action.

Note that throughout the preamble and the RIA for this final rule, the terms ''EPA,'' ''Agency'' and ''we'' are used interchangeably.

C. What is the Agency's statutory authority for taking this action?

These regulations are promulgated under the authority of §§ 2002, 3001, 3002, 3004, and 3018 of the Solid Waste Disposal Act (SWDA) of 1970, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6912, 6921, 6922, 6924, and 6939.

D. What are the incremental costs and benefits of this action?

As discussed in section XXI, the Regulatory Impact Analysis (RIA) for this rule estimates the annualized cost to industry to comply with the requirements is between $6.59 and $7.99 million (at a 7 percent discount rate).[3] The streamlined management standards for healthcare facilities and the regulatory relief in regard to FDA-approved OTC NRT products (*i.e.,* patches, gums and lozenges) is estimated to result in an annualized cost-savings of between $19.58 and $22.95 million (at a 7 percent discount rate). This results in a net annualized cost savings for the rule of $12.99 to $14.96 million at a 7 percent discount rate.

The provisions of the final rule are expected to improve regulatory clarity and reduce regulatory burden. As an example of the increased regulatory clarity and certainty provided in the rule, EPA eliminated the dual regulation of RCRA hazardous waste pharmaceuticals that are also DEA controlled substances by finalizing a conditional exemption. Additionally, to the extent that the rule reduces concentrations of hazardous waste pharmaceuticals in surface and drinking waters, this rule may result in improved ecosystems and human health outcomes. Ideally, the Agency would prefer to quantify and monetize the rule's human health benefits. However, only some categories of cost savings are quantifiable; sufficient data are not available to support a detailed quantitative analysis for many benefit categories. In these cases, the benefits are described qualitatively.

II. List of Acronyms

3PL Third Party Logistics Provider
AARP American Association of Retired Persons
AEA Atomic Energy Act
API Active Pharmaceutical Ingredient
ASHP American Society of Hospital Pharmacists
BDAT Best Demonstrated Available Technology
BR Biennial Report
CAA Central Accumulation Area
CCP Commercial Chemical Product
CERCLA Comprehensive Environmental Response, Compensation and Liability Act
CFR Code of Federal Regulations
CISWI Commercial, Industrial Solid Waste Incinerator
CMS Centers for Medicare and Medicaid Services
CPSC Consumer Product Safety Commission
CWA Clean Water Act
DEA Drug Enforcement Administration
DOE Department of Energy
DOT Department of Transportation
DSCSA Drug Supply Chain Security Act
DQSA Drug Quality and Security Act
EPA Environmental Protection Agency
E.O. Executive Order
FDA Food and Drug Administration

[2] September 25, 2015; 80 FR 58014.

[3] See the Regulatory Impact Analysis for the final rule in the rulemaking docket EPA–HQ–RCRA–2007–0932.

FD&C Act Federal Food, Drug, and Cosmetic Act
FR Federal Register
HIPAA Health Insurance Portability and Accountability Act
HMIWI Hospital, Medical, Infectious Waste Incinerator
HSWA Hazardous and Solid Waste Amendments
LQG Large Quantity Generator
LTCF Long-term Care Facility
LTCP Long-term Care Pharmacy
MSWLF Municipal Solid Waste Landfill
MWC Municipal Waste Combustor
NAICS North American Industry Classification System
NIOSH National Institute for Occupational Safety and Health
NODA Notice of Data Availability
NPRM Notice of Proposed Rulemaking
NRC Nuclear Regulatory Commission
NRT Nicotine Replacement Therapy
OIG Office of Inspector General
OLEM Office of Land and Emergency Management
OMB Office of Management and Budget
ONDCP Office of National Drug Control Policy
OSHA Occupational Safety and Health Administration
OSWER Office of Solid Waste and Emergency Response
OSWI Other Solid Waste Incinerators
OTC Over-the-counter
POTW Publicly Owned Treatment Works
RCRA Resource Conservation and Recovery Act
SAA Satellite Accumulation Area
SQG Small Quantity Generator
SWDA Solid Waste Disposal Act
TC Toxicity Characteristic
TCLP Toxicity Characteristic Leaching Procedure
TSDF Treatment, Storage and Disposal Facility
VSQG Very Small Quantity Generator

III. Rationale for the Final Rule

The impetus behind this final rule is to address the various concerns raised by stakeholders regarding the difficulty in implementing the RCRA Subtitle C hazardous waste regulations for the management of hazardous waste pharmaceuticals generated at healthcare facilities. EPA has met with various stakeholders to learn about compliance challenges and has received input from stakeholders through more formal mechanisms. For instance, when EPA solicited stakeholder input in a notice of data availability (NODA) and request for comment, ''Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices to Enhance Effectiveness to the Resource Conservation and Recovery Act Program'' (''Retail NODA''), retailers submitted comments detailing compliance challenges with hazardous waste pharmaceuticals in their stores.[4] Further, EPA's Office of Inspector General (OIG) published a report citing the need to clarify how hazardous waste pharmaceuticals are regulated (for more information on the Retail NODA and the OIG report, see section VI of this preamble).[5] The Retail NODA and the OIG Report, along with input from healthcare facilities and retailers, identified a number of ways in which a healthcare facility differs from a manufacturing facility when it comes to applying the RCRA Subtitle C program to the generation and management of hazardous waste pharmaceuticals.

First, under the current hazardous waste regulatory scheme, healthcare personnel, whose primary focus is to provide care for patients, are typically responsible for making hazardous waste determinations since they are at the point of generation (*e.g.,* a patient's bedside). Yet, healthcare personnel, such as nurses and doctors, do not typically have the expertise to make hazardous waste determinations. In general, healthcare personnel are not prepared to assume hazardous waste management responsibilities, nor is it EPA's expectation that they assume primary hazardous waste management responsibilities. EPA recognizes this challenge and provides a framework through this final rule that allows healthcare personnel to focus on healthcare while still ensuring that hazardous waste is directed to proper management.

Second, in the healthcare setting, a wide variety of hazardous waste pharmaceuticals are generated in relatively small quantities by a number of different employees across the facility. This situation differs from a typical manufacturing facility where fewer employees in a few locations generate comparatively much larger volumes of a smaller range of hazardous wastes. Data from the Biennial Report (BR) show that in 2013, approximately 46 percent of large quantity generators (LQGs) generated between one and five waste streams.[6] Further, a typical manufacturing facility generates a more predictable set of hazardous waste streams. In contrast, a healthcare facility can have thousands of items in its inventory at any one time and these may vary over time, based on the needs of the patients. In addition, pharmaceutical wastes come in many different forms, such as tablets (pills), transdermal patches, lozenges, gums, creams, and liquids, and are delivered by a variety of devices, such as nebulizers, intravenous (IV) tubing, syringes, etc. The combination of having thousands of different pharmaceutical products and little expertise in hazardous waste regulations makes it difficult for healthcare personnel to make appropriate hazardous waste determinations when pharmaceuticals are disposed.

Third, several of the hazardous waste pharmaceuticals that are generated by healthcare facilities are P-listed acute hazardous wastes (see § 261.33(e)), which are regulated with more stringent requirements at much smaller amounts. If a facility generates more than 1 kg of acute hazardous waste per calendar month, it is regulated more rigorously as an LQG. Aside from the pharmaceuticals themselves, residues within pharmaceutical containers that contained P-listed commercial chemical products (CCPs) must be managed as acute hazardous waste even if the pharmaceutical was fully administered, unless the container is RCRA-empty (*e.g.,* by triple-rinsing the container).[7] Triple rinsing can be impractical with certain medical devices, such as syringes and paper cups, so healthcare facilities often manage these containers as hazardous waste, which can result in being subject to the most stringently regulated generator category (*i.e.,* LQG).[8]

To facilitate compliance among healthcare facilities and to respond to these concerns, EPA is finalizing a new set of sector-specific regulations to improve the management and disposal of hazardous waste pharmaceuticals at healthcare facilities.

In addition to improving compliance and responding to stakeholder concerns, the Agency has three additional goals for this final rule. The first is to reduce

[4] See 79 FR 8926; February 14, 2014 for the Retail NODA. Also see the associated docket EPA–HQ–RCRA–2012–0426 for public comments.

[5] EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal, Report No. 12–P–0508, dated May 25, 2012). For a copy of the report, please see: *https://www.epa.gov/sites/production/files/2015-10/documents/20120525-12-p-0508.pdf* or see the docket for this final rule: EPA–HQ–RCRA–2007–0932–0177.

[6] 81 FR 85735; November 28, 2016, Hazardous Waste Generator Improvements Final Rule.

[7] P-listed hazardous waste residues in containers are themselves considered P-listed hazardous wastes (see § 261.33(c)), unless the container is considered ''RCRA empty'' either by undergoing triple-rinsing with an appropriate solvent; or cleaning with a method that has been proven in scientific literature or tests conducted by the generator to achieve equivalent removal (see § 261.7(b)(3)).

[8] On November 4, 2011, ORCR issued a memo to the Regional RCRA Division Directors highlighting three acceptable approaches, beyond triple-rinsing containers, that healthcare facilities can employ when managing P-listed container residues. Please see: Memo from Suzanne Rudzinski to RCRA Division Directors (RCRA Online #14827). As discussed in section XV of this preamble, this final rule supersedes this memo.

the amount of pharmaceuticals that are disposed of down the drain. Studies have found that many healthcare facilities, particularly long term-care facilities, are using drain disposal (*e.g.,* flushing) as a routine disposal method for pharmaceutical wastes, including those that are hazardous waste. Until this final rule, drain disposal has been an allowable disposal method for hazardous waste pharmaceuticals under RCRA (however, since 1990, the Clean Water Act regulations have prohibited the drain disposal of ignitable wastes and those wastes that result in toxic gases, vapors of fumes within the publicly owned treatment works.)[9] Although pharmaceuticals are thought to be primarily entering the environment through excretion, reducing intentional sewer disposal is one mechanism to help reduce the environmental loading of pharmaceuticals into our Nation's waters.[10] See section XIII for more information about how this final rule reduces sewer disposal and pharmaceuticals in water.

The second goal is to address the overlap between EPA's RCRA hazardous waste regulations and the DEA regulations for controlled substances. Some stakeholders have indicated that hazardous waste pharmaceuticals that are also controlled substances are stringently regulated and therefore are expensive to manage and dispose of in accordance with both sets of regulations. In addition, stakeholders have indicated that the RCRA hazardous waste pharmaceuticals that are also DEA controlled substances are most likely to be sewer disposed to avoid the costs of compliant incineration. EPA eliminates this regulatory overlap in this final rule, as it has been an unnecessary burden for healthcare facilities. Additionally, we expect that eliminating the overlap will help reduce intentional sewer disposal of pharmaceuticals.

The third goal is to clarify the regulatory status of a major practice used by healthcare facilities, including retailers in particular, for the management of unused and/or expired pharmaceuticals, known as reverse distribution (see section VI for a detailed discussion of reverse distribution). A number of states have taken enforcement actions against retailers that have raised awareness about the reverse distribution of pharmaceuticals. In particular, California has taken numerous enforcement actions against national retail chains with pharmacies for not complying with the RCRA hazardous waste regulations. In recent years, the state took enforcement actions and imposed fines on the following chains: Kmart (2009), Walmart (2010), Target (2011), CVS (2012), Costco (2012), Walgreens (2012), Rite-Aid (2013), and Safeway (2015). In at least two settlement agreements, California directed the defendants (CVS and Costco) to ''initiate work with appropriate stakeholders from business and government, including the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, and the DTSC [Department of Toxic Substances Control], and thereafter either directly or through trade associations or informal coalitions of interested parties, undertake to promote federal regulatory reform regarding the proper management of non-dispensable pharmaceuticals, including OTC medications, through 'reverse distribution.' ''[11] Through these settlement agreements, California is seeking clarity from EPA about its longstanding interpretation about the regulatory status of pharmaceuticals that are routed through pharmaceutical reverse distribution systems.

Additionally, the California legislature directed the DTSC to convene a Retail Waste Working Group with the aim of developing recommendations to the legislature for how to address many retail waste issues, including reverse distribution/logistics.[12] The Retail Waste Working Group, which consisted of large retailers, small retailers, district attorneys, certified unified program agencies, non-government organizations, local governments, other relevant state agencies as determined by DTSC (such as the California Department of Public Health, and the California Department of Resources Recycling and Recovery), manufacturers, reverse distributors, and other interested stakeholders, produced their final report in August 2017.[13] Although the group was convened by and reported to the California legislature, its membership was drawn from across the country. EPA participated in an observer role, but neither contributed to developing recommendations nor to writing the group's report. The group's work has highlighted the need for a national policy in this area.

IV. Background

A. Summary of the Proposal

On September 25, 2015, EPA proposed to add subpart P under 40 CFR part 266 (see 80 FR 58014). Part 266 is entitled ''Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities.'' In this new subpart P, we proposed a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. We proposed that healthcare facilities that are small quantity generators (SQGs) or LQGs and all reverse distributors, regardless of their RCRA generator category, would be required to manage their hazardous waste pharmaceuticals under subpart P of 40 CFR part 266, instead of the generator regulations in 40 CFR part 262. The standards were not proposed as a voluntary or optional alternative to managing hazardous waste pharmaceuticals under 40 CFR part 262; they were proposed as mandatory standards.

We discuss the proposed provisions in greater detail in subsequent sections of the preamble, but offer a brief summary of the proposal here. For healthcare facilities, we proposed different management standards for non-creditable and potentially creditable hazardous waste pharmaceuticals. We proposed that non-creditable hazardous waste pharmaceuticals (*i.e.,* those that are not expected to be eligible to receive manufacturer credit) would be managed on site at the healthcare facility similar to how they would have been under a previous proposal for managing these wastes: The 2008 Universal Waste proposal for pharmaceutical waste.[14] We proposed that when shipped off site, the non-creditable hazardous waste pharmaceuticals must be transported as hazardous wastes, including the use of the hazardous waste manifest, and sent to a RCRA-designated facility, such as an interim status or permitted TSDF. Additionally, we proposed to revise our policy regarding pharmaceuticals going through reverse distribution (*i.e.,* those which are ''potentially creditable'') such that they would be considered hazardous wastes at the healthcare facility. However, given the value associated with these potentially

[9] See the Clean Water Act regulations of 40 CFR 403.5(b)(1) and (7).

[10] C.G. Daughton, I.S. Ruhoy, Environmental footprint of pharmaceuticals: The significance of factors beyond direct excretion to sewers, Environ. Toxicol. Chem., 28 (2009), pp. 2495–2521, 10.1897/08–382.1.

[11] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0169.

[12] California SB–423. *http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520160SB423.*

[13] *https://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[14] 73 FR 73520; December 2, 2008.

creditable hazardous waste pharmaceuticals, EPA proposed flexibilities for some of the regulatory requirements. For instance, we proposed that healthcare facilities would continue to be allowed to send potentially creditable hazardous waste pharmaceuticals to reverse distributors for them to be evaluated for manufacturer credit. After considering comments received on the prior Universal Waste proposal regarding the lack of tracking of shipments, EPA's 2015 proposed standards included provisions to ensure the safe, secure and documented delivery of the potentially creditable hazardous waste pharmaceuticals to reverse distributors.

Under the proposal, reverse distributors would no longer be regulated under 40 CFR part 262 as hazardous waste generators, nor would they be regulated under 40 CFR parts 264, 265, and 270 as TSDFs. Rather, the proposal established a new category of hazardous waste entity, called pharmaceutical reverse distributors. EPA also proposed that reverse distributors would have different standards for those hazardous waste pharmaceuticals destined for another reverse distributor (and still considered potentially creditable hazardous waste pharmaceuticals) versus those that are destined for a TSDF (considered to be evaluated hazardous waste pharmaceuticals.) [15] The proposed standards for pharmaceutical reverse distributors were, in many respects, similar to the LQG standards, but with additional standards to respond to concerns expressed by commenters to the proposal to add pharmaceuticals to the Universal Waste program.

EPA proposed several additional standards that apply to both healthcare facilities and reverse distributors. First, EPA proposed to prohibit healthcare facilities and reverse distributors from disposing of hazardous waste pharmaceuticals down a toilet or drain (*i.e.,* flushed or sewered). Second, EPA proposed that hazardous waste pharmaceuticals managed under subpart P would not be counted toward calculating the site's generator category. Third, EPA proposed a conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances. Fourth, EPA proposed management standards for determining when a container with hazardous waste pharmaceutical residues is considered RCRA empty.

B. Retail Sector Notice of Data Availability (NODA)

In 2014, EPA published a NODA for the Retail Sector, in which the Agency requested, among other things, comment on a series of topics related to retail operations in order to better understand the issues retail stores face in complying with RCRA regulations.[16] Many retail commenters to the NODA mentioned that because nicotine is an acute hazardous waste (P075), retailers are considered LQGs when they discard more than 1 kg per month of unused nicotine-containing products (*e.g.,* e-cigarettes and smoking cessation products such as gums, patches and lozenges). Retailers discard these products mainly because they are either expired or they are returned by customers and the retailer does not restock them due to safety concerns. In comments to the NODA, retailers urged the EPA to provide some regulatory relief with regard to nicotine-containing products. See section V of this preamble for a discussion of EPA's amendment of the acute hazardous waste listing for nicotine and salts (P075).

C. Retail Strategy

On September 12, 2016, as a follow-up to the comments we received on the Retail NODA, EPA released its Retail Strategy. In the strategy, EPA committed to two sets of activities. First, we committed to completing rulemakings that were already underway, that, although were not specifically developed with retail in mind, contained provisions that might be helpful in resolving some issues that retailers faced in complying with RCRA regulations. This included completing the 2016 Hazardous Waste Generator Improvements final rule and the Hazardous Waste Pharmaceuticals final rule. Second, we committed to three new activities that specifically address concerns identified by commenters. First, EPA committed to developing guidance on aerosol cans. Second, EPA committed to exploring the potential for adding certain retail items, such as aerosol cans, pesticides, and/or electronics, to the federal universal waste regulations. A proposed rulemaking for adding aerosol cans to the federal universal waste regulations was published in **Federal Register** on March 16, 2018.[17] Third, EPA committed to developing a policy that addresses the reverse distribution process for the retail sector as a whole. This policy is articulated in detail in section VI of the preamble of this final rule.

D. EPA Inspector General Report

On May 25, 2012, the EPA's Office of Inspector General (OIG) issued the report, ''EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal.'' [18] The OIG reviewed EPA's process for identifying and listing pharmaceuticals as hazardous wastes. Because of this review, the OIG provided the following recommendations to the Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER): [19]

(1) Identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(2) Establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(3) Develop a nationally consistent outreach and compliance assistance plan to help states address challenges that healthcare facilities, and others as needed, have in complying with RCRA regulations for managing hazardous waste pharmaceuticals.

As detailed in OSWER's response to OIG, this final rule fulfills our obligation for addressing the third recommendation.[20] In the preamble to the proposed rulemaking we solicited comment as part of our ongoing efforts to identify additional pharmaceuticals as hazardous wastes. EPA does not address the OIG's first two recommendations as part of this final rulemaking directly. That said, the Agency believes that provisions in the final rule, such as the streamlined standards for healthcare facilities and the elimination of LQG status for the management of hazardous waste pharmaceuticals, address the first two recommendations indirectly by encouraging healthcare facilities to manage their non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals.

[15] The final rule defines an ''evaluated hazardous waste pharmaceutical'' as a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributed in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

[16] February 14, 2014; 79 FR 8926.

[17] See 83 FR 11654; March 16, 2018.

[18] EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal, Report No. 12–P–0508, dated May 25, 2012). For a copy of the report, please see: *https://www.epa.gov/sites/production/files/2015-10/documents/20120525-12-p-0508.pdf* or see the docket for this final rule: EPA–HQ–RCRA–2007–0932–0177.

[19] OSWER has since been renamed the Office of Land and Emergency Management (OLEM).

[20] For a copy of OSWER's full response to OIG, please see: *http://www.epa.gov/oig/reports/2012/12-P-0508_Agency%20Response.pdf.*

V. Amendment to the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)

A. Background

In 1980, EPA promulgated the P- and U-lists of CCPs or manufacturing chemical intermediates that are hazardous wastes if they are discarded or intended to be discarded (40 CFR 261.33(e) and (f)). Several hundred CCPs were listed on the P- and U-lists, including *nicotine and salts.*[21] The phrase ''commercial chemical product or manufacturing chemical intermediate'' refers to a ''chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient'' (see the *comment* following 40 CFR 261.33(d)).

The P-listed chemicals are identified as acute hazardous wastes and U-listed chemicals are identified as non-acute hazardous wastes when discarded in unused form. EPA listed nicotine and salts (referred to commonly as just nicotine) as acute hazardous waste P075 in 261.33(e). A chemical substance is listed in 40 CFR 261.33(e) as an acute hazardous waste if it meets any of the criteria in 40 CFR 261.11(a)(2), which, as described below, are based on human toxicity data, or dose of a chemical given orally or dermally that is lethal to 50 percent of the test animals (LD50), or the concentration of a chemical in the air that is lethal to 50 percent of the test animals (LC50). That is, when the solid waste ''has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness.''

EPA listed nicotine as an acute hazardous waste based on an estimated oral LD50 toxicity to humans of 1 mg/kg and a dermal LD50 toxicity to rabbits of 50 mg/kg. The acute toxicity criterion for humans, as discussed above, is ''fatal to humans in low doses'' (see § 261.11(a)(2)).

EPA's Background Document from April 1981 prepared in support of the commercial chemical product hazardous waste listings in § 261.33 provides a basis for what is meant by ''fatal to humans in low doses'' for chemicals that have been given through the oral route: ''fatal to humans upon ingestion of ≤100 mg/kg''.[22] This Background Document cites an estimated oral LD50 toxicity to humans for nicotine and salts as 1 mg/kg, which corresponds to 50–60 mg of nicotine as a lethal dose for an adult weighing 50–60 kg, and this estimated LD50 value falls within the criterion for ''fatal to humans in low doses.'' However, the Background Document does not provide any information regarding the nicotine product or concentration of nicotine that was used to establish this estimated oral LD50 toxicity in humans for nicotine. According to comments submitted to EPA on the proposal by the retailers, tobacco companies, and trade associations, the only nicotine products being marketed at the time when EPA listed nicotine were pesticides containing up to 40 percent nicotine sulfate. These commenters note that the low-concentration nicotine-containing products (specifically smoking cessation or NRT products) had not yet been developed and, therefore, were not considered when EPA listed nicotine as an acute hazardous waste.

Once the Agency lists chemicals on either the P- or U-lists, these chemicals are P- or U-listed hazardous wastes when discarded or intended to be discarded regardless of chemical concentrations, with two exceptions: Warfarin and salts (which are listed as waste number P001 when present at concentrations greater than 0.3% and U248 when present at concentrations of 0.3% or less) and zinc phosphide (which is listed as Waste Code P122 when present at concentrations greater than 10% and Waste Code U249 when present at concentrations of 10% or less). Therefore, the P075 hazardous waste listing is applicable to the commercial chemical product nicotine or a commercial chemical product containing nicotine as the sole active ingredient when disposed regardless of the concentration of nicotine. The Agency has previously stated that unused dermal patches containing nicotine, nicotine gum, and nicotine lozenges are listed hazardous waste P075 when discarded.[23] The Agency stated this because nicotine is a listed hazardous waste P075 when discarded, and nicotine is the sole active ingredient in patches containing nicotine, nicotine gum, and nicotine lozenges. However, once the nicotine patches, gums, and lozenges have been used for their intended purpose, regardless of the length of use, they are no longer commercial chemical products and would not be listed hazardous waste P075 when discarded.

B. Summary of Proposal

In the preamble to the proposed rulemaking, EPA provided a rationale for why it is considering the possibility of amending the P075 acute hazardous waste listing for nicotine and salts. Primarily, the retail associations, representing a broad range of retailers within the retail industry, asked EPA to undertake a rulemaking to remove low-concentration nicotine products from the P075 hazardous waste listing under RCRA. This is because the retailers did not believe their low-concentration nicotine products meet RCRA's requirements for acute hazardous waste, when discarded. Thus, according to the retailers, the acute hazardous waste classification for their discarded low-concentration nicotine products is inappropriately making them subject to RCRA's LQG requirements. (for more information, see 80 FR 58071; September 25, 2015). Consequently, EPA, in the preamble to the proposed rulemaking, presented and sought comment on two possible approaches for amending the acute hazardous waste listing for nicotine and salts and stated that, depending on the information received during the comment period, EPA could finalize one of them. Under the first approach, EPA would exempt FDA-approved OTC nicotine-containing smoking cessation products (nicotine patches, gums, and lozenges) from the P075 hazardous waste listing if toxicity information received or collected for these products supported a finding that these products, when disposed, do not warrant regulation as acute hazardous wastes under RCRA Subtitle C. We note that this preamble will collectively refer to nicotine patches, gums, and lozenges as FDA-approved OTC NRTs. EPA also stated in the preamble to the proposed rulemaking that e-cigarettes would not be exempted under this approach, because they have not been approved by FDA and the concentration of nicotine in e-cigarettes is not limited by regulation (for more information, see discussion under Comments and Responses included later in this section). Under the second approach, EPA would establish a concentration-based exemption from the P075 listing for low-concentration nicotine-

[21] See 45 FR 33124, May 19, 1980.

[22] See pp. 21–22 and 33 in Background Document dated April 1981 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0171.

[23] See letter from Robert Dellinger, USEPA to Charlotte Smith, WM Healthcare Solutions, Inc., dated August 23, 2010, RCRA Online #14817.

containing products (including e-cigarettes); in other words, a maximum concentration of nicotine in these products below which the P075 listing would not apply. This approach would require submission to EPA of supporting human toxicological data or animal LD50 data for these products at the maximum concentration of nicotine found in these products.

C. Summary of Comments

The comments received were mainly from retailers, tobacco companies, individual states, trade and government associations. The retailers, tobacco companies, and trade associations supported an exemption from the P075 hazardous waste listing for FDA-approved OTC NRTs. In addition, these commenters also generally favored an exemption from the P075 listing for all other nicotine-containing products which they considered to have low nicotine concentrations, including e-cigarettes and e-liquids. Alternatively, if the EPA decided not to exempt all low-concentration nicotine-containing products from the P075 listing, the commenters indicated they would support the reclassification of such products as non-acute (*i.e.,* U-listed) hazardous wastes or otherwise require these products to be managed as hazardous waste pharmaceuticals under 40 CFR part 266 subpart P. These commenters stated that classification of low-concentration nicotine-containing products as acute hazardous waste is unjustified. The commenters also expressed a concern that, because of this inappropriate classification, anyone generating more than 1 kg per month of this acute hazardous waste becomes subject to RCRA's LQG regulations, which result in increased economic burdens and reporting requirements. The commenters asserted that the original P075 listing was likely based on a concentration of nicotine that is orders of magnitude greater than today's low-concentration NRTs, and the human toxicity data that EPA relied upon to support the original P075 listing have been recently reassessed and could not be substantiated. They stated further that a U.S. Surgeon General's Report issued in 2014 could not find support for the 1 mg/kg median lethal dose for humans used to support the original listing.

Additionally, the retailers, tobacco companies, and the trade associations commented that EPA listed nicotine and salts as P075 acutely toxic hazardous wastes long before NRT products were in use and thus EPA did not consider if they presented a risk that should be covered by the P075 listing. According to these commenters, because the OTC NRTs (nicotine patches, gums, and lozenges) contain very low concentrations of nicotine, they clearly do not meet EPA's listing criteria for acute toxicity and in addition have been approved by FDA to be sold to the public over-the-counter (meaning these products can be purchased without a prescription). In summary, these commenters urged EPA to amend the P075 listing to exempt the low-concentration nicotine-containing products based on either (1) type of product and/or (2) a specified concentration of nicotine in these products below which the product would be exempt, because there are no credible toxicity data that would support keeping low-concentration nicotine-containing products listed as acute hazardous wastes.

All of the states and one government association (Northeast Waste Management Officials' Association or NEWMOA) that submitted comments on the proposal generally supported exempting FDA-approved OTC NRTs from the P075 listing, if EPA obtained the necessary toxicity data to show that these products are not acutely toxic. These same commenters, except for one (Oklahoma), did not support exempting e-cigarettes or nicotine-containing e-liquids from the P075 listing. Almost all of the states and NEWMOA wanted continued regulation of e-cigarettes and nicotine-containing e-liquids because the safety of these products is less widely accepted.

In summary, the Agency did not receive any comments that disagreed with the proposed approach to exempt FDA-approved OTC NRTs from the P075 listing, provided this approach is supported by sufficient toxicity information to conclude that concentrations of nicotine contained in these products are not acutely toxic.

D. Final Rule Provisions

The Agency is finalizing the first approach for amending the P075 listing discussed in preamble of the proposal. That is, EPA is amending the hazardous waste listing for hazardous waste number (commonly called ''hazardous waste code'') P075 in § 261.33(e) to exempt FDA-approved OTC NRTs. Specifically, the P075 listing for nicotine is being amended with a parenthetical phrase stating that the listing does not include patches, gums, and lozenges that are FDA-approved over-the-counter nicotine replacement therapies.

The Agency has concluded that FDA-approved OTC NRTs do not meet the acute listing criteria under 40 CFR 261.11(a)(2), based on review of available toxicity information for nicotine and nicotine-containing FDA-approved OTC NRTs (see discussion under Comments and Responses below).

E. Comments and Responses

1. Nicotine Toxicity Data

Some commenters stated that human toxicity data that EPA originally relied upon to list nicotine as P075 acutely toxic hazardous wastes are not credible and do not support classifying low-concentration nicotine-containing products as acutely toxic hazardous wastes. In addition, they also stated that available animal toxicity data do not support classifying low-concentration nicotine-containing products as acutely toxic hazardous wastes. The commenters provided references to several recent reports and an article (see discussion of these references in the following paragraphs) to support their assertions. The commenters stated that these recent reports and article provide evidence that nicotine is not as toxic as originally thought.

Commenters argued that the validity of an estimated oral LD50 toxicity to humans of 1 mg/kg (corresponding to 50–60 mg of nicotine as a lethal dose for an adult weighing 50–60 kg) for nicotine used by EPA to support the acute hazardous waste listing for nicotine has been questioned by government entities and researchers, most recently by the U.S. Surgeon General's Report, ''The Health Consequences of Smoking—50 Years of Progress'' (2014) [24] and in an article published in *Archives of Toxicology,* ''How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century'' (Mayer, 2014).[25] The U.S. Surgeon General's Report cited by commenters states that the toxicity of nicotine is dependent on dose, dose duration and frequency, route of exposure, formulation of the nicotine product, and interpersonal variability. This report also states that numerous poisonings have been documented in the literature since the use of nicotine as a pesticide became widespread in the early part of twentieth century; however, there has not been a systematic assessment of the literature to characterize the dose-response relationship. Furthermore, based on an extensive literature search, the report states that no study was located as a source for the 50–60 mg estimated dose that is commonly

[24] *https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.*

[25] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880486/.*

reported to be fatal to humans. Finally, according to the report, the literature has also shown that in one case a relatively large dose of 240 mg nicotine administered to a patient accidently did not prove to be fatal.

The Mayer article cited by commenters also points out that fatal nicotine intoxications are relatively rare and that there are countless records of subjects who have survived consumption of nicotine in amounts far higher than 60 mg. One example referenced by Mayer in his article was a person surviving following a suicide attempt with 4 grams (4000 milligrams) of pure nicotine. Mayer asserts that this example and many other literature reports on nonfatal nicotine poisonings show that the oral LD50 toxicity of nicotine to humans of 1 mg/kg does not appear to be reliable. Although Mayer did not conduct any lab testing on nicotine, he uses previously reported nonfatal poisonings to develop an estimate of the oral LD50 toxicity of nicotine to humans in the range of 6.5–13 mg/kg (based on an adult weight of 50–60 kg, this would correspond to an estimated range of 325–780 mg of nicotine as the lethal dose for adults). Mayer concludes that nicotine is less toxic than originally thought. That said, his new estimate of the oral LD50 toxicity of nicotine to humans still falls well within the range of ≤ 100 mg/kg, which was one of the reasons for listing nicotine and salts as P075 acute hazardous waste.

EPA regulations in § 261.11(a)(2) state that, in the absence of adequate human toxicity data, the criteria for identifying acute toxicity should be based on the toxicity of the materials to laboratory animals. Commenters directed us to a recently-issued report summarizing available toxicity information on nicotine by the Committee for Risk Assessment of the European Chemicals Agency (ECHA).[26] The acute toxicity of nicotine to laboratory animals presented in the report issued by the Committee for Risk Assessment in comparison to the regulatory criteria for these animals presented in 40 CFR 261.11(a)(2) are as follows: The acute oral LD50 for rat is in the range of 52.5–70 mg/kg (ECHA) compared to the acute oral LD50 regulatory criterion for rat of < 50 mg/kg (§ 261.11(a)(2)). The acute oral LD50 values for rats reported by ECHA fall just outside the acute toxicity criterion in EPA's regulations. The acute dermal LD50 for rabbit is 70.4 mg/kg (ECHA) compared to acute dermal LD50 regulatory criterion for rabbit of < 200 mg/kg (§ 261.11(a)(2)). The acute dermal LD50 for rabbit falls well below the acute toxicity criterion in our regulations. There were no comparable data available for the acute inhalation LC50 for rat.

Based on the toxicity information discussed above, and the listing criteria in 40 CFR 262.11(a)(2), the evidence is clear that nicotine is still acutely toxic to both humans and animals under the RCRA hazardous waste regulations and must continue to be listed as acute hazardous waste number P075 under § 261.33(e). As already noted, under the hazardous waste regulations the Agency generally lists commercial chemical products, if they are discarded or intended to be discarded, regardless of chemical concentrations. However, EPA is not precluded from amending (through rulemaking) an existing listing, for example, if a particular subset of wastes within that listing can be identified as not posing the risk for which the original listing was established.

2. Food and Drug Administration-Approved Nicotine Replacement Therapies

A number of commenters urged EPA to exempt low-concentration nicotine-containing products (specifically OTC NRTs) from the P075 listing. The commenters stated that millions of people use OTC NRTs daily without showing any signs of acute toxicity, and these products have been approved by FDA to be sold over the counter without a prescription. Therefore, they believe this is the best evidence that these products are not acutely toxic and safe for people to use.

As noted above, the Agency stated in the proposal that if it obtained toxicity data to support the conclusion that FDA-approved OTC NRTs do not meet the criteria for listing as an acutely hazardous waste, then it will exempt these products from the P075 listing. The FDA-approved OTC NRTs are designed to help people quit smoking by delivering controlled amounts of nicotine to ease symptoms of withdrawal and craving. The Consumer Health Products Association stated in its comments that nicotine gums and lozenges contain 2–4 mg nicotine (approximately 0.2–2 percent by weight depending on lozenge size) and nicotine patches contain 7 mg, 14 mg, or 21 mg of nicotine (approximately 2–7 percent by weight). Comments from Reynolds American Inc. Services Company (RAI Services or RAI) provided similar information on the amount of nicotine in these FDA-approved OTC NRTs.[27] According to information on FDA's website, FDA regulations ensure that OTC drug products are safe and effective for people to use.[28] In most cases, OTC drug products are regulated by FDA through OTC drug monographs. OTC drug monographs state the active ingredients and other conditions of use (including dose, dosage form, and route of administration) that are generally recognized as safe and effective to treat certain diseases or conditions without a prescription. OTC drug products that conform to a final monograph and other relevant requirements are not required to be reviewed by FDA before marketing. Products that do not conform to a final monograph must be reviewed under the new drug application process. The new drug application process is how manufacturers provide evidence to FDA to demonstrate that the new drug product is safe and effective for use as recommended in the product's labeling. Sometimes, an OTC drug product begins as an approved prescription drug and then a drug company will submit an application to FDA to switch the drug product from prescription status to OTC status. FDA reviews the information in the application, along with information about adverse events associated with the use of the drug, and determines whether the prescription drug can be used safely and effectively as an OTC drug. FDA allowed nicotine patches and gums, which were initially available by prescription only, to be switched to OTC status between 1996 and 2002. The nicotine lozenge and mini-lozenge were approved by FDA directly for OTC use in 2002 and 2009 via new drug applications.[29] [30]

FDA has determined that OTC NRTs can be used safely and effectively by people without a healthcare professional's supervision when used in accordance with their label instructions. Since FDA first approved NRTs for OTC use, FDA has reviewed a number of studies that examined use of OTC NRTs, including use of OTC NRTs in combination with other nicotine-containing products, use of OTC NRTs at higher than standard-dose, and use of OTC NRTs over periods longer than recommended, and it has not identified

[26] See ECHA's Committee for Risk Assessment Opinion Proposing Harmonized Classification and Labeling at EU Level of Nicotine, adopted 10 September 2015 (*https://echa.europa.eu/documents/10162/23665416/clh_opinion_nicotine_5579_en.pdf/0103fadb-e945-4839-c4f4-17d20854adf0).*

[27] See P.9 of RAI's comments dated December 23, 2015 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0329.

[28] *https://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm342560.htm.*

[29] See 78 FR 19718; April 2, 2013.

[30] See FDA materials for New Drug Application Numbers 21–330 and 22–360 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

any significant safety concerns.[31] It is useful to recognize one characteristic of FDA-approved OTC NRTs when considering the toxicity of nicotine contained in these products, which is that they are designed for controlled release of nicotine to approximate the nicotine amounts obtained from smoking. This characteristic of FDA-approved OTC NRTs means that nicotine enters the body over a period of time and there is a gradual increase in the level of nicotine in the blood when used in accordance with the accompanying label. According to EPA's review of FDA information and RAI's comments, FDA's Center for Drug Evaluation and Research reviewed pharmacology and toxicology data for nicotine polacrilex lozenges and made a number of observations concerning nicotine's toxicology. FDA stated that ''oral doses of nicotine that have been reported to be lethal in animals are approximately 8- to 150-fold greater than nicotine exposures that would result from use of Nicotine Polacrilex Lozenges.'' In addition, the FDA noted that ''the toxicological profile of nicotine in animals has been largely superseded by the extensive human experience with this agent. Based on the established clinical experience with similar nicotine replacement therapy products, acute toxic reactions would not be anticipated from use of Nicotine Polacrilex Lozenges at the recommended dosage.'' [32]

In summary, the most common dosage of nicotine from OTC nicotine gums and lozenges (2–4 mg) and OTC nicotine patches (7–21 mg) is absorbed slowly and results in significantly lower concentrations of nicotine in blood levels compared to the amount of nicotine that has been determined or estimated to be lethal to animals and humans. The OTC nicotine patch, the strongest of which contains 114 mg of nicotine, delivers 21 mg of nicotine at a relatively steady rate over a 24-hour period when the patch is applied to the skin. The most frequently reported side effects from use of patches are local skin reactions, which can be reduced by moving the site of the patch application daily as instructed.[33] In addition, FDA has reviewed and approved these products as being safe and effective for people to use without a prescription. Furthermore, the FDA-approved OTC NRTs have been in the market for over two decades and although some serious adverse events have been reported, based on the available information, EPA has concluded that the serious adverse events do not meet EPA's criteria for acute toxicity under 40 CFR 261.11(a)(2) (*i.e.,* fatal to humans in low doses or capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness).[34] Finally, the serious adverse events that have been reported have not caused FDA to reverse its decision to allow the NRTs to be sold as OTCs. Therefore, the Agency finds that FDA-approved OTC NRTs are not acutely toxic and is exempting them from the P075 listing.

The FDA-approved OTC NRTs, prior to the effective date of this rule, were listed hazardous waste P075 when discarded. Therefore, these wastes have been required to be managed under RCRA Subtitle C hazardous waste regulations. Following exemption from the P075 listing, these OTC NRT wastes will be considered non-hazardous wastes and can be managed under applicable non-hazardous solid waste regulations. The Agency does not have any information at this time to suggest that these wastes will be improperly managed as non-hazardous wastes or have the potential to cause human or environmental exposures. The Agency believes, because of the low concentrations of nicotine in these wastes and their design to slowly release the nicotine, any risk from plausible mismanagement scenarios would not be sufficient to cause a substantial present or potential hazard to human health or the environment. Nevertheless, the Agency encourages healthcare facilities to first consider if their unused nicotine-containing products, which are to be discarded, can be legitimately recycled to recover the nicotine. The Agency has recently stated to one recycler that legitimately recycled nicotine-containing products would not be considered solid waste and thus would not be subject to RCRA hazardous waste regulation.[35] In addition, the Agency reminds healthcare facilities, especially retail-sector pharmacies, who may decide to discard expired FDA-approved OTC NRTs in their dumpsters or regular trash, that products' labels direct them to ensure that these products are kept out of the reach of children and pets. Therefore, the Agency recommends that healthcare facilities, including retailers, take the necessary security measures to discard unused, unwanted, or expired OTC NRTs where they are not freely accessible to the public. The recommended security measures could be simple as having locks on the dumpsters and trash cans that are used for discarding OTC NRTs or placing the dumpsters and trash cans in locked areas.

3. E-Cigarettes, E-Liquids, and Prescription Nicotine Replacement Therapies

There were mixed comments on exempting e-cigarettes, nicotine containing e-liquids, and NRTs requiring a prescription from the P075 hazardous waste listing when discarded (for more information, see Summary of Comments included previously in this section). The comments from retailers, tobacco companies, and trade associations generally favored exempting these categories of products from the P075 listing when discarded, whereas comments from four of five states and NEWMOA did not support exempting these products from the P075 listing when discarded.

The e-cigarettes and nicotine-containing e-liquids (or just e-liquids) are currently not regulated by FDA in the same manner as NRTs. NRTs are regulated as drugs by FDA while e-cigarettes and e-liquids are regulated as tobacco products by FDA. Consequently, the FDA has not been able to evaluate the health risks to the public from e-cigarettes and e-liquids to the same extent as it has been able to for drugs. Moreover, the concentrations of nicotine in e-cigarettes and e-liquids are not limited by any FDA regulation or approval process and are therefore unpredictable. The supplemental comments on the proposal submitted to EPA by the Retail Associations (June 29, 2016) [36] stated that a recent promulgation of a final rule by FDA referred to as the ''Deeming Rule'' (81 FR 28973; May 10, 2016) will ensure against ''unpredictable'' nicotine concentrations in e-cigarette products and, therefore, strengthens the case for reclassification or exemption of these

[31] See 78 FR 19718; April 2, 2013.

[32] See pages 5 and 6 of the Pharmacology Review for the New Drug Application Number 21–330 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

[33] *International Journal of Health Sciences (Qassim).* ''Nicotine Replacement Therapy: An Overview'' (July, 2016) 10(3): pp. 425–435.

[34] See the following four FDA documents included in the docket for this rulemaking EPA–HQ–RCRA–2007–0932: (1) Letter from Janet Woodcock responding to a citizen petition, dated June 4, 2015; (2) Memo from Kellie Taylor et al. on citizen petition response, dated May 8, 2015; (3) Memo from Joslyn Swann providing a review of Abuse, Misuse, and Overdose associated with Nicotine Replacement Therapy products, dated October 1, 2010; and (4) Nicoderm OTC Switch Medical Officer Review (NDA 20–165), dated August 7, 1995.

[35] See letter from Barnes Johnson, USEPA to Scott DeMuth, g[2] Revolution, LLC., dated May 8, 2015, RCRAOnline #14851.

[36] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0392.

products from the P075 listing. The Deeming Rule extended FDA's regulatory authority to all tobacco products, including electronic nicotine delivery systems (or e-cigarettes). This rule allows FDA to evaluate factors such as ingredients (*e.g.,* nicotine and its concentration), product design, and health risks to both users and non-users. The Deeming Rule ensures that newly regulated tobacco products, before they are introduced into the market, meet certain requirements, including warning labels, prohibiting sales to minors, registering with FDA, and obtaining marketing authorization from FDA. It is, however, important to note that FDA's review and approval process for introducing new tobacco products to the market is not as rigorous in assessing their safe use as review and approval of drug products. Furthermore, in August 2017, the FDA extended the compliance deadline for the newly regulated noncombustible tobacco products in the Deeming Rule, such as e-cigarettes, from November 8, 2017 to August 8, 2022. Therefore, without controls on the concentration of nicotine in e-cigarettes and e-liquids or FDA's approval of these products as being safe and effective for people to use, the Agency lacks adequate information and certainty to conclude that these nicotine-containing products will not pose the risks similar to those for which the P075 listing was established. For all of the above reasons, at this time the Agency cannot support exempting e-cigarettes and nicotine-containing e-liquids from the P075 listing.

Furthermore, in the short time that e-cigarettes have been in the U. S. marketplace (since about 2007), the calls to poison control centers related to exposures to this product, mostly among young children, have increased substantially. This significant increase can be attributed largely to the rapid rise in the use of e-cigarettes by the public. According to an article published in the Journal *Pediatrics,* ''Pediatric Exposure to E-Cigarettes, Nicotine, and Tobacco Products in the United States'' (May 2016), the monthly number of exposures among young children (younger than six years old) associated with e-cigarettes increased by almost 1500 percent from January 1, 2012 (14 exposures) to April 30, 2015 (223 exposures).[37] During the same period, children under two years old accounted for 44.1 percent of the exposures associated with e-cigarettes. Exposures of children to unregulated nicotine concentrations in e-cigarette cartridges and refill solutions (e-liquids) have the potential to cause much more severe toxic effects compared to exposures of children to FDA-approved OTC NRTs. This is because e-liquid refill containers are available in concentrations up to 100 mg/mL that are then diluted before use. The liquid nicotine, ingested or absorbed through skin, is likely to result in more severe toxic effects because it is available in higher concentrations and absorbed rapidly by the body. In December 2014, a 1-year old child died from liquid nicotine poisoning, the first such death in the U.S.[38]

Prescription NRTs, like OTC NRTs, must be approved for use by FDA as drugs. However, the FDA considers OTC drug products to be safe enough to take without the guidance of a health professional. A prescription for a drug is written by a health professional for an individual at a specific dose after the health professional has diagnosed an illness. Generally, nicotine-containing prescription drugs (*e.g.,* nicotine inhaler and nicotine spray) contain an aqueous solution intended for administration as a metered spray, which means, in comparison to FDA-approved OTC NRTs, nicotine can be delivered rapidly to the body. When a prescription pharmaceutical is transitioned to OTC status, the key question for FDA is whether consumers can achieve the desired medical result without the intervention of a health care professional and without endangering their safety.[39] For example, FDA has to review information about adverse events and serious adverse events resulting from use of a prescription drug before it can make a determination on whether a prescription drug is safe to switch over to an OTC drug. FDA has not yet made that determination for the existing prescription NRTs and EPA also did not receive any toxicity or health effects information on prescription NRTs. Prescription NRTs are also expected to be used less frequently than FDA-approved OTC NRTs, and, thus, should not exist in the same quantities at retailers as FDA-approved OTC NRTs. Furthermore, prescription NRTs are not expected to be returned to retailers like FDA-approved OTC NRTs, because they are prescribed by health professionals for specific individuals and can't be resold once dispensed. Therefore, the comments from retailers also expressed less concern about the disposal of prescription NRTs causing a change in their hazardous waste generator category.

Based on the information discussed above and the comments from a majority of the states and NEWMOA, the Agency is not exempting e-cigarettes, e-liquids, or prescription NRTs from the P075 hazardous waste listing. The Agency believes that any plausible mismanagement or diversion of these waste products, if exempted and allowed to be managed as non-hazardous wastes, has the ability to cause substantial present or potential hazard to human health and the environment. This is because prescription NRT products can contain nicotine at much higher concentrations and in a more readily available form (*i.e.,* in liquid and mist), which acts faster on the body, than the nicotine contained in FDA-approved OTC NRTs. Instead, the Agency is allowing e-cigarettes, e-liquids, and prescription NRTs to be managed as hazardous waste pharmaceuticals under 40 CFR part 266 subpart P when they are discarded.

4. Concentration-Based Exemption

Some commenters stated that the data and information they provided to EPA should be adequate to support a concentration-based exemption for nicotine-containing products. These commenters requested that EPA exempt from the P075 listing all present and future nicotine-containing products with less than a particular nicotine concentration (*e.g.,* less than 3% or 5%).

The Agency stated in the proposal that it would consider a concentration-based exemption for low-concentration nicotine-containing products if toxicology data (*e.g.,* animal LD50 data) for nicotine-containing products at maximum concentration of nicotine in these products became available. On June 9, 2017, Perrigo submitted additional comments along with oral and dermal LD50 toxicity studies for nicotine gums and lozenges manufactured by Perrigo.[40] The gums and lozenges tested contain 5% nicotine polacrilex. Nicotine polacrilex is a nicotine-containing resin which contains 15% nicotine. With 5% nicotine polacrilex in the gums and lozenges, the total nicotine in these products is less than 1%. The Perrigo LD50 studies reported oral and dermal rat LD50 toxicity values of greater than 5000 mg/kg for both nicotine gum and lozenge products. Based on their data, Perrigo asked the Agency to exempt

[37] *http://pediatrics.aappublications.org/content/early/2016/05/05/peds.2016-0041?utm_source=TrendMD&utm_medium=TrendMD&utm_campaign=Pediatrics_TrendMD_1.*

[38] *https://www.healthychildren.org/English/safety-prevention/at-home/Pages/Liquid-Nicotine-Used-in-E-Cigarettes-Can-Kill-Children.aspx.*

[39] *https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143547.htm.*

[40] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0398.

from the P075 listing nicotine at concentrations below 5%.

EPA's review of the Perrigo LD50 studies revealed several critical flaws in the way these studies were conducted. First, the studies were conducted using nicotine polacrilex instead of nicotine itself. A concentration-based listing for nicotine would require toxicity data for nicotine itself. The amount of nicotine in gums and lozenges with 5% nicotine polacrilex, as stated above, is less than 1% and it is in a form that is not readily available when ingested or applied (nicotine is designed to be released slowly when it is in the form of nicotine polacrilex). In fact, the nicotine will not release from the nicotine-containing resin (nicotine polacrilex) until it is exposed to an aqueous solution or proper pH, such as found in saliva. Therefore, nicotine polacrilex would not be expected to be absorbed dermally. In contrast, nicotine is readily absorbed dermally, as indicated by nicotine patches. To support a concentration-based exemption of nicotine, Perrigo should have conducted the toxicity studies for nicotine using the percent of nicotine (not nicotine polacrilex) in the gums and lozenges, since this would have provided data on toxicity of nicotine (the P075 listed chemical). Second, for acute oral testing, a single bolus dose of nicotine should have been administered to the test animals all at once (or over a short period of time) instead of over a period of 24 hours. Third, in EPA's listing regulations under § 261.11(a)(2), the dermal LD50 toxicity value is based on studies with rabbits, but Perrigo's studies used rats. Fourth, Perrigo did not provide LD50 toxicity data for nicotine patches (this could be because Perrigo does not manufacture nicotine patches). Finally, no explanation or justification was included for using their toxicity data which was for nicotine polacrilex with concentrations of nicotine at less than 1%, to extrapolate to exempting all nicotine with a concentration below 5%.

EPA, for the reasons previously stated, has already determined that FDA-approved OTC NRTs are not acutely toxic and is exempting them from the P075 listing. The toxicological data submitted by Perrigo are for nicotine polacrilex, instead of nicotine, and are not considered to be adequate to support a concentration-based exemption for nicotine-containing products. Therefore, the Agency has no other information to conclude that a particular nicotine concentration can be exempt from the P075 listing.

VI. Reverse Distribution and Reverse Logistics

A. Summary

Based on information collected from outreach efforts and comments received on the proposed rulemaking, EPA is finalizing regulations for the reverse distribution of prescription hazardous waste pharmaceuticals, codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals,[41] and establishing a policy for the reverse logistics of other unsold retail items.[42] In the case of prescription pharmaceuticals, EPA maintains its position as stated in the proposed rulemaking preamble that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility (*e.g.,* retail store).[43] In contrast, EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store[44] if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose)[45] or reclaimed.[46] Additionally, EPA is establishing a policy that other retail items that are sent through reverse logistics are not solid waste at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed. The remainder of this section proceeds as follows. First, EPA provides a brief background on the Agency's work to better understand the retail sector and provide guidance on RCRA's applicability to the retail sector. EPA then describes the proposal to revise the Agency's position regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors under the pharmaceuticals proposed rulemaking. Finally, EPA provides the rationale for finalizing distinct regulations and policies for the reverse distribution of prescription hazardous waste pharmaceuticals and the reverse logistics of other unsold retail items and nonprescription pharmaceuticals and describes new information received in comments on the proposed rulemaking.

B. Background

In 2008, EPA initiated a review of RCRA's applicability to the retail sector in order to understand the challenges the retail sector faces in complying with RCRA. EPA's review consisted of discussions with various members of the retail community and states through meetings, conferences, and site visits. In 2014, EPA published a NODA for the Retail Sector in order to better understand the concerns from all stakeholders regarding RCRA's applicability to that sector.[47]

Subsequent to issuance of the NODA, EPA continued conducting outreach efforts (*e.g.,* meetings, conferences, site visits) with stakeholders to gather information regarding the management of unsold retail items. EPA's outreach efforts, combined with an analysis of comments received on the NODA, improved the Agency's understanding of the challenges that the retail sector faces when managing items that have become unsalable at stores for a variety of reasons. Unsold retail items include excess inventory, such as expired or outdated items, seasonal items,

[41] Under the final rule, the definition of pharmaceutical includes, but is not limited to, prescription drugs, over-the-counter drugs, dietary supplements, and homeopathic drugs. See the definition of pharmaceutical in § 266.500. For the remainder of this section, EPA refers to over-the-counter drugs, dietary supplements, and homeopathic drugs as nonprescription pharmaceuticals. Prescription pharmaceuticals are defined by 21 CFR 203.3(y).

[42] Under the final rule, other unsold retail items can include any non-pharmaceutical unsold retail item from a retail store that if discarded would otherwise meet the definition of hazardous waste. Examples include but are not limited to aerosol cans, pool chemicals, mercury-containing lightbulbs, some pesticides, certain cleaning products, paint thinner, ammunition, and fireworks.

[43] Under the final rule, the definition of healthcare facility includes, but is not limited to, retail facilities such as pharmacies and retailers of over-the-counter medications. See the definition of healthcare facility in § 266.500.

[44] Throughout this section, EPA uses the term ''retail store'' to describe facilities that send nonprescription pharmaceutical and other unsold retail items through reverse logistics. EPA's understanding is that the retail sector is the only industry that sends nonprescription pharmaceuticals and other unsold items through reverse logistics. However, EPA's final policy that nonprescription pharmaceuticals and other unsold retail items, excluding prescription pharmaceuticals, that are sent through reverse logistics are not solid wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed, is not limited to the retail sector.

[45] Commenters from the retail industry commonly use the terms ''liquidation'' or ''donation'' to refer to legitimate methods of redistribution. For example, see comment numbers EPA–HQ–RCRA–2007–0932–0312 and EPA–HQ–RCRA–2007–0932–0340 in the docket. Under RCRA's definition of solid waste regulations in § 261.2(e), redistribution would be referred to as use/reuse.

[46] See § 261.1(b)(4) for the definition of reclamation and § 261.1(b)(5) for the definition of use/reuse.

[47] February 14, 2014 (79 FR 8926).

overstock, recalled items, and returned items that cannot be returned to stock/inventory. In the NODA, EPA used the terms ''reverse distribution'' and ''reverse logistics'' to describe the process or system employed by the retail sector to manage these unsold retail items.

Based on information gathered through outreach and comments to the Retail NODA, EPA developed a cohesive plan to address the unique challenges faced by the retail sector in complying with RCRA regulations. This plan is called the ''Strategy for Addressing the Retail Sector under the Resource Conservation and Recovery Act's Regulatory Framework'' (Retail Strategy) and was made publicly available on September 12, 2016.[48]

Throughout the Retail Strategy, EPA used the term ''reverse distribution'' to describe the system through which unsold retail items flow and the term ''reverse logistic center'' to describe the facilities managing the reverse flow of these items. In crafting the Retail Strategy, EPA recognized that the reverse distribution process that retail stores employ to send unsold retail items to reverse logistics centers is a well-established business practice in the retail sector and retail stores sometimes rely upon arrangements with manufacturers[49] to determine the ultimate disposition of these goods. EPA also noted that a number of questions have been raised by both retailers and regulators regarding how the reverse distribution process is regulated, or should be regulated, under RCRA. In addition, this issue becomes more complicated for national retailers with store locations in multiple states, as states have taken various positions on how RCRA regulations apply. The Agency's understanding when crafting the Retail Strategy was that ''reverse distribution'' is the term most commonly used for the return of all pharmaceuticals (both prescription and nonprescription) that have the potential to receive manufacturer credit, whereas ''reverse logistics'' is the term used for the reverse flow of retail items other than pharmaceuticals.[50]

Because of the challenges facing the retail sector in complying with RCRA, EPA stated in the Retail Strategy its intent to develop a policy addressing the reverse distribution process for the retail sector as a whole. In the Retail Strategy, EPA agreed to develop a comprehensive policy that applied to all unsold retail items, not just pharmaceuticals. In order to fulfill EPA's intent to address the reverse distribution process for the retail sector as a whole, EPA is establishing a policy for the reverse logistics of other unsold retail items in addition to finalizing regulations for the reverse distribution of prescription hazardous waste pharmaceuticals and codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals.

C. EPA's Proposed Regulations for Reverse Distribution of Pharmaceuticals

In the proposed Management Standards for Hazardous Waste Pharmaceuticals, EPA proposed to revise the Agency's position regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors to obtain manufacturer credit. EPA's original position was outlined in two RCRA policy memos released in 1981 and 1991.[51] In the first memo, EPA agreed that pharmaceuticals did not become wastes until the decision to discard was made at a manufacturing plant. EPA's interpretation was based on the understanding that the decision to either return goods for reclamation or dispose of them took place only at the manufacturing plant. In the second memo, EPA agreed that pharmaceuticals returned to a manufacturer, wholesaler, or third-party service company would not be considered wastes until a decision to discard has been made. In this 1991 memo, EPA specifically noted that, ''to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered waste until a determination to discard them is made.'' Although EPA made a statement in the preamble to the 2008 Pharmaceutical Universal Waste proposal that linked the value of these pharmaceuticals, in the form of manufacturers credit, to the idea that these pharmaceuticals would not be considered waste, EPA never finalized this universal waste rule or that interpretation. Thus, the 1991 memo describes EPA's interpretation regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors prior to this final rulemaking.

In the preamble to the proposed rulemaking, EPA indicated the Agency's intent to modify its position regarding the point of generation in circumstances where a pharmaceutical is sent to a reverse distributor. EPA proposed that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical. That is, EPA proposed that, once the decision is made to send a potentially creditable hazardous waste pharmaceutical[52] from a healthcare facility to a reverse distributor, a decision to discard has been made and the pharmaceutical is considered a solid waste. This proposed change of policy was based on the EPA's understanding that in almost all cases, pharmaceuticals returned to a reverse distributor for manufacturer credit are ultimately discarded.[53] Under the proposed rulemaking, the definition of ''pharmaceutical reverse distributor'' included any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Additionally, under the proposed rulemaking, the definition of ''pharmaceutical'' included not just prescription pharmaceuticals but also nonprescription pharmaceuticals. Therefore, under the proposal, potentially creditable prescription pharmaceuticals and nonprescription pharmaceuticals transported to a facility that facilitates or verifies manufacturer credit, even in cases where a credit determination is yet to be made, would be considered discarded and, therefore, solid wastes at the healthcare facility.

In proposing this shift, EPA specifically stated that, although a pharmaceutical may retain monetary value within the reverse distribution system (*i.e.,* potential exists for a manufacturer to issue credit), the

[48] EPA's Retail Strategy is available at *https://www.epa.gov/hwgenerators/strategy-addressing-retail-sector-under-resource-conservation-and-recovery-acts.*

[49] EPA has not distinguished among the terms ''supplier'' and ''vendor'' (the latter more commonly used in the retail industry) versus ''manufacturer'' and these terms are used interchangeably in this preamble, although the Agency realizes that the flow of goods/products more commonly occurs between retailers and suppliers/vendors (or agents thereof) and that suppliers themselves may also be manufacturers or product formulators.

[50] As discussed subsequently in this preamble, the distinction between ''reverse distribution'' and ''reverse logistics'' has become important in light of the Agency's response to comments received on the proposed rule.

[51] Refer to the preamble of the proposed rule (pages 58042 and 58043), which includes discussion of the two EPA policy memos, dated May 13, 1981 (RCRA Online #11012) and May 16, 1991 (RCRA Online #11606).

[52] Potentially creditable hazardous waste pharmaceutical in the proposal was generally defined as a hazardous waste pharmaceutical that has the potential to receive manufacturer credit and is (1) unused or un-administered; and (2) unexpired or less than one year past expiration date. See 80 FR 58014.

[53] See further discussion in the proposed rule preamble at 80 FR 58043.

pharmaceutical would still be considered a solid waste. The ''decision point'' on whether a pharmaceutical is a solid waste is when it has been discarded or when the decision has been made to discard the material. That is, when a pharmaceutical is discarded determines whether it is a solid waste, not whether the pharmaceutical has value. This interpretation is consistent with EPA's approach under RCRA that materials that are discarded are solid wastes, regardless of their monetary value or the economics of the system in which those discarded materials are handled. EPA has long maintained, and continues to maintain, the interpretation that value is not determinative of solid waste status.

In 1986, EPA released a memo on the regulation of hazardous wastes that are recycled, and wrote that ''persons transporting and storing hazardous wastes before recycling are similar to persons transporting and storing hazardous waste before disposal: There is nothing about the waste that makes it so valuable that safe handling is assured absent regulation.'' [54] EPA reaffirmed this interpretation in a 1989 memo on the regulatory status of solder skimmings (tin/lead alloy) purchased for reclamation, writing that even though the skimmings have value, they are still considered a solid waste.[55]

In a more recent application of this interpretation, EPA outlined its position on chlorofluorocarbons (CFCs) that are processed back into the refrigerant market or sent for destruction, but receive carbon offset credits and thus have value, in two memos signed in 2017.[56] Irrespective of whether facilities pay for hazardous CFCs or receive carbon offsets for the destruction of CFCs, the material is considered a solid waste. As another example of a material that is discarded as solid waste but has monetary value, EPA maintains that spent lead acid batteries being reclaimed are regulated as hazardous waste under part 266 subpart G or under universal waste irrespective of the fact that the batteries may have value and that reclamation facilities sometimes buy batteries due to the monetary value of the lead.[57] This finding was upheld in *United States* v. *Ilco Inc.,* 996 F. 2d 1126, where the court found that the fact that the batteries were discarded ''does not change just because a reclaimer has purchased or finds value in the components.'' EPA also maintains that recyclable materials that are reclaimed to recover economically significant amounts of gold, silver, and other various precious metals are still regulated as hazardous waste under part 266 subpart F despite the fact that the precious metals have monetary value. Additionally, the holdings of multiple court decisions is that simply because a hazardous waste has, or may have, monetary value does not mean the material loses its status as a solid waste. See *American Petroleum Institute* v. *EPA,* 906 F.2d 741 n.16 (D.C. Cir. 1990); *United States* v. *ILCO Inc.,* 996 F.2d 1126 1131–32 (11th Cir. 1993); *Owen Steel* v. *Browner,* 37 F.3d 146, 150 (4th Cir. 1994).

D. EPA's Final Reverse Distribution Regulation and Reverse Logistics Policy

1. Introduction

In light of comments received on the proposed rulemaking, along with EPA's understanding of current business practices, the Agency is making a clear distinction in the final rule between the reverse distribution of prescription pharmaceuticals and the reverse logistics of other unsold retail items, including nonprescription pharmaceuticals. In addition to receiving information from comments on the proposed rulemaking, EPA gathered information from site visits and by participating as an observer in the Retail Waste Working Group.[58] In the case of prescription pharmaceuticals, EPA is finalizing, as proposed, that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility. However, EPA notes that these tailored RCRA regulations for prescription pharmaceuticals going through reverse distribution are designed with existing business practices in mind. For more explanation, see section 4 below and section XVII of this preamble. EPA is also codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals. EPA makes it clear in § 266.501(g)(2) that nonprescription pharmaceuticals are not solid wastes because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed (also see section IX of this preamble). Also in this preamble, EPA is establishing a policy that other unsold retail items that are sent through reverse logistics are not solid wastes at the retail store because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

2. Comments on EPA's Proposed Reverse Distribution Regulation

EPA received numerous comments on the proposed position that the decision to send potentially creditable pharmaceuticals through reverse distribution is a decision to discard. States were generally supportive of the proposed change in position, while many comments from the retail industry objected to the Agency's proposed change in position.

EPA received many broad comments on EPAs proposed position regarding the waste status of pharmaceuticals going through reverse distribution and reverse logistics, which are discussed in further detail in section XVII. EPA also received many comments describing the potential burden that the revised interpretation would place on the retail industry, which are also discussed in further detail in section XVII. The remainder of this section focuses on comments received on the distinction between the reverse distribution of prescription pharmaceuticals and the reverse logistics of nonprescription pharmaceuticals and other unsold retail items.

EPA received numerous comments that described the key distinctions between reverse distribution and reverse logistics as they pertain to the waste status of pharmaceuticals and other unsold retail items going through these two processes. Multiple commenters argued that EPA mistakenly concluded that pharmaceuticals, including nonprescription pharmaceuticals, transported to facilities that facilitate or verify manufacturer credit are in most, if not all cases, discarded.[59] Commenters argued that the Agency failed to take into account the ability to donate, liquidate, or reclaim nonprescription pharmaceuticals that are sent through reverse logistics. However, commenters did confirm that prescription pharmaceuticals are in

[54] See RCRA Online #12762 for the October 8, 1986 letter from EPA to Senator John Glenn titled ''Hazardous Wastes that are Recycled, Handling.''

[55] See RCRA Online #11446 for the July 20, 1989 memo from EPA to Electrum Recovery Works, Inc.

[56] See docket number EPA–HQ–RCRA–2007–0932 for the January 30, 2017 letter from EPA Region 5 to Tradewater, LLC and the July 14, 2017 letter from EPA to A-Gas U.S. Holdings, Inc.

[57] See docket number EPA–HQ–RCRA–2007–0932 for notes from a November 19, 2013 site visit to a lead acid battery recycler.

[58] See the report prepared by the Retail Waste Working Group, ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[59] See the preamble to the proposed rule for a discussion of the comments received on the 2008 Pharmaceutical Universal Waste proposal and the 2014 Retail Notice of Data Availability that argued that pharmaceuticals transported to reverse distributors to receive credit are rarely, if ever, repurposed, recycled, or reused (80 FR 58043).

most, if not all cases, discarded. Commenters argued that this fact contradicts EPA's rationale in proposing that all pharmaceuticals, including nonprescription pharmaceuticals, going through reverse distribution and reverse logistics are wastes at the healthcare facility.

Overall, commenters encouraged EPA to adopt the terminology used by industry where ''reverse distribution'' only refers to the process by which prescription pharmaceuticals are sent to a reverse distributor for the evaluation of manufacturers credit and ''reverse logistics'' refers to the process by which nonprescription pharmaceuticals and other unsold retail items are sent to a reverse logistics center and evaluated for legitimate use/reuse or reclamation. Commenters requested that if EPA intends to finalize that a decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical, that EPA also adopt separate and distinct policies regarding how RCRA applies to prescription pharmaceuticals going through ''reverse distribution'' and to nonprescription pharmaceuticals and other unsold retail items going through ''reverse logistics.'' [60] One commenter noted that reverse logistics is an integral component of inventory management, product recall confirmation, sale through liquidation, donation for use, and reclamation of commercial products—contributing billions of dollars to the retail industry annually.[61] Moreover, this commenter noted that the reverse logistics operations help maximize the amount of OTC pharmaceuticals and dietary supplements that can be reused or reclaimed. Another commenter made a similar argument, writing that the purpose of reverse distribution of prescription pharmaceuticals is to determinate creditworthiness while the primary purpose of reverse logistics of nonprescription pharmaceuticals is to aggregate and redirect viable products into another supply chain.[62]

One commenter honed in on the argument that EPA failed to take into account the ability to legitimately use/reuse or reclaim nonprescription pharmaceuticals that are sent through reverse logistics.[63] This commenter pointed out that stringent chain-of-custody documentation and disposal requirements under DEA regulations and state Board of Pharmacy Requirements only apply to prescription pharmaceuticals. In contrast, most nonprescription pharmaceuticals are not susceptible to the same diversion risks as prescription pharmaceuticals and do not face the same documentation and disposal requirements. This makes it possible to use/reuse or reclaim nonprescription pharmaceuticals.

Walmart Stores Inc. commented that pharmaceuticals going through reverse distribution that are ultimately discarded are likely prescription pharmaceuticals.[64] Walmart wrote that only a small percentage of the consumer goods [65] managed at Walmart's six Return Centers, which will be considered reverse logistics centers under EPA's final policy, are discarded. According to Walmart's data, only 2% of the consumer goods managed at Walmart's Return Centers are discarded by Walmart, while 28% are donated, recycled, or liquidated and 70% are returned to the vendor.[66] Further, for the consumer products that are considered RCRA hazardous waste when discarded, only 1% are discarded, 33% are liquidated or donated, and 66% are returned to the vendor.[67] Inmar, Inc. also argued that only a small percentage of the OTC pharmaceuticals returned to a reverse logistics center are disposed rather than liquidated, donated, or returned to the vendor.[68] Inmar does not maintain specific data on this issue, but wrote that it would not be unusual for one of their subsidiary reverse logistics centers handling nonprescription pharmaceuticals and other consumer goods to send as little as 5% of the products for destruction.

Retail Industry Leaders Association (RILA) et al. pointed out that nonprescription pharmaceuticals do not face the same restrictions that preclude the redistribution or donation of prescription pharmaceuticals.[69] RILA et al. added that nonprescription pharmaceuticals are regularly donated and liquidated and cited data from two retailers.

Inmar Inc. also noted that when an item is returned because an expiration date has been exceeded, disposal is more often the required disposition, but the products may be returned to the manufacturer for further evaluation for potential liquidation.[70] Inmar also wrote that nonprescription pharmaceuticals with ''best by'' dates (as opposed to expiration dates) can still be donated or liquidated after the date has passed.

Overall, these comments help to underscore the differences between how prescription pharmaceuticals and other unsold retail items, including nonprescription pharmaceuticals, are managed within the reverse supply chain. These comments led EPA to make a clear distinction in the final rule between the reverse distribution of prescription pharmaceuticals and the reverse logistics of all other unsold retail items, including nonprescription pharmaceuticals.

3. Distinction Between Reverse Distribution and Reverse Logistics

EPA acknowledges that reverse distribution and reverse logistics processes share common elements in terms of the role each plays in the management of pharmaceuticals. However, based on the comments received on the proposal, especially those summarized above, the Agency recognizes that there is a key distinction between how prescription pharmaceuticals and nonprescription pharmaceuticals (see definition of pharmaceutical in § 266.500) are managed in the reverse supply chain. The key distinction is that there is not a reasonable expectation of legitimate use/reuse (*e.g.,* lawful redistribution for its intended purpose) or reclamation for prescription pharmaceuticals, except in very limited circumstances, but there is for other retail items, including nonprescription pharmaceuticals.

Prescription pharmaceuticals shipped from healthcare facilities to reverse distributors for the evaluation of manufacturer credit are almost always discarded. EPA is aware that prescription pharmaceuticals are sometimes lawfully donated, in which case the pharmaceuticals would not be

[60] For example, see comment number EPA–HQ–RCRA–2007–0932–0377.

[61] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket.

[62] See comment number EPA–HQ–RCRA–2007–0932–0312 in the docket.

[63] Ibid.

[64] See comment number EPA–HQ–RCRA–2007–0932–0340 in the docket.

[65] EPA uses the term ''unsold retail items'' to refer to excess inventory, such as expired or outdated items, seasonal items, overstock, recalled products, and returned items that cannot be returned to stock/inventory. Walmart and other commenters from the retail industry use the term ''consumer goods'' to refer to similar items.

[66] EPA has not distinguished among the terms ''supplier'' and ''vendor'' verses ''manufacturer'' and the terms are used interchangeably throughout the preamble. The Agency more frequently used the term ''manufacturer'' while retail industry commenters more frequently used the term ''vendor.''

[67] EPA did not receive data on the ultimate disposition of consumer products returned to the vendor. EPA further discusses our policy on unsold retail items that are returned to the vendor in section ''e.) Nonprescription Pharmaceuticals and Other Retail Items Going through Reverse Logistics Are Not Wastes.''

[68] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket.

[69] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket.

[70] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket.

a solid waste.[71] In the case of nonprescription pharmaceuticals and other unsold retail items that are sent to a reverse logistics center, there is often a reasonable expectation that they will be legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

EPA recognizes that the awarding of credit for unsold pharmaceuticals is a critical element of both the reverse distribution and reverse logistics processes as it provides a healthcare facility financial incentive to not only stock a particular pharmaceutical but also to defray costs associated with transporting a pharmaceutical to a reverse distributor or reverse logistics center. However, it is EPA's position that the inherent monetary ''value'' conferred on any pharmaceutical due to the potential to receive manufacturer credit is not a proper indicator of waste status. Rather, the decision to discard is determinative of when an unsold product becomes a solid waste. Under EPA's final rule and preamble, if a nonprescription pharmaceutical or other retail item becomes unsalable at a retail store it can continue to be considered a product until a reverse logistics center or other subsequent entity makes the decision to discard it, as long as there is a reasonable expectation of it being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

4. Prescription Pharmaceuticals Going Through Reverse Distribution Are Wastes at the Healthcare Facility

In the case of prescription pharmaceuticals, EPA maintains its position, as stated in the proposed rulemaking preamble and reflected in the regulatory text, that prescription pharmaceuticals moving through reverse distribution are solid wastes starting at the healthcare facility. This includes prescription pharmaceuticals that, as potentially creditable hazardous waste pharmaceuticals, are sent from a retail facility or healthcare facility to a reverse distributor for manufacturer credit evaluation (see definition of potentially creditable hazardous waste pharmaceutical in § 266.500). Although the potential exists for a manufacturer to issue credit for a prescription pharmaceutical, the ''decision point'' on when a pharmaceutical is a solid waste is when the decision has been made to discard the item. That is, a pharmaceutical is a solid waste when the decision has been made to discard regardless of whether the pharmaceutical has value. Although prescription pharmaceuticals are evaluated for, and in many cases ultimately receive, manufacturer credit, it remains apparent to EPA that these pharmaceuticals will seldom, if ever, be legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed after they are sent to a reverse distributor. Thus, a decision to send prescription pharmaceuticals to a reverse distributor is a decision to discard the material. None of the comments on the proposed rule alter EPA's position regarding the likelihood of redistribution or reclamation of prescription pharmaceuticals being managed through reverse distribution. Rather, EPA received many comments that agreed with EPA's proposed interpretation that the decision to send a pharmaceutical to a reverse distributor is a decision to discard as it pertains to prescription pharmaceuticals because there are limited opportunities to legitimately use/reuse or reclaim prescription pharmaceuticals. In circumstances when prescription pharmaceuticals are lawfully donated for their intended purpose, they would not be considered a solid waste and we have specifically noted this in the regulations (see § 266.501(g)(1) and the definition of hazardous waste pharmaceutical in § 266.500).

Many of the broad comments in support of the proposed reinterpretation provided examples but did not distinguish between prescription pharmaceuticals and nonprescription pharmaceuticals. For example, multiple commenters argued that pharmaceuticals transported to a reverse distributor are rarely redistributed or reclaimed, and are usually destroyed, but did not explain if this applied only to prescription pharmaceuticals. One commenter observed that many manufacturers contract with reverse distributors to dispose of unsold pharmaceuticals after review for credit eligibility is complete, suggesting that use/reuse or reclamation does not generally occur. This commenter was only aware of one instance of potential reuse of a pharmaceutical after being sent through reverse distribution.[72] That being said, based on what EPA has learned from retail industry commenters, site visits, and discussions with retailers about prescription pharmaceuticals verses nonprescription pharmaceuticals, EPA can infer that these comments likely refer to the reverse distribution of prescription pharmaceuticals.[73] EPA's inference is supported by other comments received on the proposal. For example, Walmart argued that the comments EPA received on the 2008 Pharmaceutical Universal Waste proposal (where pharmaceuticals were defined only as prescription pharmaceuticals) and the 2014 Retail Notice of Data Availability that pharmaceuticals going through reverse distribution are ultimately discarded were likely talking about prescription pharmaceuticals.[74]

In conclusion, a material is considered a solid waste if it is accumulated or stored before or in lieu of being disposed of, burned, or incinerated (§ 261.2(b)(3)). Even if the healthcare facility intends to receive credit for the prescription pharmaceutical and the reverse distributor intends to evaluate the prescription pharmaceutical for credit, the pharmaceutical is still considered a discarded material (§ 261.2(a)(2)(i)) because it is being accumulated and stored prior to being sent for treatment (rather than being accumulated or stored prior to being used/reused or reclaimed). Although the healthcare facility or reverse distributor intends to elicit credit from the prescription pharmaceutical in the interim period before it is sent for treatment, the pharmaceutical is still considered a discarded material. An intent to receive credit does not preclude the pharmaceuticals from being discarded; they are not mutually exclusive.

Although EPA maintains its position that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility, this final rule establishes streamlined, practical standards for managing potentially creditable hazardous waste pharmaceuticals that will reduce regulatory burden on retailers and align with the existing practices of the retail sector. Thus, EPA's position that prescription pharmaceuticals moving

[71] EPA is aware of one non-profit organization that facilitates donations of prescription pharmaceuticals. See comment from SIRUM in the docket (EPA–HQ–RCRA–2007–0932–0353). EPA is also aware of multiple states, including Iowa, Wyoming, and Oklahoma, that run prescription pharmaceutical return and reuse programs. For more information, see ''State Prescription Drug Return, Reuse and Recycling Laws'' at *http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.*

[72] The example cited was an unconfirmed claim that a rodent poison manufacturer could use discarded pharmaceutical warfarin tablets as feedstock in its process. See comment number EPA–HQ–RCRA–2007–0932–0358 in the docket.

[73] See docket number EPA–HQ–RCRA–2007–0932 for reverse distributor responses to EPA's questions about reverse distribution of pharmaceuticals, notes from Agency meetings with retail industry representatives, and notes from site visits to reverse distribution facilities.

[74] See comment number EPA–HQ-RCRA-2007-0932-0340 in the docket.

through reverse distribution are solid wastes at the healthcare facility only subjects these hazardous waste pharmaceuticals to the streamlined part 266 subpart P standards versus the full RCRA Subtitle C regulations. For example, EPA does not require healthcare facilities to use a hazardous waste manifest or a hazardous waste transporter when shipping potentially creditable hazardous waste pharmaceutical to a reverse distributor. See section XVI.D for a discussion of the shipping standards for potentially creditable hazardous waste pharmaceuticals.

Because the point of generation of potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, EPA can impose the RCRA Subtitle C cradle-to-grave management of hazardous wastes. Specifically, it allows us to impose consistent and enforceable tracking of hazardous waste pharmaceuticals from healthcare facilities en route to reverse distributors. Lack of tracking was identified as a regulatory gap by many commenters on our 2008 proposal to add pharmaceuticals to the Universal Waste program. The tracking provides the benefit of reducing the risk of diversion of these unused hazardous waste pharmaceuticals onto the black market, thus fulfilling our statutory mandate of protecting human health.

5. Nonprescription Pharmaceuticals and Other Retail Items Going Through Reverse Logistics Are Not Wastes if They Have a Reasonable Expectation of Being Legitimately Used/Reused or Reclaimed

Although EPA includes nonprescription pharmaceuticals in the definition of ''pharmaceutical'' under the final rule, the Agency makes it clear in the definition of ''hazardous waste pharmaceutical'' that nonprescription pharmaceuticals are not solid wastes, and therefore not hazardous waste pharmaceuticals, if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. The applicability of the final rule also has a new provision in § 266.501(g)(2) making it clear that a nonprescription pharmaceutical that is not a solid waste because it has a reasonable expectation of being legitimately used/reused or reclaimed is not subject to parts 260–273. Additionally, the final definition of reverse distributor has been revised so that it applies only to the reverse distribution of prescription pharmaceuticals.

In the final rule, EPA is reaffirming the Agency's previous policies on redistribution expressed in memos in 1981 and 1991 with respect to nonprescription pharmaceuticals and other retail items that have become unsalable at the retail store and are being managed by a reverse logistics center through the reverse logistics process. That is, EPA is maintaining a policy that nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. EPA recognizes that reverse logistics centers are designed to evaluate unsold retail items, analyze secondary markets, and assess the suitability of the unsold retail items for reuse in those secondary markets. These services promote the donation, liquidation, and reuse of unsold retail items and reduce overall waste. Importantly, these activities are distinct from the activities of reverse distributors of prescription pharmaceuticals. Reverse distributors of prescription pharmaceuticals are not designed to evaluate unsold prescription pharmaceuticals and assess the suitability of the prescription pharmaceuticals for reuse in secondary markets. As mentioned previously, commenters pointed out that the purpose of reverse distribution of prescription pharmaceuticals is to determinate creditworthiness while the primary purpose of reverse logistics of nonprescription pharmaceuticals is to aggregate and redirect viable products into another supply chain.

Although EPA is reaffirming this policy, EPA remains concerned about the potential for overuse of reverse logistics centers, a concern we originally raised in a 1991 memo related to reverse distribution: ''a reverse distribution system cannot be used as a waste management service to customers/generators without the applicable regulatory controls on waste management being in place . . . to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them.'' [75] To reiterate, in order to avoid being considered solid waste, items, including nonprescription pharmaceuticals, sent through reverse logistics, must have some reasonable expectation of being legitimately used/reused or reclaimed. The 199l guidance allowing pharmaceuticals to go through reverse distribution without being considered solid waste was based on the notion that they had the potential for recycling by use/reuse. Over the years, however, many have come to disregard the intent behind this guidance and erroneously believed that it was a blanket statement that pharmaceuticals going through reverse distribution were not solid wastes, even if they did not have a reasonable expectation of being redistributed or recycled. We strongly encourage the use of reverse logistics centers to facilitate redistribution and legitimate recycling to the fullest extent possible, and thus, reduce the amount of waste being generated. But we also caution reverse logistic centers not to become *de facto* waste management facilities for their customers. If this were to occur, it could be the case that the decision to discard for nonprescription pharmaceuticals and other retail items would have occurred at the retail store or healthcare facility.

Of course, once a reverse logistics center makes a decision to discard an item, it becomes a solid waste and, if it is listed or exhibits a characteristic, a hazardous waste. The reverse logistics center is subject to the applicable RCRA regulations, such as part 262, for the generation and accumulation of hazardous waste, including hazardous waste pharmaceuticals, but not part 266 subpart P.

EPA notes that although nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed, the items must be shipped in accordance will all applicable Department of Transportation (DOT) regulations. For example, DOT promulgated a final rule in March 2016 on the reverse logistics of hazardous materials. This rule includes provisions to help ensure that items, including consumer grade fireworks, are in original packaging when shipped from a retail store to a manufacturer, supplier, or distribution facility.[76]

There are six issues that came to EPA's attention when shaping this final reverse logistics policy. The first issue regards the ultimate disposition of unsold retail items moving through reverse logistics. The second issue regards unsold retail items that have expired. The third issue involves instances when retail items cannot be

[75] See memo dated May 16, 1991, From Lowrance to Schulz, RCRA Online #11606.

[76] See 81 FR 18527; March 31, 2016.

legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) because the items are subject to a ''destroy disposition.'' The fourth issue regards the crediting process for unsold retail items. The fifth issue involves instances when nonprescription pharmaceuticals and other unsold retail items become subject to a voluntary, federally mandated, or state mandated recall. The final issue involves instances when nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics because they are broken, damaged, or leaking.

a. *Unsold retail items returned to the manufacturer or vendor.* The first issue regards the ultimate disposition of unsold retail items moving through reverse logistics. As noted previously, data from commenters suggests a majority of unsold retail items moving through reverse logistics are returned to the manufacturer or vendor.[77] EPA did not receive data on the ultimate disposition of retail items that are returned to a manufacturer or vendor from a reverse logistics center. For this final action, EPA assumes the items are not wastes if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. However, if nonprescription pharmaceuticals or other retail items do not have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed after they are returned to a manufacturer or vendor, then the nonprescription pharmaceutical or other unsold retail item would be a solid and potentially hazardous waste at the reverse logistics center.

b. *Unsold retail items that have expired.* The second issue regards unsold retail items that have expired.[78] As mentioned previously, commenters noted that when an item is sent to a reverse logistics center because an expiration date has been exceeded, disposal is most often the required disposition, however the items may be returned to the manufacturer for further evaluation for potential liquidation.[79] Furthermore, nonprescription pharmaceuticals with ''best by'' dates (as opposed to expiration dates) often can still be donated or liquidated after the date has passed. In addition to information received from commenters suggesting that expired products might be considered eligible for redistribution, FDA occasionally allows the donation of drugs that are past the expiration date shown on the label when provided sufficient information to show the expired pharmaceuticals are safe and effective and other specific criteria have been met.[80] Thus, for this final action, EPA assumes that nonprescription pharmaceuticals and other unsold retail items that have expired are not wastes if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. These items are in their original, intact packaging and do not pose a high risk of release to the environment. Further, this position is consistent with the goal of the RCRA statute to reduce waste, as EPA is concerned that considering unsold retail items that have expired to be wastes at the retail store could introduce an unintended incentive for retailers to remove those items from shelves in advance of expiration dates, resulting in an unnecessary increase in overall waste generation.

c. *Unsold retail items subject to a destroy disposition.* The third issue involves instances when retail items cannot be legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) because the items are subject to a ''destroy disposition.'' A destroy disposition is when a manufacturer has established ''business rules'' that prohibit unsold retail items from being redistributed for their intended purpose (*i.e.,* liquidated or donated). The term ''business rules'' (*i.e.,* manufacturer return policies) refers to the rules that govern the disposition of retail items agreed to by the manufacturer, retailer, and reverse distributor or reverse logistics center.[81] The Agency's understanding is that manufacturers adopt destroy dispositions over concerns related to liability and brand protection and that assigning a destroy disposition is not a common practice because it precludes income from potential redistribution and results in disposal costs.[82] For this final action, if a manufacturer has established business rules that prohibit unsold retail items from being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) because the items are subject to a ''destroy disposition,'' *and* that prohibit the unsold retail items from being reclaimed, the items are considered solid waste at the retail store or healthcare facility. However, if a manufacturer has established business rules that do not imply that disposal is the ultimate disposition for unsold retail items, and there is a reasonable expectation the items will be reclaimed, these items would not be solid wastes at the retail store when they are sent through reverse logistics. Thus, a manufacturer can adopt business rules that prohibit the lawful redistribution of retail items for their intended purpose (*i.e.,* liquidation or donation), but allow for the items to be sent through reverse logistics for reclamation. These items would not be wastes at the retail store if there is a reasonable expectation the items will be reclaimed.

d. *Crediting process for unsold retail items.* The fourth issue regards the crediting process for unsold retail items. It is the Agency's understanding that there are two primary credit models. The first is the ''traditional approach'' whereby credit is awarded after unsold retail items are returned to a reverse logistics center for processing. The second is the adjustable rate policy, which is also commonly referred to as a ''swell allowance,'' whereby credit is awarded up-front based on an assumption that a certain percentage of items will become unsalable for various reasons at the primary retailer.[83] EPA's understanding is that one of the goals of the adjustable rate policy is to reduce the amount of unsold items sent through to reverse logistics centers and to encourage sale at the primary retailer—even if this means discounting those items. EPA's understanding is that under such an approach, retailers are responsible for managing unsold retail items and determining the ultimate disposition since the manufacturer is not involved in the disposition decision. That being said, retailers can utilize reverse logistics to assist in the management and disposition of unsold retail items sold under an adjustable rate policy. More importantly, under EPA's final policy, although the

[77] See comment number EPA–HQ–RCRA–2007–0932–0340 in the docket.

[78] EPA uses the term ''expired'' consistent with Food and Drug Administration regulations. See 21 CFR part 201.66, part 201.17, and 211.137.

[79] See comment number EPA-HQ-RCRA-2007-0932-0377 in the docket.

[80] See U.S. Food and Drug Administration ''Question and Answers for the Public: Donating Drugs to International Humanitarian Relief Efforts'' available at: *https://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM249617.pdf.*

[81] This definition is derived from the definition of ''business rules'' in the ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[82] See discussion of ''destroy dispositions'' in the ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[83] Additional information on the Adjustable Rate Policy and other reimbursement policies for unsalable items can be found in the publication entitled, 2008 Joint Industry Unsaleables Management Study: The Real Causes and Actionable Solutions. This publication is available at *http://www.gmaonline.org/downloads/research-and-reports/UnsaleablesFINAL091108.pdf.*

potential exists for a manufacturer to issue credit for an unsold retail item, the ''decision point'' on whether a retail item is a solid waste is when the decision has been made to discard the material. In other words, a pharmaceutical is a solid waste when the decision has been made to discard regardless of whether the pharmaceutical has value. Thus, for this final action, the credit model is not relevant to the waste status of unsold retail items. EPA assumes that nonprescription pharmaceuticals and other unsold retail items that receive credit up-front through an adjustable rate policy are not wastes if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

e. *Unsold retail items subject to a recall.* The fifth issue involves instances when nonprescription pharmaceuticals and other unsold retail items become subject to a voluntary, federally mandated, or state mandated recall. Almost all pharmaceutical recalls are overseen by FDA. However, under the Poison Prevention Packaging Act, the U.S. Consumer Product Safety Commission (CPSC) has authority regarding special packaging (sometimes called child resistant packaging) of certain household products, including drugs (as that term is defined in the Federal Food, Drug, and Cosmetic Act).[84] Similarly, under the child Nicotine Poisoning Prevention Act of 2015, CPSC has authority for administering special packaging requirements for liquid nicotine containers.[85] Thus, CPSC oversees a recall if there is a problem with a pharmaceutical's special packaging or containers for liquid nicotine. Additionally, CPSC has jurisdiction over recalls of many other consumer products sold at retail stores.[86] EPA is choosing not to apply RCRA regulations to nonprescription pharmaceuticals and other unsold retail items while they are subject to a recall, provided the recall is regulated and overseen by FDA or CPSC. This is true whether they become subject to a recall at a reverse logistics center, healthcare facility, or retail store. It is possible that recalled nonprescription pharmaceuticals and other unsold retail items are not a solid waste if they are legitimately used/reused or reclaimed. For example, if CPSC oversees a recall if there is a problem with a pharmaceutical's packaging (*e.g.,* an item's packaging poses a threat because it is not sufficiently child resistant), it is possible the pharmaceutical could still be sent for reclamation. Although it is difficult for EPA to make a blanket determination on whether all recalled nonprescription pharmaceuticals and other unsold retail items are or are not solid wastes, EPA is choosing not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items provided the recall is overseen by FDA or CPSC. When FDA directs the destruction of some or all of the recalled retail items, or CPSC grants permission to dispose or destroy some or all of the recalled items, the materials that are hazardous waste must be managed in accordance with RCRA, including the hazardous waste generator regulations standards in 40 CFR part 262.

Although FDA and CPSC are the federal agencies that primarily regulate recalled nonprescription pharmaceuticals and other unsold retail items, other federal agencies regulate some recalled retail items. For example, the National Highway Traffic Safety Administration oversees motor vehicle defects and safety recalls. Although other federal agencies may occasionally regulate recalled retail items, EPA is only choosing not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items when the recall is overseen by FDA or CPSC. CPSC requires manufacturers to develop a recall strategy that outlines all of the actions to be taken on behalf of the manufacturer from start to finish. FDA requires firms that initiate a recall to develop a recall strategy and recommends that firms that initiate a FDA-requested recall develop a recall strategy.[87] Included as a required component of a comprehensive recall strategy is a requirement that FDA or CPSC approves a manufacturer's decision to take the action to discard some or all of the recalled items. Thus, EPA believes it is reasonable not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items when the recall is overseen by FDA or CPSC. However, the Agency will continue to evaluate recalled nonprescription pharmaceuticals and other unsold retail items managed by other federal agencies on a case-by-case basis. As an example, see the memo that EPA released in 2017 that describes how RCRA regulations apply to recalled Takata airbag inflators while they are being held under the 2015 DOT preservation order.[88] EPA's policy does not apply to unused pesticides that are suspended or canceled under the Federal Insecticide, Fungicide, and Rodenticide Act and recalled, as these can be managed as universal waste under 40 CFR part 273. Finally, while EPA is not applying RCRA regulations in these situations, we note that if recalled nonprescription pharmaceuticals and other unsold retail items are not managed and stored in a manner that prevents release to the environment, they may be considered a solid waste and a hazardous waste under sections 3007, 3013, and 7003 of RCRA.

f. *Unsold retail items that are broken, damaged, or leaking.* The sixth issue involves instances when nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics because they are broken, damaged, or leaking. In recent years, EPA took multiple enforcement actions against national retailers for sending hazardous waste, in the form of broken and/or leaking items with hazardous contents, to unpermitted TSDFs (in the form of reverse distributors and reverse logistics centers), among other RCRA violations.[89] The resulting settlements specify that unsold retail items with broken and/or leaking packaging are waste at the retailer and, if they are hazardous, cannot be sent to a reverse distributor or reverse logistics center. CVS commented on the proposed rulemaking and asked that EPA clarify that when pharmaceutical packaging is in sufficiently poor condition that it is broken, leaking, or otherwise unable to be used for its intended purpose, that those pharmaceuticals become solid waste at the healthcare facility.[90] CVS noted that this is consistent with their current practice, whereby broken and leaking items are managed as waste at their facilities and are not sent through reverse distribution or reverse logistics.

Although EPA affirms the resulting settlements and agrees that nonprescription pharmaceuticals and other retail items cannot be sent through reverse logistics when they are broken, damaged, or leaking, the Agency is aware that there is inherent uncertainty

[84] See 15 U.S.C. 1471–1477 for the Poison Prevention Packaging Act.

[85] Public Law 114–116 (January 28, 2016).

[86] The CPSC has jurisdiction over more than 15,000 kinds of consumer products used in and around the home, in sports, recreation and schools. See *https://www.recalls.gov/cpsc.html* for more information.

[87] See 21 CFR 7.46(a)(8) and 21 CFR 7.45(b), respectively.

[88] See RCRA Online #14893 for the June 23, 2017 memo titled ''Recalled Takata Airbag Inflators.''

[89] Walmart Consent Agreement and Final Order, Docket Nos. RCRA–HQ–2013–4001 and FIFRA–HQ–2013–5056.

[90] See comment number EPA–HQ–RCRA–2007–0932–0312 in the docket.

surrounding when these items are considered broken, damaged, or leaking. For example, a nonprescription pharmaceutical could experience damage to the outer packaging while the inner container remains intact. For this final action, unsold retail items, including nonprescription pharmaceuticals, are not considered waste at the retail store if their packaging is in good condition, with no leaks or other continuing or intermittent unpermitted releases of the materials to the environment,[91] and they are contained to prevent releases to the environment,[92] and they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. Thus, the Agency intends that nonprescription pharmaceuticals and other unsold retail items can be sent to a reverse logistics center and are not considered wastes at the retail store if they meet this standard. For example, if an outer cardboard box containing vials of nonprescription pharmaceuticals is damaged, but the vials are intact and not damaged or leaking, EPA does not consider the item to be damaged such that it cannot go through reverse logistics.

In order to prevent exposures to personnel, the public, and the environment, if items are not in good condition, or are leaking or releasing to the environment, these items must be managed as wastes at the stores in accordance with the applicable hazardous waste regulations. Specifically, if the broken, damaged, or leaking item is a hazardous waste pharmaceutical, the retail store must manage it under the streamlined standards of part 266 subpart P (unless it is a VSQG for all its hazardous waste). Otherwise, the retail store would manage hazardous wastes under the applicable RCRA regulations, including part 262 generator regulations.

E. Applicability of the Household Hazardous Waste Exemption to Retail Items

One commenter suggested that the ''household hazardous waste'' exclusion at 40 CFR 261.4(b)(1) apply to retail items purchased by a customer and subsequently returned to the retailer.[93] The Agency has already addressed the issue of retail wastes as part of a previous rulemaking that responded to a petition from the American Retail Federation. As explained in a November 13, 1984, final rule[94], EPA excluded household hazardous waste because the legislative history of RCRA indicated an intent to exclude such wastes and not because these wastes can never pose the risks associated with hazardous wastes. Additionally, consistent with legislative history, when evaluating the American Retail Federation's petition, EPA determined that it was necessary to establish two criteria that must be met to qualify for this exclusion. First, the waste must be generated by individuals on the premises of a temporary or permanent residence and, second, the waste stream must be composed primarily of materials found in wastes generated by consumers in their homes. In this final rule, EPA denied the American Retail Federation's petition to exempt consumer household hazardous waste generated by retail sources because these wastes fail to meet both criteria. The Agency reaffirmed this position in the Retail Strategy, arguing that retail goods, including those that could become wastes when discarded, do not satisfy the criteria for this exclusion.

The Agency believes that this interpretation extends to retail items purchased by a customer and subsequently returned to a retail store. Hazardous waste generated at retail stores, including retail items purchased by a customer that are subsequently returned, does not meet the first criterion for the household hazardous waste exemption. Specifically, the decision to discard does not occur at the residence, it occurs at the retail store. In fact, many retail items that are returned are restocked and sold at the store (*e.g.* lawfully redistributed for their intended purpose) and are not solid wastes.

On the other hand, the Agency notes that a household pharmaceutical that is collected from individuals by a healthcare facility (*e.g.,* retail store) as part of a DEA pharmaceutical take-back program maintains the household hazardous waste exemption as long as it is not sewered, and is destroyed by a method that DEA has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the types of combustors identified in § 266.506(b). For more discussion on DEA take-backs of household pharmaceuticals, please see section XIV of this preamble.

VII. Scope of the Final Rule

A. What facilities are subject to the final rule?

This final rule is a sector-based rule that applies to the management of hazardous waste pharmaceuticals that are generated and managed by healthcare facilities and reverse distributors. Subsequent sections of the preamble will discuss in detail the definitions of these terms, as well as what provisions of the rule apply to each type of facility (see section VIII for a discussion of each definition and section IX for Applicability). Healthcare facilities and reverse distributors will use the regulations finalized under 40 CFR part 266 subpart P in lieu of the RCRA generator regulations in 40 CFR part 262 to which they were previously subject.

B. What facilities are not subject to the final rule?

1. Pharmaceutical Manufacturers

Part 266 subpart P does not apply to the management of hazardous waste pharmaceuticals that are generated by pharmaceutical manufacturers. A pharmaceutical manufacturer remains subject to part 262 and all applicable RCRA subtitle C regulations for the management of its hazardous waste, including its hazardous waste pharmaceuticals. Pharmaceutical manufacturers do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals in accordance with the federal RCRA subtitle C regulations (for an explanation of the challenges healthcare facilities face, see discussion in section III of the preamble). The types of hazardous waste pharmaceuticals generated by manufacturers are less variable and therefore more predictable, and the staff have the necessary expertise to determine which pharmaceutical waste is hazardous waste. However, when any facility, including a pharmaceutical manufacturer, meets the definition found in this proposal for a reverse distributor, it would be subject to the final regulations for reverse distributors with respect to those operations.

2. Households

The Agency emphasizes that the regulatory requirements in this final rule do not apply to households that discard pharmaceuticals. Pharmaceuticals that are discarded by households are not regulated as hazardous waste and are generally considered municipal solid waste. While a small percentage of these

[91] As defined in § 260.10, unpermitted releases are releases that are not covered by a permit (such as a permit to discharge to water or air) and may include, but are not limited to, releases through surface transport by precipitation runoff, releases to soil and groundwater, wind-blown dust, fugitive air emissions, and catastrophic unit failures.

[92] These conditions are derived from the definition of contained as defined in § 260.10.

[93] See comment number EPA–HQ–RCRA–2007–0932–0277 in the docket for this rulemaking.

[94] See 49 FR 44978; November 13, 1984.

household waste pharmaceuticals meet the definition of hazardous waste under RCRA, the federal RCRA hazardous waste regulations include an exclusion for all hazardous wastes generated by households.[95] Thus household hazardous waste pharmaceuticals—like other household hazardous wastes—are not subject to the federal RCRA hazardous waste regulations.

Despite the fact that household hazardous wastes are not regulated as hazardous wastes, it is important to note that ''EPA excluded household wastes because the legislative history of RCRA indicated an intent to exclude such wastes, though *not* because they necessarily pose no hazard.'' [96] Some household products, including pharmaceuticals, contain ignitable, corrosive, reactive, or toxic ingredients. As a result, for household hazardous waste collected at a household hazardous waste collection program, the Agency has historically recommended that communities operating the collection programs manage the collected household hazardous waste as hazardous waste, even though it is not required by RCRA.[97]

Similarly, the Agency recommends that, whenever possible, households utilize pharmaceutical collection events as the preferred disposal option for their unwanted pharmaceuticals.[98] For consumers without access to a pharmaceutical take-back event, FDA provides information on the disposal of unused pharmaceuticals and step-by-step guidance for disposing of pharmaceuticals in the household trash.[99]

In a 2012 memo, the Agency recommended that collected household waste pharmaceuticals be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.[100] The Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Additionally, incineration is commonly used to meet the non-retrievable standard of destruction required by DEA for controlled substances collected from consumers (''ultimate users,'' as DEA refers to them). The Agency included this recommendation as a requirement for household waste pharmaceuticals that have been collected (see § 266.506).[101] See section XIV of this preamble for a detailed discussion of this provision.

3. Farmers, Ranchers and Fisheries

This final rule is a sector-specific rulemaking that applies to healthcare facilities and reverse distributors. As such, this final rule does not apply other generators of hazardous waste pharmaceuticals such as farmers, ranchers, and fisheries. Although these businesses might administer pharmaceuticals to their animals in the regular course of their business, they would not fall within the definition of a healthcare facility or a reverse distributor. The Agency designed this final rule to address the unique needs of the healthcare sector and concluded that it would not be appropriate to apply it to all sectors that generate hazardous waste pharmaceuticals. Other generators of hazardous waste pharmaceuticals, such as farmers, ranchers and fisheries, remain subject to the part 262 generator regulations. As discussed in detail in section VIII of this preamble, the definition of healthcare facility does include veterinary clinics and veterinary hospitals.

4. RCRA-Permitted or Interim Status Treatment, Storage and Disposal Facilities

This final rule does not affect how RCRA-permitted or interim status TSDFs manage hazardous waste pharmaceuticals at their facilities, except indirectly when they treat hazardous waste pharmaceuticals to meet the land disposal restrictions (LDRs). See section X.H. of this preamble for additional detail.

C. Scope of Hazardous Wastes Addressed by This Final Rule

1. Hazardous Waste Pharmaceuticals

These final regulations pertain only to those pharmaceutical wastes that are RCRA hazardous wastes that are generated by healthcare facilities or managed by reverse distributors. Under this rulemaking, EPA has not added additional pharmaceuticals to the hazardous waste listings or expanded the hazardous waste characteristics to include additional pharmaceuticals. Although we solicited ideas from commenters for possible methods or approaches for regulating additional pharmaceuticals as hazardous waste, any action taken to address the comments we received in response to this request would be a separate action taken by the Agency in the future and is not part of this final rulemaking.

2. Related Federal or State Regulations

The generation, accumulation, transportation, treatment, storage, and disposal of hazardous waste pharmaceuticals are regulated under RCRA Subtitle C. However, hazardous waste pharmaceuticals may also be subject to a number of other statutes and implementing regulations administered by state or other federal agencies. Examples include pharmaceuticals that are subject to the Controlled Substances Act and DEA regulations; infectious pharmaceutical wastes that are subject to state and local medical waste regulations; pharmaceuticals with a radioactive component that are subject to the Atomic Energy Act (AEA) and pharmaceuticals that are hazardous waste as defined in 40 CFR 261.3 that are subject to OSHA's Hazardous Waste Operations and Emergency Response standard. These potentially overlapping requirements make the appropriate management of pharmaceutical wastes a complex matter. The following discusses the impact of this final rule on various dually regulated hazardous waste pharmaceuticals.

a. *Controlled substances.* Under prior regulations, any healthcare facility generating or managing a RCRA hazardous waste pharmaceutical that is also a DEA controlled substance listed in Schedule II–V[102] had to comply with the RCRA hazardous waste requirements, as well as the requirements of the Controlled Substances Act and DEA regulations. DEA regulations from 2014 to implement the Secure and Responsible Drug Disposal Act of 2010 require that

[95] See the household waste exclusion at § 261.4(b)(1), which is often referred to as the household hazardous waste or HHW exclusion.

[96] See 49 FR 44978; November 13, 1984.

[97] See memo November 1, 1988, from Porter to Regions (RCRA Online #11377).

[98] For pharmaceuticals, these collection events are often referred to as pharmaceutical take-back events. As used in this preamble, a take-back event refers to one-day collection events, such as the DEA bi-annual pharmaceutical take back days, while a take-back program refers to an ongoing collection program, such as a DEA-approved collection receptacle at a retail store.

[99] For more information on the safe disposal of household waste pharmaceuticals, please see: *http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm.*

[100] See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online# 14833).

[101] Since pharmaceutical collection programs typically commingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.

[102] See 21 CFR part 1308 for a complete list of controlled substances.

controlled substances be destroyed so that they are ''non-retrievable.'' [103] In the preamble to both the proposed and final DEA rules, DEA stated that flushing alone will not meet DEA's new non-retrievable standard.[104] Due to difficulties associated with managing these hazardous waste pharmaceuticals that are also controlled substances, the Agency is finalizing a conditional exemption from the RCRA regulatory requirements for the handful of pharmaceuticals that are both a RCRA hazardous waste and a DEA controlled substance. That is, this final rule eliminates the dual regulation for RCRA hazardous waste pharmaceuticals that are also DEA controlled substances. A more detailed discussion of this conditional exemption is found in section XIV of this final rule.

b. *Medical wastes.* There are instances when a hazardous waste pharmaceutical will also pose a biological hazard. The healthcare industry often refers to pharmaceutical wastes that are both RCRA hazardous and a biological hazard as ''dual wastes,'' and such wastes must be managed in accordance with RCRA and state and/or local medical waste regulations. As a result, the healthcare facility must send these dual wastes to a hazardous waste TSDF that is also permitted by their state to accept medical wastes. Some examples of dual wastes include partially administered syringes containing hazardous waste pharmaceuticals (*e.g.,* physostigmine) or intravenous (IV) bags containing residues of a hazardous waste pharmaceutical that are attached to the tubing and needles used to administer the pharmaceutical. The RCRA hazardous waste pharmaceutical component of these dual wastes are included within these final subpart P management standards so that healthcare facilities can obtain the benefits of this new subpart, while ensuring the hazardous waste component of the waste is managed appropriately and ultimately delivered to RCRA-permitted TSDFs. Healthcare facilities must still manage the biological hazard in accordance with state and/or local medical waste requirements. EPA notes that autoclaving alone is not an acceptable method of treating hazardous wastes (pharmaceutical or non-pharmaceutical) that are also medical waste. In addition, as discussed in section XV of this preamble, EPA is exempting from RCRA regulation the residues of hazardous waste pharmaceuticals remaining in empty (*i.e.,* fully administered) syringes.

c. *Hazardous waste pharmaceuticals with a radioactive component.* Hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (AEA) (which are often referred to as ''mixed waste'') are also regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA Subtitle C programs, while either the Nuclear Regulatory Commission (NRC) or the Department of Energy (DOE) regulates the radioactive component of the waste under the AEA.[105] Healthcare facilities can use this final rule to meet the obligation of complying with the RCRA Subtitle C hazardous waste regulations for hazardous waste pharmaceuticals while also complying with the appropriate AEA regulations. Although we do not believe that anything in this subpart is inconsistent with the AEA, § 1006(a) of RCRA states that if the RCRA requirements are inconsistent with the AEA requirements, then the RCRA requirements do not apply. Therefore, if a healthcare facility that manages hazardous waste pharmaceuticals encounters specific RCRA requirements that are inconsistent with specific AEA requirements, only the AEA requirements would apply.

As is discussed in the Joint NRC/EPA Guidance on Testing Requirements for Mixed Radioactive and Hazardous Waste an inconsistency occurs when compliance with one statute or set of regulations would necessarily cause non-compliance with the other statute or set of regulations.[106] Relief from the regulatory inconsistency would be provided by the AEA requirement overriding the specific RCRA requirement. It is important to note, however, that the determination of an inconsistency would relieve the healthcare facility only from compliance with the specific RCRA requirement(s) that is deemed inconsistent with the AEA requirement(s); the healthcare facility would still be required to comply with all of the other hazardous waste pharmaceutical management standards.

d. *Clean Air Act.* The combustion of hazardous waste pharmaceuticals is subject to both RCRA and to § 112 of the Clean Air Act. In general, the Clean Air Act protects human health and the environment from the harmful effects of air pollution by requiring reductions in the emissions of air pollutants. These pollutants, which are known or suspected to cause serious health problems, such as cancer or birth defects, are referred to as hazardous air pollutants (HAPs) and include several metals that are found in pharmaceuticals, such as selenium, mercury, and chromium compounds. Under § 112 of the Clean Air Act, EPA is required to list categories of major and area sources of HAPs; EPA has listed Hazardous Waste Combustors as one of these categories.

EPA is also required to establish National Emission Standards for Hazardous Air Pollutants (NESHAPs) for the control of HAP emissions from listed sources. The NESHAPs are to reflect the maximum degree of reduction in emissions of HAPs that is achievable. This is known as ''maximum achievable control technology'' (MACT) and is based on emission levels that are achieved by the best-performing sources within a source category. On October 12, 2005, EPA promulgated NESHAP for Hazardous Waste Combustors that set MACT standards for HAPs from this source category.[107] The owner or operator of a hazardous waste combustor is required to comply with specific emission standards that control HAPs to levels that reflect MACT. These standards vary based on the type of hazardous waste combustion source (*e.g.,* incinerator, cement kiln, boiler), and in some instances based on the amount of HAPs that are emitted by the facility (*e.g.,* boilers that are area sources can elect to comply with fewer HAP emission standards). Generally speaking; however, hazardous waste combustors are required to comply with emission standards for chlorinated dioxins and furans, mercury, lead, cadmium, arsenic, beryllium, chromium, hydrochloric acid/chlorine gas, as well as particulate matter as a surrogate to control five additional metals, and carbon monoxide, hydrocarbon, and destruction removal efficiency as surrogates to control nondioxin/furan organic HAPs.

Hazardous waste combustors may be subject to more stringent emission limitations issued under the RCRA omnibus authority provisions (§ 3005(c)(3)). This is usually where site-specific circumstances indicate that a MACT standard is not protective of health and the environment. In other words, some hazardous waste combustors also have a RCRA permit

[103] Final rule: September 9, 2014; 79 FR 53520.

[104] Proposed rule: December 21, 2012; 77 FR 75784, see page 75803; and final rule: September 9, 2014; 79 FR 53520, see page 53548).

[105] The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

[106] 62 FR 62079, 62085; November 20, 1997.

[107] 70 FR 59402; October 12, 2005.

limit that further reduces emissions of certain HAPs (*e.g.,* mercury) beyond that which is required by the Clean Air Act MACT standard.

The combustion of pharmaceuticals that meet the definition of a RCRA solid waste but do not meet the definition of RCRA hazardous waste (*i.e.,* non-hazardous waste pharmaceuticals) is regulated by § 129 of the Clean Air Act and implementing regulations. These regulations established emission limits for nine substances or mixtures (*i.e.,* particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium, as well as opacity where appropriate) from several categories incineration units, including: municipal waste combustors (MWCs); hospital, medical and infectious waste incinerators (HMIWIs); commercial and industrial solid waste incinerators (CISWIs); and other solid waste incinerators (OSWIs). The emission limits are based on the application of MACT and reflect the emission levels achieved by the best performers in each category.

3. Drug Supply Chain Security Act

On November 27, 2013, the Drug Quality and Security Act was signed into law, amending the Federal Food, Drug and Cosmetic Act (FD&C Act).[108] The Drug Quality and Security Act consists of two titles: Title I is known as the Compounding Quality Act and Title II is known as the Drug Supply Chain Security Act (DSCSA). The FDA was given the responsibility of developing the implementing regulations for both titles of the Drug Quality and Security Act. In a summary of the DSCSA written by the Congressional Research Service, a nonpartisan division of the Library of Congress, it states that the Act ''Establishes requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain.'' [109] Prior to enactment of this federal law, several states had passed similar laws to ensure the pedigree of the drug supply chain. Because each state law was slightly different, it made compliance difficult for companies operating in multiple states. As a result, Congress amended the FD&C Act to add § 585, entitled Uniform National Policy, which moots the pedigree laws already in effect (to the extent they are inconsistent with the DSCSA) and prevents states (and others) from enacting inconsistent pedigree laws in the future. This section, which was added by the DSCSA, includes sub-sections that are sometimes referred to as ''preemption clauses.'' [110]

Since the DSCSA was signed into law, some have argued to EPA and RCRA-authorized states that § 585 of the FD&C Act (as amended by the DSCSA) preempts all state hazardous waste regulatory authority as it may relate to the documentation of the disposition of hazardous waste pharmaceuticals. EPA disagrees with this interpretation of the DSCSA. Section 585 specifically avoids preempting state requirements, such as RCRA hazardous waste laws, that are unrelated to the tracing of products within the prescription drug distribution supply chain and other issues expressly addressed by the DSCSA. As stated in § 585(c), ''Nothing in this section shall be construed to preempt State Requirements related to the distribution of prescription drugs *if such requirements are not related to product tracing* as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under § 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder)'' (emphasis added).

This provision makes clear that § 585 applies only to state requirements related to distribution of prescription drugs and only to the extent that these requirements are related to product tracing or other issues specifically addressed by the DSCSA, such as licensure. Thus, as EPA interprets § 585, it would not apply to state requirements related to documentation of RCRA hazardous waste management activities, including disposal, because those activities are distinct and unrelated to the product tracing and other requirements of the DSCSA.

And indeed, in EPA's consultation with FDA on this issue, FDA agreed with EPA's conclusion that § 585 does not preempt state hazardous waste regulations related to the documentation of the management of hazardous waste pharmaceuticals. EPA's position is based upon our review of both the direct language and intent of the statute.[111]

To understand the connection between state hazardous waste regulations and the DSCSA, it is important to understand the relationship between the federal and state hazardous waste regulations. The federal RCRA program is implemented by state RCRA programs that are authorized by EPA under RCRA section 3006, 42 U.S.C. 6926. Authorized state hazardous waste regulations must, at a minimum, be equivalent to federal RCRA hazardous waste regulations. Under RCRA, EPA authorizes state hazardous waste programs to operate in lieu of the federal hazardous waste program.[112] Authorized state requirements are federally enforceable as requirements under RCRA Subtitle C.

Nothing in the DSCSA indicates that Congress intended to impliedly repeal federal RCRA requirements. Such an implied repeal would leave gaps in RCRA coverage and result in no hazardous waste regulations of any kind—federal or state—applying to the documentation of the management of hazardous waste pharmaceuticals. Given that (i) there is no indication of Congressional intent to repeal hazardous waste documentation regulations via the DSCSA (indeed, there is no mention of hazardous waste in the DSCSA at all), and (ii) § 585(c) of the FD&C Act, as added by the DSCSA, expressly notes the limits of the statute's preemptive effect, we believe it is clear that Congress did not intend to impliedly repeal RCRA authorized state hazardous waste requirements as they apply to the documentation of the management, including disposal, of hazardous waste pharmaceuticals. The general rule enunciated by the U.S. Supreme Court is that ''when two [federal] statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.'' [113] Here, both RCRA and the DSCSA coexist easily, because neither the language nor the purpose of the DSCSA is in conflict with RCRA.

In addition, some commenters have argued that, in the case of nonsaleable pharmaceutical products, DSCSA requirements preempt RCRA requirements and that nonsaleable pharmaceutical products are regulated exclusively by the FDA pursuant to the provisions of the DSCSA.[114] Commenters have also argued that under the DSCSA, nonsaleable pharmaceutical products that are sent from wholesale distributors, dispensers, and repackagers as nonsaleable may be sent to a returns processor reverse

[108] Public Law 113–54.

[109] *https://www.congress.gov/bill/113th-congress/house-bill/3204/summary/49;* accessed September 13, 2017.

[110] See sections 585(a) and 585(b)(1) of the FD&C Act, as amended by the DSCSA.

[111] For a more thorough legal analysis of this issue, see EPA's letter to the Minnesota Pollution Control Agency, dated April 9, 2015, in the docket for this rulemaking EPA–HQ–RCRA–2007–0932. EPA consulted with FDA in the development of this letter and FDA agrees with the analysis and conclusions set forth in the letter.

[112] RCRA section 3006(b), 42 U.S.C. 6926(b).

[113] Morton v. Macari, 417 U.S. 535, 551(1974).

[114] The DSCSA uses the term ''drug product.''

logistics provider for handling as products. These commenters believed that, at a minimum, the mere fact that a pharmaceutical product becomes nonsaleable does not mean that such pharmaceutical product is now a solid waste under the RCRA hazardous waste regulations.

EPA does not agree with these comments. The preemption provisions added to the FD&C Act by the DSCSA—both § 585(a) and § 585(b)—only apply to the protection of the drug supply chain and do not apply to waste management requirements under RCRA.[115] Under RCRA, EPA regulates pharmaceuticals differently than FDA does under the DSCSA since the goals of the statutes serve different purposes. The purpose of the DSCSA is to protect the security, pedigree, and quality of pharmaceutical products in the drug supply chain. One of the many purposes of RCRA is to ensure that any waste that is generated is ''treated, stored or disposed of so as to minimize the present and future threat to human health and the environment.'' [116] In addition, we note that the DSCSA applies only to prescription drug products (not to OTC drug products), so there can be no conflict between DSCSA and RCRA for nonsaleable OTC drug products.

As explained in further detail throughout this preamble, whether a pharmaceutical has monetary value (such as when it receives manufacturer credit) is not determinative of whether it is a waste under RCRA. Under RCRA, one considers whether a material is discarded—and not whether it receives credit, or holds value or no value—to determine whether it is waste. Thus, prescription pharmaceuticals that are sent by healthcare facilities to reverse distributors and that will be discarded (even if these pharmaceuticals receive credit) will first be considered wastes at the healthcare facility when the decision is made by the healthcare facility to send them to a reverse distributor.

Furthermore, EPA disagrees with commenters that a nonsaleable pharmaceutical product sent to reverse distributors should not be considered a waste. Nonsaleable pharmaceutical products sent to reverse distributors are not sent for reuse or donation, but are sent for disposal, and thus would be considered wastes at the healthcare facility. In its comments to the FDA on the Draft Guidance for Industry, Identifying Trading Partners Under the Drug Supply Chain Security Act,[117] an industry trade association appears to confirm this point when it says, ''Most fundamentally, returns processors are unlike the trading partners described in the DSCSA. Trading partners are dedicated to moving products forward for dispensing and administration to patients. Returns processors' activities come at the end, when the product is no longer retained for distribution or dispensing and is safely removed from the supply chain.''[118] The commenter goes on to say that ''the assumptions that product is being distributed for further use, rather than only for credit assessment and/or disposition'' do not appear to apply to returns processors (known as reverse distributors in this final rule.[119] Similarly, a reverse distributor also submitted comments to the FDA on the same draft guidance, stating that ''once these products reach the returns processors for creditability assessment and final disposition management, they are forever removed from commerce.'' [120] Furthermore, during a site visit to a large reverse distributor, EPA was told that none of the pharmaceuticals on site would be donated or redistributed or otherwise returned to commerce.[121] After they are evaluated for manufacturer credit, the pharmaceuticals are sent for incineration. Under § 261.2(b)(3) of the RCRA regulations, ''Materials are solid waste if they are abandoned by being . . . Accumulated, stored, or treated (but not recycled) before or in lieu of being abandoned by being disposed of, burned, or incinerated.'' The pharmaceuticals at reverse distributors are being accumulated prior to being incinerated and therefore are solid wastes. Additionally, in a 2013 memo EPA includes a series of questions to help determine whether a commercial chemical product is a solid and hazardous waste. One set of questions relates to whether the facility appears to be selling into commerce the material being evaluated. If the facility has no customers or market for the material, it can be an indication that the material is a solid waste.[122]

As explained elsewhere in the preamble, EPA distinguishes between reverse distributors (as defined in this rule) and reverse logistics centers. Reverse distributors do not reuse or donate, but in fact, dispose of the pharmaceuticals they receive. In sum, what DSCSA would consider to be a nonsaleable product is still considered to be a solid waste under RCRA when it is discarded according to the RCRA regulations, and the DSCSA does not preclude pharmaceuticals from being waste under RCRA.

EPA notes that many of the implementing regulations for the DSCSA are still under development by the FDA and the FDA has announced that it is delaying enforcement of certain requirements.[123] Section 584(d) of the FD&C Act, as added by the DSCSA, directs the FDA to issue licensing regulations for third party logistics providers (3PLs) within two years of the date of enactment of the DSCSA.[124] Draft FDA guidance issued in August 2017 indicates that FDA plans to consider a returns processor or reverse logistics provider to be a type of 3PL.[125] However, FDA has not yet finalized this guidance or issued proposed or final regulations for licensing 3PLs. The listing for the relevant regulation in the most recent version of the public list of planned federal rulemaking (the Unified Agenda of Regulatory and Deregulatory Actions, or ''Unified Agenda'') indicates that FDA plans to issue a *proposed* DSCSA licensing regulation within the next year.[126]

Furthermore, since 3PLs, such as reverse logistics providers, do not take ownership of the drugs that they manage at their facilities, the DSCSA requirements related to tracing drugs

[115] Section 585(a) of the DSCSA contains a preemption provision for state requirements for tracing drug products through the distribution system. Section 585(b) of the DSCSA contains a preemption provision for state requirements for wholesale prescription drug distributors and third-party logistics providers.

[116] See 42 U.S.C. 6902(b).

[117] August 2017, docket number FDA–2017–D–1956.

[118] See page 6 of comment FDA–2017–D–1956–0013.

[119] See page 7 of comment FDA–2017–D–1956–0013.

[120] See page 14 of comment FDA–2017–D–1956–0011.

[121] See notes from site visit to Med-Turn, October 10, 2017 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932. Med-Turn is a subsidiary of Inmar.

[122] See Section 3 of Attachment A of memo entitled Checklist to Assist in Evaluating Whether Commercial Chemical Products or Solid and Hazardous Waste Under the Resource Conservation and Recovery Act, May 14, 2013, Devlin to RCRA Division Directors, RCRA Online #14837.

[123] On June 30, 2017, FDA issued a draft guidance, Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy. *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf.*

[124] The DSCSA was enacted on November 27, 2013; therefore, the 3PL licensing regulations were scheduled to be issued by FDA by November 27, 2015.

[125] August 2017, Identifying Trading Partners Under the Drug Supply Chain Security Act—Guidance for Industry. *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572252.pdf.*

[126] See the Spring 2018 Unified Agenda, available at *https://www.reginfo.gov/public/do/eAgendaMain.*

through the supply chain, including transaction information (TI), transaction history (TH), and transaction statements (TS), do not apply to them. In the absence of relevant FDA regulations, it is difficult for EPA to consider the possibility of deferring to FDA for the regulation of reverse distributors, who we consider to be managing hazardous wastes. In the future, if there are duplicative regulations, EPA may need to revisit the regulation of reverse distributors after the FDA issues proposed and final licensing regulations for 3PLs in accordance with the DSCSA.

D. Wastes Generated at Healthcare Facilities That Are Not Included in the Scope of This Final Rule

Wastes that are not included in the scope of this proposed rulemaking include non-hazardous wastes and non-pharmaceutical hazardous wastes. Pharmaceutical wastes that are not listed or characteristic hazardous wastes under RCRA Subtitle C may nonetheless pose some risks to public health and the environment. These wastes are discussed further below.

1. How should non-hazardous waste pharmaceuticals be disposed?

A large portion of the pharmaceutical wastes generated at healthcare facilities will not meet the definition of a RCRA hazardous waste under RCRA Subtitle C. This final rule, therefore, does not require that healthcare facilities manage these waste pharmaceuticals under the RCRA Subtitle C hazardous waste regulations, including this final rule. However, a healthcare facility may choose to manage its non-hazardous and hazardous waste pharmaceuticals together (as hazardous waste pharmaceuticals) under the new subpart P regulations. Because all healthcare facilities operating under this subpart are regulated in the same way regardless of quantity of hazardous waste pharmaceuticals generated, managing non-hazardous waste pharmaceuticals as hazardous waste under this subpart would not affect the facility's hazardous waste generator category. While not regulated by the federal RCRA hazardous waste requirements, non-hazardous waste pharmaceuticals that are not managed under subpart P are still considered solid wastes under the federal regulations and must be managed in accordance with applicable federal, state, and/or local regulatory requirements. Moreover, some waste pharmaceuticals that do not qualify as ''hazardous wastes'' under RCRA can nonetheless be extraordinarily hazardous thus, extreme care may be warranted.[127] These are discussed below in section VII.D.1.a.

If a healthcare facility decides to segregate its hazardous and non-hazardous waste pharmaceuticals, EPA recommends that healthcare facilities follow the best management practices (BMPs) outlined in ''Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States,'' (Blueprint) [128] an EPA guidance document for the management, treatment, storage and disposal of non-hazardous waste pharmaceuticals. The following summarizes the recommended BMPs found in the Blueprint for various categories of pharmaceutical wastes, including those wastes that possess hazardous waste-like qualities yet are not regulated as hazardous waste under RCRA Subtitle C.

a. *Recommended best management practices for healthcare facilities managing non-hazardous waste pharmaceuticals possessing hazardous waste-like qualities.* Currently, most pharmaceuticals are not regulated as RCRA hazardous wastes when discarded by healthcare facilities. These ''non-RCRA-hazardous'' pharmaceuticals can be divided into two categories: Those that possess hazardous waste-like qualities and those that do not. As outlined in the Blueprint, there are pharmaceuticals that possess hazardous waste-like qualities, but for various reasons, are not regulated by the RCRA Subtitle C hazardous waste regulations. The Agency supports the Blueprint's recommendation of hazardous waste incineration as the BMP for healthcare facilities and reverse distributors discarding pharmaceuticals that may possess hazardous waste-like qualities, but are not regulated as RCRA hazardous waste. This recommendation would apply to pharmaceuticals with more than one active ingredient listed on the P- or U-lists,[129] chemotherapeutic agents characterized as bulk wastes,[130] pharmaceuticals which meet the hazardous drug criteria set by the National Institute for Occupational Safety and Health (NIOSH),[131] pharmaceuticals with LD50s ≤ 50 mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals.

b. *Recommended best management practices for other non-hazardous waste pharmaceuticals (not possessing hazardous waste-like qualities).* As far as other non-hazardous waste pharmaceuticals (*i.e.,* those not possessing hazardous waste-like qualities), disposing of non-hazardous waste pharmaceuticals at healthcare facilities via drain disposal is strongly discouraged and not recommended by EPA. Therefore, EPA endorses the Blueprint's recommendation of municipal solid waste incineration or medical waste incineration for any non-hazardous waste pharmaceuticals, even when they do not possess hazardous waste-like qualities. The potential risk remains for active pharmaceutical ingredients (APIs) to be released into the environment if medical waste autoclaves or municipal solid waste landfills are used for the purposes of pharmaceutical waste treatment and disposal. For example, autoclaves are designed to kill pathogens and do not achieve the temperatures required to destroy most APIs during the autoclaving process. As a result, when wastewater is generated either by cleaning an autoclave, or during automatic blow down from autoclaves equipped with steam generators, there is the potential for wastewater containing APIs to be generated and discharged into the sewer. In addition, some limited studies have shown APIs present in landfill leachate collected in municipal solid waste landfill leachate

[127] See, for example, *https://www.cdc.gov/niosh/review/peer/isi/hazdrug2018-pr.html* or NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016–161 (Supersedes 2014–138). *https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.*

[128] Practice Greenhealth, Revised August 2008. Published in 2006, the development of the original Blueprint was funded by the Office of Solid Waste and Emergency Response and managed by EPA Region 1. The 2008 revision of the Blueprint was funded by the Healthcare Environmental Resource Center. *http://practicegreenhealth.org/sites/default/files/upload-files/pharmwasteblueprint.pdf.*

[129] As noted in the comment after § 261.33(d), the phrase ''commercial chemical product'' includes formulations in which the P- or U-listed chemical is the sole active ingredient. Therefore, formulations with more than one active ingredient do not meet the specifications of the P- and U-listings even if one, two or all of the active ingredients are listed on the P- and/or U-lists.

[130] The descriptions ''bulk'' and ''trace'' when applied to chemotherapeutic wastes are industry terms and are not defined by the federal RCRA regulations.

[131] See NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016–161 (Supersedes 2014–138). *https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.*

systems.[132] [133] Typically, the collected landfill leachate is subsequently sent to wastewater treatment plants for treatment, but their treatment technologies are not designed to remove all APIs from the wastewater (See section XIII for more information regarding the prohibition on sewering hazardous waste pharmaceuticals).

2. How should non-pharmaceutical hazardous waste be disposed?

These newly promulgated subpart P regulations will pertain only to hazardous waste pharmaceuticals. Therefore, other types of hazardous wastes generated at healthcare facilities and reverse distributors that do not meet the definition of a hazardous waste pharmaceutical cannot be managed in accordance with this new subpart (as previously discussed, non-hazardous waste pharmaceuticals may be managed under this new subpart). For example, hazardous wastes generated in hospital laboratories or during cleaning and maintenance of the facility are not considered hazardous waste pharmaceuticals and are not included within the scope of this final rule. The generation of non-pharmaceutical hazardous wastes is often more routine and does not trigger the same concerns that healthcare facilities experience when managing hazardous waste pharmaceuticals. Also note that the 2016 Hazardous Waste Generator Improvements final rule added new flexibility for episodic generators of non-pharmaceutical hazardous waste under part 262 subpart L.

VIII. What terms are defined in this final rule? (§ 266.500)

A. Definition of Pharmaceutical

1. Summary of Proposal

EPA proposed to define ''pharmaceutical'' as any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition included, but was not limited to dietary supplements as defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), prescription drugs, OTC drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from the spills of pharmaceuticals. This proposed definition of ''pharmaceutical'' was intended to include all dose forms, including, but not limited to, tablets, capsules, medicinal gums or lozenges, medicinal liquids, ointments and lotions, IV or other compound solutions, chemotherapy pharmaceuticals, vaccines, allergenics, medicinal shampoos, antiseptics, and any delivery device, including medicinal dermal patches, with the primary purpose to deliver or dispense the pharmaceutical.

EPA relied on the FD&C Act's definition of ''drug'' to develop the proposed definition of ''pharmaceutical'' but expanded on the definition based on comments to the 2008 Universal Waste proposed rulemaking. In particular, stakeholders requested that the Agency take a broad view in delineating what items are included in the definition of pharmaceutical so that the proposed standards applied broadly. Thus, the proposed definition of ''pharmaceutical'' did not exclude pharmaceuticals with a radioactive component and included items not specifically recognized by the FDA as drugs, such as dietary supplements, pharmaceutical residues in non-empty containers (including delivery devices), personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from spills of pharmaceuticals.

2. Summary of Comments

The most frequent comment EPA received on the definition of ''pharmaceutical'' was on the inclusion of personal protective equipment and clean-up material in the definition of pharmaceutical. Many commenters argued that personal protective equipment and clean-up material should not be included in the final definition. One commenter suggested that loose tablets be included in the definition of pharmaceutical but that personal protective equipment should not be included. Waste Management National Services, Inc. suggested that only ''overtly contaminated'' personal protective equipment or clean-up materials be included in the definition, but not personal protective equipment and clean-up materials with trace contamination.[134] Two commenters asked EPA to clarify which personal protective equipment is included in the definition of ''pharmaceutical.''

One state expressed concern that EPA proposed to take a broad view in delineating what items are included in the definition of ''pharmaceutical.'' The New Jersey Department of Environmental Protection pointed out that although ''sharps'' did not meet the proposed definition of ''pharmaceutical'' that IV bags, tubing and syringes that come in contact with blood or pathogens could fall under the definition of ''pharmaceutical.'' They asked that EPA exclude these items from the definition.[135]

EPA requested comment on the Agency's decision to include dietary supplements in the definition of ''pharmaceutical'' under the final rule. Four states and one industry association supported the Agency's proposal to include dietary supplements under the definition of ''pharmaceutical.'' One state and five industry associations did not support including dietary supplements in the definition of ''pharmaceutical.'' Multiple commenters requested that EPA only include dietary supplements that are regulated as drugs and exclude supplements regulated as foods.

EPA requested comment on the possibility of including low-concentration nicotine products, such as electronic nicotine delivery systems (e-cigarettes), in the definition of ''pharmaceuticals'' under the final rule. EPA received multiple comments on whether to include e-cigarettes and liquid nicotine (e-liquids) in the final definition. Hawaii State Department of Health and the Hematology/Oncology Pharmacy Association did not support including e-cigarettes or e-liquids in the final definition of ''pharmaceutical.'' [136] RILA requested that EPA exempt all low-concentration nicotine products from the P075 listing, including e-cigarettes and e-liquids, but agreed that if EPA did not exempt these products from the P075 listing, that e-cigarette products should fall under the definition of ''pharmaceutical.'' [137]

The American Dental Association asked that EPA specifically exclude

[132] Barnes, K.K., Christenson, S.C., Kolpin, D.W., Focazio, M.J., Furlong, E.T., Zaugg, S.D., Meyer, M.T. and Barber, L.B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. Groundwater Monitoring & Remediation, 24: 119–126

[133] Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (June 2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. Bulletin of Environmental Contamination and Toxicology, V82.6:635–659.

[134] See comment number 0257 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[135] See comment number 0235 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[136] See comment numbers 0238 and 0264 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[137] See comment number 0295 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

dental amalgam from the final definition of ''pharmaceutical.'' [138]

Multiple commenters pointed out that the same chemical may have a pharmaceutical and non-pharmaceutical use (*e.g.,* isopropyl alcohol is used to clean wounds and to clean instruments and surfaces). [139] Commenters asked EPA to clarify that they are regulated differently.

Stericycle, Inc. requested that investigational or research drugs be considered pharmaceuticals because they are difficult to characterize.[140]

3. Final Rule Provisions

In this final rule, ''pharmaceutical'' means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (*e.g.,* electronic cigarette or vaping pen), or any liquid nicotine (e-liquid) packaged for retail for use in electronic nicotine delivery systems (*e.g.,* pre-filled cartridges or vials). This definition includes, but is not limited to dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); OTC drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

The final definition of pharmaceutical includes both prescription drugs, as defined by 21 CFR 203.3(y) and OTC drugs. As previously mentioned, commenters pointed out that the same chemical may have a pharmaceutical and non-pharmaceutical use.[141] If an OTC product is required by the FDA to include ''Drug Facts'' on the label, it would be considered a pharmaceutical for the purposes of this rule.[142] In rare cases, some items that are OTC pharmaceuticals may not be labeled appropriately with a ''Drug Facts'' label. It is the Agency's understanding, however, that all OTC drugs must contain a Drug Facts label. Therefore, if an item meets the criteria to be considered a pharmaceutical under subpart P but is not labeled with Drug Facts, it should still be managed as a pharmaceutical. Any non-pharmaceutical hazardous wastes must be managed pursuant to all other applicable RCRA regulations. The final definition of ''pharmaceutical'' also includes any pharmaceutical residuals remaining in non-empty containers, such as the pharmaceutical residuals remaining in dispensing bottles, IV bags and tubing, vials, unit dose packages, and delivery devises, such as syringes and patches. However, the final definition does not include sharps (*e.g.,* needles from IV bags or syringes). Used sharps, such as needles or syringes with needles, are not included under the final definition of pharmaceutical because sharps are considered medical wastes, presently regulated at both the state and local level. Further, as discussed in section XV of this preamble, EPA is finalizing regulations for when pharmaceutical containers are considered empty.

The final definition of ''pharmaceutical'' also includes items contaminated with or containing pharmaceuticals, such as personal protective equipment contaminated with pharmaceuticals or related spill clean-up materials (including loose tablets accumulated during pharmacy floor sweepings). EPA's decision to include contaminated personal protective equipment under the definition of ''pharmaceutical'' reflects the Agency's interest in promoting a similar management scheme for the personal protective equipment containing pharmaceuticals and other types of pharmaceuticals. Only personal protective equipment that is already considered hazardous waste under the ''contained in'' policy because it is contaminated with pharmaceuticals will fall under the definition of pharmaceutical.[143] These items are included in the definition so that facilities can manage more types of hazardous waste commonly found in healthcare settings under the same standards. For example, the contained in policy would not apply to gloves that have touched a warfarin pill during the course of patient care. However, if a healthcare worker spills a hazardous waste pharmaceutical on their personal protective equipment and it cannot be removed from the personal protective equipment, the personal protective equipment would be considered a hazardous waste pharmaceutical. If the personal protective equipment only has trace amounts of contamination it would not be considered a hazardous waste and therefore not be considered a hazardous waste pharmaceutical.

The final definition of ''pharmaceutical'' includes dietary supplements for the same reason—in order to promote a consistent management scheme for similar waste streams. Dietary supplements are commonly found in various healthcare settings because they are recommended or prescribed by healthcare providers to patients.[144] Further, retail pharmacies routinely sell vitamins and other medicinal minerals and supplements. When EPA uses the term ''dietary supplements'' in the definition of ''pharmaceutical,'' EPA is referencing the definition for dietary supplement used by the FD&C Act, as amended by the Dietary Supplement Health and Education Act of 1994 (21 U.S.C. 321 (ff)).[145] If a dietary supplement is required by the FDA to include a ''Supplement Facts'' panel on the label, it would be considered a pharmaceutical for the purposes of this rule.[146] The FD&C Act categorizes dietary ingredients and dietary supplements under the general umbrella of foods and therefore does not review them before being marketed. In fact, several commenters suggested that because the FD&C Act does not regulate supplements as drugs, EPA does not have the authority to regulate them as pharmaceuticals under RCRA. EPA disagrees with the commenters, noting that any waste that is listed or exhibits a characteristic is regulated as a hazardous waste when discarded, including supplements. This final rule does not newly apply RCRA to the disposal of supplements that meet the definition of hazardous waste, as some commenters suggest; it changes which regulations apply when discarding supplements that are hazardous waste. EPA recognizes that healthcare facilities may benefit from managing dietary supplements along with drugs under the

[138] See comment number 0294 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[139] See comment numbers 0246, 0280, 0296 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[140] See comment number 0280 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[141] See comment numbers 0246, 0280, 0296 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[142] See 21 CFR 201.66

[143] See memo from Lowrance to Fields, January 3, 1989 (RCRA Online #11387).

[144] Including dietary supplements under the definition of ''pharmaceutical'' does not supersede the requirements of the Dietary Supplement Health and Education Act of 1994, the Federal Food, Drug and Cosmetic Act, or FDA regulations.

[145] The substance of the definition is: A Product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A): A vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); For the complete definition of dietary supplement, please see: *https://www.gpo.gov/fdsys/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21-chap9-subchapII.pdf.*

[146] See 21 CFR 101.36.

final regulation, and thus, is including it in the final definition of ''pharmaceutical.'' Although dietary supplements are considered pharmaceuticals under this definition, only the dietary supplements that meet the definition of hazardous waste (*e.g.,* exhibits the toxicity characteristic for metal content) would be regulated under part 266 subpart P as hazardous waste pharmaceuticals (see the definition of ''hazardous waste pharmaceutical'').

The final rule specifically excludes dental amalgam from the final definition of pharmaceutical. EPA promulgated new pretreatment standards in June 2017 to reduce discharges of mercury from dental offices into publicly owned treatment works.[147] If EPA included dental amalgam in the final definition of pharmaceutical, it would subject dentists to duplicative regulatory requirements.

The final definition of ''pharmaceutical'' includes electronic nicotine delivery systems and liquid nicotine (e-liquid) packaged for retail for use in electronic nicotine delivery systems. These items are included in the definition ''pharmaceutical'' so that facilities can manage more types of hazardous waste commonly found in healthcare settings under part 266 subpart P. The final definition of ''pharmaceutical'' applies to finished product electronic nicotine delivery systems, including components and parts, sealed in final packaging intended for consumer use (*e.g.,* electronic cigarettes and vaping pens) and e-liquid that is packaged for retail for use in the electronic nicotine delivery systems (*e.g.,* pre-filled cartridges and vials that are sold separately to consumers or as part of kits). EPA intends that e-liquid used by manufacturers of tobacco products (as defined by the FD&C Act) not be included in the final definition of ''pharmaceutical.'' [148] That is, a pre-filled e-liquid cartridge sealed in final packaging that is to be sold or distributed to a consumer for use is included in the definition, but in contrast, an e-liquid that is sold or distributed for further manufacturing, mixing, or packaging into a finished electronic nicotine delivery system is not included.[149] EPA believes that finished products sealed in packaging intended for consumer use pose a lower risk for leaks and other releases to the environment than e-liquid that is sold or distributed for further manufacturing. E-liquid that is packaged for retail for use in electronic nicotine delivery systems, such as e-liquid that is in pre-filled cartridges and vials, is typically sold at lower concentrations and smaller quantities than e-liquid that is sold or distributed for further manufacturing.

The final definition of ''pharmaceutical'' includes investigational drugs. One commenter asked EPA to include investigational drugs in the definition because these drugs are difficult to characterize. The investigational drugs might have proprietary ingredients that the manufacturer might not be willing to divulge during trials. The final definition includes investigational drugs in order to provide clarity on how to manage these items when discarded. See section IX.B.2.e regarding the applicability of subpart P to discarded investigational drugs.

B. Definition of Hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed to define ''hazardous waste pharmaceutical'' as a pharmaceutical that is a solid waste, as defined in § 261.2, and is listed in part 261 subpart D, or exhibits one or more characteristics identified in part 261 subpart C. The Agency proposed to define the term ''hazardous waste pharmaceutical'' in order to clarify its intent that only pharmaceuticals that meet the definition of hazardous waste when disposed or discarded need to be managed under the new subpart P management standards.

2. Summary of Comments

EPA requested comment on the proposed definition of ''hazardous waste pharmaceutical'' and specifically on whether any dietary supplements currently on the market meet or could potentially meet RCRA's definition of hazardous waste.

The New Mexico Environment Department requested that EPA broaden the definition of ''hazardous waste pharmaceutical'' to include antineoplastic agents. The New Mexico Environment Department argued that EPA has not updated the P- and U-hazardous waste lists even though new pharmaceuticals have been developed that should be considered hazardous waste.[150] Public Employees for Environmental Responsibility also argued that the definition of ''hazardous waste pharmaceutical'' is too narrow because not enough pharmaceuticals meet the definition.[151] American Pharmacists Association expressed concern that the definition is difficult to understand because the P- and U-hazardous waste lists are not comprehensive.[152]

Waste Management National Services Inc., supported the proposed definition of ''hazardous waste pharmaceutical'' and pointed out that there are dietary supplements on the market that meet the RCRA definition of hazardous waste because the supplements contain selenium or chromium.[153]

3. Final Rule Provisions and Response to Comments

In this final rule, ''hazardous waste pharmaceutical'' means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C, or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (*e.g.,* lawfully donated for its intended purpose) or reclaimed. An OTC pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

The Agency is including in the final definition of ''hazardous waste pharmaceutical'' that a pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical if it is lawfully donated. The Agency included this language to clarify that pharmaceuticals are not solid waste if they are donated for use (see section IX.B for more discussion).

The Agency is defining the term ''hazardous waste pharmaceutical'' in order to clarify its intent that only pharmaceuticals (as defined in this final rule) that are hazardous waste when disposed or discarded need to be managed under the final subpart P management standards. For example, warfarin (brand name Coumadin) is a listed hazardous waste and when discarded meets the definition of hazardous waste pharmaceutical. The Agency notes that hazardous waste pharmaceuticals are hazardous wastes; more specifically, they are a subset of

[147] 82 FR 27154; June 14, 2017.

[148] 26 U.S.C. 5702 (d)

[149] This distinction is adapted from the term ''finished tobacco product'' used by FDA in its regulations for e-cigarettes, cigars, and all other tobacco products. 81 FR 28973; May 10, 2016.

[150] See comment number 0211 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[151] See comment number 0247 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[152] See comment number 0321 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[153] See comment number 0257 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

hazardous waste. The term hazardous waste is defined in § 260.10 as ''a hazardous waste as defined in § 261.3.'' Therefore, even though we do not reference § 261.3 in the definition of hazardous waste pharmaceutical, a hazardous waste pharmaceutical is also hazardous waste as defined in § 261.3. This is relevant to the OSHA Hazardous Waste Operations and Emergency Response standard (29 CFR 1910.120), which apply to hazardous wastes, as defined by § 261.3. This final rule does not impact the applicability of the OSHA Hazardous Waste Operations and Emergency Response standards.

Multiple commenters suggested that the proposed definition of ''hazardous waste pharmaceutical'' was too narrow because the P- and U-hazardous waste lists have not been updated even though new pharmaceuticals have been developed. Although we solicited ideas from commenters for possible methods or approaches for regulating additional pharmaceuticals as hazardous waste, any action taken to address the comments we received in response to this request would have to be a separate action taken by the Agency in the future and is not part of this final rulemaking. Therefore, these comments are considered to be out of the scope of this final action and we do not plan to address them at this time. That said, we do anticipate that because subpart P lowers regulatory barriers to over-managing non-hazardous waste pharmaceuticals, some healthcare facilities will choose to over-manage non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals even if they do not meet a current listing or exhibit a hazardous waste characteristic.

C. Definition of Reverse Distributor [154]

1. Summary of Proposal

EPA proposed to define reverse distributor as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. EPA proposed that any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer credit would be considered a reverse distributor. Pharmaceutical manufacturers often offer credit to healthcare facilities for unused and/or expired pharmaceuticals.[155] Manufacturers issue credit for a variety of reasons: it can be a marketing incentive tool, it helps protect against illicit diversion [156] or improper disposal, and it allows manufacturers to collect data on the returned items, which then can be used to help plan for future pharmaceutical production. Reverse distributors contract with both manufacturers and healthcare facilities to act as an intermediary to facilitate the crediting process.

EPA proposed new standards for shipping potentially creditable hazardous waste pharmaceuticals to reverse distributors and management standards of potentially creditable hazardous waste pharmaceuticals by reverse distributors. Thus, EPA proposed to define ''reverse distributor'' to clearly delineate which types of facilities were subject to the proposed rulemaking. The agency solicited public comment on its proposed definition of ''reverse distributor.'' Specifically, EPA asked for comment on whether the definition of ''reverse distributor'' captures the universe of facilities acting as reverse distributors for pharmaceuticals.

2. Summary of Comments

Commenters requested that EPA clarify who would be considered a reverse distributor and what the functions of a reverse distributor are. States and industry, including manufacturers, wholesalers, and waste management companies, wanted to know if any facility that performed reverse distribution functions would be encompassed in this definition. Reverse distributors asked for clarification in how 3PLs fit into the definition of reverse distributor and whether all functions performed by their business would fall under the definition.

3. Final Rule Provision

Under the final rule, reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

In response to comments, EPA made two changes to the definition of ''reverse distributor'' for the final rule. First, EPA proposed to use the term ''pharmaceutical reverse distributor'' but the final rule uses the term ''reverse distributor.'' EPA dropped the word ''pharmaceutical'' from reverse distributor because the definition of pharmaceutical is overly broad given that it refers to both prescription and nonprescription pharmaceuticals. EPA received comments from stakeholders pointing out that in the terminology of the industry, reverse distributors receive prescription pharmaceuticals, while reverse logistics centers receive nonprescription pharmaceuticals and other unsold retail items. This distinction is useful to EPA in making the same distinction in these regulations and EPA has adopted it.

The second change EPA made was to add the word prescription to the definition to further clarify that the definition does not include reverse logistics centers that receive nonprescription pharmaceuticals or other unsold retail items that are evaluated for legitimate use/reuse or reclamation. EPA's definition of ''reverse distributor'' only includes prescription hazardous waste pharmaceuticals that are evaluated for credit and then disposed. EPA made this clarification to be consistent with the policy for the reverse logistics of nonprescription pharmaceuticals and other unsold retail items. See section VI of this preamble for discussion of the regulations for the reverse distribution of prescription hazardous waste pharmaceuticals and the policy for the reverse logistics of other unsold retail items, including nonprescription pharmaceuticals.

EPA incorporated the changes to the final definition of ''reverse distributor'' in response to the comments summarized below.

4. Comments and Responses

EPA received comments from states and industry, including manufacturers, wholesalers and waste management companies, asking for clarification on who would be considered a reverse distributor. For example, commenters asked whether wholesalers, forward distributors and 3PLs meet the definition of ''reverse distributor'' even if reverse distribution is only a part of their business. For example, a facility

[154] The proposed rule used the term ''pharmaceutical reverse distributor'' but the final rule uses the term ''reverse distributor.'' To avoid confusion, we use the term ''reverse distributor'' in this preamble, even when discussing the proposed rulemaking.

[155] As noted in the definition of ''potentially creditable hazardous waste pharmaceutical,'' manufacturers provide credit for those pharmaceuticals that are less than one year past the expiration date.

[156] Through the return of pharmaceuticals by a pharmacy for manufacturer credit, manufacturers are able to maintain control of the pharmaceutical up to the point of its disposal, thereby, decreasing the risk of diversion of the pharmaceutical.

might act as a sorting and shipping facility or a pharmacy might act as a consolidation center but not evaluate for manufacturer credit. The definition of ''reverse distributor'' specifically states that any person, including forward distributors (*e.g.,* wholesalers), 3PLs, or pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. Any person that is performing the function of a reverse distributor, even if it is a small part of their business, would need to operate under the reverse distributor standards. If a facility is not processing any hazardous waste prescription pharmaceuticals for facilitating or verifying manufacturer credit, then it would not meet the definition of ''reverse distributor.''

The retail industry was especially concerned with need to differentiate between reverse distributors and reverse logistics centers. Reverse logistics centers that receive nonprescription pharmaceuticals (such as OTC pharmaceuticals) would not fall under this definition. Likewise, wholesale distributors receiving returns from their customers would not be considered reverse distributors. This is because wholesale distributors do not facilitate manufacturer credit. Further, according to comments received from Healthcare Distribution Management Association, in 2013, approximately 94% of the returns to wholesale distributors, were saleable.[157] [158] As saleable products, the pharmaceuticals returned to wholesale distributors would remain subject to the track and trace requirements of the DSCSA. Reverse logistics centers, which evaluate nonprescription pharmaceuticals for legitimate use/reuse and reclamation do not fit this definition.

EPA is also finalizing the definitions for potentially creditable and non-creditable hazardous waste pharmaceuticals (in parts D and E of this section) to differentiate between reverse distributors' function in evaluation of credit versus the traditional TSDF role in waste disposal. It is the Agency's intent that potentially creditable hazardous waste pharmaceuticals can be sent to reverse distributors for the determination of credit under subpart P. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as storage facilities or TSDFs for other hazardous waste.

Multiple state commenters asked EPA to clarify what is meant by ''facilitate.'' The facilitation of credit encompasses the role that reverse distributors serve between healthcare facilities and manufacturers. A reverse distributor receives potentially creditable hazardous waste pharmaceuticals for evaluation of manufacturer credit. Once the evaluation is complete and it is determined that credit can be given, reverse distributors will issue the manufacturer credit on behalf of the manufacturer to the healthcare facility.

Reverse distributors wanted to add all the other functions performed by reverse distributors to the regulatory definition to more fully define their role. EPA did not add reverse distributors' other functions to the definition of ''reverse distributor'' in the final rule. While a reverse distributor may continue to perform other lawful activities, they are not relevant for the purpose of defining a reverse distributor under this final rule. EPA's definition of reverse distribution focuses on issuing of manufacturer credit because although the pharmaceuticals are hazardous waste, they have value to the healthcare facility and the reverse distributor. Since these hazardous waste pharmaceuticals have value, there is a greater economic incentive to manage them with more care than typical hazardous waste. The final definition captures the handling of prescription hazardous waste pharmaceuticals that fall under RCRA and the rest of the functions can be regulated, as needed, under local, state and other federal regulations.

The waste management industry requested clarification on the intersection of DEA reverse distributors and RCRA reverse distributors and how a reverse distributor that receives a DEA controlled substance as a waste would determine if they are also subject to subpart P. A hazardous waste pharmaceutical that is also a DEA controlled substance is not subject to subpart P, provided they meet the terms of the conditional exemption in § 266.506. The conditional exemption for DEA controlled substances that are also RCRA hazardous waste is covered in section XIV of the preamble.

The Agency also wants to clarify the difference between what is defined as a reverse distributor under this final rule and how DEA regulations define ''reverse distribute.'' The recently amended DEA regulatory definition of ''reverse distribute'' is to ''acquire controlled substances from another registrant or law enforcement for the purposes of: (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or (2) Destruction.'' [159]

Under DEA's definition, a reverse distributor does not necessarily process pharmaceuticals for the purpose of determining manufacturer credit: Often a reverse distributor's main function under DEA's definition is to destroy the controlled substances. Under EPA's definition, however, a reverse distributor is defined as a facility that accepts potentially creditable pharmaceuticals for the purposes of evaluating manufacturer credit. These potentially creditable hazardous waste pharmaceuticals may or may not be identified as controlled substances by DEA.[160] Therefore, a DEA-registered reverse distributor may or may not meet EPA's definition of a reverse distributor and vice versa. For example, a reverse distributor that accepts DEA controlled substances that are also hazardous waste pharmaceuticals for the purpose of destruction (*e.g.,* incineration) would be regulated as a DEA-registered reverse distributor and as a RCRA TSDF (or other regulated incinerator, depending on what other wastes it combusts), but not as a reverse distributor under part 266 subpart P. Conversely, a reverse distributor that processes pharmaceuticals for manufacturer credit, but is not a DEA registrant and therefore, cannot accept controlled substances, would meet the subpart P reverse distributor definition, but not DEA's reverse distributor definition. However, EPA has heard from stakeholders that most, if not all, entities that facilitate manufacturer credit are also DEA-registered reverse distributors. Therefore, such reverse distributors would meet both EPA's definition of reverse distributor and the DEA's definition of reverse distributor. Lastly, EPA's definition for reverse distribution does not alter or supersede the requirements of the Controlled Substances Act and DEA regulations.

In addition, the DOT's Pipeline and Hazardous Materials Safety Administration has defined the closely related term, ''reverse logistics,'' in a

[157] Healthcare Distribution Management Association has since been renamed Healthcare Distribution Alliance.

[158] See comment #EPA–HQ–RCRA–2007–0932–0276.

[159] See 21 CFR 1300.01. On September 9, 2014, DEA finalized new definitions for ''reverse distribute'' and ''reverse distributor.'' Please see 79 FR 53520. The term ''reverse distributor'' is defined as ''a person registered with the Administration [DEA] as a reverse distributor.''

[160] In order for a reverse distributor to be able to accept controlled substances, the reverse distributor must be a DEA registrant. See 21 CFR part 1308 for a complete list of controlled substances.

recent rulemaking.[161] EPA coordinated with the Pipeline and Hazardous Materials Safety Administration to ensure that our rules are compatible, even if the definitions differ. It is important to note that their final rule does not supersede EPA's RCRA Subtitle C regulations for solid or hazardous waste determinations or hazardous waste management.

D. Definition of Potentially Creditable Hazardous Waste Pharmaceutical

1. Summary of Proposal

In order to distinguish hazardous waste pharmaceuticals that are sent by a healthcare facility to RCRA TSDFs from those hazardous waste pharmaceuticals that are sent by a healthcare facility to a reverse distributor for a determination or verification of manufacturer credit, the Agency proposed a definition for ''potentially creditable hazardous waste pharmaceutical.''

EPA proposed to define ''potentially creditable hazardous waste pharmaceutical'' to mean a hazardous waste pharmaceutical that has the potential to receive manufacturer credit and is

(1) unused or un-administered; and

(2) unexpired or less than one year past expiration date.

The proposed term did not include evaluated hazardous waste pharmaceuticals, residues of pharmaceuticals remaining in containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals. These pharmaceuticals are typically unopened and in their original packaging and include both generic and name brand pharmaceuticals.

Whether a pharmaceutical is eligible for manufacturer credit is determined solely by the manufacturer's return policy. Based on comments received for the 2008 Universal Waste proposed rulemaking and through discussions with various stakeholders, the Agency understands that the return policies of manufacturers change regularly. As a result, healthcare facilities are not always aware if a particular pharmaceutical will be creditable at the time that it is pulled from the shelves. However, the Agency also understands that there are instances where it is well known that a pharmaceutical will not be creditable. Examples of these instances include the following: If the pharmaceutical has been removed from the original container and repackaged for dispensing purposes; if an attempt was made to administer a pharmaceutical, but the patient refused to take it; if the hazardous waste pharmaceutical was generated during patient care; if the pharmacy receives a return of a dispensed pharmaceutical for which they had already received compensation by a third-party payer; or if the pharmaceutical is more than one year past its expiration date. In these instances, as well as others, the healthcare facility knows that it will not receive manufacturer credit. It is the Agency's intent for the proposed definition of ''potentially creditable hazardous waste pharmaceutical'' to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of credit. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for those hazardous waste pharmaceuticals.

Also, based on communication with stakeholders and the public comments received on the 2008 Universal Pharmaceutical Waste proposal, EPA understands that pharmaceutical manufacturers' policies often allow for credit to be issued on the return of ''partials.'' ''Partials'' is a term used in the industry to refer to opened containers that have had some contents removed. Under the proposed definition, the Agency considered partials to be potentially creditable hazardous waste pharmaceuticals.

2. Summary of Comments

States, manufacturers and waste management companies commented that word changes to this definition would clarify which hazardous waste pharmaceuticals could or could not be returned to reverse distributors. Manufacturers, some states and healthcare facilities argued that all pharmaceuticals should go to reverse distributors to relieve the burden on healthcare facilities to make these individual determinations. Pharmacists and reverse distributors wanted further clarification on what distinguishes a potentially creditable hazardous waste pharmaceutical and how it relates to credit.

3. Final Rule Provision

In response to comments, EPA has made five changes to the definition of ''potentially creditable hazardous waste pharmaceutical'' from the proposal. First, the final definition specifically includes prescription pharmaceuticals only. Second, we added the phrase ''reasonable expectation'' to clarify that the healthcare facility does not have to definitively know whether something will receive manufacturer credit but rather indicates that they should have a reasonable expectation that it will. We also note that EPA could have proposed to use the term ''creditable hazardous waste pharmaceuticals,'' but chose to use the term ''potentially creditable hazardous waste pharmaceutical'' to convey the same concept (*i.e.,* that a healthcare facility does not have to definitively know whether a specific item will receive manufacturer credit.) Third, we replaced ''unadministered'' with the term ''undispensed'' to make clear that it is not just that a patient refused to take a prescription pharmaceutical, but rather that it was never dispensed to a patient at all. Fourth, we removed the word ''unused'' from the definition since the use of this term could introduce some confusion given that ''partials'' can get manufacturer credit. Fifth, we specified that the pharmaceuticals be in the ''original manufacturer's packaging'' since repackaged prescription pharmaceuticals are not typically eligible for credit.[162]

For the final rule, a potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is (1) in original manufacturer's packaging (except pharmaceuticals that were subject to recall); (2) undispensed; and (3) unexpired or less than one year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, OTC drugs, homeopathic drugs, and dietary supplements.

4. Comments and Responses

a. Definitional Wording. EPA received many comments from states and industry on revising the definition to clarify which hazardous waste pharmaceuticals could and could not be returned to reverse distributors. States especially stressed that ''potentially creditable'' should be changed to ''reasonable expectation of credit'' or that EPA should define potentially creditable hazardous waste pharmaceuticals as those that are

[161] 79 FR 46748; August 11, 2014. The Pipeline and Hazardous Material Safety Administration's definition of reverse logistics ''is the process of moving goods from their final destination for the purpose of capturing value, recall, replacement, proper disposal, or similar reason.''

[162] See email correspondence from Nicole Wilkinson of CVS dated February 21, 2018 and Erica Burwell of Inmar dated February 22, 2018, both in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

accepted by reverse distributors for evaluation, as compared to those that are not. Manufacturers and states asked us to clarify whether we mean ''unadministered'' or ''undispensed'' or whether the term ''unopened'' should be added to the definition. The waste management industry had some concern that adding expiration dates to the definition might prevent potentially creditable hazardous waste pharmaceuticals from being returned to the reverse distributor.

In the final definition of potentially creditable hazardous waste pharmaceuticals, EPA has added some new phrases such as ''reasonable expectation of credit'' to the definition to be clear that not all hazardous waste pharmaceuticals should be going back to reverse distributors. We have also changed words like ''unadministered'' to ''undispensed'' since the expectation of credit ends once a pharmaceutical has been dispensed to a patient regardless of whether the patient takes the pharmaceutical and deleted ''unused'' since that could imply it has been dispensed but not used and/or that it was never opened.

We are specifically not adding the word ''unopened'' to the definition as some commenters had suggested, since it is EPA's understanding that ''partials'' can be given credit under certain circumstances and some pharmaceuticals may be repackaged. Although the definition does not include the word ''intact'' when describing original manufacturer's packaging, the definition of ''potentially creditable hazardous waste pharmaceutical'' does not include anything that is leaking or damaged.

Some commenters also argued that EPA was limiting manufacturers from changing policies by defining potentially creditable hazardous waste pharmaceuticals and giving examples of what those are. EPA recognizes that special circumstances may arise where a prescription hazardous waste pharmaceutical may be given credit but not fit squarely within this definition. We have added an example of this in our definition by noting that a recalled pharmaceutical may be given credit although it is not in original packaging. This definition is meant to give examples of what is commonly done and to aid healthcare facilities in being able to more easily identify a potentially creditable from a non-creditable hazardous waste pharmaceutical. It is not intended to prevent a manufacturer from changing its credit policies.

b. Evaluation of Hazardous Waste Pharmaceuticals and Credit. In their comments regarding potentially creditable hazardous waste pharmaceuticals received by reverse distributors, manufacturers and reverse distributors expressed concern about the burden being added to healthcare facilities by not allowing them to send all the hazardous waste pharmaceuticals together and putting the onus on them to determine if something is ''potentially creditable''. Healthcare facilities were concerned that credit policies are frequently updated by manufacturers and that a healthcare facility would not know if credit would be issued for any given pharmaceutical or not.

Commenters also addressed the question of a bright line as to what is and what is not potentially creditable hazardous waste pharmaceuticals. Commenters asked whether generics were considered ''potentially creditable.'' The waste management industry commenters asked how many times credit must be rejected before a type of pharmaceutical is no longer considered potentially creditable.

It is the Agency's intent in our definition of ''potentially creditable hazardous waste pharmaceutical'' to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of manufacturer credit. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for certain hazardous waste pharmaceuticals.

EPA recognizes that in some cases a healthcare facility may not know if the hazardous waste pharmaceuticals will be given credit. We do not want to deter healthcare facilities from sending their hazardous waste pharmaceuticals to a reverse distributor if there is a reasonable expectation of credit. Whether or not credit is actually given is not a defining factor and it is not within EPA's expertise to know how many times a potentially creditable hazardous waste pharmaceutical needs to be rejected before it is considered ''non-creditable.'' Each pharmaceutical is different and is or is not creditable for various reasons as dictated by the manufacturer. EPA has learned since the proposal that generic prescription drugs can have a reasonable expectation of receiving manufacturer credit. EPA also agrees with commenters that ''partials'' can be given credit.

EPA's intent is to prevent hazardous waste pharmaceuticals that are clearly ineligible for credit and are ready for disposal, due to their condition, previous use with a patient, or other reason, from being sent to the reverse distributor. Hazardous waste pharmaceuticals that are in original packaging and have not been dispensed to a patient would fit under this definition of ''potentially creditable hazardous waste pharmaceutical.''

E. Definition of Non-Creditable Hazardous Waste Pharmaceutical

1. Summary of Proposal

In order to distinguish hazardous waste pharmaceuticals that have the potential for credit from those that have no expectation of receiving credit, the Agency proposed to define the term ''non-creditable hazardous waste pharmaceutical.'' The proposed definition of a ''non-creditable hazardous waste pharmaceutical'' is a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer credit. Examples include, but are not limited to pharmaceuticals that have been removed from the original container and repackaged for dispensing purposes; a pharmaceutical refused by a patient after an attempt to administer it; hazardous waste pharmaceuticals generated during patient care; dispensed pharmaceuticals returned to a pharmacy after the pharmacy had already received compensation by a third-party payer (*e.g.,* health insurance company); or pharmaceuticals that are more than one year past their expiration dates. Non-creditable hazardous waste pharmaceuticals are typically opened and not in their original packaging and have been dispensed (though not administered) to a patient. These conditions of the non-creditable pharmaceutical are what makes them not creditable rather than the manufacturer's policy on the specific type of pharmaceutical.

2. Summary of Comments

Commenters expressed a variety of opinions on EPA's proposed definition of ''non-creditable hazardous waste pharmaceutical.'' Some states, manufacturers and the waste management industry stated that they were satisfied with the proposed definition of ''non-creditable hazardous waste pharmaceutical.'' Wholesalers argued that the definition should be struck and the regulations should allow all intact hazardous waste pharmaceuticals to go back to a reverse distributor. Pharmacists, some states, and the retail industry argued that EPA should define ''non-creditable hazardous waste pharmaceuticals'' as those hazardous waste pharmaceuticals that are not accepted by reverse distributors for manufacturer credit.

3. Final Rule Provision

For the final rule, EPA made three major changes to the definition of ''non-creditable hazardous waste pharmaceutical'' to address comments. First, EPA has added the word ''prescription'' to the first portion of the definition to be consistent with the use of terminology in the final rule that reverse distribution is the reverse flow of prescription hazardous waste pharmaceuticals. Second, the Agency has added new language to the definition to reflect the fact that nonprescription hazardous waste pharmaceuticals can also be considered non-creditable hazardous waste pharmaceuticals that must be managed under the healthcare facility standards in § 266.502 when they do not have a reasonable expectation to be legitimately used/reused or reclaimed. For purposes of this definition, the determination is being made that at the healthcare facility, prescriptions that have already been dispensed to a patient, and free samples given to healthcare facilities do not have a reasonable expectation of receiving manufacturers credit. Third, EPA has also added examples of non-creditable hazardous waste pharmaceuticals.

Under the final rule, non-creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

While not specifically laid out in the definition, other examples of non-creditable hazardous waste pharmaceuticals can be pharmaceuticals that have been removed from the original container and repackaged for dispensing purposes; pharmaceuticals in their original packaging when the packaging is leaking or otherwise damaged; a pharmaceutical refused by a patient after an attempt was made to administer it; pharmaceuticals generated during patient care; dispensed pharmaceuticals returned to a pharmacy after the pharmacy already received compensation by a third-party payer (*e.g.,* health insurance company); or pharmaceuticals at are more than one year past their expiration date.

4. Comments and Responses

Wholesalers and some reverse distributors recommended that we do not differentiate between potentially creditable and non-creditable hazardous waste pharmaceuticals and allow all hazardous waste pharmaceuticals that are intact and in original packaging to go to the reverse distributors. EPA disagrees with the commenters. EPA proposed this differentiation between potentially creditable and non-creditable hazardous waste pharmaceuticals to distinguish between a traditional TSDF and the function served by a reverse distributor. A reverse distributor should not act as a hazardous waste disposal facility for healthcare facilities. It is serving as the manufacturer's agent for determination of credit. If a reverse distributor is not determining credit, EPA views it as managing hazardous waste pharmaceuticals that do not have monetary value and thus would be subject to TSDF regulations. If a reverse distributor begins to routinely receive non-creditable hazardous waste pharmaceuticals, then it is serving as a TSDF. EPA has made this differentiation to correctly represent the reverse distributor role as a manufacturer's agent for facilitating credit and not like a more traditional hazardous waste management facility.

Pharmacists, the retail industry and some states recommended that we define non-creditable hazardous waste pharmaceuticals as those hazardous waste pharmaceuticals that do not receive credit. There are some situations in which pharmaceuticals are well known to not be eligible for credit, such as leaky containers, samples or when pharmaceuticals were already dispensed to patients. The Agency did not finalize the commenters' recommendation, however, because it could potentially lead to situations where a healthcare facility sends a hazardous waste pharmaceutical to a reverse distributor in good faith that manufacturer credit is forthcoming, but credit is not issued. If EPA accepted this recommendation, the reverse distributor could be determined to unlawfully be in possession of non-creditable hazardous waste pharmaceuticals. For this reason, the Agency added into the definition that non-creditable hazardous waste pharmaceuticals are prescription pharmaceuticals that do not have a reasonable expectation of receiving manufacture credit, or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. It should be clear to healthcare personnel that leaking containers, for example, are not eligible for credit and should be sent to a designated facility for disposal (*e.g.,* a TSDF). However, it is often not clear to the healthcare facility personnel making the determination which hazardous waste pharmaceuticals will receive manufacturer credit if they were not dispensed and/or are in their original packaging (*i.e.,* potentially creditable). The Agency does find it reasonable that healthcare personnel may not know if a manufacturer credit policy for a particular pharmaceutical has changed.

Because it is not always clear that all hazardous waste pharmaceuticals will be eligible for credit due to frequent changes in manufacturers' policies, it is inappropriate to create a bright line in the definition solely based on whether the hazardous waste pharmaceutical would or would not receive manufacturer credit. Instead, this final definition takes into account this uncertainty and the difficulty it poses for healthcare facilities and allows for instances where a potentially creditable hazardous waste pharmaceutical can be correctly sent to a reverse distributor under the subpart P regulations despite not actually receiving manufacturer credit.

F. Definition of Evaluated Hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed a definition for evaluated hazardous waste pharmaceuticals. After potentially creditable hazardous waste pharmaceuticals arrive at a reverse distributor, they are evaluated by the reverse distributor to determine whether they are eligible for manufacturer credit or whether they need to be transferred to another reverse distributor for additional verification of manufacturer credit. Hazardous waste pharmaceuticals that need to be transferred to another reverse distributor for additional verification of manufacturer credit will continue to be considered potentially creditable hazardous waste pharmaceuticals. EPA proposed that hazardous waste pharmaceuticals for which manufacturer credit has been issued (and no further verification of credit is required), as well as those that do not receive credit, be referred to as ''evaluated hazardous waste pharmaceuticals.''

EPA proposed to define an ''evaluated hazardous waste pharmaceutical'' as a hazardous waste pharmaceutical that

was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a reverse distributor to establish whether it is eligible for manufacturer credit and will not be sent to another reverse distributor for further evaluation or verification.

It is important to define this term since the proposed management and shipping standards for potentially creditable hazardous waste pharmaceuticals differ from the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals and the regulations must therefore distinguish between them. For a discussion of the proposed shipping and management standards for potentially creditable hazardous waste pharmaceuticals, see section XVI.D. and for a discussion of the proposed shipping and management standards for evaluated hazardous waste pharmaceuticals, see section XVI.B.

2. Summary of Comments

There were few comments pertaining to this definition. One state sought clarification on whether under this definition, an evaluated pharmaceutical could be sent on to another reverse distributor. Pharmacists wanted further clarification that evaluated hazardous waste pharmaceuticals are not eligible for credit.

3. Final Rule Provision

For the final rule, EPA made two changes to the definition of ''evaluated hazardous waste pharmaceuticals'': (1) Adding the word ''prescription'' to be consistent with our decision to distinguish between reverse distribution and reverse logistics and (2) focusing the definition on the evaluation process and does not rely as heavily on manufacturer credit.

EPA is finalizing that ''evaluated hazardous waste pharmaceutical'' means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

Under the definition of evaluated hazardous waste pharmaceutical, if credit has been determined and no other verification is needed, then the waste would be considered evaluated. If the prescription hazardous waste pharmaceutical needs further evaluation for credit, it can be sent on to another reverse distributor for that determination. It will not be considered evaluated until the credit is verified.

The Agency notes that an evaluated pharmaceutical still at the reverse distributor is not precluded from ever being awarded manufacturer credit. A manufacturer may change a credit policy while an evaluated pharmaceutical is being accumulated at a reverse distributor. However, as an evaluated pharmaceutical, it is no longer managed as a potentially creditable pharmaceutical at the reverse distributor, then it must be managed as an evaluated hazardous waste pharmaceutical even if credit is awarded after the initial evaluation. Please refer to section XVII.C of this preamble for a detailed discussion of the reverse distributor standards.

G. Definition of Household Waste Pharmaceutical

1. Summary of Proposal

EPA proposed to define the term ''household waste pharmaceutical'' as a solid waste, as defined in § 261.2, that also meets the definition of pharmaceutical, but is not a hazardous waste because it is exempt from RCRA Subtitle C regulation by the household waste exclusion in § 261.4(b)(1).

We proposed this term to distinguish this type of waste pharmaceutical from the hazardous waste pharmaceuticals that are proposed to be regulated under this new subpart.

2. Summary of Comments

Commenters generally agreed with EPA's definition of ''household waste pharmaceutical'' as proposed but were concerned with applicability of this definition and where the household waste exclusion can be used. For example, one commenter asked if it extended to schools. A few commenters wanted to know if this applied to all DEA take back programs and requested that the words ''including those generated by DEA regulations'' be added. Lastly, commenters asked us to clarify the significance of the household waste pharmaceutical definition with respect to long-term care facilities (LTCFs).

3. Final Rule Provisions

EPA is finalizing the definition of ''household waste pharmaceutical'' as proposed with one minor change. EPA changed the word ''exempt'' to ''excluded'' to be consistent with the title of § 261.4(b). In the final rule, ''household waste pharmaceutical'' means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).

4. Comments and Responses

In response to some of the commenters' concerns, EPA is defining the term ''household waste pharmaceutical'' as a matter of convenience in crafting the regulatory language as well as the preamble. By defining the term, we do not alter the criteria we have consistently relied on for determining whether a waste is considered a household hazardous waste. The two criteria that must be met to be a household hazardous waste are (1) the waste must be generated by individuals on the premise of a temporary or permanent residence and (2) the waste stream must be composed primarily of materials found in wastes generated by consumers in their homes. Section 261.4(b)(1) defines household to include single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds and day-use recreation areas. This exclusion does not include schools. Schools generate hazardous waste from various sources throughout the school grounds such as chemicals from labs, cleaning supplies and hazardous waste pharmaceuticals from medical clinics. These wastes are not being generated at a temporary or permanent residence and are not the types of wastes that would ordinarily be generated by a consumer at their home. Pharmaceuticals generated at schools would not be considered household waste pharmaceuticals. However, hazardous waste pharmaceuticals generated at dormitories at schools would be considered household waste pharmaceuticals and thus excluded, because the dormitories are residences.

Some types of healthcare facilities could be considered households. This final rule defines the term LTCF in § 266.500. LTCF means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities. The types of healthcare facilities listed at the end of this definition that are not considered to be LTCFs are not subject to subpart P requirements and hazardous waste pharmaceuticals generated there continue to be excluded from RCRA as household hazardous wastes. For a more thorough discussion of the applicability

of the household hazardous waste exclusion at LTCFs, see section VIII.K of this preamble.

While DEA controlled substances can sometimes be household waste pharmaceuticals, once these wastes are collected at a take back event or by law enforcement, DEA regulations require that any proper disposal must meet the DEA non-retrievable standards of destruction. Furthermore, this EPA rule finalizes specific requirements for the destruction of collected household waste pharmaceuticals, see section XIV of this preamble for details. Therefore, it could have been confusing to add ''including waste under DEA regulations'' to the definition of household waste pharmaceutical.

H. Definition of Non-Hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed to define the term ''non-hazardous waste pharmaceutical.'' While hazardous waste pharmaceuticals are regulated under this new subpart, non-hazardous waste pharmaceuticals are not regulated under RCRA Subtitle C, including this new subpart. The Agency proposed this definition since we believed it was important to clearly delineate what is and is not regulated under this new subpart.

The Agency proposed to define the term ''non-hazardous waste pharmaceutical'' as a pharmaceutical that is a solid waste, as defined in § 261.2, but is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C. The characteristics of hazardous waste are ignitability, corrosivity, reactivity, and toxicity.

2. Summary of Comments

Most commenters agreed with the definition of ''non-hazardous waste pharmaceutical'' as proposed. There were some comments concerning commingling of hazardous and non-hazardous waste. These comments are addressed in detail in section X.C. and XI.A. of this preamble.

3. Final Rule Provision

The Agency is finalizing the definition of ''non-hazardous waste pharmaceutical'' as proposed, with no changes. In this rule, a ''non-hazardous waste pharmaceutical'' is a pharmaceutical that is a solid waste, as defined in § 261.2, but is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

I. Definition of Non-Pharmaceutical Hazardous Waste

1. Summary of Proposal

Like the previous definition, we proposed to define non-pharmaceutical hazardous waste to help delineate what is and what is not regulated under this new subpart. We proposed to define the term ''non-pharmaceutical hazardous waste'' as a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical as defined in this section.

The proposed definition was needed because the management of non-pharmaceutical hazardous wastes is not regulated under subpart P; rather, generators of non-pharmaceutical hazardous wastes, including healthcare facilities and reverse distributors, remain subject to part 262 and other applicable Subtitle C hazardous waste regulations for the management of those hazardous wastes.

2. Summary of Comments

There were only a few comments on the proposed definition of ''non-pharmaceutical hazardous waste.'' Commenters generally agreed with the definition, but two commenters wanted EPA to clarify how to classify a waste with an ingredient that is used in both pharmaceutical and non-pharmaceutical items.

3. Final Rule Provisions

EPA is finalizing the definition of non-pharmaceutical hazardous waste, as proposed, with no changes. In this final rule, ''non-pharmaceutical hazardous waste'' is a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical as defined in § 266.500.

4. Comments and Responses

Multiple commenters asked EPA to clarify how a hazardous waste should be managed when it is used as an ingredient in both pharmaceuticals and non-pharmaceutical, *e.g.,* isopropyl alcohol, which can be used both as an antiseptic and a degreaser. Please see the definition in section VIII.A. for discussion about what meets the definition of pharmaceutical, including how to apply the definition in this type of scenario. Any hazardous waste not meeting the definition of pharmaceutical is considered a non-pharmaceutical hazardous waste and should be managed under all applicable RCRA standards.

J. Definition of Healthcare Facility

1. Summary of Proposal

EPA proposed to define ''healthcare facility'' as any person that provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or sells or dispenses OTC or prescription pharmaceuticals. The proposed definition was adapted from the definition of ''health care'' that the Department of Health and Human Services promulgated as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR part 160.103).[163] The proposed definition of ''healthcare facility'' included, but was not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, LTCFs, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of OTC medications; and veterinary clinics and hospitals.

EPA proposed to include coroners and medical examiners in the definition of ''healthcare facility'' despite the fact that the services coroners provide occur after life. Coroners will often inventory, and then dispose of, any pharmaceuticals that may be found at the scene of a death, and commonly sewer dispose of pharmaceuticals by putting them down the drain.[164] In order to reduce sewer disposal of pharmaceuticals and provide these facilities with the same management options that are available to other healthcare facilities, EPA included coroners in the proposed definition of healthcare facility.

The proposed definition of healthcare facility did not include pharmaceutical manufacturers and their representatives, wholesalers, or any other entity that is involved in the manufacturing, processing, or wholesale distribution of pharmaceuticals. EPA proposed to

[163] 45 CFR part 160 *http://aspe.hhs.gov/admnsimp/final/pvctxt01.htm.*

[164] For more information on the disposal process, please see: Ruhoy, I.S. and Daughton, C.G. ''Types and Quantities of Leftover Drugs Entering the Environment via Disposal to Sewage—Revealed by Coroner Records,'' Sci. Total Environ., 2007, 388(1–3):137–148. *https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=168384.*

exclude manufacturing facilities from the definition of healthcare facility because the Agency did not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities.

2. Summary of Comments

EPA requested comment on including coroners in the definition of ''healthcare facility.'' EPA received three comments supporting the inclusion of coroners in the definition of ''healthcare facility.'' One stakeholder was aware of coroner facilities that sewer dispose of pharmaceuticals and argued to include them in the definition in order to reduce the sewer disposal of pharmaceuticals. Two commenters expressed concern about including coroners in the definition of ''healthcare facility.'' One commenter stated that including coroners in the definition could discourage coroners from promoting take-back programs.

EPA also took comment on including compounding pharmacies in the definition of ''healthcare facility.'' Three commenters supported the inclusion of compounding pharmacies in the definition. One commenter stated that compounding pharmacies should be included because they do not predictably generate a known range of hazardous wastes and face problems similar to that of a healthcare facility.

The most frequent comment the Agency received on the definition of ''healthcare facility'' was that EPA should define wholesale distributors and third-party logistics providers as healthcare facilities or to create a separate definition for wholesale distributors and third-party logistics providers, but allow them to operate under the same standards as healthcare facilities.

3. Final Rule Provisions

EPA is finalizing a definition for ''healthcare facility'' so that it is clear to whom these final regulations apply. EPA is finalizing that ''healthcare facility'' means any person that is lawfully authorized to (1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) distribute, sell, or dispense pharmaceuticals, including OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, LTCFs, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, and veterinary clinics and hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Although EPA uses the term ''person,'' in the definition of healthcare facility, the definition of healthcare facility does not necessarily apply to individual healthcare providers at a site. As defined in § 260.10, ''person'' means ''an individual, trust, firm, joint stock company, Federal Agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.'' Accordingly, a healthcare facility can have multiple healthcare providers or a sole healthcare provider. For example, an individual healthcare provider who works at a hospital with multiple healthcare providers is not considered a healthcare facility, but the hospital is considered a healthcare facility, under the final definition. Additionally, a doctor's office with a sole healthcare provider would also be considered a healthcare facility under this final rule.

The proposed definition of ''healthcare facility'' did not apply to pharmaceutical manufacturers' representatives, wholesale distributors, third-party logistics providers, or any other entity that is involved in the wholesale distribution of prescription or OTC pharmaceuticals. Commenters argued that excluding wholesale distributors and third-party logistics providers from the definition of ''healthcare facility,'' in combination with the revised interpretation that the point of generation for potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, could hinder wholesale distributors' and third-party logistics providers' ability to send potentially creditable pharmaceuticals through reverse distribution. These commenters were concerned that if they were not included in the definition of ''healthcare facility'' they would be precluded from using reverse distributors. Commenters also pointed out that wholesale distributors and third-party logistics facilities are likely to generate hazardous waste pharmaceuticals unpredictably and that their workers typically do not have the expertise to make hazardous waste determinations. Due to these comments, the Agency anticipates that wholesale distributors and third-party logistics facilities face similar issues as healthcare facilities and therefore is including them in the final definition of ''healthcare facility.''

The final definition of ''healthcare facility'' includes wholesale distributors, third-party logistics providers that engage in forward distribution, and military medical logistics facilities. Including wholesale distributors and third-party logistics facilities in the definition of ''healthcare facility'' ensures that these facilities can continue sending potentially creditable hazardous waste pharmaceuticals through reverse distribution. EPA recognizes that wholesale distributors and third-part logistics providers are not accustomed to referring to themselves as healthcare facilities. However, it is helpful to have a single, umbrella term when discussing who is subject to this subpart.

The final definition of ''healthcare facility'' does not apply to pharmaceutical manufacturers or any other entity that is involved in the manufacturing of OTC or prescription pharmaceuticals. The purpose for these sector-based regulations is to address the various issues that healthcare facilities and reverse distributors face when managing hazardous waste pharmaceuticals. The Agency does not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities, and therefore are excluded from the definition of ''healthcare facility'' under this rule.

The final definition of ''healthcare facility'' includes locations that sell pharmaceuticals over the internet, through the mail, or through other distribution mechanisms. A pharmacy does not necessarily have to have a ''brick and mortar'' or ''store front'' presence to be considered a healthcare facility for the purposes of this final rule. The final definition of a ''healthcare facility'' also applies to entities that engage in drug compounding. In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. EPA solicited comment on including compounding

pharmacies in the definition of healthcare facility and received three comments supporting and no comments opposing the inclusion of compounders in the definition. The final definition of ''healthcare facility'' applies to state-licensed pharmacies, federal facilities, and licensed physicians that compound drugs in accordance with section 503A of the FD&C Act, and to outsourcing facilities that compound drugs in accordance with section 503B of the FD&C Act.

4. Comments and Responses

The final definition does not include independently located coroners and medical examiners. EPA made this change in response to commenter concern that including coroners and medical examiners in the definition could discourage coroners and medical examiners from promoting take-back programs for household pharmaceuticals. However, coroners and medical examiners that are co-located with healthcare facilities, such as hospitals, will fall under the definition of ''healthcare facility,'' because they are physically part the healthcare facility.

K. Definition of Long-Term Care Facility

1. Summary of Proposal

The proposed definition of healthcare facility specifically included LTCFs as an example of a type of healthcare facility. Since the term ''long-term care facility'' does not have a standardized, industry definition, EPA proposed to define the term for purposes of this rule. We proposed to define a LTCF as a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities.

The facilities we proposed to include as LTCFs are licensed care facilities that are more similar to hospitals than to standard residences. Although group homes may be licensed care facilities, they are typically very small (fewer than 10 beds) and therefore were not included within the proposed definition. Similarly, independent living communities are not licensed care facilities, but rather are residences made up of individual units such as townhomes or apartments and therefore were not included within the proposed definition. Finally, we clarified in the preamble to the proposed rulemaking that private residences with visiting nurses would not be considered long-term care facilities.

By proposing to define a LTCF as a type of healthcare facility, EPA was proposing to revise its policy regarding the regulatory status of hazardous waste from long-term care facilities. We proposed that hazardous waste from LTCFs would no longer be excluded as household hazardous waste; rather, it would be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the standards proposed for hazardous waste pharmaceuticals under part 266 subpart P. In other words, the proposed revision to our policy regarding long-term care facilities pertained to all of the facilities' hazardous waste, not just the hazardous waste pharmaceuticals.

The Agency proposed revising its interpretation with regard to hazardous wastes generated at LTCFs based on a reevaluation of how such facilities operate. Specifically, in order to qualify for the household hazardous waste exclusion of § 261.4(b)(1), waste must meet two criteria: (1) The hazardous waste must be generated by individuals on the premises of a household, and (2) the hazardous waste must be composed primarily of materials found in the wastes generated by consumers in their homes.[165] In the preamble to the proposed rulemaking, EPA explained that hazardous waste generated at LTCFs, even those pharmaceuticals that are under the control of the patient or resident, does not meet either criterion for the household hazardous waste exemption.

In brief, the explanation provided in the preamble to the proposed rulemaking was two-fold. First, a LTCF is more similar to a hospital than it is a typical residence and EPA does not consider a hospital to be a household. LTCFs are licensed, residential care settings that offer their residents a wide range of services, many of which are centered on administering medications and providing healthcare by various professional healthcare providers, such as medical technicians, nurse's aides, nurses, and doctors. Other services provided involve assistance in performing activities of daily living, such as bathing and eating. Given that LTCFs are licensed settings for the care of their residents and routinely provide healthcare services, EPA believes that LTCFs more closely resemble hospitals than typical residences.

Second, we explained, the hazardous wastes generated by LTCFs do not meet the second criteria for the waste to be considered household hazardous waste. This is primarily due to the quantity and breadth of pharmaceutical wastes that are often generated on the premises of LTCFs when compared to a typical residence. This distinction about volume and breadth of waste is analogous to the distinction that EPA has made in the past about contractor or do-it-yourself waste from households: Waste from ''routine residential maintenance'' is exempt as household hazardous waste, while waste from ''building construction, renovation, demolition'' is not excluded.[166]

2. Summary of Comments

EPA received a number of comments requesting changes to the proposed definition of ''LTCF'' that were instrumental in the final definition in the rule. We also received a number of comments related to whether hazardous waste from LTCFs should be excluded from RCRA Subtitle C regulations as household hazardous waste.

3. Final Rule Provisions

Based on comments, we have made some changes to the proposed definition of LTCF. The final definition retains the descriptive portion of the definition, but the list of types of facilities included as a LTCF has been revised to be more consistent with how the term is used by DEA and the Centers for Medicare and Medicaid Services (CMS). This final rule defines ''LTCF'' as a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

The primary change we have made to the proposed definition relates to assisted living facilities. Under the proposed definition, an assisted living facility was considered a type of LTCF.

[165] See November 13, 1984; 49 FR 44978.

[166] Memo from Petruska to McNally, February 28, 1995; RCRA Online #11897 that discusses the distinction about what renovation waste is household hazardous waste and what is not.

Under the final definition, an assisted living facility is not considered a type of LTCF. This change is responsive to commenter's concerns and will make EPA's definition more consistent with how the term is used by both DEA and CMS. The DEA's definition of ''long term care facility'' is ''a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.'' [167] DEA does not consider assisted living facilities to be long-term care facilities. CMS also does not consider assisted living facilities to be long-term care facilities. One commenter pointed out that ''As primary regulatory oversight of [assisted living] resides at the state level, regulatory requirements and applicable definitions differ state by state. This is why the Centers for Medicare and Medicaid Services (CMS) excluded [assisted living] in its definition of Long Term Care Facilities.'' [168]

Furthermore, commenters argued, and EPA agrees, that assisted living facilities differ from LTCFs in at least two ways. First, some assisted living facilities do not provide medication management.[169] In some cases, assisted living facilities are actually prohibited from managing medications.[170] Second, many assisted living facilities do not have on-site nursing or other medical staff.[171] EPA believes it is easier for implementation of this rule, to make a determination about assisted living facilities as a category, rather than on the basis of whether they provide medication management of have on-site medical staff. Therefore, for ease of implementation as well as consistency with DEA and CMS, EPA is not considering assisted living facilities to be long-term care facilities for purposes of subpart P.

4. Comments and Responses

a. *Long-term care facilities and the household hazardous waste exclusion.* Aside from the comments about what types of facilities should and should not be considered LTCFs, we received many comments about whether LTCFs should be eligible to use the household hazardous waste exclusion of § 261.4(b)(1). Three states, the Hematology/Oncology Pharmacy Association, Stericycle, Inc., Healthcare Waste Institute, National Waste and Recycling Association, and Public Employees for Environmental Responsibility agreed that LTCFs should be considered healthcare facilities and therefore not eligible to use the household hazardous waste exemption. The American Society of Consultant Pharmacists and the National Community Pharmacists Association disagreed with EPA's proposed change of interpretation that hazardous waste (including pharmaceuticals) generated at LTCFs will no longer be considered exempt as household hazardous waste. The American Society of Consultant Pharmacists expressed concern that this change would be a substantial learning curve for LTCFs and the costs may be significant. Covanta Energy LLC expressed concern that the impacted facilities do not have robust financials and would pass the costs on to consumers. An assisted living community commented that the facility does not have the authority to compel residents to surrender their medications for disposal and therefore the new requirement would cause the assisted living community to be perpetually in noncompliance. One state opposed classifying group homes as healthcare facilities rather than as households. Waste Management National Services, Inc. suggested that self-administered pharmaceuticals that are under residents' control should be considered household waste.

EPA is finalizing that LTCFs are included within the final definition of healthcare facility. Accordingly, EPA is also finalizing that hazardous waste (including pharmaceuticals) generated at LTCFs will no longer be excluded as household hazardous waste: It will be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the final subpart P management standards for hazardous waste pharmaceuticals. EPA is revising its interpretation with regard to hazardous wastes generated at LTCFs based on a reevaluation of how such facilities operate. Specifically, in order for hazardous waste to qualify for the household hazardous waste exclusion of § 261.4(b)(1), it must meet the two criteria. EPA continues to believe that hazardous waste generated at LTCFs, does not meet either criterion for the household waste exclusion.

In summary, EPA is finalizing that LTCFs may no longer use the household hazardous waste exclusion. LTCFs need to manage their hazardous waste pharmaceuticals in accordance with the healthcare facility specific management standards in this final rule and their non-pharmaceutical hazardous wastes in accordance with the applicable RCRA hazardous waste generator regulations in § 262.14 (for VSQGs), § 262.16 (for SQGs), or § 262.17 (for LQGs), as well as § 262.15 (for satellite accumulation areas (SAAs)). However, even though LTCFs will no longer be eligible to use the household hazardous waste exclusion, EPA estimates that there are between 2,875 and 4,770 LTCFs that generate hazardous waste and that 98–99 percent of the facilities are VSQGs regulated under § 262.14 and therefore not subject to part 266 subpart P (except the sewer prohibition, the empty container provisions and the optional provisions of § 266.504).[172] This means that this change in policy will primarily affect the larger long-term care facilities, which are far fewer in number (1–2 percent of LTCFs).

It is also important to note that, because of the change to the definition of LTCF, this change in policy regarding the household hazardous waste exclusion and LTCFs will not impact residents in assisted living facilities. As discussed previously, assisted living facilities will not be considered healthcare facilities and therefore will continue to be considered residences that are eligible to use the household hazardous waste exclusion in 40 CFR 261.4(b)(1). Under the household hazardous waste exclusion, assisted living facilities are not required to manage their residents' hazardous waste, including their hazardous waste pharmaceuticals, under the RCRA regulations. Commenters confirmed our data that two-thirds of assisted living facilities are small facilities with 25 residents or less, many of whom would presumably be VSQGs.[173] Therefore, we believe that this revised interpretation will have minimal environmental impact: instead of assisted living facilities being exempt as VSQGs, residential waste from assisted living facilities will be exempt as household hazardous waste. That said, under RCRA, states may be more stringent than the federal government and we are aware that some states already have a more stringent interpretation and do not consider assisted living facilities to be exempt from RCRA as households.

[167] See 21 CFR 1300.01.

[168] Medicare Prescription Drug Benefit Manual—Chapter 5, § 10.2, as cited by commenter EPA–HQ–RCRA–2007–0932–0289.

[169] See comment EPA–HQ–RCRA–2007–0932–0242.

[170] See comment EPA–HQ–RCRA–2007–0932–0289.

[171] Overview of Assisted Living, 2009, A collaborative research project of American Association of Homes and Services for the Aging (AAHSA), American Seniors Housing Association (ASHA), Assisted Living Federation of American (ALFA), National Center for Assisted Living (NCAL), and National Investment Center for the Seniors Housing and Care Industry (NIC).

[172] Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[173] See commenter EPA–HQ–RCRA–2007–0932–0289.

As noted previously, EPA's household hazardous waste exclusion in 40 CFR 261.4(b)(1) exempts hazardous waste that meets two criteria: (1) It is generated on the premises of a temporary or permanent residence for individuals and (2) the waste stream is composed primarily of materials found in the waste generated by consumers in their homes.[174] Therefore, only hazardous wastes that are generated in the residential areas of an assisted living facility would be excluded as household hazardous waste. On the other hand, hazardous wastes that are generated by an assisted living facility outside of the residential areas would not be considered excluded as household hazardous waste. This interpretation regarding non-residential hazardous waste generated at assisted living is consistent with our interpretation regarding dry cleaning wastes generated at hotels. Specifically, our interpretation has been that while hazardous waste generated in hotel rooms is excluded as household waste, ''dry cleaning wastes produced by the hotel do not meet both criteria for household waste and will not qualify for the household waste exclusion.'' [175] Similarly, when it comes to assisted living facilities, this final rule will rely on the interpretation that we initially expressed in the preamble to the proposed rulemaking to add pharmaceuticals to Universal Waste: ''the [long-term care] facility itself may generate hazardous waste as a result of its central management of pharmaceuticals in its pharmacy or pharmacy-like area. These hazardous pharmaceutical wastes would be subject to the RCRA hazardous waste generator regulations since the pharmaceuticals are under the control of the facility, and thus, the resulting wastes are generated by the facility. However, patients and residents in long-term care facilities may generate hazardous wastes. Those pharmaceuticals that are under the control of the patient or resident of this LTCF, when discarded, would be subject to RCRA's household hazardous waste exclusion (§ 261.4(b)(1)). Hazardous pharmaceutical wastes generated by the resident are excluded from regulation because they are considered to be derived from the household.'' [176]

Under the final rule, group homes and independent living communities are also not defined as LTCFs but rather are considered residences that are eligible to use the household hazardous waste exclusion. An assisted living facility, group home and independent living facility are eligible for the household hazardous waste exclusion whether they are stand-alone facilities, or whether they are part of a continuing care retirement community. Conversely, a nursing facility or skilled nursing facility is considered a LTCF, and hence a healthcare facility, whether it is a stand-alone facility or part of a continuing care retirement community. Therefore, a continuing care retirement community will likely have portions of the facility that are excluded from RCRA regulation as households, while other portions of the facility will be regulated under RCRA for their hazardous waste generation and management, including hazardous waste pharmaceuticals.

b. *Other comments.* Commenters asked us to clarify the difference in regulatory status between in-home hospice care and in-patient hospice facilities. One commenter points out that ''Most hospice care is provided in the private residence of a patient.'' [177] Hazardous waste pharmaceuticals that are generated by in-home medical care, such as in-home hospice care, would be eligible for the household hazardous waste exclusion. On the other hand, hospice *facilities* are not considered residences and are not eligible for the household hazardous waste exclusion. Nevertheless, as discussed in section XII.D. of this preamble, long-term care facilities, including hospice facilities, that have 20 beds or fewer will be presumed to be VSQGs. Healthcare facilities that are VSQGs are subject to the sewer prohibition for hazardous waste pharmaceuticals under this final rule, the empty container standards in § 266.507, and the optional provisions of § 266.504, but otherwise are regulated by the reduced regulations of 40 CFR 262.14 for the generation and accumulation of hazardous waste, including hazardous waste pharmaceuticals.

IX. Applicability (§ 266.501)

Part 266 subpart P was proposed to replace the standard RCRA generator regulations in part 262 for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. We proposed separate regulations for healthcare facilities and reverse distributors. Further, we proposed separate regulations for the management of the two types of hazardous waste pharmaceuticals—potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals. When a healthcare facility disposes hazardous waste pharmaceuticals directly by sending it to a hazardous waste treatment, storage, or disposal facility, we proposed that these would be considered non-creditable hazardous waste pharmaceuticals. On the other hand, when a healthcare facility disposes of hazardous waste pharmaceuticals indirectly through a reverse distributor that facilitates manufacturer credit, we proposed that these would be considered potentially creditable hazardous waste pharmaceuticals. We proposed that when a reverse distributor receives the potentially creditable pharmaceuticals, it must evaluate them to determine whether they need to go onto another reverse distributor, in which case the pharmaceuticals would still be considered potentially creditable, or whether they will go to a TSDF, in which case they will be considered evaluated hazardous waste pharmaceuticals. Although EPA proposed that potentially creditable pharmaceuticals destined for reverse distributors would be considered hazardous wastes, we also recognized that due to the considerable value they retain in the form of potential credit from manufacturers, there was a strong incentive to manage them appropriately and we did not need to apply the standard RCRA regulations to them or to the reverse distributors that manage them. In contrast, once the credit has been established for the evaluated hazardous waste pharmaceuticals, the incentive to manage them appropriately no longer exists and we needed to apply more rigorous regulations. This section of the preamble discusses the types of facilities and pharmaceuticals that are and are not subject to this rulemaking. Subsequent sections of the preamble discuss the details of the regulations for healthcare facilities managing non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals as well as the regulations that pertain to reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated pharmaceuticals.

A. What facilities are subject to the final rule?

1. Healthcare Facilities (§§ 262.10(n) and 266.501(d))

a. *Summary of proposal.* The Agency proposed that healthcare facilities that

[174] 49 FR 44978; November 13, 1984.

[175] See RCRA Online #13736, March 1995.

[176] See 73 FR 73525, December 2, 2008. Note that while the Universal Waste proposal used the term ''hazardous pharmaceutical wastes,'' this final rule uses the term ''hazardous waste pharmaceuticals''.

[177] CareFirst, Commenter EPA–HQ–RCRA–2007–0932–0239.

are not VSQGs will be required to manage all hazardous waste pharmaceuticals generated at their facilities in accordance with the new part 266 subpart P (see § 262.10(n)) in lieu of the part 262 generator regulations. In other words, we proposed that these new management standards apply to any healthcare facility that generates more than 100 kg of hazardous waste per calendar month *or* more than 1 kg of acute hazardous waste per calendar month (*e.g.,* P-listed hazardous waste) *or* more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e) per calendar month. We proposed that part 266 subpart P applies to all healthcare facilities that generate above the VSQG monthly quantity limits, including LTCFs.

Further, we proposed that subpart P is not optional for healthcare facilities that generate above the VSQG monthly quantity limits. EPA proposed to make subpart P mandatory to promote national consistency, a goal championed by stakeholder comments as well as EPA. We reasoned that having one set of standards applicable to hazardous waste pharmaceuticals would be less confusing to the regulated community, which should lead to better compliance.

We also proposed that any healthcare facility that generates hazardous waste above VSQG limits is subject to the same set of standards for the management of its hazardous waste pharmaceuticals. That is, unlike under part 262, the stringency of the proposed regulations for healthcare facilities operating under part 266 subpart P does not increase as the amount of hazardous waste generated increases. Put another way, we proposed that there is no generator category for hazardous waste pharmaceuticals under part 266 subpart P. The SQG and LQG categories under the part 262 RCRA requirements will only be relevant for the healthcare facilities' non-pharmaceutical hazardous waste because non-pharmaceutical hazardous waste remains subject to those 40 CFR part 262 generator regulations (along with other applicable sections of the subtitle C regulations).

We proposed that healthcare facilities generating non-creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.502, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.508.

We proposed that healthcare facilities generating potentially creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.503, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.509.

We expect that most potentially creditable hazardous waste pharmaceuticals will be sent to reverse distributors; however, that may not always be the case. For example, in some cases, manufacturer credit can get awarded without having to physically send the potentially creditable hazardous waste pharmaceuticals to a reverse distributor. In such cases, we proposed that if they are not destined for a reverse distributor, then they must be managed by the healthcare facility as non-creditable hazardous waste pharmaceuticals.

b. *Summary of comments.* Comments on the applicability section addressed several main areas of concern. First, commenters weighed in on whether the VSQGs should be subject to part 266 subpart P in its entirety, as opposed to just the sewer prohibition. Second, commenters weighed in on whether the new subpart should be mandatory. Third, commenters weighed in on our proposed revision to our policy related to the reverse distribution of pharmaceuticals. While some commenters agreed with our proposed revised position that pharmaceuticals going through reverse distribution would be considered solid waste, many commenters strongly objected to our proposed revised position. We have made several changes to the final regulations that affect applicability, although several of these changes are to definitions, rather than to the applicability section of § 266.501. The primary focus of this section is to discuss changes made to the applicability section of § 266.501, although changes to definitions that affect applicability are also noted.

c. *Final rule provisions.* The final rule applies to all healthcare facilities that generate above any of the VSQG monthly quantity thresholds. Healthcare facilities that are not VSQGs do not have the choice of opting into part 266 subpart P in lieu of part 262. Further, all healthcare facilities that are subject to part 266 subpart P are regulated the same with respect to their hazardous waste pharmaceuticals, regardless of how much hazardous waste pharmaceuticals they generate. Note that we have made two changes to § 262.10(n). First, we have revised the regulations so that only a healthcare facility that *generates* above the VSQG quantity thresholds are subject to part 266 subpart P. A healthcare facility that *accumulates* above the VSQG quantity thresholds would not be subject to part 266 subpart P; it would remain subject to part 262 (although as with any VSQG, it would be allowed to opt into subpart P). The 2016 Hazardous Waste Generator Improvements final rule amended the part 262 regulations to make it clear that a VSQG that accumulates above the quantity thresholds must manage its hazardous waste in accordance with the conditions of either the SQG or LQG regulations, but the generator would remain a VSQG.[178] Second, in response to comments, we have added the following clarifying sentence at the end of the paragraph: A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to part 266 subpart P, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.[179]

We have made four changes to the proposed regulatory language of § 266.501(d). First, we have made a conforming change to reflect the change in terminology in this final rule. That is, in § 266.501(d)(1)(ii), ''pharmaceutical reverse distributor'' has now been replaced by ''reverse distributor.'' The second change we made is to omit the reference to § 266.504 in both § 266.501(d)(1) and (2). Section 266.504 only applies to healthcare facilities that are VSQGs and should not have been referenced when discussing the requirements for other healthcare facilities. The third change is to clarify in § 266.501(d)(2), that healthcare facilities managing potentially creditable hazardous waste pharmaceuticals are also subject to the notification and withdrawal standards of § 266.502(a). While EPA believes it is extremely unlikely that a healthcare facility would only manage potentially creditable hazardous waste pharmaceuticals, as proposed, in this situation a healthcare facility would not need to notify as a healthcare facility. EPA is clarifying in the final rule, that

[178] See § 262.14(a)(3) for accumulating >1 kg of acute hazardous waste and § 262.14(a)(4) for accumulating >1000 kg non-acute hazardous waste.

[179] See comment number EPA–HQ–RCRA–2007–0932–0341.

should this situation arise, a healthcare facility only managing potentially creditable hazardous waste pharmaceuticals and no non-creditable hazardous waste pharmaceuticals is subject to notification.

The fourth, and far more substantive change we made is to § 266.501(d)(2). This paragraph has been revised to reflect our decision that healthcare facilities are regulated under part 266 subpart P for the management of prescription hazardous waste pharmaceuticals going through reverse distribution but healthcare facilities are not regulated under part 266 subpart P for the management of nonprescription pharmaceuticals, such as OTCs, homeopathic drugs, and dietary supplements, going through reverse logistics because they are not considered solid or hazardous wastes, provided they have the potential to be lawfully redistributed or legitimately reused or reclaimed. To summarize, part 266 subpart P applies to healthcare facilities managing *non-creditable* hazardous waste pharmaceuticals, whether the pharmaceuticals are prescription or nonprescription. But part 266 subpart P applies to healthcare facilities managing *potentially creditable* hazardous waste pharmaceuticals only if they are prescription hazardous waste pharmaceuticals. The comments we received in this area and the reasoning for our decision have been discussed at length in section VI of the preamble to this final rule.

Due to changes in the definition of healthcare facility and LTCF, there are effectively additional substantial changes to the applicability of the final rule. These two definitional changes have already been discussed, but are summarized here. In short, due to changes to the definition of ''healthcare facility,'' wholesale distributors will now be regulated under part 266 subpart P as healthcare facilities for the management of their hazardous waste pharmaceuticals. This includes 3PLs when they perform the function of a wholesale distributor. Unlike wholesale distributors, 3PLs do not take ownership of the pharmaceuticals; however, both wholesale distributors and 3PLs take physical custody of pharmaceuticals. Under RCRA, a 3PL would meet the definition of a hazardous waste generator, regardless of whether they own the hazardous waste pharmaceuticals.

The final rule still applies to long-term care facilities, because they are still considered healthcare facilities. However, we have amended the proposed definition of LTCF such that assisted living facilities will not be considered long-term care facilities. Further, we have finalized a rebuttable presumption that long-term care facilities with 20 beds or fewer will be presumed to be VSQGs. The combined impact of these changes is that this final rule will apply to far fewer long-term care facilities than the when the rule was proposed.

In other respects, § 266.501(d) of the final rule remains the same as the proposal. That is, healthcare facilities generating non-creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.502, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.508. And healthcare facilities generating potentially creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.503, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.509. Finally, if potentially creditable hazardous wastes are not destined for a reverse distributor, then they must be managed by the healthcare facility as non-creditable hazardous waste pharmaceuticals. For example, if a healthcare facility receives manufacturer credit for a prescription pharmaceutical without shipping it to a reverse distributor, then the healthcare facility is required to manage the hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals.

d. *Comments and responses.* Several commenters asked us to consider making part 266 subpart P an optional alternative to part 262, instead of mandatory. They argued that EPA's previous sector- or waste-specific regulations, such as the Academic Laboratories Rule or Universal Waste, are not mandatory and that generators have the option to use them in lieu of the standard RCRA generator regulations under part 262. On the other hand, several states agreed that having ''one set of standards will be less confusing to the regulated community.'' [180]

As discussed previously, part 266 subpart P will be mandatory for all healthcare facilities generating above VSQG monthly quantity thresholds. Previous sector or waste specific regulations have all been considered either less stringent (Universal Waste) or equally stringent (Academic Laboratories rule) as the standard RCRA generator regulations. In contrast, part 266 subpart P is considered, on the whole, more stringent than the standard RCRA regulations. EPA has never made a more stringent RCRA regulation optional. In part, this is because it seems unlikely that anyone would opt into a more stringent regulatory scheme. If healthcare facilities chose to remain operating under part 262, they would not be subject to the sewer prohibition, which is a cornerstone of this new subpart.

Further, if part 266 subpart P were not mandatory, another result would be that healthcare facilities would not be able to use the new provisions for empty containers or the conditional exemptions for hazardous waste pharmaceuticals that are also DEA controlled substances. But the most important consideration is that this final rule revises our previous policy regarding pharmaceuticals being sent to reverse distributors for manufacturer credit such that they are now considered solid, and possibly hazardous, wastes. Under part 262, a generator can only send its hazardous waste to an off-site facility that has a RCRA permit or interim status. This would require reverse distributors to get RCRA storage permits to be able to accept hazardous waste from off-site. In light of all these considerations, with the exception of VSQG healthcare facilities, EPA has concluded that it is not feasible to make part 266 subpart P an optional alternative to part 262.

That said, we recognize that some commenters are concerned that this final rule will impact their established programs for managing hazardous waste pharmaceuticals. In response, we would point out that, in some cases, compliant practices by healthcare facilities under part 262 would also meet the standards under part 266 subpart P. For example, the training provisions for SQGs (§ 262.16(a)(9)(iii)) and LQGs (§ 262.17(a)(7)) would meet the training provisions for healthcare facilities under part 266 subpart P (§ 266.502(b)). In fact, the subpart P regulatory language for training personnel at healthcare facilities in managing non-creditable hazardous waste pharmaceuticals is identical to the regulatory language in part 262 for SQGs. For labeling, under part 266 subpart P, containers of non-creditable hazardous waste pharmaceuticals part 266 subpart must

[180] See comment numbers: EPA–HQ–RCRA–2007–0932–0242 and EPA–HQ–RCRA–2007–0932–0304.

be labeled with the words ''hazardous waste pharmaceuticals,'' but nothing would prohibit additional labeling by the healthcare facility. Likewise, under part 266 subpart P, healthcare facilities are not required to accumulate their non-creditable hazardous waste pharmaceuticals in a central accumulation area (CAA), but nothing would prohibit them from being accumulated in a CAA. Furthermore, healthcare facilities have up to one year to accumulate non-creditable hazardous waste pharmaceuticals on site under part 266 subpart P, but nothing would prohibit a healthcare facility from accumulating for the shorter time-frames dictated by the SQG (180 days) or LQG (90 days) regulations in part 262.

2. Reverse Distributors (§§ 262.10(m), 264.1, 265.1, 266.501(e), and 270.1)

a. *Summary of proposal.* The proposed rulemaking responded to stakeholders who have asked EPA to clarify how reverse distributors are regulated under RCRA, as states have applied varied hazardous waste regulatory approaches to reverse distributors.[181] EPA proposed specific standards in 40 CFR part 266 subpart P for reverse distributors (as defined in this proposed rulemaking) that incorporated various generator standards, as well as some TSDF standards. EPA proposed that reverse distributors that accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are subject to this new subpart. We proposed that reverse distributors are only subject to part 266 subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals; if a reverse distributor also treats and/or disposes of hazardous waste pharmaceuticals, we proposed that it would be subject to the applicable RCRA Subtitle C TSDF regulations, including the requirement to have a permit or interim status. We proposed that all reverse distributors would be regulated the same for the accumulation of hazardous waste pharmaceuticals under part 266 subpart P, including any reverse distributors that would be considered VSQGs under part 262 (see § 262.10(m)). Under the applicability section in § 266.501(e), we proposed that reverse distributors would be subject to the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, the shipping standards in § 266.508 and § 266.509, and the reverse distributor standards in § 266.510, for the management of hazardous waste pharmaceuticals. As with healthcare facilities, if a reverse distributor generates other, non-pharmaceutical hazardous waste, it remains subject to part 262 and all other applicable portions of the Subtitle C regulations (see § 266.501(c)).

b. *Summary of comments.* We received a large number of comments regarding the foundational question of whether the pharmaceuticals going through reverse distribution should be considered solid or hazardous wastes. In section VI of the preamble we have responded thoroughly to that threshold question; therefore, we do not elaborate here. We received a few comments on other areas related to the applicability of part 266 subpart P to reverse distributors, which have led to some conforming changes in the final rule.

c. *Final rule provisions.* Other than changing the term ''pharmaceutical reverse distributor'' to ''reverse distributor,'' we are finalizing the regulatory text of § 262.10(m) and § 266.501(e), as proposed. As a result, all reverse distributors will be subject to part 266 subpart P for the management of their hazardous waste pharmaceuticals instead of part 262. This includes any reverse distributors that would have been considered VSQGs under part 262. This also includes third-party logistics providers (3PLs) when they perform the function of a reverse distributor. Reverse distributors and 3PLs acting as reverse distributors do not take ownership of the pharmaceuticals; however, both take physical custody of hazardous waste pharmaceuticals from off-site healthcare facilities and both facilitate the awarding of manufacturer credit for potentially creditable hazardous waste pharmaceuticals.

Under part 266 subpart P, there are no generator categories for the accumulation of hazardous waste pharmaceuticals; all reverse distributors will be regulated the same with respect to the management of their hazardous waste pharmaceuticals, regardless of the quantity. All reverse distributors will be subject to the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, the shipping standards in § 266.508 and § 266.509, and the reverse distributor standards in § 266.510, for the management of hazardous waste pharmaceuticals.

d. *Comments and responses.* It is important to note that, although we have not made any substantive changes to the applicability section of the regulations pertaining to reverse distributors, a change we have made to the definition of reverse distributor has effectively made a change to the applicability of the final rule. Under the final rule, the term ''reverse distributor'' has been narrowed considerably, so that it only includes reverse distributors of prescription pharmaceuticals. This change has been described and explained thoroughly in previous sections of the preamble and will be discussed here only briefly. In short, under the proposed rulemaking, the term ''pharmaceutical reverse distributor'' included facilities that facilitated manufacturer credit for both prescription and nonprescription pharmaceuticals (*e.g.,* OTCs and dietary supplements). In this final rule, we have adopted the distinction drawn by commenters between reverse distributors, who manage prescription pharmaceuticals, and reverse logistics centers, who manage nonprescription pharmaceuticals (and all other, non-pharmaceutical retail items). While reverse distributors are regulated by part 266 subpart P, reverse logistics centers are not regulated by part 266 subpart P.

Additionally, we have made several conforming changes to §§ 264.1, 265.1 and 270.1. Specifically, we added paragraphs §§ 264.1(g)(13), 265.1(c)(16), and 270.1(c)(2)(x). Together, these paragraphs make it clear that reverse distributors complying with the conditions for accumulating hazardous waste pharmaceuticals under part 266 subpart P are not required to operate under the regulations for permitted TSDFs in part 264 or interim status TSDFs in part 265; nor are they required to get a RCRA permit under part 270.

3. Very Small Quantity Generators (§§ 266.501(a) and (b))

a. *Summary of proposal.* VSQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 262.14.[182] We proposed that subpart P would preserve

[181] Note that the proposed rule used the term ''pharmaceutical reverse distributor'' but final rule uses the term ''reverse distributor;'' therefore, the preamble will use the term ''reverse distributor,'' even when discussing the proposed rule.

[182] Not all authorized states recognize the VSQG (or CESGQ) category and may have more stringent regulatory requirements for VSQGs. Therefore, as noted previously, EPA recommends that facilities that qualify as VSQGs under the federal regulations contact their state and/or local environmental regulatory agencies to determine whether more stringent regulatory requirements apply to VSQGs in their state.

this current regulatory structure for the most part, such that healthcare facilities that generate hazardous waste pharmaceuticals and qualify as VSQGs would maintain their conditional exemption under § 262.14 and would not be subject to *most* aspects of the proposal. However, as part of this rulemaking, EPA proposed a prohibition on sewer disposal of hazardous waste pharmaceuticals by all healthcare facilities, including VSQG healthcare facilities (and all reverse distributors). (See section XIII of this preamble for a more detailed discussion on the sewer prohibition.) We also proposed that healthcare facilities that are VSQGs would be able to use the standards in § 266.504 for the management of their hazardous waste pharmaceuticals, as well as the standards in § 266.507 for determining when their containers of pharmaceutical are considered empty (See sections XII and XV for detailed discussion of those sections of the regulations). We also proposed that VSQG healthcare facilities would have the ability to opt into using part 266 subpart P in lieu of the conditional exemption in § 262.14.

b. *Summary of comments.* Many of the comments on the applicability section for VSQG healthcare facilities were related to whether EPA should maintain the conditional exemption for VSQG healthcare facilities or whether we should make them fully subject to subpart P. Several commenters urged us to be clearer in our regulatory language and preamble about how a healthcare facility determines whether it is a VSQG or not. Although this section will address this area of confusion, see section IX.C of the preamble for additional information about not counting hazardous waste pharmaceuticals toward generator category when they are managed under subpart P.

c. *Final rule provisions.* In the final rule, healthcare facilities that are VSQGs (when counting all their hazardous waste, both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste) remain mostly exempt from part 266 subpart P. Note that all healthcare facilities, including healthcare facilities that are VSQGs, and all reverse distributors are subject to the sewer prohibition of § 266.505.

Healthcare facilities that are VSQGs are also subject to § 266.504 which includes optional provisions specifically for healthcare facilities that are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. We note that although § 266.501(a) states that VSQGs are subject to § 266.504, all of the provisions in § 266.504 are optional. For example, a healthcare facility that is a VSQG operating under § 262.14 for all of its hazardous waste is not required to send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Rather, we are providing a regulatory mechanism that allows a VSQG healthcare facility to use a reverse distributor to obtain manufacturer credit. Nor is a VSQG healthcare facility required to send its hazardous waste pharmaceuticals off site to be consolidated at another healthcare facility that is operating under subpart P. Again, subpart P provides a regulatory mechanism for those VSQG healthcare facilities that wish to manage their hazardous waste pharmaceuticals in a more environmentally protective manner. A VSQG that elects to use any of the optional provisions of § 266.504 will not be considered to be opting into subpart P. See section XII of the preamble for a further discussion of § 266.504.

Several states asked us to expand the applicability of the final rule so that all of the healthcare facility standards in part 266 subpart P would be mandatory for all healthcare facilities, including VSQGs. For example, Colorado wrote that ''. . . healthcare professionals can be highly mobile across the healthcare industry. As a result, professionals that leave a hospital setting and move to the [long-term care] setting have to relearn a new process for waste management, adding opportunity for more confusion and mismanagement. Colorado strongly encourages EPA to consider regulating all healthcare facilities (including CESQGs) that generate hazardous waste pharmaceuticals under the proposed regulations to minimize confusion and promote consistency across the entire spectrum of the healthcare industry settings.'' [183] Although we agree with Colorado, we also believe that it would pose a burden on the large number of small healthcare facilities and divert resources from regulatory agencies to expand the applicability of the final rule to include healthcare facilities that are VSQGs. We have concluded that it would be best to let the individual states that adopt this new subpart to decide whether to expand the applicability to healthcare facilities that are VSQGs.

Additionally, in the final rule we have retained the ability for healthcare facilities that are VSQGs to opt into part 266 subpart P in lieu of operating under § 262.14. A VSQG healthcare facility may choose this option if it does not want to have to keep track of how much hazardous waste pharmaceuticals and acute hazardous waste pharmaceuticals it is generating on a monthly basis or if it generates an unpredictable or fluctuating amount of hazardous waste pharmaceuticals each month that might exceed one or more of the VSGQ monthly quantity thresholds. If a healthcare facility that is a VSQG (counting all of its hazardous waste, including pharmaceuticals and non-pharmaceuticals) chooses to opt into subpart P, it must comply with all the standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals, including notification as a healthcare facility.[184] The VSQG healthcare facility may not selectively pick which provisions of part 266 subpart P it chooses to comply with; it would be treated the same as any other healthcare facility that is subject to part 266 subpart P. More specifically, if a VSQG healthcare facility chooses to opt into subpart P, then it would be subject to all the provisions identified in § 266.501(d) rather than the optional provisions of § 266.504 for VSQGs or § 262.14. The final regulatory language has been amended to be more specific in this regard. That is, rather than saying a healthcare facility has the option of complying with ''this subpart,'' we have changed the regulations to say that a healthcare facility has the option of complying with ''§ 266.501(d),'' which identifies the specific sections of the regulations that non-VSQG healthcare facilities must comply with. Further, the final regulatory language clarifies that a VSQG healthcare facility that opts into part 266 subpart P would no longer be able to use the optional provisions for VSQG healthcare facilities in § 266.504.

We have made four additional changes to the applicability section of the regulations pertaining to healthcare facilities that are VSQGs. The first two changes are conforming changes to reflect the 2016 Hazardous Waste Generator Improvements final rule; this includes changing the term ''conditionally exempt small quantity generator'' to ''very small quantity generator'' and changing the regulatory citation for VSQGs from § 261.5 to § 262.14.

[183] See comment number: EPA–RCRA–HQ–2007–0932–0242.

[184] A VSQG healthcare facility that opts into part 266 subpart P for managing its hazardous waste pharmaceuticals would still have to keep track of its monthly generation of non-pharmaceutical hazardous waste to verify that it is, in fact, a VSQG. Assuming it is a VSQG, the healthcare facility could manage its non-pharmaceutical hazardous waste under § 262.14.

The third change was made to address commenters' concerns that the use of the term VSQG in § 266.501(a) and (b) was confusing. The Generator Improvements final rule has now defined the term VSQG in 260.10, which should help reduce confusion. Nevertheless, in response to the comments, we also have added language to § 266.501(a) and (b) to make it clearer that we are referring to VSQGs that are below the VSQG quantity thresholds for all of their hazardous waste combined—including both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. Such VSQGs are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. In large part, VSQGs are not subject to subpart P for the management of their hazardous waste pharmaceuticals (except the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional standards of § 266.504). This type of VSQG stands in contrast to what might be referred to as a ''subpart P VSQG,'' meaning a healthcare facility that generates over one or more of the VSQG quantity thresholds and is therefore subject to subpart P for its hazardous waste pharmaceuticals but becomes a VSQG for its non-pharmaceutical hazardous waste after complying with subpart P because it is no longer required to count its hazardous waste pharmaceuticals toward its generator category.

The fourth change to § 266.501(a) is to the reference to the new empty container regulations of § 266.507. We proposed in § 266.501(a) that a VSQG would be subject to § 266.507(a) and (b). In both the proposed and final rules, these two paragraphs of § 266.507 define when unit dose containers and dispensing vials, and syringes, respectively, are empty. The purpose of the reference was to allow a healthcare facility to use the new empty container provisions in determining how much hazardous waste pharmaceuticals it generates and therefore whether it is subject to subpart P. Under the final rule, a healthcare facility is still able to use the new empty container provisions in § 266.507 when determining how much hazardous waste pharmaceuticals it generates, but we have concluded that this reference should include all of § 266.507, rather than just paragraphs (a) and (b) because § 266.507 (c) and (d) include provisions for determining whether IV bags and other types of containers of hazardous waste pharmaceuticals are empty. Additionally, we have also amended the associated language in § 261.7 which defines when a container of hazardous waste is considered empty. We had already proposed to add a new paragraph (c) to § 261.7 to direct healthcare facilities and reverse distributors to § 266.507. The final rule modifies the proposed paragraph such that the new empty container regulations in § 266.507 are no longer limited to healthcare facilities and reverse distributors operating under part 266 subpart P. Section 266.507 defines when containers of hazardous waste pharmaceuticals are empty and apply regardless of whether they are being managed by a healthcare facility, a reverse distributor, or another entity. Generators, including healthcare facilities, can use the new provisions in § 266.507 in determining when the containers of hazardous waste pharmaceuticals are empty and the residues are no longer regulated as hazardous waste. In turn, this will help generators determine how much hazardous waste they generate and; therefore, whether they are subject to part 266 subpart P and/or part 262. See section XV of this preamble for further information about § 266.507.

d. *Comments and responses.* A few commenters had suggestions for alternative organization or placement of the applicability section pertaining to healthcare facilities that are VSQGs. One commenter suggested that we combine all of the subpart P regulations that pertain to VSQG healthcare facilities in one place, under § 266.504, rather than have some in § 266.501 and others in § 266.504.[185] We generally agree with the commenter and have included all substantive standards for VSQG healthcare facilities in § 266.504 (see section XII of the preamble for a further discussion of § 266.504). However, we believe that, when discussing the central question of who the subpart applies to, it is best to keep together in § 266.501 all the regulations that address applicability. And since the applicability section of § 266.501 appears before the VSQG healthcare facility standards of § 266.504, we believe that it is more helpful to the reader to know, up front in the regulations, whether the subpart applies. Another commenter thought we should move the entire applicability section so that it appears before the definitions section in the regulations, in order to allow ''the reader to determine if [s]ubpart P applies to his facility before reviewing any of its requirements.'' [186] Although we agree that the applicability section is critical to the reader, we believe that the reader must have a full understanding of terms used in the applicability section in order to accurately determine whether the subpart applies. As a result, we have declined to make this suggested change. We requested comment on whether the applicability section for VSQG healthcare facilities should appear in § 262.14 (formerly § 261.5) rather than in subpart P and a couple of commenters responded that we should.[187] Although that would have been an acceptable option for crafting the new regulations, we have concluded that we prefer the option of keeping the regulatory language related to hazardous waste pharmaceuticals contained within the same subpart when possible. As a result, we have declined to make this suggested change, as well.

B. What facilities or pharmaceuticals are not subject to the final rule? (§§ 266.501(c) and 266.501(f) and 266.501(g))

1. Summary of Proposal

EPA proposed that the new part 266 subpart P management standards would apply only to hazardous waste pharmaceuticals generated or managed by healthcare facilities and reverse distributors. This new subpart was designed as a sector-specific rulemaking to address the unique circumstances of the healthcare sector and the reverse distribution of their hazardous waste pharmaceuticals. In § 266.501(f), we proposed that other entities that generate or manage hazardous waste pharmaceuticals would not be subject to part 266 subpart P, but would remain subject to the standard generator regulations in part 262, along with other applicable Subtitle C regulations. For example, in the preamble to the proposed rulemaking we stated that pharmaceutical manufacturers and wholesalers would remain subject to part 262 generator regulations because they do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals. We reasoned that manufacturers and wholesalers generate hazardous waste pharmaceuticals that are more predictable and the staff have the necessary expertise to determine which pharmaceuticals are considered hazardous waste. However, we noted in the proposal that when any facility, including a pharmaceutical

[185] See comment number: EPA–HQ–RCRA–2007–0932–0280.

[186] See comment number: EPA–HQ–RCRA–2007–0932–0231.

[187] See comment numbers: EPA–HQ–RCRA–2007–0932–0231 and 0280.

manufacturer, meets the definition of a reverse distributor, it would be subject to the new regulations for reverse distributors with respect to those operations.

In § 266.501(c), we also proposed that this new subpart would only apply to the management of hazardous waste pharmaceuticals. The proposed new subpart was sector-specific as well as waste stream-specific. We proposed that other, non-pharmaceutical hazardous wastes generated or managed by healthcare facilities and reverse distributors would remain subject to all applicable hazardous waste regulations.

2. Final Rule Provisions and Comments and Responses

This final rule remains a sector-specific rule as well as a waste stream-specific rule. Accordingly, § 266.501(c) of the final rule remains as proposed. That is, a healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste. Likewise, as discussed previously, a number of commenters requested that we include wholesale distributors in part 266 subpart P as healthcare facilities and in response we have amended the definition of healthcare facility to include wholesale distributors. This, of course, affects which entities are subject to the rule, but as we have made this change through amending the definition of healthcare facility, it does not necessitate a change to § 266.501 of the regulations, which is entitled Applicability. Therefore, the final rule applies to the generation and management of hazardous waste pharmaceuticals only by healthcare facilities and reverse distributors and not to others that might generate or manage hazardous waste pharmaceuticals, such as pharmaceutical manufacturers.

We have added paragraph (g) to § 266.501 of the final rule, substantially expanding the list of types of wastes that are not subject to part 266 subpart P or to RCRA regulation in general. In some cases, the additions grew out of comments and in some cases, the additions grew out the need for additional clarity. Each of the types of waste that are not subject to this subpart are discussed individually below.

a. *Donations.* As discussed previously, we have amended the definition of hazardous waste pharmaceutical to make it clear that a pharmaceutical is not a solid waste, as defined in § 261.2, and therefore, not a hazardous waste, if it is lawfully donated for its intended purpose. We have made the same change to the applicability section of this subpart to similarly indicate that pharmaceuticals are not subject to subpart P when they are lawfully donated for their intended purpose.[188] In fact, because pharmaceuticals that are lawfully donated or are otherwise legitimately used/reused or reclaimed are not solid wastes, as defined by § 261.2, they would not be subject to RCRA at all. Although this is common for nonprescription pharmaceuticals, it is rare for prescription pharmaceuticals. Sirum, a commenter that is a non-profit organization that ''helps implement State-based programs to recycle unused medication to indigent patients'' in four states, concurred that ''repurposing pharmaceuticals happens under narrow circumstances'' and that ''in most cases, pharmaceuticals transported back to a reverse distributor are discarded by the reverse distributor.'' [189] State donation and repository laws dictate the conditions under which pharmaceuticals may be donated. These laws are tracked by the National Conference of State Legislatures.[190] EPA would note that, in addition to the state regulations, the FDA has guidelines for the donation of pharmaceuticals for international relief efforts,[191] as does the World Health Organization (WHO).[192]

Sirum is providing a valuable and commendable service and EPA does not wish to impede their operations, which support the waste minimization goal of RCRA. We have amended both the definition of hazardous waste pharmaceutical and the applicability section to clarify that pharmaceuticals that are lawfully donated are not solid or hazardous wastes and therefore are not subject to RCRA, including this subpart. This would include donations to a charity, non-governmental organization, or to a healthcare facility that is participating in a donation or repository program that is authorized by the state. EPA concurs with Sirum that this should act ''as an incentive and path forward for socially responsible reverse distributors [and others] to donate rather than destroy pharmaceuticals within the safety of existing state laws that allow for these practices.'' [193]

b. *Over-the-counter pharmaceuticals going through reverse logistics.* As discussed at length in section VI of the preamble, OTC pharmaceuticals, and other items meeting our definition of pharmaceutical that do not require a prescription, such as dietary supplements, or homeopathic drugs, will only be subject to this subpart when they are discarded by a healthcare facility. OTCs and other nonprescription pharmaceuticals are not considered solid or hazardous wastes when they are sent through reverse logistics for the purpose of determining whether they can be redistributed for their intended purpose or legitimately reused or reclaimed. We have added § 266.501(g)(2) to the applicability section to codify this position regarding OTC pharmaceuticals, dietary supplements and homeopathic drugs.

c. *Recalled hazardous waste pharmaceuticals.* The Agency initially proposed standards for recalled non-creditable hazardous waste pharmaceuticals at healthcare facilities in § 266.502(g)(3), and for potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors in § 266.510(a)(5). The finalized recall provisions for all hazardous waste pharmaceuticals are now in the applicability section in § 266.501(g)(3) and (4).

The Agency proposed that healthcare facilities managing recalled non-creditable hazardous waste pharmaceuticals could request an extension from the EPA Regional Administrator should they need to accumulate them for longer than the allotted one-year period. Likewise, the Agency proposed that reverse distributors managing recalled potentially creditable hazardous waste pharmaceuticals could request an extension from the EPA Regional Administrator should they need to accumulate them for longer than the allotted 90-day period. In the proposed regulations, the reasons for requesting an extension were characterized as ''any unforeseen circumstances beyond the control'' of the healthcare facility or reverse distributor. In the proposed preamble, we gave the specific examples of recalls and litigation as circumstances that are the beyond the control of the healthcare facility or reverse distributor, which could require longer accumulation than the proposed time frames. The proposed provision in both sections required that an extension

[188] See 40 CFR 266.501(g)(1).

[189] See comment number EPA–HQ–RCRA–2007–0932–0353.

[190] *http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.*

[191] See Questions and Answers for the Public Donating Drugs to International Humanitarian Relief Efforts *https://www.fda.gov/downloads/newsevents/publichealthfocus/ucm249617.pdf.*

[192] *http://www.who.int/selection_medicines/emergencies/guidelines_medicine_donations/en/.*

[193] See comment number EPA–HQ–RCRA–2007–0932–0353.

request be sent in writing (electronic or paper) to the EPA Regional Administrator explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals accumulated beyond the corresponding time period, and the amount of extra time requested. The Agency also proposed to allow the Regional Administrator discretion to grant, modify, or deny extension requests on a case-by-case basis. Lastly, the Agency solicited comment on the proposed mechanism to request a time extension.

The proposed recall provisions only applied to hazardous waste pharmaceuticals that had limited accumulation times, *i.e.,* non-creditable hazardous waste pharmaceuticals at healthcare facilities, and potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors. The finalized recall provisions, however, apply to all recalled hazardous waste pharmaceuticals.

These proposed extension provisions were opposed by many commenters from both industry and state governments. Industry commenters were concerned about the additional burden that would arise from having to generate, transmit, and maintain an additional set of records every time they would need to request an extension of the accumulation time period. The commenters suggested that these situations occur more often than EPA indicated in the proposal. Similarly, many state agencies were concerned about the added burden imposed on them by requiring notifications that must be processed, analyzed, afforded appropriate consideration, and responded to. In addition, many commenters mentioned the possibility that these provisions would conflict with other federal oversight authorities, in particular, recalls overseen by the FDA and CPSC. Commenters were also wary of the discretion these proposed provisions afforded the Regional Administrator to grant extensions, primarily due to the lack of a mechanism to coordinate those extensions with other agencies that might require longer accumulation times. Commenters were concerned this would likely lead to a scenario in which the EPA Regional Administrator does not grant sufficient accumulation time needed to comply with other federal requirements for recalls.

To address these adverse comments, the Agency has modified the final rule. The modifications also address the fact that the duration of a recall is highly variable, making it unreasonable to prescribe a specific time frame for accumulation. The Agency is finalizing provisions to ensure that recalled hazardous waste pharmaceuticals are properly managed without imposing requirements that are superfluous or conflict with other federal regulations and procedures.

In an effort to avoid overreach and potentially overlapping regulations, the Agency consulted with FDA and CPSC to better understand their procedures and policies in regulating and overseeing recalls of OTC and prescription pharmaceuticals. We learned that almost all pharmaceutical recalls are overseen by FDA, however, CPSC occasionally oversees a recall if an item's packaging does not comply with special (also called child resistant) packaging requirements. We also learned that third-party companies (typically reverse distributors, as defined in subpart P) serve as recall facilitators contracted by the manufacturer of the recalled item, to provide recall logistics such as aggregating recalled items, tracking recall progress, and making disposition determinations. Nearly all pharmaceuticals sent to a recall facilitator as part of a recall are ultimately destroyed. However, in some cases, the content of a recalled item is reclaimed and put back into commerce. For example, if the outer packaging has incorrect information, the manufacturer may choose to place the contents in updated packaging so they can be lawfully sold.

Although retailers are not permitted to sell a pharmaceutical that is subject to a CPSC recall, participation in a recall is not compulsory on the part of every consignee (entity that has purchased those items), which means that there is no way to compel participation, whether the recall is voluntary or federally mandated. The Agency had considered taking the position that all pharmaceuticals subject to a recall are waste when the recall is issued. However, because some recalled pharmaceuticals have the potential to be legitimately used/reused or reclaimed, combined with the fact that they sometimes can be lawfully dispensed by the consignee (but not sold by a retailer), we concluded that pharmaceuticals subject to a recall do not necessarily become waste simply by virtue of being subject to that recall.

Although many pharmaceuticals being sent by a healthcare facility to a recall facilitator as part of a recall could be considered solid waste, the Agency has determined that the combination of regulations, guidance and/or oversight provided by FDA and CPSC is sufficiently protective of human health and the environment while pharmaceuticals are subject to a recall. Therefore, EPA is choosing not to apply RCRA regulations on hazardous waste pharmaceuticals that are subject to a voluntary or federally-mandated recall until the decision is made to send some or all items for destruction (see below for further discussion).

EPA is not attaching any requirements to recalled hazardous waste pharmaceuticals while subject to a recall. In the final rule, healthcare facilities and reverse distributors will not be required to request an extension of the accumulation time period for recalled non-creditable hazardous waste pharmaceuticals or potentially creditable hazardous waste pharmaceuticals as proposed. This decision is also responsive to commenters who were concerned about having to operate under multiple and possibly conflicting federal regulatory schemes. It is also worth noting again that FDA and CPSC are the only federal agencies that regulate recalled pharmaceuticals and special packaging for pharmaceuticals, respectively.

When a pharmaceutical recall is initiated, the manufacturer must develop, and the corresponding agency must accept, a recall strategy which outlines all of the actions to be taken on behalf of the manufacturer from start to finish. A disposition determination is a required component of a comprehensive recall strategy. It is EPA's understanding that items being managed under an FDA or CPSC recall may be periodically sent for destruction as part of the disposition strategy (other disposition options allowed by FDA and CPSC can include redirection, and in rare circumstances, reconditioning). It is at this point (upon the decision to send some or all of the recalled pharmaceuticals for destruction) that the Agency will apply RCRA regulations these hazardous waste pharmaceuticals.

Any recalled pharmaceutical that is sent for destruction as part of the disposition strategy and is a RCRA hazardous waste, must be managed according to RCRA Subtitle C and any applicable provisions of this new subpart. This strategy is also in line with FDA and CPSC recall procedures in that they both specify that items being sent for destruction must comply with other applicable state, local and federal regulations, which may include DOT's Hazardous Material Regulations (HMR) and RCRA. In other words, this rule maintains the framework that any entity sending recalled items for destruction under a FDA or CPSC recall must comply with RCRA regulations but imposes these new subpart P regulations

at the point at which RCRA regulations already applied in lieu of the generator regulations in 40 CFR part 262.

d. *Preservation orders, investigations, and judicial proceedings.* In addition to recalls, the proposed rulemaking included litigation holds as an example of a circumstance that is beyond the control of a healthcare facility or reverse distributor, which would be a valid reason to request an extension of the accumulation period. Similar to the proposed standards for recalled hazardous waste pharmaceuticals, the standards for hazardous waste pharmaceuticals under litigation holds were also included in § 266.502(f)(3) for non-creditable hazardous waste pharmaceuticals at healthcare facilities, and in § 266.510(a)(5) for potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors. As with recalls, we have moved the section of the regulations that addressed accumulation time extensions for litigation holds out of the healthcare facility standards and reverse distributor standards and into the applicability section of § 266.501(g)(5). The final rule also uses terminology that is more encompassing than just litigation holds, such that we are choosing not to apply RCRA regulations on hazardous waste pharmaceuticals that are being held pursuant to preservation orders, investigations, and judicial proceedings (which would include litigation holds).[194] Accordingly, the hazardous waste pharmaceuticals under a preservation order, investigation, or judicial proceeding are not subject to part 266 subpart P until after the preservation order, investigation or judicial proceeding has concluded and/or a decision is made to discard the hazardous waste pharmaceuticals. As with recalled hazardous waste pharmaceuticals, the final rule no longer requires healthcare facilities and reverse distributors to request an extension of the accumulation time period for hazardous waste pharmaceuticals under a preservation order, investigation, or judicial proceeding, as was originally proposed.

Some commenters were concerned that the Agency had proposed that any item under a preservation order, investigation, or judicial proceeding would be considered waste. We would like to emphasize that non-waste hazardous pharmaceuticals do not automatically become a waste upon being directed to participate in a preservation order.

The Agency has determined that any pharmaceuticals that were, prior to a preservation order, investigation, or judicial proceeding, determined to be waste, are not subject to RCRA when under the preservation order, investigation, or judicial proceeding. The Agency believes that sufficient protections are in place to be duly protective of human health and the environment while the preservation order, investigation, or judicial proceeding is ongoing. In addition, the extreme variability and multijurisdictional nature of judicial actions and Agency investigations make it impractical to impose RCRA standards while a corresponding preservation order, investigation, or judicial proceeding is ongoing. When lifted—for any portion or the entire complement of items—a new waste determination must be made. The location at which the waste determination is made will be the new point of generation. If the items are ultimately determined to be hazardous waste pharmaceuticals, all applicable standards in this subpart apply and the time frames for accumulation, inventory, etc., begin anew.

e. *Investigational drugs.* Similar to recalls, FDA has specific regulations pertaining to investigational new drugs, including that an investigational new drug application must be developed and approved by FDA, in accordance with 21 CFR part 312. These regulations include a requirement that ''The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug.'' [195] Because FDA requires these investigational drugs to be returned to the sponsor of the new drug application, EPA would not consider these returned investigational new drugs to be solid wastes and therefore, they would not be subject to RCRA, including this subpart. However, when a decision is made to discard the investigational new drug, or when the FDA approves the destruction of the investigational new drug, at that point it would be considered a solid waste, and if it is a hazardous waste, then it would be subject to subpart P, if the investigational new drug is discarded by a healthcare facility or a reverse distributor. However, typically, investigational new drugs that are part of a clinical trial are returned to the manufacturer at the conclusion of the clinical trial. In that case, if the investigational new drug is discarded by a manufacturer, then it would be subject to part 262, not part 266 subpart P. We have added § 266.501(g)(6) to carve out investigational new drugs for which an investigational new drug application is in effect in accordance with the FDA regulations in 21 CFR part 312. But we have also included a sentence to make it clear that, when the decision of discard has been made, the investigational new drug is subject to subpart P, if it meets the definition of hazardous waste and it is discarded by a healthcare facility or a reverse distributor.

f. *Household pharmaceuticals.* In the proposed rulemaking, we indicated that pharmaceuticals from households would continue to be excluded as household hazardous waste under § 261.4(b)(1). However, this was only a discussion in the preamble, we did not include regulatory language in part 266 subpart P. Additionally, we proposed a conditional exemption for collected household pharmaceuticals in § 266.507. For added clarity in the final rule, we have included in the applicability section a new paragraph § 266.501(g)(7). This paragraph indicates that household waste pharmaceuticals are not regulated under part 266 subpart P or other RCRA regulations. A household waste pharmaceutical is defined as a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1). This exclusion is for the residential generator of the household waste pharmaceuticals, as well as the collection and disposal of the residential trash as municipal solid waste.

As discussed later in this preamble, we are finalizing a conditional exemption in § 266.506(a)(2) for household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration). To remain exempt as household waste pharmaceuticals, these collected pharmaceuticals may not be sewered and have to be destroyed by a method that the Drug Enforcement

[194] See the following three memos: (1) June 23, 2017, from Johnson to Regional RCRA Division Directors, RCRA Online #14893; (2) August 11, 1988, from Lowrance to McGuire, RCRA Online #11363; and (3) January 6, 2014, from Devlin to Mitlo, RCRA Online #14881.

[195] See 21 CFR 312.59.

Administration has publicly deemed in writing to meet their non-retrievable standard of destruction, or combusted at one of the types of combustors identified in § 266.506(b). We have included in the applicability section in § 266.501(g)(7) references to the conditional exemption in § 266.506(a)(2) and the conditions in § 266.506(b) to clarify that household waste pharmaceuticals that are collected as part of a take-back event or program are distinct and different from those that are not part of a collection program. That is, when discarded directly at a residence, the household waste pharmaceuticals remain excluded as household hazardous waste, without any conditions; however, when the household waste pharmaceuticals are collected in a take-back event or program, they must be destroyed in accordance with the conditions in § 266.506 to remain exempt. See section XIV of this preamble for a more detailed discussion of the conditional exemption for household waste pharmaceuticals that are collected in a take-back event or program.

C. Do Not Count Hazardous Waste Pharmaceuticals Managed Under Subpart P Toward Determining Generator Category (§§ 262.13(c)(9))

1. Summary of Proposal

EPA proposed that hazardous waste pharmaceuticals that are managed under part 266 subpart P are not required to be counted in determining a facility's hazardous waste generator category under part 262. There were two primary reasons this provision was proposed. First, we received support for this provision when we initially proposed it as part of the 2008 proposal to add pharmaceuticals to the Universal Waste program. Second, and more importantly, under part 266 subpart P, there are no generator categories; therefore, it is not necessary to know the quantity of hazardous waste pharmaceuticals being generated. EPA emphasized that a healthcare facility must be managing its hazardous waste pharmaceuticals under subpart P in order to have the benefit of not counting them towards its generator category (see section XIX for further discussion).

2. Summary of Comments

There was widespread support among commenters for this proposed provision. However, a number of the commenters expressed some confusion and asked for further explanation and clarity regarding the effect this may have on determining a facility's hazardous waste generator category.

3. Final Rule Provisions

We are finalizing this provision with a minor edit. Additionally, the provision is now in a different place in the final regulations. First, the minor edit was made in response to Connecticut Depart of Energy and Environmental Protection's (CT DEEP) objection to the phrasing of the proposed regulatory language. Specifically, CT DEEP thought the phrase ''managed under 40 CFR part 266 subpart P'' could lead to confusion if a healthcare facility was operating under part 266 subpart P, but was not in full compliance with part 266 subpart P and whether that would be considered to be ''managed under 40 CFR part 266 subpart P.'' [196] In response, and to avoid this potential area of confusion, we have changed the regulatory language so that ''a hazardous waste pharmaceutical *subject to* or managed in accordance with 40 CFR part 266 subpart P'' does not have to be counted toward determining a facility's generator category. The second change is a conforming change necessitated by the reorganization of the generator regulations in the 2016 Hazardous Waste Generator Improvements final rule. The list of hazardous wastes that do not have to be counted toward generator category had been listed in § 261.5(c), but when the Hazardous Waste Generator Improvements final rule reorganized the generator regulations, this list was moved to § 262.13(c). Under this final rule, hazardous waste pharmaceuticals that are subject to part 266 subpart P do not have to be counted toward determining a facility's generator category. This provision now appears in § 262.13(c)(9). Finally, for clarity we have added that the hazardous waste pharmaceuticals that are also DEA controlled substances and are conditionally exempt under § 266.506, do not have to be counted toward determining generator category.

4. Comments and Responses

Several commenters asked us to clarify when a healthcare facility does and does not count its hazardous waste pharmaceuticals toward determining a facility's generator category. A healthcare facility must count all of its hazardous waste—including hazardous waste pharmaceuticals—to determine whether it is subject to part 266 subpart P. If a healthcare facility generates below all of the VSQG monthly quantity limits, then it remains subject to § 262.14 for all of its hazardous waste and it is not subject to subpart P for its hazardous waste pharmaceutical, except for the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504. On the other hand, if a healthcare facility generates above any of the VSQG monthly quantity limits, then the healthcare facility is subject to subpart P for its hazardous waste pharmaceuticals. But since subpart P is only for the management of hazardous waste pharmaceuticals, the healthcare facility remains subject to part 262 for its non-pharmaceutical hazardous waste.

The next step is for the healthcare facility to determine its new generator category under part 262 so it knows how to manage its non-pharmaceutical hazardous waste. At this point, a healthcare facility does not need to count its hazardous waste pharmaceuticals in determining its generator category for its non-pharmaceutical hazardous waste. EPA continues to emphasize that a healthcare facility must be managing its hazardous waste pharmaceuticals under subpart P in order to have the benefit of not counting them towards its generator category. Put another way, a healthcare facility managing its hazardous waste pharmaceuticals under subpart P does not have a generator category for the hazardous waste pharmaceuticals, but it will be a VSQG, SQG or LQG for its non-pharmaceutical hazardous waste.

When a healthcare facility that manages its hazardous waste pharmaceuticals under subpart P no longer counts the hazardous waste pharmaceuticals to determine its part 262 generator category, the healthcare facility may experience a change in RCRA generator category for its non-pharmaceutical hazardous waste. For example, a healthcare facility may shift from being an LQG to an SQG or even VSQG by not counting its hazardous waste pharmaceuticals toward its generator category, especially when acute hazardous waste pharmaceuticals such as warfarin (brand name: Coumadin) no longer need to be counted. A shift in generator category, should it occur, would allow a healthcare facility to manage its non-pharmaceutical hazardous waste, such as hazardous waste from laboratories, according to the reduced part 262 generator regulations for a smaller category.

For reverse distributors, it works somewhat differently than with healthcare facilities, because all reverse distributors are subject to part 266 subpart P for the management of their hazardous waste pharmaceuticals, including reverse distributors that are

[196] See comment number: EPA–HQ–RCRA–2007–0932–0341.

VSQGs. In other respects, the regulations work the same, because reverse distributors also are not required to count their hazardous waste pharmaceuticals when determining their part 262 generator category for their non-pharmaceutical hazardous waste.

Again, we emphasize, such dropping down in generator category only pertains to non-pharmaceutical hazardous waste and is only possible when the hazardous waste pharmaceuticals are being managed under subpart P. Further, EPA points out that universal wastes also are not counted toward a facility's generator category and what we are finalizing for hazardous waste pharmaceuticals has been implemented successfully for years within the universal waste program for facilities that generate both universal waste and other hazardous waste.

Below are a diagram and a table to help summarize the preceding sections of the preamble related to the applicability of the final rule and the provision that allows a healthcare facility or a reverse distributor to not count hazardous waste pharmaceuticals when determining the facility's generator category for its non-pharmaceutical hazardous waste.

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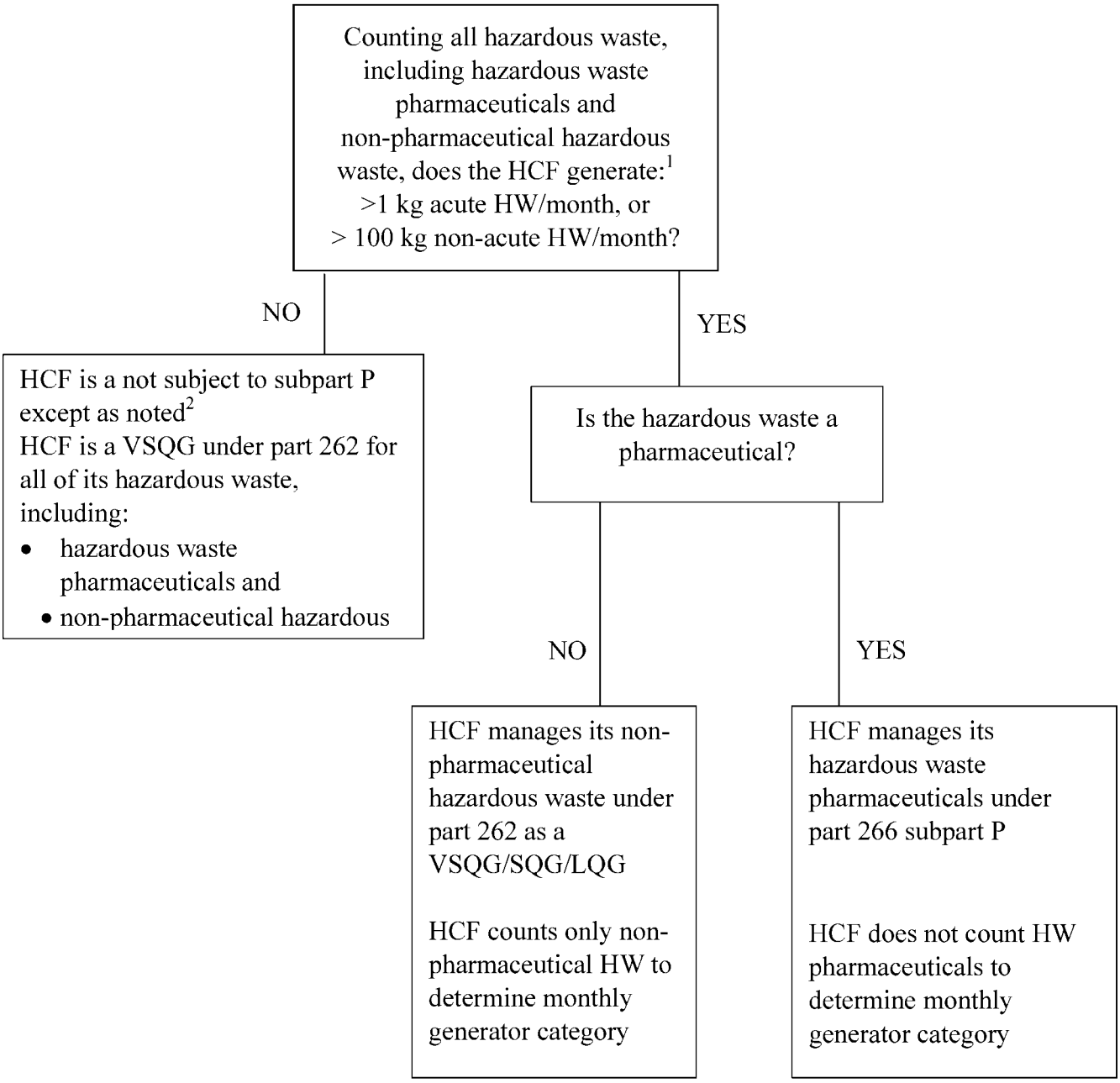
Diagram 1: When is a Healthcare Facility Subject to Part 266 Subpart P?



HW = Hazardous Waste HCF = Healthcare Facility RD = Reverse Distributor Rx = Prescription

[1] Non-Rx pharmaceuticals are not solid or hazardous waste if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed. Reverse logistics facilities are subject to the generator standards in part 262.

[2] All VSQGs are subject to the sewer prohibition of § 266.505 and the empty container standards of § 266.507, and can use the optional provisions of § 266.504.

BILLING CODE 6560–50–C

Table 2: Applicability of Subpart P and Part 262 Generator Category for Healthcare Facilities

Hazardous Waste Pharmaceutical			Non-Pharmaceutical Hazardous Waste		Total Hazardous Waste		Part 266 Subpart P?	Part 262 Generator Category of Healthcare Facility		
Acute	Non-Acute		Acute	Non-Acute	Acute	Non-Acute		LQG	SQG	VSQG
Any amount		and	>1 kg and/or ≥1000 kg		>1 kg and/or ≥1000 kg		Yes	✓		
Any amount		and	≤1 kg and >100 and <1000 kg		≤1 kg and >100 and <1000 kg		Yes		✓	
>1 kg and/or >100 kg		and	≤1 kg and ≤100 kg		>1 kg and/or >100 kg		Yes			✓[2]
≤1 kg and ≤100 kg		and	≤1 kg and ≤100 kg		>1 kg and/or >100 kg		Yes			✓[2]
≤1 kg and ≤100 kg		and	≤1 kg and ≤100 kg		≤1 kg and ≤100 kg		No[1]			✓[3]
Long-Term Care Facilities with ≤ 20 beds							No[1]			✓[4]

[1] All VSQGs healthcare facilities are subject to the sewer prohibition of § 266.505, and the empty container standards of § 266.507, and can use the optional provisions in § 266.504

[2] VSQGs for non-pharmaceutical hazardous waste only ("subpart P VSQG")

[3] VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste

[4] Presumed to be a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste

X. Standards for Healthcare Facilities That Manage Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502)

A. Notification/Withdrawal Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(a))

1. Summary of Proposal

To address commenters' concerns from the 2008 Pharmaceutical Universal Waste proposal that regulatory agencies are unaware of hazardous waste pharmaceutical management activities, EPA proposed to require that a healthcare facility that does not qualify as a VSQG to submit a one-time notification as a ''healthcare facility'' to the appropriate EPA Regional Administrator. EPA proposed that healthcare facilities subject to 40 CFR part 266 subpart P will have to submit a notification even if the healthcare facility has previously obtained an EPA identification number. The required notification was meant to enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals subject to the 40 CFR part 266 subpart P requirements.

At any point, a healthcare facility's hazardous waste pharmaceutical generation may change due to waste minimization efforts or other reasons, causing the facility to legitimately decrease its total monthly hazardous waste generation enough to qualify as a VSQG. In this case, if the healthcare facility withdraws from the 40 CFR part 266 subpart P requirements due to qualifying as a VSQG, EPA proposed that the healthcare facility must re-notify EPA of its choice to withdraw.

Alternatively, if a healthcare facility determines that it is a VSQG, but does not want to keep track of the amount of hazardous waste pharmaceuticals it generates and whether it is above or below the VSQG threshold, we proposed that it can choose to operate under subpart P. By choosing to operate under subpart P, the VSQG healthcare facility must comply with all of the requirements, including the one-time notification that it is operating under 40 CFR part 266 subpart P. We proposed that healthcare facilities that are not VSQGs, however, are required to operate under 40 CFR part 266 subpart P for the management of their hazardous waste pharmaceuticals.

The Agency proposed that this notification occur using the RCRA Subtitle C Site Identification Form (EPA Form 8700–12; or Site Identification Form). EPA believes that notification via the Site Identification Form is the preferred approach for notification purposes for several reasons. First, both state environmental regulatory agencies and hazardous waste generators are familiar with the form, as it is the form currently used by hazardous waste generators to notify regulators of their RCRA Subtitle C activities. Second, as stated previously, the use of the Site Identification Form will allow for EPA and state regulatory agencies to monitor the healthcare facilities utilizing the new regulatory requirements. Lastly, public comments received on previous EPA actions (*e.g.,* Academic Laboratories Rulemaking (73 FR 72912; December 1, 2008)) have indicated that notification via the Site Identification Form is the notification approach typically preferred by the regulated community. We proposed that healthcare facilities can submit their notification as part of the Biennial Report, if the healthcare facility will be required to submit a Biennial Report due to its non-pharmaceutical hazardous waste. This was intended to take advantage of an existing reporting mechanism for LQGs or other generators already required to submit the Biennial Report and avoid duplicative notification requirements. Otherwise, healthcare facilities are required to notify within 60 days of this new subpart becoming effective, or within 60 days of becoming subject to this new subpart. We also proposed that a healthcare facility would have to keep a record of its notification as long as it is subject to this subpart.

The Agency did not anticipate that the proposed notification requirement would place any undue economic burden upon healthcare facilities or the environmental regulatory agencies that process these notifications (see the Regulatory Impact Analysis for the proposed rulemaking in the rulemaking docket EPA–HQ–RCRA–2007–0932). In fact, under the proposed regulations, healthcare facilities would no longer need to count the hazardous waste pharmaceuticals managed under 40 CFR part 266 subpart P towards a healthcare facility's generator category. As a result, EPA anticipates that many healthcare facilities will reduce their generator category to either an SQG or VSQG for their other non-pharmaceutical hazardous wastes. So, while the notification requirement ensures that the environmental regulatory agencies are informed of all hazardous waste pharmaceutical management activities subject to the 40 CFR part 266 subpart P requirements, the fact that some healthcare facilities will no longer qualify as LQGs will reduce the number of healthcare facilities in the LQG universe.

The Agency solicited comment on the notification requirement for healthcare facilities, the method of notification via the Site Identification Form, and whether this notification requirement will result in any undue burden to either healthcare facilities or state environmental regulatory agencies.

2. Summary of Comments

While there was general support for requiring healthcare facilities to notify the EPA Regional Administrator that they are operating under this subpart, a number of states and industry commenters provided opposition to the proposed 60-day time frame. States supported notification but were concerned that they would not be able to process all of the notifications in a timely manner given that all VSQG and SQG facilities operating under subpart P would have to notify within 60 days of the effective date of this rule. One suggestion was to instead require notification on a rolling or staggered basis to give resource-limited states enough time to process the notices within a timely manner.

States also voiced concern about the provision allowing healthcare facilities that are LQGs because of their non-pharmaceutical waste to notify as part of their normal Biennial Reporting schedule.[197] Depending on the timing of the Final Rule, states were concerned about the possibility that LQGs would not have to notify that they are operating under this subpart for up to two years, during the course of which they could be generating large amounts of pharmaceutical waste and managing it under the reduced restrictions of this subpart unbeknownst to the state or EPA. Meanwhile VSQGs and SQGs would have to notify within 60 days.[198] Another state recommended that healthcare facilities be required to list on the notification what their generator category would be if they were to count their pharmaceutical waste. The state was concerned that a healthcare facility could be generating LQG amounts of pharmaceutical waste but because they are now VSQGs, would be a much lower inspection priority.[199]

There was, however, no opposition to the provision that a healthcare facility

[197] § 262.18(d)(2) requires LQGs to renotify EPA by March 1 of each even-numbered year thereafter using EPA Form 8700–12. An LQG may submit this renotification as part of its Biennial Report required under § 262.41.

[198] EPA–HQ–RCRA–2007–0932–0341.

[199] EPA–HQ–RCRA–2007–0932–0235.

be required to maintain a copy of its notification on file as long as it is subject to this subpart.

3. Final Rule Provisions

EPA is finalizing the notification provisions for healthcare facilities managing non-creditable hazardous waste pharmaceuticals as proposed, with no changes.

All healthcare facilities as defined in § 266.500 that are subject to the requirements of this subpart (all healthcare facilities that generate above the VSQG thresholds and healthcare facilities that are VSQGs choosing to operate under this subpart) will have to submit a notification to the EPA Regional Administrator using the Site ID Form (EPA Form 8700–12) stating that they are a healthcare facility and will be operating under this subpart. A healthcare facility that already has an EPA Identification Number must re-notify the EPA Regional Administrator that it will be operating under this subpart within 60 days of becoming subject to subpart P. Healthcare facilities that do not have an EPA Identification Number will be required to obtain one by submitting the Site Identification Form (EPA Form 8700–12) within 60 days from the effective date of this rule if they are not otherwise required to submit Biennial Reports. A healthcare facility that undergoes a change in generator category causing them to become subject to the requirements of this subpart must notify the EPA Regional Administrator within 60 days of the event that triggered the change in generator category.

Healthcare facilities that are LQGs for their non-pharmaceutical hazardous waste, and therefore must submit a Biennial Report, may notify the EPA Regional Administrator according to their normal reporting cycle. SQGs that are required by their state to submit a Biennial Report may also notify EPA that they are operating under subpart P on their normal reporting cycle. Healthcare facilities that are required to submit a Biennial Report are not, however, required to wait to notify EPA that they are operating under subpart P on their Biennial Report, and may notify EPA at any point prior to submitting the Biennial Report. The Agency notes that any healthcare facility that is required to operate under subpart P must begin complying with its requirements as soon as the final rule becomes effective. VSQGs that opt into subpart P may notify the EPA whenever they choose, but they become subject to the requirements of this subpart on the date they submit the notification. All healthcare facilities must retain a copy of the notification as long as they are operating under this subpart.

4. Comments and Responses

Some states were concerned about their ability to process notifications in a timely manner given the 60-day time frame after the effective date of this rule within which all non-LQG healthcare facilities must notify EPA that they are operating under this subpart. The Agency reasserts, however, that the added burden is reasonable and necessary for the Agency and implementing states to gain a timely understanding of the facilities within the universe of this rule.

The Agency also notes that this final rule goes into effect six months from the date it is published in the **Federal Register** in EPA Territories and states that do not have an authorized RCRA program. That time frame could be even longer in authorized states which must first adopt this rule for it to become effective. Therefore, healthcare facilities in all states have a minimum of six months from the day this rule is published in the **Federal Register**, plus the 60 days in this requirement, to notify their state that they are operating under this subpart.

One commenter suggested that the agency implement a staggered roll-out of this notification provision to prevent them from becoming inundated with incoming notifications, preventing them from processing notifications in a timely manner. The Agency would note, however, that there is no provision requiring a healthcare facility to receive approval before it can operate under this subpart and states and regions can process the notifications by whatever time frames and methods they choose. All healthcare facilities must operate under this subpart immediately upon becoming subject to this rule. Therefore, as long as a healthcare facility that does not submit a BR notifies its state within 60 days that it is operating under this subpart, it will be in compliance. In addition, we did not propose and are not finalizing any time frames within which regional or state offices must process notifications, therefore, we defer to those agencies to develop their own best practices.

Another state suggested that EPA develop a ''smart-form'' tool for RCRAInfo—EPA's database of RCRA-related information from required reporting— that would allow healthcare facilities to notify the state electronically that they are operating under subpart P, directly input their own information, and update their information on a regular basis. EPA notes that it has developed an online tool called myRCRAid which allows generators to complete and submit the Site Identification Form electronically, which the Agency expects will reduce states' administrative burden by reducing the number of notifications that have to be manually input, while simultaneously reducing the potential for error while transferring data.

In addition, the Site Identification Form will be modified by EPA in a separate action to add a section for a healthcare facility to indicate that it generates hazardous waste pharmaceuticals. The healthcare facility will no longer be required to identify on the Site Identification Form the specific types of hazardous waste pharmaceuticals it generates. The Agency also intends to add a checkbox to the new section which will allow a healthcare facility to indicate that its generator category is changing to a VSQG and it is no longer managing its hazardous waste pharmaceuticals according to 40 CFR part 266 subpart P.

Some states disagreed with the provision that allows healthcare facilities that file a BR to notify EPA that they are operating under subpart P on their normal reporting schedule, as opposed to notifying within 60 days of this rule becoming effective, or becoming subject to subpart P. This means that healthcare facilities that file a BR could potentially operate under this subpart for up to two years without having to notifying the Agency, depending on when their normal BR date falls in relation to the effective date of this rule. They recommended that all facilities, regardless of generator category, be required to notify within 60 days. While the Agency agrees that the possibility for a healthcare facility to operate for up to two years under this subpart without notifying EPA does, in fact, exist, we do not wish to impose duplicative notification requirements.

One state requested that a healthcare facility be required to list on the notification what its generator category would be if it were required to count its hazardous waste pharmaceuticals. They were concerned that some facilities that are LQGs because of their hazardous waste pharmaceuticals would reduce their generator category as a result of this rule, making them a low priority for inspections, even though they could still be generating LQG quantities of pharmaceutical waste. We understand the state's concern, however, making a change like this would not be in line with the goals of this rule to provide streamlined standards. However, options available to the states with similar concerns are adopting more stringent requirements or using

historical notifications and Biennial Report data.

B. Personnel Training Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(b))

1. Summary of Proposal

a. Performance-based training standards. EPA believes that the part 262 LQG training regulations are excessive for healthcare personnel who sporadically generate hazardous waste pharmaceuticals at healthcare facilities, but believes it is necessary to have some familiarity with the dangers that hazardous waste pharmaceuticals can pose, making the VSQG training standards insufficient. Therefore, the Agency proposed healthcare facility-specific personnel training requirements that are akin to the training requirements for SQGs and small quantity universal waste handlers, for all healthcare facilities subject to subpart P. Specifically, we proposed that healthcare facilities managing hazardous waste pharmaceuticals in accordance with subpart P must inform all employees that handle or have responsibility for generating and/or managing hazardous waste pharmaceuticals of the proper handling and emergency procedures appropriate to their responsibilities during normal facility operations and emergencies. We indicated in the preamble to the proposed rulemaking that this training information can be disseminated through verbal communication or through distribution of pamphlets or other documentation. However, a healthcare facility that is an LQG due to its non-pharmaceutical hazardous wastes may choose to continue to use its existing training program as an LQG so as not to have different training programs.

Under part 262 regulations, an LQG healthcare facility had to provide full RCRA training to its personnel involved in the generation and/or management of hazardous waste according to the standards in § 262.17(a)(7). These personnel training requirements include either classroom instruction, on-line training, or on-the-job training in RCRA and require the facility to maintain documentation of that training. On the other hand, before this rule was finalized, under the part 262 regulations, an SQG healthcare facility had to meet a performance-based standard when training personnel involved in the generation and/or management of hazardous waste pharmaceuticals. Specifically, this entailed ensuring ''that all employees are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.'' [200] For comparative purposes, healthcare facilities that are considered VSQGs did not have any personnel training requirements under the part 262 regulations. Similarly, SQGs and LQGs, including healthcare facilities, were not required to provide RCRA training to personnel that only work in SAAs regulated under § 262.15. That said, healthcare personnel that are involved in the generation of hazardous waste pharmaceuticals must be familiar enough with the pharmaceuticals with which they work to know when they have generated a hazardous waste so that it will be managed in accordance with the RCRA regulations.

b. Documentation of training. Although no regulations were proposed, EPA also sought comment in the preamble to the proposed rulemaking on whether documentation of training is necessary in order to verify compliance with the training requirement.

2. Summary of Comments

a. Performance-based training standards. There were a variety of comments on the proposed training standards, both in support and opposition. Although most states agreed with the assessment that standard LQG regulations would be excessive if applied to healthcare facilities, some wanted EPA to provide more stringent and prescriptive language. Commenters from the waste management industry were also opposed to the proposed performance-based standards for similar reasons.

Pharmacy trade groups generally agreed with the proposed standards, citing the same rationale provided in the preamble of the proposed rulemaking, which states that the variability in waste generated and turnover in employees warrants a performance-based standard, and any subsequent training should be left up the healthcare facility. They stated that most pharmacy staff are trained on proper handling and management of radiation and other pharmaceuticals that can pose significant risks as required by other accreditation and standard-setting agencies and any prescriptive training standards under subpart P would be duplicative.

b. Documentation of training. There were mixed comments on whether to require that a healthcare facility document that its personnel have been trained according to the standards set forth in 40 CFR 266.502(b). All of the states that commented on this issue were supportive of the requirement to document training. These states were mostly concerned with their ability to cite specific violations of the training provisions during inspections. Another state mentioned that many facilities already maintain documentation of training as a best management practice.

Waste management companies also wanted EPA to require healthcare facilities to document that employees have been trained. They argued that the training standards will not have their intended effect if there is no requirement for documentation because healthcare facilities will not feel compelled to comply with them.

Pharmacy trade groups were concerned that requiring documentation of training would result in added burden and generally opposed this provision. They argued that there are a number of standard-setting and accreditation agencies that already require documentation that employees have been trained, and as such, this requirement would be redundant and overly burdensome.

3. Final Rule Provisions

a. Performance-based training standards. EPA is finalizing the performance-based training standards as proposed. A healthcare facility must train employees to the extent that they are thoroughly familiar with the proper handling and emergency procedures relevant to their responsibilities during normal operations and emergencies. The information can be disseminated verbally, via printed materials, or other means. These standards are similar to the training standards for SQGs and small quantity handlers of universal waste.[201] [202] The agency feels that these standards provide consistency across generator types and do not impose any added burden on inspection and enforcement actions beyond what is already in place within the Universal Waste program.

b. Documentation of training. EPA has decided not to finalize a standard that would have required healthcare facilities to document that the performance-based training standards have been met. The Agency thinks this requirement would have resulted in an undue increase in the regulatory burden for healthcare facilities. Also, there is no such requirement in the part 262 SQG training requirements or for small quantity handlers of universal waste.

[200] § 262.16(b)(9)(iii)

[201] 40 CFR part 262.16 (a)(9)(iii).

[202] 40 CFR part 273.16.

The agency feels this approach is consistent with other RCRA regulations and would improve consistency with the Universal Waste program, especially since the requirements for healthcare facilities managing hazardous waste pharmaceuticals were purposefully modeled after the requirements for small quantity handlers of universal waste. The Agency ultimately concluded that, because this approach is sufficient for universal waste, it is also acceptable for hazardous waste pharmaceuticals.

4. Comments and Responses

a. Performance-based training standard. There were a number of commenters from states and the waste management industry that recommended more rigorous and prescriptive training standards such as more specific minimum requirements, recurring training, and that the Agency specify the job titles subject to the training requirements. The Agency is not finalizing any of these recommendations, however, because we believe that the proposed performance-based standards are protective of human health and the environment without imposing undue burden either on states or industry. These standards strike an appropriate balance between ensuring proper management of hazardous waste pharmaceuticals and reducing the regulatory burden on healthcare facilities and healthcare personnel in a manner that also encourages compliance with these new regulations.

One commenter mentioned that prescriptive RCRA training requirements would be duplicative given the training requirements of the various accreditation entities. The Agency responds that any waste management training for healthcare personnel would not be duplicative because accreditation training typically focusses on managing pharmaceuticals prior to becoming a waste, whereas the training required in subpart P is targeted specifically at management practices after the pharmaceuticals have become waste. As mentioned previously, the Agency is not finalizing prescriptive training standards in an effort to minimize regulatory burden and allow healthcare facilities to tailor their training programs in a way that best fits their circumstances.

These training standards apply only to healthcare personnel. Healthcare personnel includes any person that manages hazardous waste pharmaceuticals at a healthcare facility (*e.g.,* employees, volunteers, students). Environmental health and safety personnel are likely to manage hazardous wastes other than just hazardous waste pharmaceuticals at a healthcare facility, in which case, they would be subject to other RCRA Subtitle C training requirements.

The Agency acknowledges that there are many pharmaceuticals that pose significant risk to human health and the environment, yet are not RCRA hazardous when they become waste. We in no way intend to imply that these items pose any less of a risk by virtue of being considered non-hazardous under RCRA and encourage healthcare facilities to provide all relevant training to healthcare personnel and observe industry best management practices.

b. Documentation of training. After requesting comment on documentation of training, the Agency decided not to finalize any requirements for healthcare facilities to document and maintain records verifying that healthcare personnel have met the training requirements. We considered the many adverse comments and ultimately agreed that such requirements would be overly burdensome and more stringent than the training requirements in the Universal Waste rule, which were largely emulated in this rule. Many comments that advocated for a requirement to document training were from states. Although such a requirement is not being finalized at the federal level, any authorized state has the ability to impose more stringent regulations. If a state chooses to require documentation of training, that would be considered more stringent and permissible under RCRA.

C. Healthcare Facilities Making a Hazardous Waste Determination for Non-Creditable Pharmaceuticals (§ 266.502(c))

1. Summary of Proposal

EPA proposed that, similar to the current part 262 generator requirements, healthcare facilities operating under subpart P would be required to make hazardous waste determinations on pharmaceutical wastes in order to determine the applicable management standards. Specifically, we proposed that when a healthcare facility generates a solid waste pharmaceutical, the healthcare facility must determine if the discarded pharmaceutical is listed in 40 CFR part 261 subpart D and/or if it exhibits one or more of the four characteristics of hazardous waste identified in 40 CFR part 261 subpart C. We proposed that, if the non-creditable pharmaceutical waste is determined to be a hazardous waste, then the healthcare facility must manage the non-creditable hazardous waste pharmaceuticals in accordance with part 266 subpart P instead of 40 CFR part 262. Pharmaceutical wastes—both potentially creditable and non-creditable—not meeting the definition of a hazardous waste (*i.e.,* non-hazardous waste pharmaceuticals) must be managed in compliance with applicable federal, state and local regulations.

EPA understands that healthcare facilities utilize various approaches when making hazardous waste determinations. For example, healthcare facilities may hire consultants to review their formularies and identify those pharmaceuticals that are hazardous wastes when discarded. These facilities may then identify hazardous waste pharmaceuticals at the pharmacy level, marking these pharmaceuticals with a special label so that healthcare personnel know how to properly dispose of the pharmaceutical when it becomes a waste. Other healthcare facilities may instruct personnel to dispose of all pharmaceutical wastes into one RCRA hazardous waste collection container. These healthcare facilities may then choose to manage all of the contents of the container as hazardous waste or they may choose to sort the hazardous waste portion from the non-hazardous waste pharmaceutical portion in an on-site hazardous waste accumulation area, also known as a CAA. Due to the various ways that healthcare facilities make the hazardous waste determination, the Agency did not propose that a specific approach be utilized when making the hazardous waste determination, only that the facility performs the hazardous waste determination.

We also proposed that healthcare facilities have the option to manage all of their pharmaceutical wastes as hazardous, and thus, if a healthcare facility chooses this approach, they would not need to make individual hazardous waste determinations. Instead, they would have made a generic decision that all of their discarded pharmaceuticals are hazardous and manage them as hazardous waste pharmaceuticals in accordance with the requirements in 40 CFR part 266 subpart P. Accumulating all non-creditable waste pharmaceuticals in one container (except for those that are incompatible or cannot be incinerated according to the dilution prohibition) [203] and

[203] § 268.3(c) Dilution prohibited as a substitute for treatment. See appendix XI of part 268 for a full list of hazardous wastes that are prohibited from being combusted.

managing them under subpart P would relieve healthcare facilities from the burden associated with making individual hazardous waste determinations.

2. Summary of Comments

There were a wide variety of comments on this provision. Many in the regulated community requested some sort of a reference or compendium containing a comprehensive and up-to-date list of the waste pharmaceuticals that would be considered RCRA hazardous.

Commenters from states were generally supportive of the provision allowing all waste pharmaceuticals to be managed as hazardous waste pharmaceuticals. They believe the provision will encourage healthcare facilities to manage all of their waste pharmaceuticals in an environmentally protective manner. One commenter did suggest that healthcare facilities be required to choose whether they will make individual hazardous waste determinations for their waste pharmaceuticals or manage all of them as hazardous waste pharmaceuticals under this subpart and maintain documentation reflecting their decision.

Retail industry commenters were opposed to what they believe are contrary requirements, specifically, allowing a healthcare facility to manage all of its waste pharmaceuticals as hazardous but still require them to segregate incompatible hazardous waste and those prohibited from combustion as required by § 266.502(d)(4). They believe having to segregate incompatible and non-combustible waste significantly diminishes the intended relief.

3. Final Rule Provisions

EPA has finalized the provisions of this section with minor edits that further clarify that this section applies only to non-creditable pharmaceuticals. A healthcare facility that generates solid waste that is a non-creditable pharmaceutical has two options for hazardous waste determination. It may choose to either; (1) determine if each non-creditable pharmaceutical is a listed or characteristic hazardous waste to determine whether it is subject to the subpart P requirements, or (2) manage all of its non-creditable waste pharmaceuticals under the subpart P requirements as non-creditable hazardous waste pharmaceuticals. A healthcare facility that chooses the latter option, instead of making individual hazardous waste determinations at the point of generation, would have made a generic decision that all of their non-creditable pharmaceutical waste is hazardous and place it into a container or containers that are managed under part 266 subpart P.

The Agency wanted to provide maximum flexibility to healthcare facilities managing non-creditable waste pharmaceuticals while ensuring protection of human health and the environment, which is why we are finalizing the provision to allow healthcare facilities the option of managing all of their waste pharmaceuticals under subpart P. If a healthcare facility chooses to manage all of its non-creditable waste pharmaceuticals under the subpart P requirements, healthcare personnel are relieved from having to make individual hazardous waste determinations which might otherwise distract from their efforts in providing patient care.

4. Comments and Responses

A number of commenters asked if a third party can come on site and make individual hazardous waste determinations for commingled non-creditable waste pharmaceuticals. If a healthcare facility chooses to use a third party, typically a hazardous waste transport company, to come on site and make hazardous waste determinations at any time (typically in preparation for transport off site), that would also be permissible under this subpart.

Many comments were focused on the lack of an EPA-provided reference guide of which pharmaceuticals are hazardous waste when discarded. The RCRA generator regulations have always placed the onus on the generator of a waste to determine whether it is solid and hazardous waste. Nevertheless, EPA has made efforts to aid healthcare facilities in making hazardous waste determinations by developing the Hazardous Waste Pharmaceuticals wiki.[204] The website has served as a central location where users (*e.g.,* healthcare facilities, states) can share their knowledge about which pharmaceuticals are listed or characteristic hazardous waste, and other related information. EPA has also funded a compliance assistance center for healthcare facilities, which provides information on which pharmaceuticals are hazardous waste as well as other hazardous wastes found in a healthcare setting.[205] [206]

[204] Hazardous Waste Pharmaceuticals Wiki. *http://hwpharms.wikispaces.com.* Wiki spaces is phasing out its business of hosting wiki pages. The Agency plans to preserve the information that has been contributed to the wiki on EPA's website, but the content will be static.

[205] Healthcare Environmental Resource Center. *http://www.hercenter.org.*

D. No Central Accumulation Area and Satellite Accumulation Area Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

1. Summary of Proposal

Hazardous waste pharmaceuticals are generated at numerous locations across a healthcare facility. Under the part 262 generator regulations, each location at the healthcare facility with a RCRA hazardous waste receptacle for the disposal of hazardous waste pharmaceuticals is considered an SAA and is subject to volume accumulation limits and other provisions. Of particular concern regarding the SAA regulations for healthcare facilities is the one-quart accumulation limit for acute hazardous wastes (*i.e.,* P-listed wastes) and the requirement that hazardous waste must be accumulated at or near the point of generation. In particular, hospitals have noted that their difficulties are with having an SAA in each hospital room. As a result, the proposed December 2008 Pharmaceutical Universal Waste rule did not require the establishment of any accumulation areas (neither central nor satellite) for hazardous waste pharmaceuticals. This proposed approach was consistent with the current federal universal waste program, since facilities are not required to designate a special centralized area for the accumulation of universal wastes, nor are they required to have SAAs for universal wastes. Nevertheless, EPA understands that healthcare facilities will often accumulate their universal wastes within their 90- or 180-day hazardous waste accumulation areas. The part 262 generator regulations, including the SAA and CAA regulations, were designed more for industrial and manufacturing operations. Part 266 subpart P is a sector-based regulatory approach designed to work better with how the healthcare sector operates. Therefore, consistent with the approach initially taken in the Universal Waste proposed rulemaking, the Agency designed the proposed standards for healthcare facilities accumulating hazardous waste pharmaceuticals under subpart P to operate in lieu of the SAA regulations or the CAA regulations (also sometimes called '' less than 90- or 180-day are as'').

[206] EPA makes no claims, promises, or guarantees about the accuracy, completeness, or adequacy of the contents of these sites.

2. Summary of Comments

The majority of commenters on this provision were states. All but one state and all other commenters agreed with the proposal to eliminate requirements for SAAs and CAAs for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. The lone dissenting state agreed with eliminating requirements for SAAs but expressed concern about not requiring CAAs. They recommended that hazardous waste pharmaceuticals be accumulated in or near a 90-day or 180-day accumulation area for LQGs and SQGs respectively.

3. Final Rule Provisions

The agency is finalizing the approach for part 266 subpart P to operate in lieu of requiring CAAs and SAAs for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. The SAA regulations, in particular, were not a good fit for how healthcare facilities operate. Additionally, there was near-unanimous agreement among commenters that SAAs and CAAs are not necessary to accumulate hazardous waste pharmaceuticals, further supporting the agency's decision.

Although there is no requirement that a healthcare facility accumulate its hazardous waste pharmaceuticals in a CAA, doing so is, nonetheless, acceptable. A healthcare facility may choose to accumulate hazardous waste pharmaceuticals within its 90-day or 180-day CAA if it has one established for its other hazardous wastes, as long as it maintains compliance with the accumulation time limit and container requirements of 40 CFR part 266 subpart P. If a healthcare facility chooses to accumulate its hazardous waste pharmaceuticals in a CAA, those hazardous waste pharmaceuticals will only be subject to the requirements of part 266 subpart P and not the part 262 hazardous waste generator standards.

E. Container Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(d))

1. Summary of Proposal

The container standards discussed in this section apply to those containers used by healthcare facilities to accumulate non-creditable hazardous waste pharmaceuticals. First, we would note that due to the relatively small quantities of hazardous waste pharmaceuticals that are typically accumulated and stored at a healthcare facility, the Agency understands that other types of waste management units, such as tanks, are not used for the management of waste pharmaceuticals. Therefore, we only proposed standards for containers as defined in 40 CFR 260.10. However, the Agency solicited comment as to whether other types of waste management units are also used by healthcare facilities to accumulate and store hazardous waste pharmaceuticals and whether EPA should establish technical standards for other types of waste management units.

The Agency proposed to require that healthcare facilities place hazardous waste pharmaceuticals into containers that are structurally sound and that are compatible with the hazardous waste pharmaceuticals that will be contained within them. EPA intends this requirement to mean that containers used for holding non-creditable hazardous waste pharmaceuticals must be in good condition, with no severe rusting, apparent structural defects, nor deterioration. EPA also proposed that containers also must not have any evidence of leakage, spillage, or damage that could result in the release of waste under reasonably foreseeable circumstances. Furthermore, the Agency proposed to require that incompatible wastes not be placed in the same container, unless the commingling of incompatible hazardous wastes is conducted in such a way that it does not have the potential to (1) generate extreme heat or pressure, fire or explosion, or violent reaction; (2) produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health; (3) produce uncontrollable flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; (4) damage the structural integrity of the facility or container containing the hazardous waste pharmaceuticals; or (5) through other like means threaten human health or the environment. For example, the majority of a healthcare facility's non-creditable hazardous waste pharmaceuticals are likely organic in nature, and thus, compatible with each other and can be accumulated together, especially since they will most likely be incinerated once they are transported to a TSDF.

The Agency believes that these technical standards, like similar technical standards that EPA has promulgated in § 265.17(b) for interim status TSDFs,[207] would ensure that hazardous waste pharmaceuticals are properly managed and would not be released into the environment, while at the same time providing flexibility to the healthcare facility in selecting those containers that are most appropriate for their situation.

In addition to the proposed container standards, the Agency also proposed that accumulation containers for hazardous waste pharmaceuticals be secured in a manner that prevents unauthorized access to the contents in order to prevent the diversion of hazardous waste pharmaceuticals or inadvertent exposures to them. Unlike most other hazardous wastes, some hazardous waste pharmaceuticals might still retain considerable value to individuals or on the black market, which can increase the likelihood of diversion for illicit purposes.

Some non-creditable hazardous waste pharmaceuticals, such as metal-bearing wastes not containing sufficient organics (*e.g.,* P012, arsenic trioxide), are prohibited from being incinerated under the dilution prohibition.[208] Dilution is not a substitute for treatment of certain restricted wastes because the hazardous constituents are not destroyed, removed, or immobilized before being disposed of on the land.[209] EPA proposed that the hazardous waste pharmaceuticals that cannot be incinerated must be accumulated separately from organic wastes destined for incineration.

2. Summary of Comments

There was considerable interest in this section with a broad range of comments in support, in opposition, and suggesting modifications. While some states were in support of the proposed standards, others were concerned that they would not be easily understood by healthcare facility workers, and that we should provide more detail about what constitutes a closed container. There was also a comment that recommended we clarify that hazardous waste pharmaceuticals can only be accumulated in containers, and not tanks or other accumulation units, and also what would constitute an acceptable container. For example, the commenter asked if re-sealable plastic storage bags or plastic pill bottles are considered a container under this subpart.

[207] § 265.17 General requirements for ignitable, reactive, or incompatible wastes is available. *https://www.gpo.gov/fdsys/pkg/CFR-2017-title40-vol28/pdf/CFR-2017-title40-vol28-part265.pdf.*

[208] § 268.3(c) Dilution prohibited as a substitute for treatment. See appendix XI of part 268 for a full list of hazardous wastes that are prohibited from being combusted.

[209] See RCRA Policy Statement: Clarification of the Land Disposal Restrictions' Dilution Prohibition and the Combustion of Inorganic Metal-Bearing Hazardous Waste. *https://www.epa.gov/hw/policy-statement-clarification-dilution-prohibition-and-combustion-inorganic-metal-bearing.*

Commenters from the waste management industry were generally in support of the proposed container standards although one commenter took issue with the security standards in 40 CFR 266.502(d)(3), stating that they are not adequate and recommending that we incorporate existing DEA guidance on container security standards. The commenter also suggested the final regulations incorporate an additional security provision stating that hazardous waste pharmaceuticals be put into a ''product or container that is specifically designed to render them inaccessible, non-consumable, and/or irretrievable prior to final disposal.'' A different waste management company echoed the concerns shared by the previously mentioned state that the final rule should specify that hazardous waste pharmaceuticals can only be accumulated in containers and not in other types of waste accumulation units.[210] No commenters indicated that any other types of waste management units are used to accumulate hazardous waste pharmaceuticals.

Trade associations representing a range of stakeholders also generally supported the proposed provisions but were concerned about the requirements to segregate hazardous waste pharmaceuticals that cannot be incinerated. One waste treatment trade association recommended that the regulatory language that allows the incineration of certain mercury-bearing hazardous waste pharmaceuticals be changed to discourage the incineration of such wastes even though it is permissible. They believe that the proposed language may be interpreted as advocating for their incineration. A state association was concerned about the possible subjectivity of the language in 40 CFR 262.502(d)(2), which contains standards for facilities that manage ignitable or hazardous waste pharmaceuticals or that mix or commingle incompatible wastes in the same container. They recommend instead, that the final rule employ the ''traditional prohibition'' on incompatibility.[211]

3. Final Rule Provisions

The Agency is finalizing the container standards for non-creditable hazardous waste pharmaceuticals as proposed. A healthcare facility must place its non-creditable hazardous waste pharmaceuticals in containers that are structurally sound, compatible with the contents, and that would prevent any leaks or spills under reasonably foreseeable conditions. If incompatible hazardous waste pharmaceuticals are commingled in a container, the healthcare facility must manage the container such that it does not have the potential to generate dangerous heat and/or pressure, emit any toxic substances (*e.g.,* mists, fumes, dust), produce flammable fumes or gases, damage the structural integrity of the container, or otherwise endanger human health and the environment.

To address the concerns of commenters, EPA would like to emphasize that, while it is permissible for hazardous waste pharmaceuticals containing metals such as mercury to be incinerated if the total organic carbon is greater than 1%,[212] we strongly recommend that they be segregated out and treated via other acceptable methods that comply with the land disposal restrictions.

EPA is clarifying that the container standards like the other standards for non-creditable hazardous waste pharmaceuticals do not apply to hazardous waste pharmaceuticals that are also DEA controlled substances because these DEA controlled substances are conditionally exempt from RCRA.[213] Section XIV further discusses hazardous waste pharmaceuticals that are also DEA controlled substances.

To reduce the risk of illicit diversion, the Agency is finalizing the requirement preventing unauthorized access to the contents of containers used to accumulate non-creditable hazardous waste pharmaceuticals. EPA intended this requirement to be performance-based and did not finalize prescriptive regulatory requirements for this standard. Healthcare facilities may choose to utilize containers that are designed to prevent unauthorized access to their contents when located in areas with uncontrolled access or store containers in areas with controlled access, such as locked storage lockers, locked closets, or locked rooms, to prevent unauthorized access to the contents of the containers. Containers used to accumulate non-creditable hazardous waste pharmaceuticals may also be kept behind a pharmacy counter because of the restricted access to those areas.

The Agency received no comments indicating that non-creditable hazardous waste pharmaceuticals are accumulated in any waste management units other than containers. Therefore, these standards apply only to containers used to accumulate non-creditable hazardous waste pharmaceuticals. Other types of hazardous waste accumulation units are not permitted for the accumulation of non-creditable hazardous waste pharmaceuticals.

4. Comments and Responses

Section (d)(4) of this provision regarding the requirement to segregate certain metal-bearing non-creditable hazardous waste pharmaceuticals was added as a reminder that, due to existing LDR regulations, a few hazardous waste pharmaceuticals cannot be incinerated and therefore must be segregated. This is not a new requirement for healthcare facilities and does not represent a change in the regulatory burden.

One commenter asked if plastic bags are considered a container as defined in § 260.10. If hazardous waste is placed inside a plastic bag, it meets the definition of a RCRA container and is subject to all applicable standards in 40 CFR 264 subpart I and 40 CFR 265 subpart I. Specifically, to be in compliance, a plastic bag must be compatible with the waste, able to prevent the contents from leaking, kept closed during storage except when it is necessary to add or remove waste, and handled or stored in a manner that prevents rupture and/or causes leaking. EPA would also note that, even though this commenter did not mention other types of containers, that cups, pill bottles, vials, etc. are also considered a container under RCRA.[214]

Regarding the state association that suggested EPA apply the ''traditional prohibition'' on mixing or commingling incompatible wastes in the same container because they were concerned about the possible subjectivity of the five specified conditions in 40 CFR 262.502(d)(2), that regulatory language was taken directly from the general requirements for ignitable, reactive, or incompatible wastes, in the General Facility Standards at 40 CFR 265.17(b). This is not a newly designed requirement. Healthcare facilities that manage hazardous waste pharmaceuticals are already required to comply with this provision.

[210] See comment number EPA–HQ–RCRA–2007–0932–0257.

[211] See comment number EPA–HQ–RCRA–2007–0932–0216.

[212] § 268.3 (c) Dilution prohibited as a substitute for treatment.

[213] § 266.506.

[214] See memo November 11, 2011, Rudzinski to the Regional RCRA Division Directors (RCRA Online #14827).

F. Labeling Standards on Containers for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(e))

1. Summary of Proposal

During the period of accumulation, the Agency proposed that containers of hazardous waste pharmaceuticals be marked with the words ''Hazardous Waste Pharmaceuticals.'' The Agency did not propose to require that the hazardous waste numbers (often referred to as hazardous waste codes) of the container's contents be listed on the label. Healthcare personnel (*e.g.,* nurses) typically generate the hazardous waste pharmaceuticals. Healthcare personnel are not usually intimately familiar with RCRA and its regulations and are primarily focused on patients and their health. In addition, while a healthcare facility may have an environmental compliance manager or environmental consultant that is knowledgeable about RCRA and its regulations and can make hazardous waste determinations, this individual cannot be present to assign a hazardous waste code and label the collection receptacle each time a hazardous waste pharmaceutical is generated. For these reasons, EPA did not believe it would be practical to require individual hazardous waste codes on the hazardous waste pharmaceutical collection container at the healthcare facility.

The Agency solicited comment on the appropriateness of the proposed general labeling requirement. The Agency also requested comment on security concerns regarding having the word ''pharmaceutical'' marked on the containers.

2. Summary of Comments

The issues of determining waste codes and whether they should be required on labels and/or manifests cuts across a number of provisions in this rule. Many commenters intertwined their opinions on container labeling standards with manifest requirements, waste code determinations by healthcare workers, and LDRs. While the Agency understands the inter-relatedness of these issues, this section pertains specifically to the proposed standards of requiring the words ''Hazardous Waste Pharmaceuticals'' on containers used to accumulate hazardous waste pharmaceuticals, and whether having the word ''Pharmaceutical'' displayed on those containers increases the risk of illicit diversion. Many of the comments alluded to these container labeling requirements during on-site accumulation, but did not address them directly, instead focusing on how the proposed labeling standards to not require hazardous waste codes on containers will affect the manifesting, shipping, and LDR processes. We will address those comments in subsequent sections as appropriate.

States had mixed views with a few voicing support for the proposed labeling standards, while another asked that the Agency provide more leeway in the required wording on the container label. Another state agreed with not requiring individual waste codes, but recommended that EPA require some sort of identification of potentially incompatible wastes to help prevent their inadvertent mixing. Two states were opposed to the proposed standards and recommended requiring individual hazardous waste codes on container labels to reduce the risk of mismanagement and incorrect treatment.

One reverse logistics company tacitly agreed with the proposal to not require hazardous waste codes on containers (or manifests) and instead, write ''Hazardous Waste Pharmaceuticals'' on the container and comply with DOT requirements. They expressed agreement with the agency's proposal to not require hazardous waste codes on the manifest, which leads the Agency to conclude that not requiring hazardous waste codes on containers is acceptable to them as well.

Comments from the waste treatment sector were mixed as well. One commenter agreed with the proposal to not require hazardous waste codes on container labels but wanted more flexibility in labeling. Other commenters from the waste treatment industry were wholly opposed to the proposed labeling requirements citing the need for waste codes by TSDFs to meet LDR standards.[215]

One medical waste trade association did not explicitly agree that hazardous waste codes should not be required on container labels, but they did request that, at a minimum, hazardous waste codes should be included on the manifest.

Stericycle initially disagreed with the proposal to require the word ''pharmaceutical'' on labels in addition to ''Hazardous Waste'' when it commented on the 2008 proposal to add pharmaceuticals to the Universal Waste rule. It has subsequently, through first-hand experience, determined that including the word ''pharmaceutical'' on containers does not increase the risk for illicit diversion. Therefore, in its comments to this proposed rulemaking, it is now in support of labeling containers of hazardous waste pharmaceuticals with the words ''Hazardous Waste Pharmaceuticals.''

Multiple commenters representing regional and national healthcare systems currently label their containers with the word ''pharmaceuticals'' and feel it is appropriate.[216] A commenter from the healthcare waste association also agrees that including the word ''pharmaceutical'' on containers is current practice and does not present any additional risk of diversion.[217]

3. Final Rule Provisions EPA is finalizing the container labeling requirements as proposed. Specifically, containers of non-creditable hazardous waste pharmaceuticals must be marked with the words ''Hazardous Waste Pharmaceuticals'' when accumulating on-site. This final rule provision is consistent with the container labeling requirements in the Hazardous Waste Generator Improvements rule,[218] in that generators are not required to label containers with hazardous waste codes during on-site accumulation. Previously, the regulations did not specify when hazardous waste codes needed to be added to container labels.

The Agency was concerned about increasing the risk of diversion resulting from displaying the word ''pharmaceutical'' on a container. However, given the general support from commenters, in this final rule, EPA is comfortable including the word ''pharmaceutical'' on the label of containers used to accumulate hazardous waste pharmaceuticals. There was no opposition from commenters representing healthcare systems and pharmacy trade groups. In fact, many commented that this is has been standard practice for some time and has not resulted in any increased diversion.

4. Comments and Responses

One state was concerned that allowing the commingling of hazardous waste pharmaceuticals could inadvertently lead to incompatible hazardous waste pharmaceuticals being mixed together, and suggested that EPA add a requirement to label containers with potentially incompatible wastes. It is the Agency's understanding that there are only a few pharmaceuticals that are incompatible according to DOT. Pressurized aerosols are the most common, although both DOT and EPA are considering relaxing their

[215] See comment numbers EPA–HQ–RCRA–2007–0932–0333 and EPA–HQ–RCRA–2007–0932–0297.

[216] See comment number EPA–HQ–RCRA–2007–0932–0297.

[217] See comment number EPA–HQ–RCRA–2007–0932–0296.

[218] Final rule: November 28, 2016; 81 FR 85808.

management requirements in the near future. Other DOT incompatible wastes include oxidizers, acids, and bases, yet they occur infrequently in dosage form.[219] In addition, there are a limited number of cases in which commingled incompatible pharmaceutical waste has caused a problem. Therefore, the Agency has determined that the risk does not rise to the level of requiring a specific provision and is not finalizing any additional labeling requirement for incompatible hazardous waste pharmaceuticals.

One commenter from the waste management industry suggested that EPA add the flexibility to label containers of hazardous waste pharmaceuticals with the words ''hazardous waste'' or other words that communicate the hazards per § 262.34(c)(1)(ii).[220] The Agency is not finalizing this suggestion. EPA recently revisited these provisions in the 2016 Hazardous Waste Generator Improvements rule to require that generators label containers with both the words ''hazardous waste'' and other words that indicate the nature of the hazard partially because the Agency felt that the previous requirements were too vague. In addition, § 262.34 applied only to containers in SAAs whereas there are no SAAs in a subpart P healthcare facility.

G. Accumulation Time Limits for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(f))

1. Summary of Proposal

a. One-year accumulation time limit. A few hazardous waste pharmaceuticals are P-listed acute hazardous wastes, the most common being warfarin. Under the part 262 generator regulations, if a generator generates more than 1 kg of acute hazardous waste per calendar month, the generator is regulated as an LQG and subject to a 90-day limit on accumulation. Due to this low generation/accumulation threshold associated with P-listed wastes, healthcare facilities are often LQGs. However, while healthcare facilities can generate enough P-listed waste to become LQGs, they often do not generate sufficient total amounts of hazardous waste pharmaceuticals within the allowed accumulation period of 90 days to make off-site shipments using a hazardous waste transporter cost-effective.

Under the 2008 proposed amendment to add pharmaceuticals to the Universal Waste program, handlers of pharmaceutical universal waste would have had one year to accumulate their hazardous waste pharmaceuticals in order to facilitate proper treatment and disposal. Commenters on the proposed 2008 Pharmaceutical Universal Waste rule indicated support for the one-year accumulation time limit. Thus, under part 266 subpart P, the Agency proposed to allow healthcare facilities to accumulate non-creditable hazardous waste pharmaceuticals for up to one year without triggering interim status or the need to obtain a RCRA permit. EPA proposed one year as an appropriate time frame because it strikes a balance between allowing healthcare facilities enough time to accumulate enough non-creditable hazardous waste pharmaceuticals to make it economically viable to transport their hazardous waste pharmaceuticals off site while ensuring that the hazardous wastes are not accumulated beyond the one-year storage limit under the LDR program (see § 268.50). Under the LDR storage prohibition, the Agency assumes that any accumulation for up to one year is for the purpose of facilitating proper treatment and disposal.

EPA proposed that healthcare facilities could use various approaches to demonstrate the length of time that non-creditable hazardous waste pharmaceuticals are accumulated on site. For example, EPA proposed that a healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, identify in the accumulation area the earliest date that a hazardous waste pharmaceutical became a hazardous waste, or any other method that clearly demonstrates the length of time that the hazardous waste pharmaceutical has been accumulated from the date it became a hazardous waste.

b. Extensions to accumulation time limits. In the proposed time frames to accumulate non-creditable hazardous waste pharmaceuticals, EPA included a provision that allowed any healthcare facility needing longer than the one-year accumulation time frame to request an extension from the appropriate EPA Regional Administrator. The Agency provided several examples of situations when a healthcare facility might request an extension. The reasons included litigation (now referred to as preservation orders, investigations or judicial proceedings),[221] recalls, and circumstances that are beyond the control of the healthcare facility. The proposed extension provision required that healthcare facilities send a request in writing (electronic or paper) to the Regional EPA Administrator explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals to be accumulated beyond the one year, and the amount of extra time requested. The Agency then proposed to allow the Regional Administrator the discretion to grant, modify, or deny the requested extension on a case-by-case basis. Lastly, the Agency solicited comment on the proposed mechanism to request a time extension.

2. Summary of Comments

a. One-year accumulation time limit. One commenter from industry agreed with the proposed time limits, but expressed concern about the ability of a healthcare facility to track accumulation times of their waste, and recommended that there be an additional requirement to inventory container contents in a manner that will ensure that the 1-year limit is not exceeded. Another state commenter also recommended that § 266.502(f)(2)(iv), which would have allowed containers to be marked in ''any other method which clearly demonstrates the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating from the date it first became a waste,'' be eliminated because it is too vague.

b. Extensions to accumulation time limits. The proposed extension provisions were opposed by a majority of commenters from both industry and state governments. Industry commenters were concerned about the additional burden that would likely arise from having to generate, transmit, and maintain an additional set of records for a scenario (the need to accumulate hazardous waste pharmaceuticals beyond the one-year allotment) that they say occurs more often than EPA seems to have been aware of at the time of proposal. Similarly, many state agencies were concerned about the added burden that would be imposed by a novel

[219] Smith, Charlotte A. ''Managing Pharmaceutical Waste: A New Implementation Blueprint.'' Pharmacy Practice News, Special Edition, 2011.

[220] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking. The regulation cited by the commenter has been since moved to 262.16(b)(6) as part of the 2016 Hazardous Waste Generator Improvements Final Rule.

[221] Subsequent to the proposal, the Agency became aware that the term ''litigation'' was not sufficiently broad to encompass all of the legal actions that might require a hazardous waste pharmaceutical to be preserved. To maintain consistency throughout the final rule, all instances where the term ''litigation'' or ''litigation holds'' appeared in the proposed rule have been changed to ''preservation order, investigation, or judicial proceeding,'' except in this section which discusses what was proposed.

source of administrative workload in the form of written requests that must be processed, analyzed, afforded appropriate consideration/discretion, and responded to. In addition, many commenters mentioned the possibility that these provisions would conflict with existing federal regulations, those of FDA for recalls, in particular. Other commenters brought up similar concerns about pharmaceuticals being stored pursuant to a litigation hold because of their protracted and unpredictable nature.

3. Final Rule Provisions

a. One-year accumulation time limit. The Agency is finalizing a one-year accumulation time limit for healthcare facilities accumulating non-creditable hazardous waste pharmaceuticals. Healthcare facilities may use one of three approaches to demonstrate the length of time that non-creditable hazardous waste pharmaceuticals are accumulated on site. A healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, or identify in the accumulation area the earliest date that a hazardous waste pharmaceutical became a hazardous waste.

The Agency reiterates that the one-year accumulation time limit only applies to a healthcare facility's non-creditable hazardous waste pharmaceuticals and does not apply to any other types of non-pharmaceutical hazardous waste generated on-site nor to potentially creditable hazardous waste pharmaceuticals.

The provision in § 266.502(f)(2)(iv) has been eliminated. It would have allowed for the accumulation start date to be labeled in any manner that clearly indicates the length of time that it first began accumulating non-creditable hazardous waste pharmaceuticals. One commenter argued that the provision was overly broad and EPA agreed.

b. Extensions to accumulation time limits. The Agency is not finalizing any of the proposed provisions in § 266.502(f)(3) that would have allowed a healthcare facility to request an extension of the one-year accumulation period for non-creditable hazardous waste pharmaceuticals and has addressed commenter concerns in other areas of the rule.

Recalls and preservation orders, investigations, or judicial proceedings (formerly referred to as litigation in the proposed rulemaking) were the two specific situations that the Agency attempted to address in the proposal as examples of unforeseen circumstances beyond the control of the healthcare facility. Pharmaceuticals that are subject to a voluntary or federally-mandated recall (most likely overseen by FDA, rarely CPSC) must be managed according to the requirements of either one or both agencies, as appropriate. Although many of these items could likely be considered RCRA solid waste, EPA is choosing not to apply RCRA regulations upon recalled pharmaceuticals that are managed under a voluntary or federally-mandated recall until a decision is made to destroy those items either in part or in whole. Similarly, the agency also determined that pharmaceuticals being stored pursuant to a preservation order, investigation, or judicial proceeding are not RCRA hazardous waste. Both scenarios are addressed in the Applicability section of the final rule in the preamble and regulations (see §§ 266.501(g)(4) and 266.501(g)(5)). Because pharmaceuticals that have been recalled and/or are being stored pursuant to a preservation order, investigation, or judicial proceeding are not subject to this subpart, the Agency does not see the need to include a provision for extending accumulation time. Recall managers (likely reverse distributors) and states will not be burdened by producing and responding to such requests.

The proposed rulemaking also discussed other unforeseen circumstances (other than a recall or preservation order, investigation, or judicial proceeding) as a legitimate reason for requesting an extension of the one-year period to accumulation of non-creditable hazardous waste pharmaceuticals. However, the only circumstances mentioned by commenters that would necessitate an extension were recalls and litigation (preservation orders, investigations, or judicial actions). Because both of those scenarios are now addressed individually in the finalized Applicability section of the preamble and regulations, and have no associated accumulation time limits, the Agency saw no need to codify a provision to allow a healthcare facility to request an extension of the accumulation time limit for other reasons beyond their control. Therefore, the EPA is not finalizing the proposal to allow healthcare facilities to request an extension of the one-year accumulation time frame from the Regional Administrator for any reason.

H. Land Disposal Restrictions for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(g) and § 266.502(d)(4))

1. Summary of Proposal

As required by HSWA and consistent with part 262 generator requirements, EPA proposed that healthcare facilities must comply with the LDR requirements prior to land disposal of the hazardous waste pharmaceuticals they generate. Since healthcare facilities are generators, even though they are not subject to the 40 CFR part 262 requirements for the management of hazardous waste pharmaceuticals, we proposed that they must comply with the LDR requirements found at 40 CFR part 268. The LDRs required by HSWA are in place to ensure that toxic constituents present in hazardous waste are properly treated to reduce their mobility or toxicity before hazardous waste is placed into or onto the land (*i.e.,* land disposed). With limited exceptions, hazardous waste must be treated by a RCRA-permitted or interim status TSDF.

In general, generators of hazardous waste assign the appropriate hazardous waste numbers (commonly called hazardous waste codes) to allow TSDFs to determine the specific treatment standard(s) for each prohibited waste. The Agency proposed that healthcare facilities generating non-creditable hazardous waste pharmaceuticals do not have to label the containers with the words ''hazardous waste'' or the hazardous waste codes when transporting them off site, but rather must label the containers with the words ''hazardous waste pharmaceuticals.'' Healthcare facilities do, however, need to make determinations as to whether wastes must be treated to meet LDR treatment standards. While most hazardous waste pharmaceuticals are likely organic in nature and may be incinerated, some hazardous waste pharmaceuticals may not be suitable for incineration and, therefore, must be segregated from the organic wastes. The hazardous waste pharmaceuticals not suitable for incineration include characteristic metal wastes (*i.e.,* D004–D043) prohibited from being combusted because of the dilution prohibition of § 268.3(c), as well as the listed wastes U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide), unless they contain greater than 1% total organic carbon. Put another way, hazardous waste pharmaceuticals with these metals that also contain greater than 1% total organic carbon may be incinerated.

In order to comply with the LDRs, healthcare facilities will need to segregate these wastes from the organic hazardous waste pharmaceuticals so that they can be properly treated by the TSDF. Although the Agency did include a requirement to segregate these metal-bearing low total organic carbon hazardous waste pharmaceuticals in proposed § 266.502(d)(4), the Agency requested comment on whether it is necessary to incorporate into the regulations at § 266.502(g) a requirement to segregate these wastes and whether additional labeling requirements are necessary to identify the hazardous waste pharmaceuticals that are not suitable for incineration.

Because EPA proposed that containers of non-creditable hazardous waste pharmaceuticals would not be required to list the hazardous waste codes on the label, we also proposed that waste codes are not required on the LDR notification.

2. Summary of Comments

There were a variety of comments on this provision, primarily regarding four issues: (1) The segregation of hazardous waste pharmaceuticals unsuitable for incineration, (2) the incineration of hazardous waste pharmaceuticals with numeric treatment standards, (3) the LDR notification, and (4) the need for hazardous waste pharmaceuticals-specific waste code and treatment standard.

Commenters from both states and the waste management industry requested that the agency add a requirement for healthcare facilities to segregate any hazardous waste pharmaceuticals that are unsuitable for incineration into separate containers and label them with the appropriate waste codes. They argued that there would be an increased likelihood that pharmaceuticals containing metals subject to the dilution prohibition would be inadvertently incinerated, resulting in noncompliance with LDR standards.

Many waste management companies expressed concern about their ability to meet LDR standards without knowing specific waste codes and the added burden they would incur from having to test their ash for the seven hazardous waste pharmaceuticals with numeric treatment standards—lindane, chloroform, m-cresol, dichlorodifluoromethane, trichloromonofluoromethane, phenacetin and phenol.[222] They did, however, agree that healthcare workers should not have to make hazardous waste determinations. They stated that they would have to alter or augment their testing protocols for residual ash which would add undue burden. One commenter suggested that, at a minimum, segregation be performed before a shipment of hazardous waste pharmaceuticals are transported off site for disposal, but having waste codes either on a label or the manifest would be preferable. They generally stated that they do not feel waste management should bear all of the added burden of LDR compliance under this rule.

Another common theme among commenters, from the waste management industry in particular, was a recommendation for a new, single hazardous waste code for all hazardous waste pharmaceuticals with a corresponding alternate treatment of standard of combustion (CMBST). One commenter representing the retail industry expressed concern that the relief provided by this rule will be negated by the requirement to list waste codes on the LDR notice.

3. Final Rule Provisions

The Agency is finalizing the LDRs for non-creditable hazardous waste pharmaceuticals as proposed. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the LDRs of 40 CFR part 268. A healthcare facility that generates hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (*i.e.,* hazardous waste codes) on the LDR notification.

To address commenters' concerns about whether hazardous waste codes are required on the LDR notification, the Agency has added clarifying language to specify that waste codes are, in fact, not required on the LDR notification. The Agency would note, however, that the proposed regulatory language did, in fact, specify in § 266.502(g) that waste codes are not required on the LDR notice. Due to the number of commenters who were under the impression that waste codes would still be required on the LDR notice, we added an additional clarification to make it more obvious that waste codes are not required on the LDR notice.

The final rule requires healthcare facilities that generate non-creditable hazardous waste pharmaceuticals to comply with the LDRs. In response to comments, we have made one minor change for added clarity. The Agency has added a requirement to § 266.502(d)(4) for healthcare facilities that generate non-creditable hazardous waste pharmaceuticals that are unsuitable for incineration to segregate them into separate containers from those containing commingled non-creditable hazardous waste pharmaceuticals, and label them with the appropriate hazardous waste codes. We would note, however, that the dilution prohibition of § 268.3 already necessitates such segregation, therefore, this addition in § 266.502 (d)(4) is for the purposes of clarity and does not substantially change any of the proposed LDR requirements for hazardous waste pharmaceuticals.

4. Comments and Responses

Waste management companies opposed the provision to not require healthcare facilities to label containers with hazardous waste codes because of the added burden they argue would result from having to conduct additional testing for pharmaceuticals with numeric treatment standards. Nevertheless, the Agency is not finalizing a requirement for healthcare facilities to label containers of non-creditable hazardous waste pharmaceuticals with hazardous waste codes, nor is the Agency finalizing any additional requirements for healthcare facility personnel to segregate the seven pharmaceuticals that have numeric treatment standards, although a vendor could include such a requirement in its contract with a healthcare facility.

Unlike metal-bearing hazardous waste pharmaceuticals that may not be incinerated, the seven hazardous waste pharmaceuticals with numerical treatment standards may be incinerated or treated using any other treatment method to meet LDR values. Therefore, the Agency thinks it would cause confusion and add burden to require healthcare facilities to segregate the hazardous waste pharmaceuticals with numeric treatment standards. Further, the Agency has determined that several of the seven organics with numeric treatment standards also appear in non-pharmaceutical hazardous waste, which means that hazardous waste combustors are already required to test their ash to ensure compliance with LDRs for those constituents.

Because this rule does not require that healthcare facilities label their waste with the hazardous waste codes, TSDFs will now have to analyze their incinerator residue (ash) for the seven organics that have numerical treatment standards according to the conditions established in the facility waste analysis plan, as they could possibly be present in any shipment of organic hazardous

[222] See 40 CFR 268.40 table ''Treatment Standards for Hazardous Wastes,'' which identifies maximum concentration values for all hazardous constituents in the waste/treatment residue prior to land disposal.

waste pharmaceuticals or treatment residues. Organic hazardous waste pharmaceuticals (other than arsenic trioxide) may all be incinerated at RCRA-permitted or interim status hazardous waste combustors. Most organic wastes have a specified treatment standard of combustion (CMBST). The remaining seven organics have numerical treatment standards, such that no particular treatment technology is required to achieve the numerical LDR treatment standards. While these wastes may be incinerated, the ash must be analyzed for these seven organic constituents to demonstrate compliance with the LDR treatment standards before that ash can be land disposed. The Agency is not finalizing any standards that would affect the frequency of testing, simply that TSDFs test their ash for these seven constituents as part of their existing protocol.

EPA is not finalizing recommendations from commenters that the Agency implement a new waste code or alternative treatment standards specifically for hazardous waste pharmaceuticals. Because the Agency did not propose any new waste codes or treatment standards for hazardous waste pharmaceuticals, the recommendation is outside the scope of this rule. The Agency does agree that implementing an alternative treatment standard of combustion for hazardous waste pharmaceuticals that currently have numeric treatment standards would be a viable solution to mitigate any added burden imposed on TSDFs that will have to modify their testing protocol; however, we did not receive the necessary data to propose such a change prior to proposal, and therefore cannot finalize an alternative treatment standard in this rule. The Agency is, however, open to considering alternative treatment standards for hazardous waste pharmaceuticals in possible future rulemakings.

In their comments on this rule and the 2008 Universal Waste proposal, Environmental Technology Council (ETC) suggested revising the treatment standards for the organic hazardous waste pharmaceuticals that have numerical treatment standards to the specified treatment standard of combustion. Specifying combustion would relieve the TSDFs from demonstrating compliance with the numerical treatment standards.[223] EPA explored the feasibility of making combustion an alternative treatment standard for the seven organic hazardous waste pharmaceuticals that currently have numeric LDR treatment standards. In fact, EPA notes that the numerical treatment standards were developed based on levels achieved through combustion. However, EPA has indicated a preference for numerical treatment standards over specifying treatment standards whenever possible, to allow maximum flexibility. Furthermore, it is not clear that pharmaceuticals would be the sole source of the seven organic constituents in question. Therefore, even if we proposed an alternative treatment standard of combustion for the seven organic pharmaceuticals, hazardous waste combustors would still be required to test their ash for these constituents to demonstrate compliance with numeric treatment standards if they received the organics from another, non-pharmaceutical source.

Again, EPA notes that autoclaving is not an acceptable method of treating hazardous waste.[224]

I. Procedures for Healthcare Facilities Managing Rejected Shipments of Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(h))

1. Summary of Proposal

In rare circumstances, a healthcare facility may send its non-creditable hazardous waste pharmaceuticals to a designated facility that is unable to manage the hazardous waste. For such situations, we proposed that healthcare facilities follow the same procedures listed in 40 CFR part 262 (see § 262.23(f)). EPA believes that it is appropriate to continue current practices for rejected shipments that are part of the generator regulations of 40 CFR part 262 because rejected shipments are relatively rare and the procedures currently used for rejected shipments is relatively straightforward. In addition, healthcare facilities should be familiar with these procedures already.

2. Summary of Comments

There were relatively few comments on this section of the proposed rulemaking. One state and one waste management company agreed with the standards as proposed. Another state suggested that, as written, the regulatory language contradicts itself. Specifically, the commenter said that proposed § 266.502(h)(4) implies that a healthcare facility that receives a rejected shipment of non-creditable hazardous waste pharmaceuticals (a shipment that it initiated) must offer it for shipment to a new designated facility upon receipt, as opposed to the 90-day additional accumulation period mentioned in § 266.502(h). They reason that, because there are no time frames in the requirement, the Agency intended to mean upon receipt.

3. Final Rule Provisions

The agency is finalizing the provisions in this section as proposed with the added clarification that a healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility must have an understanding that the designated facility can accept and manage the waste. However, if the healthcare facility later receives the shipment back as a rejected load, the healthcare facility must sign the manifest that was used to return the shipment, provide the transporter a copy of the manifest, send a copy of the manifest within 30 days to the designated facility that returned the shipment and ship the non-creditable hazardous waste pharmaceuticals to a new designated facility. The Agency also added additional clarification to § 266.502(h)(4), to respond to comments, specifying that a healthcare facility has up to 90 days to ship the rejected shipment to a new designated facility.

J. Reporting Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(i))

1. Summary of Proposal

We proposed that healthcare facilities that are required to submit a BR would no longer be required to include their non-creditable hazardous waste pharmaceuticals in the report. In addition, the Agency proposed that healthcare facilities managing non-creditable hazardous waste pharmaceuticals have reporting requirements similar to generators regulated under 40 CFR part 262—that is, the exception reporting requirement under § 262.44(b) and the additional reporting requirement under § 262.44(c).

We proposed to incorporate and adapt the generator exception reporting procedures of 262.44(b) for this new subpart. Specifically, we proposed that if a healthcare facility does not receive a copy of the hazardous waste manifest from the designated facility within 60 days, the healthcare facility must submit to the EPA Regional Administrator a copy of the manifest with a statement that the healthcare facility did not

[223] Prohibited waste may be land disposed if it is treated using the technology specified in the table (*e.g.,* CMBST:''), which are described in detail in § 268.42, Table 1—Technology Codes and Description of Technology-Based Standards.

[224] See section VII.D.1.b for further discussion.

receive confirmation of the non-creditable hazardous waste pharmaceuticals' delivery, along with an explanation of the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts. Likewise, we proposed that if a shipment of non-creditable hazardous waste pharmaceuticals from a healthcare facility is rejected by the designated facility and it is shipped to an alternate facility and if the healthcare facility does not receive a signed copy of the hazardous waste manifest from the alternate facility within 60 days, it must submit to the EPA Regional Administrator a copy of the hazardous waste manifest with a statement that the healthcare facility did not receive confirmation of the non-creditable hazardous waste pharmaceuticals' delivery along with an explanation of the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

Finally, the Agency proposed that the Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of hazardous waste pharmaceuticals. This is already the case for generators operating under the 40 CFR part 262. As with 40 CFR part 262, it is a codification of statutory authority under §§ 2002(a) and 3002(a)(6) that provides the Agency some flexibility in what reports may be required.

2. Summary of Comments

The Agency received few comments on this subsection. Comments primarily addressed there being no requirement to include hazardous waste pharmaceuticals on the BR, and opinions were mixed. All pharmacy trade groups that commented were in favor of the proposal to not require hazardous waste pharmaceuticals managed under part 266 to be reported on the BR. States that commented were split. One state opposed the proposal and argued it would hinder the state's ability to reconcile what is treated at a TSDF with what is generated at a healthcare facility. Another state disagreed with the proposed provision and argued states will be forced to establish their own reporting requirements at the state level, leading to inconsistency in the way states determine their reporting fees. Another state was in agreement with the proposed provision, stating that information regarding amounts of non-creditable hazardous waste pharmaceuticals generated and treated can be captured from reverse distributor and TSDF reporting. One other state pointed out that the lack of a requirement for healthcare facilities to determine waste codes would make reporting in the BR difficult, if not impossible.

Regarding the exception reporting requirements, one state suggested that § 266.502(i)(2)(ii)(A) and (B) are unnecessary because the requirements in § 266.502 (i)(2)(i)(A) and (B) for a healthcare facility that does not receive a signed copy of the manifest within 60 days of being accepted by the initial transporter are the same, whether the shipment is lost or rejected and transferred to a new designated facility. The state suggested that § 266.502(i)(2) should be rewritten to simply state that an exception report is only necessary if the healthcare facility has not received the signed manifest from the TSDF within 60 days. One healthcare provider suggested that the proposed 60-day period for a healthcare facility to receive the manifest from the TSDF should be shortened to 45 days because shipments of other non-pharmaceutical hazardous waste require receipt of the manifest from the TSDF within 45 days.

3. Final Rule Provisions

The reporting requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals are being finalized as proposed. That is, non-creditable hazardous waste pharmaceuticals managed under this subpart at a healthcare facility are not required to be reported on the BR, healthcare facilities must submit an exception report to the Regional Administrator if they have not received a signed copy of the manifest within 60 days of the initial transporter accepting the shipment, and the Agency may require a healthcare facility to furnish additional reports regarding the quantity and disposition of non-creditable hazardous waste pharmaceuticals. When managing rejected shipments, the Agency believes it is advantageous to use established procedures that should be familiar to healthcare facilities, especially given that rejected shipments are relatively rare.

To clarify, the exception reporting regulations for healthcare facilities differ from the exception reporting regulations for reverse distributors because they were based on the differing § 262.42 exception reporting for LQGs and SQGs. The exception reporting regulations for healthcare facilities were based on the corresponding § 262.42(b) SQG regulations, whereas the reverse distributor exception reporting regulations were based on the § 262.42(a) LQG regulations.

Although commenters voiced some concern about not knowing the volume of non-creditable hazardous waste pharmaceuticals being generated at healthcare facilities, the Agency believes it is unnecessary to require healthcare facilities generating non-creditable hazardous waste pharmaceuticals to report this information. If a state or region wants to obtain such information, it can examine hazardous waste received forms in the BR submission from TSDFs. Further, one of the goals of this final rule is to reduce burden on healthcare facilities so that they will be encouraged to manage all of their waste pharmaceuticals under part 266 subpart P. Requiring a healthcare facility to report hazardous waste pharmaceuticals on its BR would discourage them from managing non-hazardous waste pharmaceuticals as hazardous. Finally, we would note that this approach is consistent with the Universal Waste program upon which the healthcare facility standards are based. Universal wastes managed under part 273 are not reported on the BR.

4. Comments and Responses

As part of the part 262 generator regulations, healthcare facilities that are LQGs must submit a BR to the Regional Administrator by March 1st of every even numbered year (see § 262.41). Among other requirements, the BR must include a description (EPA hazardous waste number and DOT hazard class) and quantity of each hazardous waste shipped off-site to a TSDF during each odd numbered year. If a healthcare facility is an LQG due to its non-pharmaceutical hazardous waste, it will continue to be required to submit a BR under part 262. However, it need not include in its BR hazardous waste pharmaceuticals managed under part 266. As discussed previously, the Agency is no longer requiring healthcare facilities to count hazardous waste pharmaceuticals managed under part 266 when determining their generator category under part 262. Instead, all healthcare facilities, with the exception of VSQGs, will be subject to this final rule for the management of hazardous waste pharmaceuticals. The Agency has determined that it does not need the information to be included in the BR because this final rule will bring a consistent approach to managing hazardous waste pharmaceuticals.

One commenter suggested that the time frame within which a healthcare facility must receive a signed manifest be shortened from 60 days to 45. The Agency did not finalize that request

because many standards in this final rule were based upon SQG and universal waste standards. Since no manifest is required for transport and there is no exception reporting standard in the Universal Waste program, the Agency used the 60-day time frame in the part 262 SQG standards. LQGs have a 45-day time frame to receive a signed manifest from a designated facility. Therefore, shortening the exception reporting time frame from 60 days to 45 would not be consistent with the goals of this rule to relieve the burden of LQG standards on healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

The Agency is not finalizing the suggestion to unify the language in § 266.502(i)(2) to cover both missing and rejected shipments. The proposed language was taken from the generator requirements in § 262.42, which addresses both situations separately. The Agency is not aware of the existing approach creating any problems for generators and is finalizing the regulatory language as proposed.

K. Recordkeeping Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(j))

1. Summary of Proposal

The Agency proposed that healthcare facilities managing non-creditable hazardous waste pharmaceuticals maintain records similar to the records that must be kept by generators regulated under 40 CFR part 262 (see § 262.40). Specifically, we proposed that healthcare facilities must keep a signed copy of each hazardous waste manifest as a record for three years from the date that the non-creditable hazardous waste pharmaceutical was accepted by the initial hazardous waste transporter. If the healthcare facility is required to file an exception report because it does not receive a signed copy of the manifest from the designated facility within 60 days of the date that the hazardous waste pharmaceutical was accepted by the initial transporter, then the healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report. In addition, EPA proposed that a healthcare facility must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals regarding which pharmaceuticals are hazardous wastes for three years from the date of the test, analysis, or other determination. The Agency also proposed that any of the retention periods be automatically extended during the course of ongoing enforcement actions against any activity associated with hazardous waste pharmaceutical management or as requested by the Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

2. Summary of Comments

There were very few comments on this proposed provision. All but one of the commenters were states, all of which agreed with the proposed standard. One commenter suggested that we specify that all three types of records (manifest, exception reports, and test results/analysis/waste determinations) be kept on site.

3. Final Rule Provisions

The recordkeeping requirement is being finalized as proposed, with two changes. First, the Agency added a fifth provision in § 266.502(j)(5) to address comments requesting that all records be kept on site. The added provision also requires that all records must be readily available upon request by an inspector. The Agency understands that some records may be kept at off-site locations (*e.g.,* headquarters), which is acceptable as long as those records are able to be produced in a timely manner upon the request of an inspector.

The second change was an addition to § 266.502(j)(3) that relieves a healthcare facility from the requirement to retain documentation of hazardous waste determinations in § 266.502(c) if it chooses to manage all of its non-creditable waste pharmaceuticals as hazardous waste under subpart P. As discussed elsewhere, a goal of this rule is to encourage healthcare facilities to manage all of their waste pharmaceuticals under subpart P to reduce the amount of pharmaceuticals entering surface and groundwater via sewering and landfill leachate. The relief provided in § 266.502(j)(3) provides additional incentive for healthcare facilities to manage their non-creditable non-hazardous pharmaceutical waste under subpart P.

A healthcare facility must keep a copy of the signed manifest for a period of at least three years from the date the shipment was accepted by the initial transporter. A healthcare facility must also keep a copy of any exception report for a period of at least three years from the date of the report. To make the recordkeeping consistent with the 2016 Generator Improvements final rule, a healthcare facility must keep any information used to support its hazardous waste determination for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal, unless it chooses to manage all of its non-creditable pharmaceutical waste as hazardous waste under subpart P. The periods of retention will be automatically extended in the event of any enforcement activity or as requested by the Regional Administrator.

L. Response to Spills for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(k))

1. Summary of Proposal

For non-creditable hazardous waste pharmaceuticals generated and managed by healthcare facilities under this subpart, the Agency proposed basic spill response requirements, including the requirement that healthcare facilities immediately contain all spills of, and other residues from, hazardous waste pharmaceuticals. In addition, we proposed that healthcare facilities determine whether any material (*e.g.,* residue, contaminated clean-up materials, or debris resulting from the spill) is or contains a hazardous waste pharmaceutical and, if so, that the healthcare facility manage it under the management standards for non-creditable hazardous waste pharmaceuticals. Commenters to the original 1993 proposed rulemaking for establishing the Universal Waste program overwhelmingly supported these release response measures (60 FR 25528; May 11, 1995). Thus, we believe it was appropriate to include them again in this proposal for healthcare facilities managing non-creditable hazardous waste pharmaceuticals since it was based on the Universal Waste program.

2. Summary of Comments

One waste management company was in support of the proposed standards while another voiced its concern with the proposed preamble language discussing the requirement to report releases into the environment greater than the reportable quantity without knowing the waste codes of the wastes that had been spilled. They recommended that the Agency establish a reportable quantity for hazardous waste pharmaceuticals so large releases are appropriately reported to EPA. Similarly, one pharmacist trade association recommended that the Agency define what constitutes a release because the proposed regulatory language and preamble are unclear, and therefore it is also unclear when a release needs to be reported to the Agency.

One state commenter pointed out that these standards should also apply to healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals. They recommend that this standard apply to all hazardous waste pharmaceuticals and that after a spill is cleaned up, the determination of credit potential must be made again. All other states agreed with the proposed standards for responding to spills.

3. Final Rule Provisions

The standards in this subsection are being substantially finalized as proposed with two changes.

First, we changed the word ''release'' to ''spill'' in the regulations in response to a commenter that expressed concern about having to comply with CERCLA requirements for spills of non-creditable hazardous waste pharmaceuticals. It was not the Agency's intent to imply that spills occurring inside a healthcare facility are automatically subject to CERCLA. The proposed preamble language was intended to differentiate between three scenarios: Spills that are cleaned up immediately, spills that are not cleaned up immediately, and releases to the environment. Spills that are cleaned up immediately must be managed under this subpart. Spills that are not cleaned up immediately would generally constitute illegal disposal, which may result in further action by EPA or an authorized state. The proposal also mentioned that hazardous waste is included in the definition of hazardous substance under CERCLA, and any release to the environment would trigger CERCLA authority in addition to RCRA. In many cases, a spill of a hazardous waste pharmaceuticals that occurs inside a healthcare facility does not constitute a release to the environment under CERCLA.[225] Therefore, this standard applies to spills that do not constitute a release to the environment, and there are no reporting requirements for spills unless they result in a release to the environment. This requirement makes no assertions about when or how CERCLA applies to spills of both non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals. The new terminology is also consistent with the term used in the definition of non-creditable hazardous waste pharmaceuticals in § 266.500, which refers to spills as opposed to releases.

Second, we addressed the comment from the state that requested a clarification regarding whether the spill response requirements apply to potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals. The Agency agrees that the applicability of this proposed provision—whether it applies only to non-creditable hazardous waste pharmaceuticals or to both potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals—was unclear. The regulatory language has been changed to reflect that the standards in this subsection apply only to spilled non-creditable hazardous waste pharmaceuticals. Further, the proposed regulations required that a healthcare facility determine whether, after being cleaned up, spilled non-creditable hazardous waste pharmaceuticals are potentially creditable or non-creditable, implying that non-creditable hazardous waste pharmaceuticals could become potentially creditable. The Agency did not intend to imply that spilled non-creditable hazardous waste pharmaceuticals could become potentially creditable. The regulatory language has been modified to simply require that spilled non-creditable hazardous waste pharmaceuticals and clean-up material be contained and managed as non-creditable hazardous waste pharmaceuticals. To address this regulatory gap that commenters identified regarding spilled potentially creditable hazardous waste pharmaceuticals, the Agency has added a corresponding subsection containing standards for response to spills of potentially creditable hazardous waste pharmaceuticals at a healthcare facility to the regulatory language at § 266.503(f).

M. Management of Non-Creditable Hazardous Waste Pharmaceuticals by Long-Term Care Facilities That Collect Them From Individuals Who Self-Administer

1. Summary of Proposal

The Agency proposed that a LTCF must collect hazardous waste pharmaceuticals from its residents that self-administer their medication and manage them under this subpart. This provision was proposed in order to require the proper management of all hazardous waste pharmaceuticals at LTCFs. LTCFs are similar to hospitals in that they are both healthcare providers, but they differ with respect to who owns the pharmaceuticals dispensed to patients. While hospitals own the pharmaceuticals they dispense, the pharmaceuticals dispensed at long-term care facilities belong to the residents of the facility. EPA understands that, while long-term care facilities often maintain each individual's pharmaceuticals in a centralized location, such as a pharmaceutical cart, there are instances where some individuals at some types of LTCFs may keep and self-administer their own pharmaceuticals. Under the proposal, long-term care facilities would have had to collect and manage all hazardous waste pharmaceuticals generated on site, regardless of ownership, in accordance with these same proposed subpart P management standards for healthcare facilities. EPA believed this approach would prohibit and prevent sewering of hazardous waste pharmaceuticals at these locations.

2. Summary of Comments

There was very little agreement with the proposed requirement for LTCFs to collect hazardous waste pharmaceuticals from patients that self-administer their medication. Most commenters argued that hazardous waste pharmaceuticals generated by residents who self-administer are household hazardous waste and that LTCFs are not allowed by law to perform any mandatory collection actions and have no authority to compel residents to surrender their unused medications. In addition, they commented that medication prescribed under Medicare Subpart D is considered the property of the resident. One commenter also pointed out that this provision would be unlawful and even dangerous to enforce because it would entail inspectors having to enter private residences, which is prohibited by many state statutes, and search through garbage bags and dumpsters to ensure that hazardous waste pharmaceuticals have not been illegally disposed.

Also, one commenter mentioned that this provision would add significant cost to the residents because waste management expenses are not covered under Medicare and pharmacies are not allowed to offer waste collection services for less than cost and would therefore be required to pass the full cost onto the residents.

3. Final Rule Provisions

The Agency is not finalizing the proposed provisions in this subsection. As discussed previously, after consideration of the comments, the Agency modified the definition of LTCF

[225] Spills are likely to occur upon impermeable surfaces both inside of and outside of a healthcare facility which limits the potential for release into the environment. Under CERCLA, a release to the environment also includes releases into the atmosphere. Since many pharmaceuticals are in pill form, spilled pharmaceuticals would rarely, constitute a release to the environment under CERCLA.

to specifically exclude assisted living facilities, group homes, independent living communities, and the independent/assisted living portions of continuing care retirement communities. The Agency agrees that the hazardous waste pharmaceuticals generated at these types of facilities meet the criteria for the household hazardous waste exclusion in § 261.4(b)(1) and are therefore not under the purview of RCRA regulations. Accordingly, we have also deleted proposed § 266.502(l) and the final rule does not require LTCFs to collect hazardous waste pharmaceuticals for their residents that have custody of and self-administer their medication. The Agency does, however, reiterate that this definition of LTCFs classified them as a type of healthcare facility. As such, LTCFs are subject to all the provisions being finalized for hazardous waste pharmaceuticals that are present in an LTCF's central pharmacy, because the hazardous waste being generated is not the property of the residents. Additionally, hazardous waste pharmaceuticals that are in the custody of the LTCF on behalf of the resident must be managed under this subpart. That said, the Agency expects that most LTCFs will be VSQGs and therefore only subject to a limited subset of the regulations in this rule, including the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504. In fact, § 266.504(d) of the final rule includes a presumption that an LTCF with fewer than 20 beds is a VSQG.

Although not regulated under this subpart, the Agency recommends that assisted living facilities, group homes, independent living communities, and the independent and assisted living portions of continuing care retirement communities develop voluntary pharmaceutical collection programs for both hazardous and non-hazardous waste pharmaceuticals as a best management practice, as allowed by DEA regulations, to ensure proper management, avoid flushing, and minimize the potential for accidental poisonings, misuse or abuse.

N. Healthcare Facilities That Accept Hazardous Waste Pharmaceuticals From Off-Site Very Small Quantity Generator Healthcare Facilities (§ 266.502(l))

1. Summary of Proposal

Typically, hazardous waste pharmaceuticals from healthcare facilities are transported either to a reverse distributor, if it is potentially creditable, or to a permitted or interim status hazardous waste TSDF, if it is not. However, stakeholders have informed EPA that in some cases, hazardous waste pharmaceuticals are transported to another healthcare facility.

Until EPA finalized the Hazardous Waste Generator Improvements rule on November 28, 2016, CESQG regulations of § 261.5 did not allow a generator to send its hazardous waste off site to another generator, unless the receiving generator was one of the seven types of facilities listed in § 261.5(f)(3)(i)–(vii) or § 261.5(g)(i)–(vii), which included landfills permitted by state law.[226] The 2016 Hazardous Waste Generator Improvements final rule added a new provision for the consolidation of hazardous waste from VSQGs to LQGs under the control of the same person.[227] Person is defined under RCRA in § 260.10 and control is defined as ''the power to direct policies at the facility under RCRA in § 260.10.'' [228] [229] This provision now allows the same company to consolidate its VSQG hazardous waste at its LQG sites.

Specific to healthcare facilities, EPA is aware of two situations in which VSQGs would like to consolidate their hazardous waste pharmaceuticals at other healthcare facilities. The first situation is LTCFs that are VSQGs that return their hazardous waste pharmaceuticals to long-term care pharmacies that they contract with. The second situation involves military bases, where the off-post clinics that are generally VSQGs would like to send their hazardous waste pharmaceuticals back to the base clinics or pharmacies on the nearby base.[230]

Since long-term care pharmacies are not generally under the control of the same person as the LTCF, the proposed healthcare facility consolidation provision was broader than what was finalized in the 2016 Hazardous Waste Generator Improvements rule to accommodate the contractual relationship between long-term care facilities and long-term care pharmacies. The Agency proposed this consolidation provision to allow healthcare facilities that are VSQGs to send their hazardous waste pharmaceuticals to another healthcare facility rather than send it to a municipal solid waste landfill.

Specifically, EPA proposed to allow VSQG healthcare facilities to send their hazardous waste pharmaceuticals to an off-site healthcare facility without a hazardous waste manifest, provided the receiving healthcare facility meets four conditions. First, the receiving healthcare facility must be contracted to supply pharmaceutical products to the VSQG LTCF, or the VSQG healthcare facility and the receiving healthcare facility must both be under the control of the same person, as defined by § 260.10.[231] Second, the receiving healthcare facility must be managing its hazardous waste pharmaceuticals in accordance with subpart P. Third, the hazardous waste pharmaceuticals from the VSQG must be managed by the receiving healthcare facility as hazardous waste pharmaceuticals in accordance with subpart P once it arrives at the receiving healthcare facility. Fourth, the receiving healthcare facility must keep and maintain records of the hazardous waste pharmaceuticals received from the off-site VSQG healthcare facilities for three years from receipt of shipment.

As proposed, these conditions would ensure the proper management of the hazardous waste pharmaceuticals: Once they are received by the healthcare facility, they are subject to the same management standards EPA proposed for hazardous waste pharmaceuticals managed by healthcare facilities.

EPA took comment on two aspects of this exclusion: (1) Whether any additional conditions should be imposed in this provision and (2) whether to expand the scope of the provision to facilities that do not meet the proposed definition of a healthcare facility in this rule.

2. Summary of Comments

Overall, states, waste management and the healthcare industry were supportive of the proposal to allow VSQG healthcare facilities to consolidate their hazardous waste

[226] The Hazardous Waste Generator Improvements final rule renamed CESGGs as VSQGs, moved the regulations from § 261.5 to § 262.14 and added an eighth type of facility.

[227] 40 CFR 262.14(a)(5)(viii).

[228] *Person* means an individual, trust, firm, joint stock company, Federal Agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.

[229] For purposes of this provision, ''control'' means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to control such healthcare facility.

[230] See notes from 11–28–12 meeting with U.S. Army Institute of Public Health in the docket for this rule (EPA–HQ–RCRA–2007–0932–0209).

[231] For purposes of this provision, ''control'' means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to control such healthcare facility.

pharmaceuticals at another healthcare facility, provided the four conditions outlined above are met. One state, however, did oppose this provision unless the receiving healthcare facility is subject to all of the LQG requirements under part 262. They recommended that hazardous waste pharmaceuticals from VSQGs be consolidated at larger healthcare facilities under the 2016 Hazardous Waste Generator Improvements final rule to ensure more stringent standards are met by the receiving facility. Some states and pharmacists raised concerns that some of the language within the conditions was too narrow to serve the purpose that the language was trying to achieve.

3. Final Rule Provision

EPA is finalizing the provision to allow healthcare facilities that are operating under subpart P to receive hazardous waste pharmaceuticals from VSQGs with minor changes. Healthcare facilities that are VSQGs for their pharmaceutical and non-pharmaceutical waste may send their potentially creditable and non-creditable hazardous waste pharmaceuticals to an off-site healthcare facility operating under subpart P, without a hazardous waste manifest, provided the receiving healthcare facility meets the four conditions in § 266.502(l)(1)–(4) or § 266.503(b)(1)–(4), as applicable.

Several conforming changes were made to reflect the change in terminology from CESQG to VSQG and to reflect the reorganization of the VSQG regulations from § 261.5 to § 262.14. There are three more substantive changes from the proposal. First, under § 266.502(l)(1) where we proposed that one way a healthcare facility could receive hazardous waste pharmaceuticals from an off-site VSQG healthcare facility was to have a contractual relationship to provide the pharmaceutical products to the LTCF, we broadened the language to allow cases in which a ''business relationship'' between the LTCF and long-term care pharmacy exists.

Under the final rule, a healthcare facility under subpart P may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the VSQG healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

(2) Is operating under subpart P for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with subpart P; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

It is important to note that a VSQG healthcare facility that chooses to send their waste for consolidation to an off-site healthcare facility is not considered to be operating under subpart P and does not need to notify as a VSQG operating under subpart P.

The second substantive change was to include a parallel provision in § 266.503 for potentially creditable hazardous waste pharmaceuticals. This addition allows healthcare facilities that are VSGQs two options for where to send their potentially creditable hazardous waste pharmaceuticals. The first option is to send them directly to a reverse distributor.[232] The second option is to send them to a healthcare facility operating under part 266 subpart P, provided the receiving facility meets the conditions of 266.503(b)(1)–(4).

The third change related to off-site consolidation of hazardous waste pharmaceuticals is to add paragraph § 262.14(a)(5)(x). Section 262.14(a)(5) of the VSQG regulations consists of a list of types of facilities to which VSQGs can send their hazardous waste. Section 262.14(a)(5)(viii) allows VSQGs to send their hazardous waste to large quantity generators under the control of the same person as the VSQG, provided certain conditions are met. This provision is similar to the provision we are finalizing in this rule for healthcare facilities that are VSQGs. Therefore, for consistency, we have added paragraph (x) to the list of facilities in § 262.14(a)(5) such that a healthcare facility that is a VSQG can send its non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals to an off-site healthcare facility (as defined in § 266.500) that meets the conditions in § 266.502(l) and § 266.503(b), as applicable.

4. Comments and Responses

Some states and pharmacists noted that language in the first condition may have the unintended consequence of prohibiting healthcare facilities from consolidating their hazardous waste pharmaceuticals due to their relationship with the consolidating facility. The first condition that a receiving healthcare facility must be under the control of the same person or contracted to supply pharmaceutical products to the VSQG's LTCF might prevent some long-term care facilities from taking advantage of this provision. Long-term care facilities that would otherwise be eligible to take advantage of this exclusion might not use it since CMS does not prevent long-term care facilities and/or their residents from using more than one long-term care pharmacy. This allows the long-term care facilities and the residents to shop for the ''best and most competitive'' pricing for medications and to change as needed.[233] Commenters believed that adding ''business relationship'' in addition to a contractual relationship for the healthcare facility and receiving facility to both be under the control of the same person would relieve this concern.

Furthermore, pharmacists raised the concern that a long-term care pharmacy would not want to take responsibility for returned pharmaceuticals under this condition as proposed unless they could confirm that they were the ones that distributed the pharmaceuticals in the first place (a receipt of purchase or similar documentation), since the management of these wastes is costly and may not be covered by the various healthcare programs. According to the CMS website, the managing of returned pharmaceuticals at long-term care pharmacies varies from state to state and is not a specific requirement of the Medicare/Medicaid program.[234] This consolidation provision was created so that VSQGs could consolidate their hazardous waste pharmaceuticals for proper management. If the provision as written is preventing long-term care facilities from potentially consolidating their hazardous waste, then it is thwarting the intended outcome of this provision and that is why EPA decided to add ''business relationship'' to the first condition for VSQG consolidation.

One state commenter recommended that the receiving healthcare facilities must either be an LQG or comply with the LQG requirements under part 262, since LQGs have more protective management standards during accumulation. First, under part 266 subpart P, healthcare facilities do not

[232] As allowed by 40 CFR 266.504(a).

[233] *https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html.*

[234] *https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html.*

have a generator category for their hazardous waste pharmaceuticals; all healthcare facilities are regulated the same under part 266 subpart P. Second, if EPA limited this consolidation provision to LQGs, then there would be a very small subset of receiving healthcare facilities that would be able to take advantage of this provision. Since subpart P allows healthcare facilities operating under this subpart to not count their hazardous waste pharmaceuticals towards their generator category, some healthcare facilities may no longer be LQGs for their other hazardous waste. It is highly unlikely that a long-term care pharmacy would remain an LQG under this rule since the majority of the hazardous waste that would be handled at these pharmacies would be pharmaceuticals. If we were to limit this provision to only LQG receiving facilities, then we would be preventing LTCFs from consolidating at long-term care pharmacies. Therefore, we determined that requiring the receiving facilities to be LQGs or to comply with LQG standards as a condition of the consolidation provision would severely limit the value of this provision.

In addition, the Agency is not finalizing a requirement for healthcare facilities that receive hazardous waste pharmaceuticals from VSQG healthcare facilities to manage the received pharmaceutical waste under the part 262 LQG standards. The Agency does not see the necessity in having more stringent management standards for healthcare facilities that receive pharmaceutical waste, because subpart P management standards are the same for all non-VSQG healthcare facilities, regardless of the amount of hazardous waste pharmaceuticals they generate. The Agency has determined that the subpart P standards are sufficiently protective of human health and the environment since all pharmaceuticals at a receiving healthcare facility must be managed under the same subpart P standards, regardless of whether they were generated on site or received from off site. If a state determines that the standards being finalized for healthcare facilities that receive hazardous waste pharmaceuticals from off-site are not adequate, that state may implement its own standards, provided they are more stringent.

The waste management industry, as well as some states, recommended that EPA require a notification when a facility was receiving hazardous waste pharmaceuticals and at least some minimal requirements for labeling, recordkeeping, and documentation of shipments. One state also recommended that we issue licenses to facilities that were receiving hazardous waste pharmaceuticals in order to track who was taking advantage of this provision. Consistent with our rationale for the limited shipping requirements for ''potentially creditable hazardous waste pharmaceuticals'' in this rule, the Agency believes that the shipping of hazardous waste pharmaceuticals poses a relatively low risk of release to the environment but a high risk for diversion of the pharmaceuticals when labeled ''pharmaceuticals.'' The hazardous waste that are being shipped often are in pill form or blister packs and not fifty-gallon drums of liquids that can be easily spilled. They are not likely to pose the same risks that typical hazardous waste could cause during shipping and transport, but there is a real risk to them being stolen if attention is brought to the contents of the containers. If the four conditions are met, the Agency believes this ensures the proper management of hazardous waste pharmaceuticals and adding new labeling and shipping requirements is unnecessary to accomplish that goal. Furthermore, the part 262 VSQG regulations do not require labeling or recordkeeping, and VSQGs might not take advantage of this consolidation provision if the requirements are too onerous, thus continuing to put their hazardous waste pharmaceuticals in municipal solid waste landfills.

The waste management industry asked for clarification on hazardous waste pharmaceuticals consolidation across state lines that have different requirements for VSQGs. There is nothing in this section that prevents a healthcare facility from sending their hazardous waste pharmaceuticals to a healthcare facility in another state provided both states have adopted this provision. Each state has their own requirements, so it would be prudent for VSQG healthcare facilities to make sure that the state in which they are consolidating has adopted this provision and does not impose any additional requirements on the receiving healthcare facility that accepts this waste.

EPA also received comments on what types of facilities could take advantage of this provision, specifically whether this provision will include wholesale drug distribution centers. In the final rule, EPA has defined wholesale distributors as a type of healthcare facility under § 266.500. Wholesale distributors were not an example that was given to us at proposal for this consolidation provision, but if all four conditions were met and there was a contractual or business relationship between the VSQG healthcare facility and the wholesale distributor, they would not be precluded from using this provision. However, we would note that when a wholesale distributor receives hazardous waste pharmaceutical return from a healthcare facility, the pharmaceuticals are usually restocked, which means they are pharmaceutical products and not hazardous waste pharmaceuticals.

Lastly, a non-profit organization asked us to clarify if these consolidated hazardous waste pharmaceuticals would be eligible for redistribution or evaluation for donation once consolidated to the receiving facility. In regard to redistribution or evaluation for donation, if the receiving healthcare facility can lawfully donate or redistribute the consolidated hazardous waste pharmaceuticals, there is nothing in this provision that prevents that from occurring, but those shipments would not fall under the consolidation provision in subpart P. If a VSQG is sending products to another facility, then the receiving facility should evaluate the received pharmaceuticals as they would any other products they receive for continued use, redistribution to secondary markets, donation and/or any other lawful possibilities. At this point, they are not a solid or hazardous waste and not subject to the requirements in § 266.502(l) or § 266.503(b).

EPA would also note that this provision is optional and it is not meant to impose undue burden on healthcare facilities. This section does not require a VSQG healthcare facility to ship their hazardous waste pharmaceuticals to a receiving healthcare facility. VSQG healthcare facilities continue to have the option, unless the state regulations are more stringent, of sending their hazardous waste pharmaceuticals to any of the types of facilities specified in § 262.14, including a municipal solid waste landfill.

XI. Standards for Healthcare Facilities That Accumulate Potentially Creditable Hazardous Waste Pharmaceuticals Prior to Shipment to Reverse Distributors (§ 266.503)

A. Healthcare Facilities Making a Hazardous Waste Determination for Potentially Creditable Pharmaceuticals (§ 266.503(a))

1. Summary of Proposal

EPA proposed standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals in § 266.503 of subpart P. As with non-creditable hazardous waste pharmaceuticals, a healthcare

facility must determine which potentially creditable pharmaceuticals are listed or characteristic hazardous wastes, in order to determine which potentially creditable pharmaceuticals are subject to regulation under this subpart.

Accordingly, we proposed that a healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable solid waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.,* is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C).

We also proposed that a healthcare facility may choose to manage all of its potentially creditable waste pharmaceuticals (both hazardous and non-hazardous) together as potentially creditable hazardous waste pharmaceuticals while accumulating on site and when shipping off site under § 266.509. If a healthcare facility chooses this approach of commingling its hazardous and non-hazardous potentially creditable waste pharmaceuticals, it would not need to make individual hazardous waste determinations, but would have made a generic decision that all of its potentially creditable waste pharmaceuticals are hazardous and would manage them as potentially creditable hazardous waste pharmaceuticals in accordance with the requirements in 40 CFR part 266 subpart P.

We proposed that healthcare facilities may choose to manage potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under the shipping standards of § 266.509. Additionally, EPA proposed that healthcare facilities would be prohibited from sending hazardous waste other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor. This was in keeping with our position that a reverse distributor's function in managing hazardous waste should be limited to managing hazardous waste pharmaceuticals that have a reasonable expectation of receiving manufacturer credit and not non-creditable hazardous waste pharmaceuticals or other non-pharmaceutical hazardous waste.

2. Summary of Comments

Pharmacists, some wholesalers, and manufacturers expressed concern that making hazardous waste determinations at their facilities would require additional staff, additional training on making hazardous waste determination, as well as more storage space in which to hold the hazardous waste as the determinations are being made.

We received mixed comments on commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals. Healthcare facilities and pharmacists were in favor of EPA allowing commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals, and the benefit it offers in handling their pharmaceutical waste or continuing the common practice of commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals when sent to reverse distributors. On the other hand, waste management and states raised concerns that commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals may prevent healthcare facilities from sending their waste across state lines or to certain reverse distributors, due to state regulations and/or reverse distributors' policies.

3. Final Rule Provisions

EPA is finalizing the standards as proposed, with some minor changes. Under this section, a healthcare facility has two choices: (1) Make a hazardous waste determination on each potentially creditable waste pharmaceutical and determine individually which are hazardous waste and thus subject to regulation under this subpart or, (2) commingle all potentially creditable pharmaceutical waste whether or not it is hazardous waste and manage the commingled pharmaceuticals under this subpart and thereby not have to make individual hazardous waste determinations.

EPA removed ''even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261 subpart C and are not listed in 40 CFR part 261 subpart D'' from the non-hazardous waste provision of this section since it was redundant with determinations of solid waste pharmaceuticals and whether they are potentially creditable or not.

EPA has also modified the regulatory language in the final rule to make clear that when a healthcare facility commingles potentially creditable non-hazardous and hazardous waste pharmaceuticals, the healthcare facility is choosing to subject the potentially creditable non-hazardous waste pharmaceuticals to all of subpart P while being managed at a healthcare facility and in preparation for shipping off-site. Once potentially creditable non-hazardous and hazardous waste pharmaceuticals are commingled they are subject to all applicable subpart P management standards while they remain commingled. As a practical matter, however, we expect that the primary impact to healthcare facilities will be that potentially creditable non-hazardous waste pharmaceuticals are subject to the shipping standards of § 266.509. Once potentially creditable non-hazardous waste pharmaceuticals are shipped off site to a reverse distributor, a reverse distributor may choose to segregate the non-hazardous waste pharmaceuticals from the hazardous waste pharmaceuticals. This process of segregation by the reverse distributor would require the reverse distributor to make new hazardous waste determinations on the commingled pharmaceuticals.

4. Comments and Responses

We received many comments on making hazardous waste determinations and commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals. While the commenters raised valid concerns on why making hazardous waste determinations can be burdensome on a healthcare facility, or why commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals may not work for all facilities, EPA made only minor editorial changes to this section of the final rule. The Agency determined that more substantive changes were unnecessary because this provision contains sufficient flexibility by providing healthcare facilities with two options.

a. *Making hazardous waste determinations.* Pharmacists, some wholesalers, and manufacturers expressed concern that being required to make hazardous waste determinations at their facilities would impose undue burden because they would have to hire additional staff and train them to make accurate waste determination. They argue that they would also need to allocate more space in which to store waste as the determinations are being made. Some commenters stated that making hazardous waste determinations may prevent healthcare facilities from sending their hazardous waste pharmaceuticals to reverse distributors at all. In support of the comments above, manufacturers and wholesalers argued that reverse distributors have the appropriate RCRA expertise to make accurate waste determinations, that they have served as a consolidation point for unused and hazardous waste pharmaceuticals for many years, and that the process has been effective and successful. The Agency notes, however, that allowing potentially creditable

pharmaceuticals to be sent to a reverse distributor without a hazardous waste determination being made at the point of generation violates a basic tenet of RCRA, because the decision to send them to a reverse distributor is effectively a decision to discard. In addition, the burden mentioned by commenters associated with making individual waste determinations would likely be significantly mitigated by exercising the option to manage all potentially creditable waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals.

b. *Commingled waste stream.* As previously noted, we received mixed comments on commingling potentially creditable non-hazardous hazardous waste pharmaceuticals.

EPA proposed the option of commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals to mitigate the burden of complying with the management standards, particularly for healthcare personnel making hazardous waste determinations. Given that many healthcare facilities currently commingle their potentially creditable non-hazardous and hazardous waste pharmaceuticals, we expect the practice to continue. However, if commingling causes undue burden on a facility due to state regulations, reverse distributor policies, or other reasons, then the healthcare facility does not have to utilize this option and can make individual hazardous waste determinations in accordance with § 266.503(a). This is an individual decision for each healthcare facility and each healthcare facility may choose what works best for managing its potentially creditable pharmaceutical waste.

Retailers and reverse distributors recommended that healthcare facilities should be allowed to make a determination about whether the item will be managed as hazardous when it becomes a waste at the time of arrival at the retail store or healthcare facility. They believe this practice would be impeded if all pharmaceuticals must be managed as potentially creditable hazardous waste pharmaceuticals when they become waste. If this is common practice among healthcare facilities, then the need to commingle their waste may not be something that is important. Allowing the commingling of all solid waste pharmaceuticals is meant to ease the burden on healthcare facilities that are not currently making hazardous waste determinations, or do not wish to make them, by allowing them to manage and ship all of their potentially creditable waste pharmaceuticals together.

B. Accepting Potentially Creditable Hazardous Waste Pharmaceuticals From an Off-Site Healthcare Facility That Is a Very Small Quantity Generator (§ 266.503(b))

1. Summary of Proposal

EPA proposed to allow healthcare facilities operating under subpart P to accept potentially creditable and non-creditable hazardous waste pharmaceuticals from an off-site VSQG healthcare facility without a hazardous waste manifest, provided four conditions are met. We proposed this provision in § 266.502(m) under the standards for managing non-creditable hazardous waste pharmaceuticals.[235] We proposed that healthcare facilities operating under subpart P could accept both potentially creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG. Previously, the part 262 VSQG regulations did not allow a healthcare facility to send its hazardous waste off-site to another healthcare facility, unless the receiving healthcare facility is one of the eight types of facilities listed in § 262.14(a)(5)(i–viii). For more detailed information on our proposal, please refer to section X.N.

2. Summary of Comments

EPA only received one comment in this section concerning changes to the generator category of the receiving facility. A trade association of pharmacists was concerned that allowing VSQG consolidation would affect the generator category of the receiving healthcare facility, and that it would need to report as an LQG.

3. Final Rule Provision

In the proposed rulemaking, EPA intended to allow healthcare facilities to accept both potentially creditable and non-creditable (including commingled) hazardous waste pharmaceuticals from an off-site VSQG healthcare facility, provided the receiving healthcare facility complies with the four conditions of § 266.502(m) (now in § 266.502(l)). In the final rule, we clarified our intention to allow healthcare facilities to accept both potentially creditable and non-creditable (including commingled) hazardous waste pharmaceuticals from an off-site VSQG healthcare facility by placing similar standards in § 266.503(b) under the standards for managing potentially creditable hazardous waste pharmaceuticals. This does not reflect a change from what was proposed, only that the consolidation standards apply to healthcare facilities receiving both non-creditable and potentially creditable hazardous waste pharmaceuticals.

Under the final rule, a healthcare facility that is a VSQG can send both its potentially creditable hazardous waste pharmaceuticals and non-creditable (including commingled) hazardous waste pharmaceuticals to an off-site healthcare facility operating under subpart P, provided the receiving healthcare facility complies with the four requirements of the respective sections. Regulations for the receiving healthcare facilities now appear in § 266.502(l) for non-creditable hazardous waste pharmaceuticals and in § 266.503(b) for potentially creditable hazardous waste pharmaceuticals. VSQG healthcare facilities that send their hazardous waste pharmaceuticals to an off-site healthcare facility are subject to the regulations in § 266.504(b), with further discussion in section XII.B of the preamble.

Under § 266.503(b) of the final rule, a healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the VSQG healthcare facility that is sending potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

(2) Is operating under subpart P for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with subpart P; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

It is important to note that a VSQG healthcare facility that chooses to consolidate its hazardous waste pharmaceuticals at an off-site healthcare facility is not considered to be operating under subpart P, and does not need to notify as a VSQG operating under subpart P.

[235] This provision is now found at § 266.502(l).

4. Comments and Responses

A pharmacists' association was concerned that allowing for VSQG consolidation would change the generator category of the receiving healthcare facilities and that the consolidating facility would need to report as an LQG. All healthcare facilities operating under part 266 subpart P are regulated the same, regardless of the amount of hazardous waste pharmaceuticals they generate. Further, healthcare facilities managing their hazardous waste pharmaceuticals under this subpart do not count their hazardous waste pharmaceuticals toward their generator category so consolidation of this additional hazardous waste pharmaceuticals at their facilities would not change the generator category of the receiving healthcare facility.

C. Accumulation Time, Container Management and Labeling for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals

Under the hazardous waste generator regulations in part 262, EPA requires specific management standards for containers that hold hazardous waste. However, potentially creditable hazardous waste pharmaceuticals pose a lower risk of release into the environment than traditional industrial hazardous waste. The risk of release is lower for several reasons.

First, potentially creditable hazardous waste pharmaceuticals must be in original manufacturers' packaging by definition and are often in their outer packaging as well, providing two layers of protection from leaks or spills.[236] Second, potentially creditable hazardous waste pharmaceuticals are typically generated in the pharmacy area of a healthcare facility where there is restricted access, creating a layer of security for these pharmaceuticals. Third, EPA has been informed that it is common practice at healthcare facilities for potentially creditable waste pharmaceuticals that are destined for a reverse distributor to be taken from the shelves of the pharmacy periodically and promptly boxed for off-site shipment.

For the reasons listed above, EPA did not propose specific standards for managing and labeling containers of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. For the same reasons, we also did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals.

This is not to say that all potentially creditable hazardous waste pharmaceuticals waste pharmaceuticals are safe and pose no risk of spill or release into the environment. It is important to note that the accumulation of some potentially creditable hazardous waste pharmaceuticals, such as liquids and aerosols, may pose more of a risk due to possible spills or leaks than solid pills. However, EPA believes that the small quantities in which liquid and aerosol potentially creditable hazardous waste pharmaceuticals are generated, along with the DOT packaging requirements (49 CFR parts 173, 178, and 180), significantly reduces the risks of spills or releases to the environment.

In addition, to further mitigate the potential for spills or leaks, as a best management practice, EPA encourages healthcare facilities to place the original containers, and packaging containing liquids and aerosols pharmaceuticals, in separate individual containers (*e.g.,* sealed storage bag) before placing them in the accumulation container.

1. Accumulation Time and Container Management of Potentially Creditable Hazardous Waste Pharmaceuticals

a. Summary of proposal. EPA did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals or specific standards for how the containers must be managed during accumulation.

b. Summary of comments. Most commenters were in favor of adding some guidelines for accumulation time and container management. Some states commented that the proposed standards for non-creditable hazardous waste pharmaceuticals should be applied to both non-creditable and potentially creditable hazardous waste pharmaceuticals to prevent confusion from having multiple accumulation standards, and to provide extra protection of human health and the environment.

c. Final rule provisions. EPA is not finalizing a time limit for accumulating containers of potentially creditable hazardous waste pharmaceuticals. EPA is also not finalizing specific container management standards for healthcare facilities that accumulate containers of potentially creditable hazardous waste pharmaceuticals

d. Comments and responses. Several states expressed concern about the security of potentially creditable hazardous waste pharmaceuticals during accumulation. These commenters agreed that potentially creditable hazardous waste pharmaceuticals should be accumulated in a designated area that is labeled and kept locked or sealed according to best management practices for that facility as an additional deterrent to illicit diversion. Commenters also expressed concerned that not having designated accumulation areas could lead to situations where healthcare facility personnel may misplace or forget the locations of accumulation containers. States were concerned that the potential for healthcare facilities to receive manufacturer credit does not sufficiently encourage proper management.

As previously discussed, potentially creditable hazardous waste pharmaceuticals do not pose the same risks as other hazardous wastes. We received many comments, especially from the retail industry, about the condition of packages being important for being eligible and receiving manufacturer credit. For example, broken and/or leaking containers cannot be sent to a reverse distributor per the definition of ''potentially creditable hazardous waste pharmaceuticals,'' so there is an incentive to manage these items carefully. There is also an incentive to not overaccumulate wastes in healthcare facilities since manufacturer credit is only issued by reverse distributors and in many cases, cannot be collected by a healthcare facility until the reverse distributor receives them.

It is also important to note that many of these potentially creditable hazardous waste pharmaceuticals are already being generated and stored in secure areas, such as pharmacies, and being handled by personnel that have pharmaceutical expertise. EPA is also recommending that liquids and aerosols be put in sealed plastic bags, containers, or other management practices during accumulation to reduce the risk of spills and releases.

As for labeling the accumulation area with the words pharmaceutical waste, the concern still remains for increasing the potential for illicit diversion of these potentially creditable hazardous waste pharmaceuticals by bringing attention to the fact that it contains pharmaceuticals. Therefore, the Agency is not finalizing a requirement for healthcare facilities to label accumulation areas for potentially creditable hazardous waste pharmaceuticals.

Finally, if a state is uncomfortable with our approach to the accumulation of potentially creditable hazardous waste pharmaceuticals, it may choose to be more stringent in this regard when it adopts the rule.

[236] See 73 FR 73529; December 2, 2008.

2. Labeling Requirements for Containers of Potentially Creditable Hazardous Waste Pharmaceuticals

a. Summary of proposal. EPA did not propose specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals while they are accumulated on-site at a healthcare facility because they are in original manufacturer packaging, they are already labeled, and any additional labeling would be duplicative or apply to secondary containers, such as boxes used to ship to reverse distributors.

In addition, due to concerns regarding illicit diversion of pharmaceuticals, EPA believes that it is safer not to call attention to the fact that these containers hold pharmaceuticals. Unlike floor or patient care pharmaceutical waste, the potentially creditable hazardous waste pharmaceuticals returned to a reverse distributor often have high black-market value that makes them susceptible to diversion. Thus, EPA did not propose to require a label for containers used to accumulate potentially creditable hazardous waste pharmaceuticals.

b. Summary of comments. Many states believe that labeling should be required for all containers of hazardous waste to ensure proper management and disposal. Proper management, according to comments, includes accumulation in designated locations with individual containers labeled for inspection.

Other commenters expressed concerns that containers that are not labeled are subject to inaccurate waste determinations and will be mishandled and treated as non-creditable hazardous waste pharmaceuticals and sent to a TSDF rather than as potentially creditable which could ultimately be destined for a reverse distributor.

c. Final rule provision. EPA is not finalizing labeling standards for containers of potentially creditable hazardous waste pharmaceuticals accumulated by healthcare facilities.

d. Comments and responses. While the commenter's concerns apply to hazardous waste in general and for hazardous waste going to a TSDF, we do not believe they are equally applicable to containers of potentially creditable hazardous waste pharmaceuticals. First, containers of potentially creditable hazardous waste pharmaceuticals are in original manufacturer's packaging (or have been repackaged for use in a LTCF) and thus the contents are easily identifiable. Second, if a healthcare facility does not label an accumulation container on site and then forgets about it or misidentifies where it needs to go, then no manufacturer credit will be issued for those potentially creditable hazardous waste pharmaceuticals. Likewise, if a healthcare facility does label the containers on site and the contents are illicitly diverted, then the healthcare facility will not receive the manufacturer credit for those items. Healthcare facilities have a monetary incentive to keep track of what is in these containers, regardless of whether they are labeled, and to make sure they arrive unmolested at the reverse distributor.

Additionally, by imposing labeling requirements, EPA does not want to deter the practice of commingling potentially creditable hazardous waste pharmaceuticals with potentially creditable non-hazardous waste pharmaceuticals since both are typically transported together to a reverse distributor.

Therefore, EPA concludes that it is not necessary to require any labeling standards for potentially creditable hazardous waste pharmaceuticals.

D. No Biennial Reporting for Potentially Creditable Hazardous Waste Pharmaceuticals Generated at Healthcare Facilities (§ 266.503(d))

1. Summary of Proposal

The Agency proposed that healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

2. Summary of Comments

One state commented that it would prefer to be notified about who is handling this waste to ensure that healthcare facilities are adhering to the prohibition on sewering, since they will not know who is handling this waste.

3. Final Rule Provision

The Agency is finalizing as proposed that healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart. Potentially creditable hazardous waste pharmaceutical quantities will be captured by the reverse distributors' required biennial reports,[237] therefore, a requirement for healthcare facilities to report quantities of potentially creditable hazardous waste pharmaceuticals generated would be duplicative.

[237] This provision is found at § 266.510(c)(9)(i)

4. Comments and Responses

One state was concerned that they would not know which healthcare facilities are generating potentially creditable hazardous waste pharmaceuticals. All healthcare facilities operating under this subpart will be required to submit a one-time notification that they are subject to subpart P (§ 266.502(a)(1)). States will, therefore, be informed of what healthcare facilities are operating under subpart P and can inspect accordingly.

E. Recordkeeping Requirements for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503(e))

1. Summary of Proposal

EPA proposed to require healthcare facilities to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors.

Specifically, we proposed that healthcare facilities that initiate a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor keep (1) records of advance notification, (2) shipping papers or bills of lading, and (3) records of delivery confirmation. We proposed that a healthcare facility must retain these records for three years after the shipment was initiated. These records document that shipments of potentially creditable hazardous waste pharmaceuticals have been taken into the control and custody of the receiving reverse distributor and have not been diverted. In most cases, retaining records for three years should be sufficient for inspection purposes; however, we proposed that the periods of retention are automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator.

2. Summary of Comments

One state agreed that three years was a sufficient retention period to enable inspectors to identify issues upon inspection. State and local governments requested clarification about what types of documentation (*e.g.,* shipping papers/bills of lading) satisfies the requirement. One commenter argued that the receiving facility should document efforts made to locate shipments that did not arrive.

3. Final Rule Provision

EPA is finalizing the proposed recordkeeping provision for potentially creditable hazardous waste pharmaceuticals for healthcare facilities and reverse distributors that initiate a

shipment to another reverse distributor with two changes. First, as we discuss later in the shipping standards, we have eliminated the requirement for healthcare facilities to provide advance notification of shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Thus, we have removed the requirement to keep a record of the advance notification. Second, EPA removed the reference to bills of lading from the recordkeeping requirement while keeping shipping papers since bills of lading are a type of shipping papers under DOT regulations. This is also responsive to comments asking for clarification. Healthcare facilities initiating shipments of potentially creditable hazardous waste pharmaceuticals must keep, (1) delivery confirmation for each shipment and (2) shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable. EPA is finalizing that these records must be retained for three years unless there is an unresolved enforcement activity or a request by the EPA Regional Administrator to keep them longer. In that case, the period of retention is automatically extended. EPA is finalizing this requirement as proposed despite input from commenters, as this is standard practice with enforcement activity. At the request of commenters, we have added a requirement that all records must be readily available upon request by an inspector.

F. Response to Spills for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503(f))

1. Summary of Proposal

EPA proposed response requirements for spills of non-creditable hazardous waste pharmaceuticals but did not propose similar response requirements for releases of potentially creditable hazardous waste pharmaceuticals.

2. Summary of Comments

A commenter suggested that spills of potentially creditable hazardous waste pharmaceuticals should also be subject to the same containment and cleanup requirements as non-creditable hazardous waste pharmaceuticals. The commenter also asked whether EPA intended that all spills of potentially creditable hazardous waste pharmaceuticals render them non-creditable.

3. Final Rule Provision

EPA agrees with comments that all spills of hazardous waste pharmaceuticals, both potentially creditable and non-creditable, must be contained, and that all spills of potentially creditable hazardous waste pharmaceuticals renders them non-creditable. Therefore, in response to this comment, we have added a similar provision to the healthcare facility standards of § 266.503(f) for responding to releases of potentially creditable hazardous waste pharmaceuticals.

The standards in this section are based upon what is being finalized in the standards for response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities in § 266.502(k). The final rule requires that a healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with subpart P.

It is EPA's understanding that unused/undispensed pharmaceuticals that remain in original manufacturer's packaging often receive manufacturer credit even if the packaging has been opened. In the event of a spill, a healthcare facility should reevaluate whether any pharmaceuticals that remain in their containers (not spilled) are still eligible to receive manufacturer credit per the definition of potentially creditable hazardous waste pharmaceutical in § 266.500. The healthcare facility must determine whether the pharmaceuticals that remain in the containers are potentially creditable and manage them according to subpart P. Even if a healthcare facility determines that the remaining pharmaceuticals are potentially creditable, it must also ensure that the decision is consistent with the manufacturer's policies. It is important to note that this only applies to whatever might be left in the container and was not spilled.

XII. How does this rule apply to healthcare facilities that are very small quantity generators for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste? (§ 266.504)

A. Very Small Quantity Generators Using Reverse Distributors (§ 266.504(a))

1. Summary of Proposal

VSQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 262.14.[238] Under § 262.14, VSQGs are limited in where they may send their hazardous waste for treatment and disposal.[239] In § 266.504(a), we proposed to allow VSQG healthcare facilities to send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Without this change, VSQGs would have been required to send all their hazardous waste pharmaceuticals, including those that are potentially creditable, to one of the types of facilities in § 262.14, which does not include a reverse distributor. Although we proposed to make this change within part 266 subpart P, we requested comment on whether stakeholders would prefer this change to be made within the VSQG regulations in § 262.14 (formerly the CESQG regulations in § 261.5) instead. VSQGs are still required to send their non-pharmaceutical hazardous waste and their non-creditable hazardous waste pharmaceuticals to one of the types of facilities listed in § 262.14.[240]

2. Summary of Comments

States, waste management and reverse distributors supported allowing VSQG healthcare facilities to send their potentially creditable hazardous waste to reverse distributors. These same commenters were also in favor of including their change in both this rule and § 262.14 to ensure that all healthcare facilities that might have potentially creditable hazardous waste pharmaceuticals would be aware of this provision and be able to take advantage of it.

3. Final Rule Provision

We are finalizing this provision as proposed, with minor edits. In general, this final rulemaking will preserve the current regulatory scheme for VSQGs: healthcare facilities that qualify as VSQGs for their total count of hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste will maintain their conditional exemption under § 262.14 and will not be subject

[238] Since the hazardous waste pharmaceutical rule was proposed, § 261.5 has been renumbered to § 262.14 as part of the reorganization of the generator regulations in the Generator Improvements final rule and this will be referenced later in this section.

[239] Since the Pharmaceutical rule was proposed§ 261.5(f)(3)(i)–(vii) for acute hazardous waste and § 261.5(g)(3)(i)–(vii) for non-acute hazardous waste has been combined and renumbered to § 262.14(a)(5)(i)–(vii) for acute and non-acute hazardous waste in the Hazardous Waste Generator Improvements final rule.

[240] A VSQG healthcare facility may be able to send its hazardous waste pharmaceuticals for consolidation at another healthcare facility operating under subpart P as allowed by § 266.504(b), or a large quantity generator and 262.14(a)(5)(viii), see section X of the preamble for further discussion.

to most aspects of this proposal. Healthcare facilities that are VSQGs are subject to three provisions of part 266 subpart P: The sewer ban in § 266.505, the empty container standards in § 266.507, and the optional provisions in § 266.504.

In response to commenter's request for clarity, the final rule makes it clear that § 266.504 applies to VSQG healthcare facilities that are VSQGs when counting both its hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste. Section 266.504 does not apply to healthcare facilities that become VSQGs under this rule as a result of not having to count their hazardous waste pharmaceuticals. Such healthcare facilities are VSQGs with respect to their non-pharmaceutical hazardous waste only and must operate under subpart P for their hazardous waste pharmaceuticals.

Under the final rule, a healthcare facility that is a VSQG when counting both its hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may choose to send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor. In response to comments, EPA has added a conforming change to the VQSG generator provision in § 262.14(a)(5)(ix) for added clarity on this point. It is a restatement of § 266.504(a) which allows VSQG healthcare facilities to send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

A healthcare facility that is a VSQG for both their hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste is given a choice. The healthcare facility may

- Operate as a standard VSQG under part 262 rules, and can use the optional provisions in § 266.504, or
- Operate under as a healthcare facility under part 266 subpart P.

4. Comments and Responses

The waste management industry requested that EPA regulate all healthcare facilities under the proposed subpart P requirements regardless of generator category. While this rule's requirements are meant to create uniformity for healthcare facilities managing hazardous waste pharmaceuticals, we want to avoid creating undue burden on VSQGs and have declined to make them subject to part 266 subpart P except for the sewer prohibition in § 266.505, the empty container provisions in § 266.507 and the optional provisions in § 266.504..

B. Off-Site Collection of Hazardous Waste Pharmaceuticals Generated by Healthcare Facilities (§ 266.504(b))

1. Summary of Proposal

EPA proposed that a healthcare facility that is a VSQG may send its hazardous waste pharmaceuticals to another healthcare facility provided the receiving healthcare facility meets certain conditions. These conditions were proposed in § 266.502(m) of this subpart.

2. Summary of Comments

One state was concerned about how consolidation might affect the generator category of the receiving facility. The commenter also raised concerns about the receiving facility performing some functions of a reverse distributor.

3. Final Rule Provision

EPA is finalizing the proposed provision with conforming changes that correspond with other sections within this rule and one additional change. The first conforming change added the words ''hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste'' to clarify that only healthcare facilities that are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste may take advantage of this provision. The second conforming change converted the term CESQG to VSQG according to the 2016 Hazardous Waste Generator Improvements final rule. EPA notes that the consolidation provisions for healthcare facilities that receive both non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from off-site were added to the regulations in §§ 266.502(l) and 266.503(b) (sections X.N and XI.B of the preamble), respectively. The final change added flexibility for VSQGs to meet the consolidation provisions that were added as part of the 2016 Hazardous Waste Generator Improvements final rule in lieu of the subpart P off-site consolidation provisions. In this case, the receiving LQG would have to meet the conditions in § 262.17(f) while the VSQG healthcare facility would have to meet the conditions in § 262.14(a)(5)(viii).

The final rule provision allows a healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste to send its hazardous waste pharmaceuticals off-site provided either of the following is met: (1) The receiving healthcare facility meets the conditions in § 266.502(1) and § 266.503(b) of this subpart, as applicable, or (2) the VSQG healthcare facility meets the conditions in § 262.14(a)(5)(viii), and the receiving large quantity generator meets the conditions in § 262.17(f).

4. Comments and Responses

One commenter asked for clarification about whether EPA will allow consolidation of a healthcare facility's potentially creditable or non-creditable hazardous waste pharmaceuticals at a reverse distributor. In response, the Agency is clarifying that subpart P does not allow healthcare facilities to consolidate any pharmaceutical waste at a reverse distributor. Healthcare facilities may only consolidate their waste at another facility that meets the definition of a healthcare facility as defined in § 266.500. See sections X.N and XI.B, respectively, for further discussion about healthcare facilities that receive non-creditable and potentially creditable hazardous waste pharmaceuticals from off-site healthcare facilities.

C. Long-Term Care Facilities That Are Very Small Quantity Generators Can Dispose Hazardous Waste Pharmaceuticals in Drug Enforcement Administration Collection Receptacles (§ 266.504(c))

1. Summary of Proposal

We proposed that a LTCF that is a VSQG that has an on-site DEA collection receptacle could use the collection receptacle for its hazardous waste pharmaceuticals, even if they are not controlled substances. We reasoned that since DEA already allows controlled substances to be commingled with non-controlled substances, it was consistent to allow VSQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA authorized collection receptacles along with controlled substances. Further, we reasoned that the management of VSQG hazardous waste pharmaceuticals as DEA controlled substances is preferable to management as municipal solid waste because it provides greater protection to patients, visitors, and workers at LTCFs to have the hazardous waste pharmaceuticals in DEA authorized collection receptacles than down the sewer or in the facility's regular trash.

2. Summary of Comments

The few comments we received on this specific provision of the proposed rulemaking were mostly supportive.

3. Final Rule Provisions

We are finalizing the provision that allows an LTCF that is a VSQG to use

a DEA authorized collection receptacle to dispose of its hazardous waste pharmaceuticals with three minor changes. The first change is to clarify again that this provision only applies to LTCFs that are VSQGs for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and are therefore not subject to subpart P (except the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504). The second change is to clarify that the DEA authorized collection receptacle that the VSQG LTCF uses to dispose of its hazardous waste pharmaceuticals must be on-site. The third change is to exclude items such as contaminated personal protective equipment or clean-up residues from being placed into the DEA authorized collection receptacle. Although these items meet our new definition of pharmaceutical, a DEA authorized collection receptacle is designed for the collection of the pharmaceuticals themselves and not larger items that might be contaminated by the pharmaceuticals, such as contaminated PPE or clean-up residues. For instance, they are required to have small openings and limited volumes, making their use for contaminated PPE and clean-up residues impractical.

4. Comments and Responses

One commenter thought that this proposed provision was ''not feasible'' because ''take-back kiosks for controlled substances are intended to be used by end users and not the DEA registrant.'' [241] In many, if not most, cases at an LTCF, the hazardous waste pharmaceuticals will be from an ultimate user and the DEA regulations permit the collection receptacles to be used for collecting both controlled and non-controlled substances from ultimate users. There are more limited cases where an LTCF may have its own inventory of non-controlled hazardous waste pharmaceuticals.

Although EPA concurs with the commenters that the DEA authorized collection receptacles are only for controlled substances from ultimate users, EPA does not believe that the same limitation needs to be placed on the pharmaceuticals from VSQGs that are hazardous waste but not controlled substances. In fact, it could be argued that long-term care facilities that are VSQGs would be allowed to use DEA authorized collection receptacles for their hazardous waste pharmaceuticals even without this new provision, provided the waste from the DEA authorized collection receptacles is treated or disposed at one of the types of facilities identified in § 262.14(a)(5) (*e.g.,* facilities that are permitted or have interim status to manage hazardous waste and facilities that are permitted, licensed or registered by a state to manage hazardous waste, municipal waste or non-municipal waste). Nevertheless, we did propose, and are finalizing the provision in § 266.504(c) making it clear that an LTCF that is a VSQG can place its hazardous waste pharmaceuticals in an on-site DEA collection receptacle.

However, as the commenter pointed out, it is important to note that the DEA regulations for controlled substances are much narrower in what may be placed in a collection receptacle; DEA only allows controlled substances from ultimate users (patients) to be placed in collection receptacles that are at long-term care facilities. As a result, if a LTCF (or any other healthcare facility) is a DEA registrant, it may not place its inventory of controlled substances in a collection receptacle, even if it is a VSQG.

D. Long-Term Care Facilities With 20 Beds or Fewer Are Presumed To Be Very Small Quantity Generators (§ 266.504(d))

1. Summary of Proposal

EPA took comment on whether we should provide a rebuttable presumption that LTCFs with fewer than 10 beds are assumed to be VSQGs and thus would not be required to keep track of the amount of hazardous waste generated each month. The Agency did not propose regulatory language for this provision. EPA asked commenters to submit data to support a 10-bed cutoff to show that LTCFs with fewer than 10 beds are generally VSQGs. Alternatively, if commenters supported a different cutoff for the rebuttable assumption, EPA asked that the commenters submit information to support their suggested cutoff.

2. Summary of Comments

Comments on the rebuttable presumption for LTCFs with fewer than 10 beds varied. One state did not support providing a rebuttable presumption for LTCFs with fewer than 10 beds and argued that all generators should be required to count the hazardous waste they generate.[242] One state expressed support for providing a rebuttable presumption and requested that EPA keep the cutoff at 10 beds.[243] One state did not support providing the rebuttable presumption because most healthcare facilities in their state, including LTCFs, have more than 10 beds but generate only VSQG quantities of hazardous waste.[244]

Two healthcare industry commenters that supported the rebuttable presumption asked that EPA increase the cutoff from 10 beds to 20 beds.[245] One healthcare industry commenter supported the rebuttable presumption and asked that EPA increase the bed cutoff from 10 beds to 15 beds.[246]

3. Final Rule Provisions

Under the final rule, EPA is finalizing a rebuttable presumption in § 266.504(d) that LTCFs with 20 beds or fewer are assumed to be VSQGs and thus are not required to demonstrate the amount of hazardous waste generated each month. Under this presumption, LTCFs are only subject to the requirements for VSQG healthcare facilities as described elsewhere in this proposal, including the requirement not to sewer hazardous waste pharmaceuticals (§ 266.505), the empty container standards (§ 266.507), and the optional provisions of § 266.504. Under the final rule, the EPA Regional Administrator has the responsibility to demonstrate that a LTCF with 20 beds or fewer generates quantities of hazardous waste that are in excess of the VSQG limits as defined in § 260.10 if the EPA Regional Administrator wishes to mandate that the LTCF operate under subpart P. A LTCF with more than 20 beds that operates as a VSQG under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the VSQG limits as defined by § 260.10.

Based on available data, EPA believes it is reasonable to be responsive to the healthcare industry commenters who supported the rebuttable presumption and to increase the cutoff to 20 beds. The available information on hazardous waste generation at LTCFs suggests that LTCFs with 20 beds or fewer are generally VSQGs. Although EPA did not receive any data from the healthcare industry commenters, one state commented that most healthcare facilities in their state, including LTCFs, have many more than 10 beds but generate only VSQG quantities of

[241] See comment number EPA–HQ–RCRA–2007–0932–0280.

[242] See comment number EPA–HQ–RCRA–2007–0932–0238 in the docket for this rulemaking.

[243] See comment number EPA–HQ–RCRA–2007–0932–0242 in the docket for this rulemaking.

[244] See comment number EPA–HQ–RCRA–2007–0932–0332 in the docket for this rulemaking.

[245] See comment numbers EPA–HQ–RCRA–2007–0932–0239 and EPA–HQ–RCRA–2007–0932–0282 in the docket for this rulemaking.

[246] See comment number EPA–HQ–RCRA–2007–0932–0328 in the docket for this rulemaking.

hazardous waste.[247] Additionally, EPA estimates that there are between 2,875 and 4,770 long-term care facilities that generate hazardous waste and that 98 to 99 percent of the facilities are VSQGs.[248] Although EPA estimates that there are few LTCF hazardous waste generators that are SQGs or LQGs, EPA does not have data on the number of beds at each facility, making it difficult to estimate a facility size threshold at which a LTCF becomes an SQG or an LQG. EPA conducted additional analysis using data on the average size of LTCFs in the United States and data on the average volume of hazardous waste generated annually at LTCFs that submitted a biennial hazardous waste report between 2001 and 2015 in order to estimate the average size at which a LTCFs become SQGs or LQGs.[249] The estimates suggest that LTCFs with fewer than 20 beds will generally be VSQGs. Therefore, EPA concludes that it is reasonable to provide a rebuttable presumption that LTCFs with 20 beds or fewer are assumed to be VSQGs and thus are not required to demonstrate the amount of hazardous waste generated each month.

XIII. Sewer Disposal Prohibition (§ 266.505)

A. Regulatory Background on the Domestic Sewage Exclusion

Under RCRA and the Subtitle C hazardous wastes regulations, if a material is not a solid waste, then it cannot be considered a hazardous waste. Under § 261.4(a)(1)(ii) of the RCRA regulations, ''Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment'' is not a solid waste for purposes of Subtitle C regulation. This exclusion was finalized by EPA on May 19, 1980, based on the reasoning that ''Mixed waste streams that pass through sewer systems to publicly-owned treatment works (POTWs) will be subject to controls under the Clean Water Act (CWA). The Agency's construction grants program provides financial assistance for the proper treatment of these wastes. In addition, the Agency's pretreatment program provides a basis for EPA and the local communities to ensure that users of sewer and treatment systems do not dump wastes in the system that will present environmental problems.'' [250]

In 1984, Congress enacted the Hazardous and Solid Waste Amendments (HSWA) to the Solid Waste Disposal Act (SWDA), as amended by RCRA. HSWA included a new Section 3018, entitled Domestic Sewage. This section directed EPA to do two things with respect to the § 261.4(a)(1)(ii) exclusion for mixtures of domestic sewage and other wastes: (1) Submit a Report to Congress (RTC) that describes the types, size and number of generators which dispose of such wastes in this manner, the types and quantities of wastes disposed of in this manner, and identify significant generators, wastes and waste constituents not regulated under existing Federal law or regulated in a manner sufficient to protect human health and the environment; and (2) based on the report, revise the appropriate existing regulations to ''ensure that substances . . . which pass through a sewer system to a publicly owned treatment works are adequately controlled to protect human health and the environment.''

EPA submitted its Report to Congress on February 7, 1986 (Domestic Sewage Study). Subsequent to the Report to Congress, EPA issued an advance notice of proposed rulemaking on August 22, 1986; [251] a response to comments on the advanced notice of proposed rulemaking on June 22, 1987; [252] a notice of proposed rulemaking (NPR) on November 23, 1988; [253] and a final rule on July 24, 1990.[254] That final rule expanded an existing prohibition on the discharge of pollutants which create a fire or explosion hazard in the POTW, so that it included, but was not limited to, ''waste streams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Centigrade using the test methods specified in 40 CFR 261.21.'' [255] Although the RCRA characteristic of reactivity (D003) was not specifically mentioned in the CWA regulations, discharges of some D003 reactive hazardous wastes are also prohibited by this section of the CWA regulations: (1) Chemicals that react violently with water [256] and (2) chemicals that form potentially explosive mixtures with water.[257]

The 1990 CWA final rule added a new prohibition such that no discharge shall ''result in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems.'' [258] Similarly, although the RCRA characteristic of reactivity (D003) was not specifically mentioned in this section of the CWA regulations, discharges of some D003 reactive hazardous wastes are also prohibited by this section: (1) Chemicals that, when mixed with water, generate toxic gases, vapors or fumes in quantity sufficient to present a danger to human health or the environment [259] or (2) cyanide or sulfide bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.[260]

In addition, some D002 corrosive hazardous wastes were prohibited prior to the 1990 CWA final rule and remain prohibited. Under RCRA, a waste is considered D002 for corrosivity if it has a pH of less than or equal to 2 (strongly acidic) or greater than or equal to 12.5 (strongly basic). Section 403.5(b)(2) of the CWA regulations prohibits discharges with a pH of less than 5.0, except under limited circumstances. Therefore, acidic D002 hazardous waste is prohibited from being discharged under the CWA regulations.

Note that although the exclusion for mixtures of domestic sewage and other wastes is found under the RCRA regulations in § 261.4(a)(1)(ii), and it was HSWA, which is an amendment to RCRA, that directed the review of and amendments to that exclusion, the sewer ban of liquid ignitable D001 hazardous wastes and some D002 and D003 hazardous wastes was established under 40 CFR 403.5(b), which is under the CWA regulations. Also note that EPA left open the possibility of additional future action when it stated in the preamble to the July 24, 1990, final rule, its intent ''to carefully review the effect of this rule and promulgate in the future any additional regulations that experience reveals are necessary to improve control over hazardous waste and other industrial user discharges to POTWs.'' [261]

[247] See comment number EPA–HQ–RCRA–2007–0932–0332 in the docket for this rulemaking.

[248] Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[249] See memorandum ''Long-Term Care Facility Summary Data and Hazardous Waste Generation Data'' in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[250] May 19, 1980; 45 FR 33097.

[251] See the advance notice of proposed rulemaking in August 22, 1986; 51 FR 30166.

[252] See the response to comments in June 22, 1987; 52 FR 23477.

[253] See the proposed rule November 23, 1988; 53 FR 47632.

[254] See the final rule in July 24, 1990; 55 FR 30082.

[255] See the prohibition in 40 CFR 403.5(b)(1).

[256] See 40 CFR 261.23(a)(2).

[257] See 40 CFR 261.23(a)(3).

[258] See 40 CFR 403.5(b)(7).

[259] See 40 CFR 261.23(a)(4).

[260] See 40 CFR 261.23(a)(5).

[261] July 24, 1990 **Federal Register**; 55 FR 30084.

B. Summary of Proposal

In 2015, EPA proposed to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and reverse distributors. That is, healthcare facilities and reverse distributors subject to part 266 subpart P would not be able to use the RCRA domestic sewage exclusion in § 261.4(a)(1)(ii) any longer for their hazardous waste pharmaceuticals. They would be prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (*i.e.,* ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (*e.g.,* sink, toilet, or floor drain).

EPA proposed this sewer prohibition of hazardous waste pharmaceuticals for several reasons. First, as described in detail in the preamble to the proposed rulemaking, a number of studies had shown that flushing of leftover medications had become a prevalent practice used in lieu of proper hazardous waste management and that experience had, indeed, revealed that additional regulations were ''necessary to improve control over hazardous waste and other industrial user discharges to POTWs.'' [262]

Second, although EPA establishes national regulations under the CWA (called effluent limitations guidelines and pretreatment standards) to reduce discharges of pollutants from industries to surface waters and POTWs, currently there are no national effluent limitations or pretreatment standards that apply to healthcare facilities discharging pharmaceuticals to POTWs. Furthermore, traditional wastewater treatment operations implemented at POTWs are designed to remove conventional pollutants, such as suspended solids and biodegradable organic compounds. They are not designed to remove pharmaceuticals that are present in discharges from medical and veterinary facilities. While some POTWs may have implemented advanced treatment technologies, these technologies are not designed to remove pharmaceuticals. EPA released a study in 2009 in which over 100 chemicals (including some pharmaceuticals) were analyzed in the influent and effluent at nine POTWs.[263] Although it was a limited study and difficult to generalize the results to all POTWs, it does indicate that the capabilities of treatment technologies currently employed by POTWs does not include treatment to remove active pharmaceutical ingredients (APIs).[264] In a more recent study, EPA measured concentrations of 56 APIs in effluent samples from 50 large POTWs across the country and discovered at least one API in each sample.[265] In addition, as stated in EPA's Health Services Industry study, ''synthetic compounds, such as pharmaceuticals, are often manufactured to be resistant to metabolic transformation. As a result, some pharmaceutical compounds that are present in the influent to POTWs may pass through treatment systems at conventional POTWs and discharge to receiving waters.'' [266]

Third, the pharmaceuticals entering the environment, through flushing or other means, are having a negative effect on aquatic ecosystems and on fish and animal populations. A recent article highlighted the scientific literature that examines the effect of pharmaceuticals on freshwater ecosystems, particularly the effect of pharmaceuticals on key ecological processes.[267] The RIA for the proposed rulemaking more fully summarized the scientific literature with regard to ecological effects.[268] The scientific research with regard to human health effects due to pharmaceuticals in the environment is still ongoing. Nevertheless, the important features and risks of the problem can be summarized as follows: [269]

(1) Pharmaceuticals are intrinsically bioactive compounds; therefore, they can potentially impact living systems.

(2) There is a continuous and worldwide increase in their use and, thus, on their subsequent input into the environment.

(3) Many of the hundreds of frequently prescribed pharmaceuticals are known for targeted effects and adverse off-target side effects, a problem that can be exacerbated by interactive effects during therapy involving co-administration and disposal.

While healthcare facilities that are VSQGs were generally not subject to the proposed rulemaking, EPA proposed that the sewer ban of hazardous waste pharmaceuticals also apply to healthcare facilities that are VSQGs. The RIA for the rule projects that the vast majority of healthcare facilities are VSQGs (81–86 percent).[270] Some particular types of healthcare facilities have an even larger proportion of VSQGs: For example, the RIA estimates that of the LTCFs that generate hazardous waste, 98–99 percent of LTCFs are VSQGs.[271] EPA was and remains concerned that these smaller healthcare facilities are more likely to dispose of their hazardous waste pharmaceuticals via the sewer. EPA estimates that there are between 50,900 and 84,800 healthcare facilities that are VSQGs.[272] Given this large number, the combined impact of sewer disposal by healthcare facilities that are VSQGs has an even greater potential to provide a substantial impact on the environment, as well as human health. EPA solicited comment on whether it was appropriate to apply the proposed ban on the sewer disposal of hazardous waste pharmaceuticals to all healthcare facilities, including healthcare facilities that are VSQGs. Comments submitted to the Agency in response to this request are discussed in the next section.

We note that EPA's proposed ban on sewering hazardous waste pharmaceuticals is consistent with other federal state, and local actions. For example, the DEA has finalized regulations to implement the Secure and Responsible Drug Disposal Act of 2010.[273] DEA's regulations require a ''non-retrievable'' method of destruction of controlled substances. The preamble to DEA's proposed and final rules state that flushing does not meet the non-retrievable standard for destruction.[274] According to the preamble of the DEA final rule, DEA received 20 comments supporting their position against

[262] July 24, 1990 **Federal Register**; 55 FR 30084.

[263] EPA, Occurrence of Contaminants of Emerging Concern in Wastewater from Nine Publicly Owned Treatment Works, August 2009; EPA–821–R–09–009.

[264] Eggen RI, Hollender J, Joss A, Schärer M, Stamm C, ''Reducing the Discharge of Micropollutants in the Aquatic Environment: The Benefits of Upgrading Wastewater Treatment Plant.'' Environmental Science and Technology 2014, 48(14) 7683–7689.

[265] Kostich MS, Batt AL, Lazorchak JM, ''Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation.'' Environmental Pollution 2014, 184:354–9.

[266] Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA–821–R–08–013.

[267] Richmond EK, Grace MR, Kelly JJ, Reisinger AJ, Rosi EJ, Walters, DM. ''Pharmaceuticals and personal care products (PPCPs) are ecological disrupting compounds (EcoDC).'' Elem Sci Anth 2017, 5:66.

[268] See page 147 of the Regulatory Impact Analysis for the proposed rule in the docket EPA–HQ–RCRA–2007–0932–0151.

[269] A. Ginebreda et al., Environmental risk assessment of pharmaceuticals in rivers: Relationships between hazard indexes and aquatic macroinvertebrate diversity indexes in the Llobregat River (NE Sapin). Environ Int. (2009), doi:10.1016/j.envint.2009.10.003.

[270] See the Regulatory Impact Analysis for the final rule in the docket EPA–HQ–RCRA–2007–0932.

[271] Ibid.

[272] Ibid.

[273] September 9, 2014; 79 FR 53520.

[274] Proposed rule: December 21, 2012; 77 FR 75784 (see page 75803); and Final rule: September 9, 2014; 79 FR 53520 (see page 53548).

flushing controlled substances.[275] The comments supporting the prohibition against sewering came from states, regional, and local hazardous waste management programs, recycling associations, non-governmental organizations (NGOs), trade associations and environmental organizations. Many of these commenters noted that wastewater treatment systems do not eliminate many of the drugs that are flushed into the sewers and requested that DEA clearly state in the regulatory language, not just preamble, that sewering is not allowable as a means of destruction.

In addition, four states, the District of Columbia, and local California jurisdictions have taken action to limit the sewering of pharmaceuticals and another state has introduced a bill. ''Colorado has prohibited the discharging of solid/hazardous waste down the drain since the adoption of RCRA in the 1980s.'' [276] In 2009, Illinois passed the Safe Pharmaceutical Disposal Act, which prohibits healthcare facilities from flushing any solid dosage form other than DEA schedule II drugs into public sewers or septic systems.[277] In 2012, New Jersey passed a similar law that prohibits healthcare facilities from discharging prescription medications into public sewers or septic systems.[278] In 2002, California banned the use of lindane in pharmaceuticals after it found that lindane was adversely impacting wastewater quality. The authors of the paper ''Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts state that ''This is the first time that a pharmaceutical has been outlawed to protect water quality.'' [279] After researching and documenting environmental benefits of the ban, the authors conclude, ''This ban serves as a model for governing bodies considering limits on the use of lindane or other pharmaceuticals.'' Also in California, some county departments, such as Sacramento County and Contra Costa County, prohibit sewering of hazardous waste pharmaceuticals.[280] And the District of Columbia has promulgated municipal regulations, effective January 1, 2011, that prohibits healthcare facilities from flushing pharmaceutical products.[281] The Connecticut legislature has also considered a bill to ban the discharge of medication into public or private wastewater collection systems or septic systems, although it has not yet become law.[282] Nevertheless, the Connecticut Department of Energy and Environmental Protection's (CT DEEP) ''current hazardous waste management regulations essentially ban sewer disposal of RCRA waste by requiring all generators in Connecticut, including [VSQGs], to ensure delivery by a licensed waste transporter with an EPA ID Number to a facility authorized to receive the waste.'' [283]

The Agency sought comment on several areas related to the prohibition on sewering hazardous waste pharmaceuticals. First, the Agency requested comment on whether the sewer ban should apply to healthcare facilities that are VSQGs. Second, we requested comment on the trade-offs inherent in prohibiting sewer disposal; that is, would the benefit of the reduction in aquatic risk be outweighed by additional opportunities for diversion and the possibility of inadvertent exposures for certain workers? Third, we sought comment on whether it would be appropriate to allow any exceptions to the sewer ban, such as for leftover portions of hazardous wastes that are also controlled substances.[284] Finally, the Agency sought comment on whether it would be helpful to incorporate in 40 CFR 261.4(a)(1)(ii), a cross-reference to the CWA regulations that prohibit the sewering of certain hazardous wastes.

C. Summary of Comments

Nearly a third of the commenters to the proposed rulemaking commented on the proposed prohibition of sewering hazardous waste pharmaceuticals. Commenters were nearly unanimous in their support for the prohibition on sewering of hazardous waste pharmaceuticals. Support was expressed by a broad and diverse set of commenters, including state and local governments, sewer districts, environmental groups, and waste management companies. Although some commenters had suggestions for minor exceptions, few commenters expressed complete opposition to the prohibition on sewering. Furthermore, there was widespread support from commenters for applying the prohibition on sewering hazardous waste pharmaceuticals to healthcare facilities that are VSQGs. As one commenter noted, ''given the large number of small generators . . . If each of these small generators were allowed to discharge even a small amount of pharmaceuticals, the overall volume would be significant.'' [285]

D. Final Rule Provisions

Given the environmental concerns described above combined with the overwhelming support that we received from commenters, we are finalizing the prohibition of sewering hazardous waste pharmaceuticals. The prohibition on sewering hazardous waste pharmaceuticals applies to all reverse distributors and all healthcare facilities, including healthcare facilities that are VSQGs. Furthermore, EPA is not providing any exceptions to the prohibition on sewering. Therefore, the prohibition on sewering hazardous waste pharmaceuticals applies to all hazardous waste pharmaceuticals that are generated by any healthcare facilities and reverse distributors, including hazardous waste pharmaceuticals that are also controlled substances and any pharmaceutical wastage from partial administration of hazardous waste pharmaceuticals. How the sewer prohibition intersects with the disposal of pharmaceutical wastage will be discussed in greater detail in section XIV.D.2. rather than this section.

In response to commenters' suggestions, we are making some minor editorial changes, including adding two cross references to the CWA prohibitions on sewering hazardous wastes in § 403.5(b). One cross reference will be added to § 261.4(a)(1)(ii) and the other cross reference will be added to § 266.505. We also eliminated the second sentence of the proposed prohibition, which read: The exclusion in § 261.4(a)(1)(ii) for mixtures of domestic sewage and other wastes that pass through a sewer system to a publicly owned treatment works does not apply to hazardous waste pharmaceuticals.

[275] September 9, 2014; 79 FR 53520 (see page 53548).

[276] See comment number: EPA–HQ–RCRA–2007–0932–0242.

[277] Illinois Public Act 096–0221.

[278] Nicknamed Bateman's Law, after Senator Christopher ''Kip'' Bateman (R-Somerset) that sponsored the legislation.

[279] Humphreys, et al. Environmental Health Perspectives. 2008 March; 116(3) 297–302.

[280] See comment number: EPA–HQ–RCRA–2007–0932–0378.

[281] DCMR Title 22–B Chapter 5 Safe Disposal of Unused Pharmaceuticals in Health Care Facilities

[282] State of Connecticut General Assembly, January Session 2013, Raised Bill No. 6439. An Act Concerning the Disposal and Collection of Unused Medication.

[283] See comment number EPA–HQ–RCRA–2007–0932–0341.

[284] In a DEA letter dated October 17, 2014, DEA refers to leftover, partially administered drugs as ''pharmaceutical wastage.'' *https://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf*

[285] See comment number EPA–HQ–RCRA–2007–0932–0337.

Oklahoma Department of Environmental Quality (OK DEQ) expressed concern that this ''second sentence could be interpreted that EPA is exerting RCRA authority over domestic sewage if it contains [hazardous waste pharmaceuticals]—an area that has been exclusively under Clean Water Act jurisdiction since the first regulations were promulgated in 1980.'' [286] EPA had proposed the second sentence in an attempt to be abundantly clear that the proposed prohibition on sewering hazardous waste pharmaceuticals supersedes the exclusion in § 261.4(a)(1)(ii). We did not intend to assert RCRA jurisdiction over domestic sewage; therefore, we have concluded that it is better to remove the sentence in order to avoid the concern expressed by OK DEQ. Nevertheless, we wish to emphasize that the prohibition on sewering hazardous waste pharmaceuticals being finalized in § 266.505 does, in fact, supersede the exclusion in § 261.4(a)(1)(ii). To make that point clear, we are amending § 261.4(a)(1)(ii) to state that any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, *except as prohibited by §§ 266.505 and Clean Water Act requirements at 40 CFR 403.5(b),* is not a solid waste.

E. Comments and Responses

Many comments suggested various ways in which we should broaden the applicability of the prohibition on sewering hazardous waste pharmaceuticals. In some cases, commenters urged us to apply the prohibition to all pharmaceuticals, not just hazardous waste pharmaceuticals. Subtitle D of RCRA, which governs the management of non-hazardous (solid) waste, does not provide EPA the statutory authority to apply the prohibition to non-hazardous waste pharmaceuticals. Nevertheless, EPA strongly recommends against sewering any pharmaceuticals. The American Water Works Association asked us to extend the prohibition to prevent the sewering of pharmaceuticals that are radioactive and patient waste containing radioactive pharmaceuticals. As discussed previously, hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (*i.e.,* ''mixed waste'') are regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA programs, while either the NRC or the Department of Energy regulates the radioactive component of the waste under the Atomic Energy Act.[287] Therefore, a ''mixed waste'' pharmaceutical that is both radioactive and RCRA hazardous waste is prohibited from being discharged to the sewer. We strongly recommend against sewering other radioactive pharmaceuticals and patient waste containing radioactive pharmaceuticals.

Other commenters suggested that the prohibition should not be limited to discharges to POTWs; rather, it should also apply to discharges to septic tanks, privately owned treatment works and federally owned treatment works. Section 261.4(a)(1)(ii) allows the discharge of what would otherwise be a hazardous waste to POTWs, without being considered a solid or hazardous waste. The prohibition on discharges of hazardous waste pharmaceuticals being finalized today is intended to reduce the scope of that exclusion in the existing regulations. Discharges of hazardous waste to other types of sewage systems, such as septic tanks, privately owned treatment works and federally owned treatment works are not allowed by exclusion in § 261.4(a)(1)(ii). Therefore, the discharge of hazardous wastes to septic tanks, privately owned treatment works and federally owned treatment works is already prohibited, even though it is not explicitly stated.

We note that although our RCRA statutory authority limits us to apply the prohibition on sewering narrowly to pharmaceuticals that are RCRA hazardous wastes, EPA strongly recommends as a best management practice to not sewer any waste pharmaceutical (*i.e.,* hazardous or non-hazardous) from any source or location. This recommendation against sewering pharmaceuticals includes households and assisted living facilities, except in the relatively rare situation when households and assisted living facilities are specifically directed by FDA guidance to flush certain potentially dangerous drugs down the toilet (as noted on pharmaceutical packaging), when a drug take-back option is not readily available, to help ensure that they are not misused or accidentally ingested or touched.[288] In lieu of sewering, we recommend that households, including residents of assisted living facilities, follow the guidelines developed by the U.S. Office of National Drug Control Policy (ONDCP), the FDA, and EPA for the disposal of unwanted household pharmaceuticals. In summary, the guidelines for households disposing of pharmaceuticals are as follows (in order of preference):

(1) Use a drug take-back event or program, when available;

(2) Dispose in household trash, after mixing the unwanted medicines with an unpalatable substance such as dirt, cat litter, or used coffee grounds and placing in a sealed container; and

(3) Only if the drug label specifically instructs you to, flush the unwanted medicine down the toilet.[289]

We also note that the CWA prohibitions on discharges of hazardous waste in § 403.5(b) are broader than just pharmaceuticals and apply beyond healthcare facilities and reverse distributors. Like all of the prohibited discharges under the CWA regulations, the prohibitions of hazardous waste discharges apply to any industrial user. Additionally, the CWA prohibitions on hazardous waste discharges apply to all D001 ignitable liquids, acidic D002 hazardous wastes, and D003 reactive hazardous wastes that (1) react violently with water,[290] (2) form potentially explosive mixtures with water,[291] or (3) result in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems,[292] not just pharmaceuticals that exhibit those characteristics.

Some commenters asked us to include some exceptions to the prohibition on discharges of hazardous waste pharmaceuticals. Specifically, one commenter who supported our proposed ban on sewering of hazardous waste pharmaceuticals, and even supported extending it to non-hazardous waste pharmaceuticals, suggested that we allow exceptions ''for those that do not contain active pharmaceutical ingredients, such as sterile water and 0.9% sodium chloride for injection and irrigation.'' [293] First, as a point of clarification, because sterile water and 0.9% sodium chloride are not hazardous waste, they would not be subject to the prohibition of discharging hazardous waste pharmaceuticals to the

[286] See commenter number EPA–HQ–RCRA–2007–0932–0231.

[287] The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

[288] *https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf.*

[289] *https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm.*

[290] See 40 CFR 261.23(a)(2).

[291] See 40 CFR 261.23(a)(3).

[292] See 40 CFR 403.5(b)(7).

[293] See comment number EPA–HQ–RCRA–2007–0932–0230.

sewer. And even though, as a general rule, we strongly recommend against sewering any pharmaceutical, regardless of whether it meets our definition of hazardous waste, we agree with the commenter that it seems unnecessary to prohibit the sewering of sterile water and 0.9% sodium chloride.

Other commenters asked us to make other exceptions to the prohibition on discharging hazardous waste pharmaceuticals. For example, the Healthcare Waste Institute suggested that we allow the discharge of hazardous waste pharmaceuticals that are specifically allowed by the local wastewater treatment agency or POTW.[294] CT DEEP made a similar suggestion, saying that we should allow discharges if they are ''explicitly authorized by a National Pollutant Discharge Elimination System (NPDES) or State pretreatment permit.'' [295] We have concluded that such an allowance is unnecessary because no known pretreatment standards or local limits have been established that specifically allow for the discharge of any pharmaceuticals. Note that 40 CFR part 439 separately regulates discharges from pharmaceutical manufacturers to POTWs and waters of the U.S. Furthermore, in the absence of water quality standards for specific drugs, we would like to avoid a situation where local wastewater treatment agencies might feel pressured to make judgments on which discharges would be acceptable without knowing the effects on aquatic life or the synergistic effects of multiple drugs.

We received few comments related to our inquiry about trade-offs inherent in prohibiting sewer disposal. Sharps Compliance did note that as ''our experience as a DEA authorized collector has shown, regulations that ban the sewering in conjunction with a proactive collection and destruction program offer the best protection against both environmental harm and the risk of diversion.'' [296] In addition, CT DEEP commented they do ''not believe there is an unfavorable risk trade-off inherent in prohibiting sewer disposal,'' indicating both risks are manageable.[297]

Eli Lilly was one of the few commenters that opposed the prohibition on sewering hazardous waste pharmaceuticals, even though, as a manufacturer, they are not subject to the prohibition.[298] They expressed two reasons for their opposition: (1) They do not believe that a total prohibition is based on sound risk management decisions and should be more flexible to exclude pharmaceuticals which FDA says should be disposed of down the drain, and (2) they believe that an effluent guideline under the CWA regulations is more appropriate and that EPA's Office of Water has decided not to promulgate an effluent guideline for the healthcare industry. As discussed previously, the prohibition on sewering hazardous waste pharmaceuticals and the FDA flush list do not conflict with one another. The prohibition applies to healthcare facilities (which does not include assisted living facilities) and reverse distributors, while the FDA flush list is directed to households and assisted living facilities and includes the caveat that flushing takes place only when a drug take-back option is not readily available. As to the commenter's second point, while it is true that the Office of Water has not yet promulgated an effluent guideline for the healthcare industry, this should not be taken as a sign that a decision has been made affirmatively that an effluent guideline is not appropriate at some time in the future. Rather, the Office of Water has preferred that the Office of Resource Conservation and Recovery (ORCR) first focus on preventing intentional discharges of hazardous waste pharmaceuticals. We firmly believe that the prohibition of sewering hazardous waste pharmaceuticals would complement any future action taken by the Office of Water to issue effluent guidelines for the healthcare industry.

XIV. Conditional Exemptions for Hazardous Waste Pharmaceuticals That Are Also Drug Enforcement Administration Controlled Substances and Household Waste Pharmaceuticals Collected in Take-Back Programs (§ 266.506)

A. Summary of Proposal

Prior to this final rulemaking, the management and disposal of a pharmaceutical that was both a RCRA hazardous waste and a DEA controlled substance was regulated under both the RCRA Subtitle C hazardous waste regulations, which is under EPA's or the authorized state's purview, and the Controlled Substances Act and its implementing regulations, which is under DEA's purview. At the time of the proposal, EPA was aware of only a handful of pharmaceuticals in common usage that are both hazardous waste and controlled substances and therefore subject to regulation by both EPA and the DEA. These are identified in Table 3:

TABLE 3—PHARMACEUTICALS STILL USED IN HEALTHCARE THAT ARE DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Chloral; chloral hydrate.	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes.	Sedative	U034, toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics.
Fentanyl sublingual spray.	Subsys	Analgesic	D001, ignitable	II	Ignitable due to alcohol content.
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001, ignitable	IV	Ignitable due to alcohol content.
Testosterone gels	Androgel, Fortesta, Testim	Hormone	D001, ignitable	III	Ignitable due to gel base.
Valium injectable	Diazepam	Anti-anxiety	D001, ignitable	IV	Ignitable due to alcohol content.

[294] See comment number EPA–HQ–RCRA–2007–0932–0296.

[295] See comment number EPA–HQ–RCRA–2007–0932–0341.

[296] See comment number EPA–HQ–RCRA–2007–0932–0248.

[297] See comment number EPA–HQ–RCRA–2007–0932–0341.

[298] See comment number EPA–HQ–RCRA–2007–0932–0249.

Chloral hydrate (U034), which is listed for toxicity, is the only dually regulated hazardous waste/controlled substance that is a listed hazardous waste.[299] The other four dually regulated hazardous wastes/controlled substances in common use are considered hazardous because they exhibit the characteristic of ignitibility (D001). While the active ingredient is not ignitable, these particular forms of the pharmaceuticals are ignitable because they are prepared in ignitable solutions, such as alcohol.

EPA is aware of three additional hazardous waste pharmaceuticals that are DEA controlled substances, but it is our understanding that they are no longer in common usage, although there may be legacy supplies remaining in healthcare facilities. See Table 4.

TABLE 4—DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES PHARMACEUTICALS THAT ARE NOT IN COMMON USE

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Paraldehyde	1,3,5-Trioxane, 2,4,6-trimethyl-; Paral	Anticonvulsant	U182 toxic	IV	No longer in common use.
Paregoric	camphorated tincture of opium	Analgesic, expectorant, antidiarrheal.	D001 ignitable	III	No longer in common use.
Opium Tincture	Laudanam	Analgesic, ... antidiarrheal	D001 ignitable	II	No longer in common use.

Similarly, as noted in Table 5, phentermine is a controlled substance, but the medical form is a phentermine salt, and the salts are no longer considered to be within the scope of the P046 listing.[300]

TABLE 5—PHARMACEUTICALS THAT ARE DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES SALT(S) NO LONGER CONSIDERED HAZARDOUS WASTE

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Phentermine	alpha, alpha-Dimethylphenethyl amine; Benzeneethanamine, alpha,alpha-dimethyl-; Adipex-P, Atti Plex P, Fastin, Ionamin, Kraftobese, Panshape M, Obe-Nix, Pentercot, Phentride, Pro-Fast, Raphtre, Supramine, Tara-8, Termene, Termine, Zantryl.	Appetite suppressant.	P046, Acutely toxic	IV	If in salt form, it does not meet the P046 listing and medical dosage forms are salts.

EPA requested comment on whether these are, indeed, the only pharmaceuticals in common usage that are regulated both as DEA controlled substances, and when discarded, as RCRA hazardous waste.

To eliminate duplicative regulation for these handful of hazardous wastes that are also controlled substances, EPA proposed to conditionally exempt from RCRA Subtitle C regulation those hazardous wastes that are also DEA controlled substances. Specifically, EPA proposed that hazardous wastes that are also controlled substances will be exempt from all RCRA Subtitle C requirements, including 40 CFR part 266 subpart P, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln) and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances.

The first condition we proposed was to ensure that the controlled substances are destroyed in an environmentally protective manner by a high-temperature combustor, such as a large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln). At the time of proposal, DEA had not specified or endorsed a method by which the controlled substances should be destroyed to meet the non-retrievable standard. Although many hazardous wastes/controlled substances were being destroyed by incineration, it was not required by DEA. At the time, EPA was concerned that in the future DEA might allow a technology that lacks environmental controls and permits. Therefore, combustion of the hazardous wastes/controlled substances, which requires permitting, operating and monitoring standards, was proposed as a condition of the exemption. However, EPA requested comment on whether there are additional technologies that would be appropriate to include for the destruction of hazardous waste pharmaceuticals that are also controlled substances.

The second condition we proposed was to ensure that dually regulated hazardous wastes/controlled substances are managed under another rigorous regulatory program since they will not be managed in accordance with the RCRA Subtitle C regulations. Although developed for different reasons, both EPA's hazardous waste and DEA's controlled substance regulatory programs are designed to track the regulated material from cradle to grave. EPA requested comment on whether the tracking that DEA requires for controlled substances is sufficient to act in lieu of the RCRA manifest.

We considered proposing a third condition that the hazardous waste pharmaceuticals that are also DEA controlled substances would be subject

[299] Note that EPA's U034 listing includes chloral hydrate, see memo dated April 6, 1998; Brandes to Knauss, RCRA Online #14175

[300] See memo dated February 17, 2012; from Devlin to RCRA Division Directors, RCRA Online #14831.

to the sewer prohibition of § 266.505. At the time of proposal, however, we concluded that because combustion in specific units was a condition of the exemption, that it was unnecessary to state that the hazardous waste/controlled substances may not be sewered.

EPA also proposed a related conditional exemption for household pharmaceuticals, including those that are collected in DEA authorized collection receptacles and commingled with DEA controlled substances. Specifically, we proposed that collected household pharmaceuticals will continue to be excluded from RCRA regulation as household hazardous waste, provided they comply with the same two conditions. The Agency has a long-standing recommendation that household hazardous waste collection programs manage the collected waste as hazardous waste.[301] As such, the Agency recommends that collected household waste pharmaceuticals be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.[302] The Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Additionally, incineration is commonly used to meet the ''non-retrievable'' standard of destruction required by DEA for controlled substances collected from consumers (ultimate users, as DEA refers to them). Nevertheless, the Agency proposed to make this recommendation a requirement for collected household waste pharmaceuticals in § 266.506.[303] We strongly believe that if a program goes to the expense of collecting the waste, including waste pharmaceuticals, it should manage the waste as hazardous waste, rather than manage it as municipal solid waste, which the household could do absent the collection program. However, the current household waste exemption does not *require* an entity that hosts a household hazardous waste collection event to manage the collected waste as hazardous waste. Typically, the parties conducting household hazardous waste collection events have been government entities—municipalities and counties. It is relatively new that retail pharmacies and others are becoming interested in performing this function. To encourage this practice, while at the same time ensuring that collection programs are managing the collected waste properly, we proposed to codify our policy that pharmaceuticals that are household hazardous waste (*i.e.,* ''household waste pharmaceuticals'') and are collected in DEA authorized collection receptacles where they may be commingled [304] with controlled substances continue to be excluded from RCRA regulation, provided they are (1) combusted at a municipal solid waste or hazardous waste combustor, and (2) managed in accordance with all applicable DEA regulations.[305]

B. Summary of Comments

Many of the commenters, including states, healthcare facilities, and waste management companies, supported both conditional exemptions as a way to eliminate the duplicative regulation by DEA and EPA and commenters thought that the DEA tracking, shipping and recordkeeping are sufficient to operate in lieu of RCRA. Several commenters suggested that we expand the types of treatment that are allowed to destroy the hazardous waste pharmaceuticals that are also controlled substances. In some cases, commenters suggested that we allow additional combustion units such as hospital, medical, infectious waste incinerators (HMIWIs); commercial, industrial solid waste incinerators (CISWIs); and other solid waste incinerators (OSWIs) to combust hazardous waste pharmaceuticals that are also controlled substances. Other commenters suggested that we allow forms of destruction beyond combustion, such as oxidation treatment[306] or chemical digestion,[307] or any technology that achieves DEA's standard of non-retrievable.[308]

C. Final Rule Provisions

We are finalizing both conditional exemptions for hazardous wastes that are also controlled substances, with some changes. First, we have amended the regulatory language in § 266.506(a)(2) to be more consistent with the preamble to the proposed rulemaking and to be more consistent with how the conditional exemption in § 266.506(a)(1) was crafted. In the preamble to the proposed rulemaking, we discussed the conditional exemption in terms of the waste pharmaceuticals from take-back events and programs, while in the proposed regulatory language, the conditional exemption was focused on the collector of the waste pharmaceuticals. We revised the regulatory language in § 266.506(a)(2) to conditionally exempt the collected household waste pharmaceuticals, as opposed to the collector of the household waste pharmaceuticals. Additionally, one commenter pointed out that the proposed regulatory language could be read to mean that if the household waste pharmaceuticals were not commingled with DEA controlled substances, then the requirement to combust them would not apply.[309] EPA did not intend to make this distinction. Although we understand that most, if not all, take-back events and programs do, in fact, commingle controlled substances with non-controlled substances, EPA proposed to place conditions on collectors of household waste pharmaceuticals with the understanding that this proposed regulatory language would capture all pharmaceuticals collected at take-back events and programs. The revised regulatory language in this final rule makes it clearer that the household waste pharmaceuticals collected during a take-back event or program must be destroyed by combustion or other DEA-approved method, whether or not the household waste pharmaceuticals are commingled with DEA controlled substances.

Also in response to comments, we are expanding the types of combustors that are allowed to destroy the conditionally exempt hazardous waste pharmaceuticals. Under the final rule, five types of combustors will be allowed to destroy hazardous waste pharmaceuticals that are also DEA controlled substances and the pharmaceuticals from take-back events and programs: (1) Permitted large municipal waste combustors (MWCs), (2) permitted small MWCs, (3) permitted HMIWIs, (4) permitted CISWIs and (5) permitted hazardous waste combustors (either an incinerator or other combustor, such as a cement kiln).

In addition to the five types of permitted combustors allowed to destroy the conditionally exempt

[301] See memo from J. Winston Porter to Regions, dated November 1, 1988; RCRA Online #11377.

[302] See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online#14833) and memo October 2, 2015, Johnson to RCRA Division Directors (RCRA Online #14853).

[303] Since pharmaceutical collection programs typically commingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.

[304] DEA does not prohibit co-mingling of controlled substances with non-controlled substances provided they are all then managed as controlled substances.

[305] See 40 CFR 26.506(a)(2).

[306] See Comment number EPA–HQ–RCRA–2007–0932–0287.

[307] See Comment number EPA–HQ–RCRA–2007–0932–0375.

[308] See Comment number EPA–HQ–RCRA–2007–0932–0333.

[309] See comment number EPA–HQ–RCRA–2007–0932–0261.

pharmaceuticals, EPA is building in flexibility to the final regulation to allow for the possibility that future technologies might be developed that meet the DEA non-retrievable standard. Specifically, we are allowing any method of destruction for the conditional exemption that DEA has publicly approved in writing as able to meet its non-retrievable standard. While it is reasonable to defer to the DEA's judgement in this matter to approve methods of destruction that are environmentally protective, we feel it is necessary to limit future allowable destruction technologies for the conditionally exempt pharmaceuticals to those that are publicly approved by the DEA as meeting the non-retrievable standard. This is intended to avoid a situation where parties might make unsubstantiated claims that their product is capable of meeting the DEA non-retrievable standard in order to qualify for the conditional exemption. Furthermore, any method that DEA might specify must not conflict with federal environmental laws or regulations. Also, because combustion is no longer specified as the only allowable method of destruction, we have concluded that an additional change to the regulations is needed to make it clear that the hazardous waste pharmaceuticals that are also DEA controlled substances are subject to § 266.505, and therefore, may not be sewered.

Both types of conditionally exempt hazardous waste pharmaceuticals (*i.e.,* those that are DEA controlled substances and those that are collected household waste pharmaceuticals) will be able to take advantage of the expanded list of allowable types of combustors. For healthcare facilities and reverse distributors that generate and manage the handful of hazardous waste pharmaceuticals that are also controlled substances, we think it will be helpful to have additional destruction methods for these previously dually regulated wastes. Also, the expanded list of allowable types of combustors will be helpful for those operating take-back programs and events. The Agency is a strong supporter of take-back programs and events for household pharmaceuticals as an alternative to disposing of leftover, unwanted medications in the trash or in the toilet or down the sink (except in cases where the FDA-approved labeling instructs patients to immediately flush the unneeded medication down the toilet if a take-back option is not readily available). In expanding the types of combustors that are allowed to burn the pharmaceuticals from take-back events, we strive to strike a balance between maximizing flexibility while still being protective of human health and the environment. Under the revised list in the final rule, the universe of allowable combustors will substantially increase in number. There are 77 municipal solid waste combustion facilities (also referred to as waste-to-energy facilities) in 22 states,[310] and 21 commercial hazardous waste combustion facilities (*i.e.,* those that accept waste from off-site) in 12 states.[311] There are currently 33 HMIWIs units in the U.S.: 11 of the 33 are commercial HMIWIs, while the other 22 HMIWI units only combust their own waste.[312] There are approximately 75 CISWIs facilities in the U.S.[313] We note that the types of combustors we are allowing to accept the conditionally exempt pharmaceuticals are not obligated to accept the conditionally exempt pharmaceuticals. Of course, we strongly encourage all the various types of allowable combustors to work with their communities and regulators in developing viable options for destroying the pharmaceuticals from take-back events. In particular, we encourage the ''captive'' combustors that currently only combust their own waste to consider amending their permits to allow them to accept pharmaceuticals from take-back events and programs.

We have concluded that it is reasonable to expand the list of allowable combustors able to accept the conditionally exempt pharmaceuticals because the combustion of pharmaceuticals that meet the definition of a RCRA solid waste but do not meet the definition of RCRA hazardous waste (*i.e.,* non-hazardous waste pharmaceuticals) is regulated by § 129 of the Clean Air Act. The statute requires EPA to establish emission limits for nine air pollutants (*i.e.,* particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium) from several categories of solid waste incineration units, including MWCs; HMIWIs; and CISWIs. EPA has established emission limits for each of the categories based on the application of maximum available control technology (MACT) which reflect the emission levels achieved by the best performers in each category.

In addition to complying with emission limitations, solid waste incineration units are also subject to comprehensive operating, monitoring and reporting requirements. In light of the common framework used to develop emission limits and requirements for MWC, CISWI, and HMIWI units, we believe that it is appropriate to include HMIWIs and CISWIs as types of combustors that are allowed to burn the pharmaceuticals from take-back events.

While the Agency has expanded the list of allowable combustors to include HMIWIs and CISWIs, we have not expanded the list to include other solid waste incinerators (OSWIs). OSWIs are small units that have fewer emission controls than other types of combustors. Further, there are only a handful of new OSWIs in operation and the legal status of existing OSWIs is uncertain due to litigation. EPA is also not expanding the list of allowable combustors to include human and pet crematoriums. Crematoriums are not regulated under the Clean Air Act and typically do not use air pollution control devices to limit toxic air pollutants such as mercury and dioxins and furans. We believe that crematoriums would not provide adequate public health and environmental protection when burning non-hazardous waste pharmaceuticals. If solid or hazardous wastes are burned in a crematorium, it would make the crematorium subject to the Clean Air Act.

D. Comments and Responses

In its comment, Cardinal Health included a list of pharmaceuticals that it manages as both RCRA hazardous waste and DEA controlled substances.[314] In most cases, their comments reinforced the list that we included in the proposed rulemaking. In two cases, Cardinal Health identified additional forms of drugs that were included in the table of DEA controlled substances and hazardous wastes in the preamble to the proposed rulemaking. First, Cardinal Health identified Axiron as the brand name of an additional form of testosterone that is a solution applied to the underarms that is also ignitable. Second, Cardinal Health identified Diastat as the brand name of an additional form of valium that is a gel intended for rectal administration that is also ignitable. We have amended our list of DEA controlled substances and RCRA hazardous wastes by including Axiron and Diastat in Table 6 below to be more

[310] Energy Recovery Council, 2016 Directory of Waste-to-Energy Facilities; *http://energyrecoverycouncil.org/wp-content/uploads/2016/06/ERC-2016-directory.pdf.*

[311] Memo from Rudzinski to Regions, dated September 26, 2012; RCRA Online #14833.

[312] See comment number EPA–HQ–RCRA–2007–0932–0280.

[313] See CISWI inventory EPA–HQ–OAR–2016–0664–0002.

[314] See comment number EPA–HQ–RCRA–2007–0932–0250.

complete and accurate. However, there is no corresponding regulatory change being made. The regulations conditionally exempt all RCRA hazardous wastes that are also DEA controlled substances; the table identifying which drugs are both is included in the preamble for informational purposes:

TABLE 6—PHARMACEUTICALS STILL USED IN HEALTHCARE THAT ARE DEA CONTROLLED SUBSTANCES & RCRA HAZARDOUS WASTES

[Amendments in bold based on comments]

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Chloral; chloral hydrate.	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes.	Sedative	U034 toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics.
Fentanyl sublingual spray.	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content.
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content.
Testosterone gels/solutions.	Androgel, Axiron, Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to alcohol content.
Valium injectable/gel	Diazepam, Diastat	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content.

Cardinal Health's comment also indicated that the company manages Somatropin (brand names Humatrope and Genotropin) as a DEA controlled substance and a RCRA hazardous waste. M-cresol, which is a contaminant identified on the toxicity characteristic list in § 261.24 (D024), is used as a preservative in Somatropin. Per legislations, all anabolic steroids are considered controlled substances; [315] however, Somatropin is considered a human growth hormone, not an anabolic steroid.[316] Therefore, although Somatropin may be a RCRA hazardous waste for its m-Cresol content, it is not a DEA controlled substance.

The two conditional exemptions we are finalizing in this rule are intended to eliminate any duplicative regulations for pharmaceuticals that are RCRA hazardous wastes and DEA controlled substances. Nevertheless, there are several remaining areas where DEA and EPA regulations intersect, even if they are not duplicative. The Agency would like to address these intersecting areas in effort to reduce confusion and aid compliance.

1. Only Household (Ultimate User) Waste May Be Collected in DEA Authorized Collection Receptacles

It is important to note that in order to qualify for the conditional exemption, a retail pharmacy (or other DEA authorized collector pharmacy) can use the DEA authorized collection receptacle to collect waste generated only at households (DEA refers to this as waste from ''ultimate users'') and brought to the store for collection. The hazardous waste generated by the retail pharmacy and store, including hazardous waste pharmaceuticals, are not excluded household wastes under RCRA and may not be placed in the DEA authorized receptacle.[317] Depending on the amount generated, the hazardous waste pharmaceuticals generated by the retail pharmacy and store must be managed under either § 262.14 (as a VSQG) or under part 266 subpart P. Furthermore, states generally regulate non-hazardous waste and it is possible that they may have licensing or permitting requirements for the collection of solid waste. Because EPA would like to see the use of DEA authorized collection receptacles become widespread, we encourage states to streamline any requirements that may create a barrier to the use of the DEA authorized collection receptacles.

2. Sewer Prohibition, Conditional Exemption and Pharmaceutical Wastage

In response to comments, EPA has decided against making any exceptions to the sewer prohibition. Some commenters suggested that EPA should allow RCRA hazardous wastes that are also DEA controlled substances to be sewered. On the other hand, many commenters suggested, and EPA agrees, that it would be inappropriate to make exceptions to the sewer prohibition, even for the handful of hazardous wastes that are also controlled substances. In part, commenters thought it was bad environmental policy to allow sewering of any hazardous waste pharmaceuticals. Commenters were also concerned that it would send a mixed message to the regulated community about our goals and lead to confusion about which hazardous waste pharmaceuticals could and could not be sewered. As a result, all hazardous waste pharmaceuticals are prohibited from being sewered, including the handful that are also DEA controlled substances.

Under the DEA regulations, a registrant's inventory of controlled substances is already prohibited from being sewered as a means of meeting the non-retrievable standard.[318] Likewise, under the CWA regulations, RCRA ignitable hazardous wastes (D001) are prohibited from being discharged to the sewer.[319] As noted in Table 6, four out of the five RCRA hazardous wastes that are also DEA controlled substances are hazardous waste due to being ignitable and hence are already prohibited from being sewered by the CWA regulations. In effect, this new RCRA regulation only prohibits the sewering of one additional DEA controlled substance that is also a RCRA hazardous waste: Chloral hydrate, which is listed for toxicity. In summary, a RCRA hazardous waste that is also DEA controlled substance that is part of a DEA registrant's inventory may not be sewered.

[315] The Anabolic Steroids Control Act of 1990 placed anabolic steroids into Schedule III of the Controlled Substances Act (CSA) as of February 27, 1991.

[316] *https://www.fda.gov/Drugs/DrugSafety/ucm237839.htm;* accessed 8/24/2017.

[317] DEA also prohibits retail pharmacy stock/inventory from being placed in the collection receptacle or mail-back envelopes (see 21 CFR 1317.05(a)).

[318] See the preamble to DEA's final rule 79 FR 53548; September 9, 2014 and the preamble to DEA's proposed rule 77 FR 75803; December 21, 2012.

[319] See the Clean Water Act regulations at 40 CFR 403.5(b)(1).

DEA does allow controlled substance ''pharmaceutical wastage'' to be disposed of in accordance with applicable federal, state, and local laws, regulations, and healthcare facility policies, including sewering or putting down the drain.[320] DEA uses the term ''pharmaceutical wastage'' to refer to leftover, unadministered pharmaceuticals (''*e.g.,* some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized'' [321]). While DEA allows pharmaceutical wastage of controlled substances to be sewered, the CWA regulations already prohibit the discharge of any RCRA ignitable hazardous waste and, under this RCRA rule, EPA is not creating any exceptions to the sewer prohibition. As a result, neither inventory nor pharmaceutical wastage of DEA controlled substances that are also RCRA hazardous wastes may be sewered.

Even though inventory and pharmaceutical wastage are prohibited from being sewered, both inventory and pharmaceutical wastage would be eligible for the conditional exemption being finalized in this rule in § 266.506 for RCRA hazardous wastes that are also DEA controlled substances. As discussed previously, EPA is finalizing the conditional exemption that the few RCRA hazardous waste pharmaceuticals that are also DEA controlled substances would be exempt from RCRA regulation, on the condition that they are (1) managed in accordance with DEA regulations and (2) incinerated by one of five types of permitted combustors or destroyed by another method that has been publicly approved by DEA, and (3) are not sewered.

Therefore, if inventory or pharmaceutical wastage is both a RCRA hazardous waste and a DEA controlled substance it would not be allowed to be sewered, it would have to be incinerated (or destroyed by another method publicly approved by DEA). Prior to incineration, however, the inventory and pharmaceutical wastage, both of which are conditionally exempt under RCRA, are regulated differently by DEA. The leftover inventory of DEA controlled substances remains fully subject to DEA regulations, which includes tracking and witnessed destruction. On the other hand, controlled substance pharmaceutical wastage is no longer regulated by DEA. Therefore, only pharmaceutical wastage could be collected in a container at the healthcare facility prior to incineration. If this container were used to collect only conditionally exempt pharmaceutical wastage prior to incineration, it would not be subject to the subpart P container standards. It is more likely, however, that a container used to collect the conditionally exempt pharmaceutical wastage would also be used to collect regulated hazardous waste, in which case the container would be subject to subpart P container standards. In either case, as DEA states in its guidance, ''Although Part 1317 does not apply to pharmaceutical wastage, the DEA strongly encourages all practitioners to continue to adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted. For example, most institutional practitioners have implemented policies that require two persons to witness and record destruction of pharmaceutical wastage.'' [322] In support of DEA's guidance, EPA strongly recommends that any container that is used to collect pharmaceutical wastage that will include DEA controlled substances contain some sort of absorbent or chemical reactant in order to bind or chemically alter the contents and thus deter the diversion of the collection container for controlled substance recovery.

3. Long-Term Care Facilities and the DEA Regulations

This section will discuss the intersection of the DEA regulations and the RCRA hazardous waste regulations that pertain to LTCFs.

Under the DEA regulations, most LTCFs are not registrants and until recently have had few options for properly and securely disposing of the controlled substances from its patients (ultimate users). DEA's 2014 final regulations to implement the Secure and Responsible Drug Disposal Act of 2010 are designed to help alleviate the problem that LTCFs face when discarding their patients' controlled substances. DEA's 2014 final rule allows, but does not require, retail pharmacies and hospital/clinics with an on-site pharmacy that are DEA registrants to modify their registrations to become ''collectors'' and to place collection receptacles at LTCFs (or at the retail pharmacy or hospital/clinic with an on-site pharmacy) for the collection of controlled substances from ultimate users. Per the DEA regulations, if a DEA authorized collection receptacle is placed in a LTCF, only the ultimate users' controlled substances may be placed in the DEA collection receptacle. If an LTCF is a DEA registrant and discards DEA controlled substances from its inventory, they may not be placed in the DEA authorized collection receptacle and must be otherwise destroyed to meet the non-retrievable standard.

Under the 2014 DEA final rule, LTCFs now have three options for managing their patients' controlled substances. First, if a DEA registered retail pharmacy or hospital/clinic with an on-site pharmacy places a collection container at an LTCF, the staff from the LTCF may place the patients' controlled substances in the collection receptacles. Second, although LTCFs are not allowed to conduct a facility-wide collection event for their patients' controlled substances for mail-back programs, they are allowed to assist patients who choose to use a mail-back program for their own controlled substances, on an individual-by-individual basis. And third, law enforcement can pick up patients' controlled substances for disposal. With these changes to DEA's regulation, LTCFs can now dispose of patients' controlled substances in a more environmentally protective way and EPA strongly encourages the use of any of these three collection methods. It should be noted that the 2014 DEA regulations do not mandate the placement of collection receptacles at long-term care facilities or patient participation in mail-back programs or take-back events.

As for the RCRA regulations, this rule finalizes the provision that hazardous waste from LTCFs will no longer be considered exempt as household hazardous waste. Instead, it will need to be managed as regulated hazardous waste. This interpretation will apply to all the hazardous waste generated by a LTCF, not just its hazardous waste pharmaceuticals (although the Agency expects that much of the hazardous waste generated by LTCFs consists of hazardous waste pharmaceuticals). Notwithstanding this revised interpretation, there are four other regulatory provisions that might affect how a LTCF will actually have to manage its hazardous waste pharmaceuticals under this final rule

First, we have added to the final rule a presumption that LTCFs with 20 beds or fewer will be VSQGs.[323] And those LTCFs that have more than 20 beds may still qualify as VSQGs (for all of their hazardous waste) if they generate less than 100 kg of hazardous waste and less

[320] See DEA letter to registrants re: Clarifying disposal of pharmaceutical wastage dated Oct 17, 2014; *http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf.*

[321] Ibid.

[322] Ibid.

[323] See 40 CFR 266.504(d).

than 1 kg of acute hazardous waste per calendar month. In fact, based on the RIA for the final rule, EPA estimates that 98–99 percent of LTCFs that generate hazardous waste are VSQGs.[324] As VSQGs, the long-term care facilities will be subject to the reduced regulatory provisions of 40 CFR 262.14 for all of their hazardous waste (including those that are controlled substances), and only the sewer prohibition provision of this new subpart for their hazardous waste pharmaceuticals. Only the other 1–2 percent of LTCFs that generate hazardous waste will be subject to part 266 subpart P.

Second, this final rule allows an LTCF that is a VSQG (for all of its hazardous waste) to send its hazardous waste pharmaceuticals to an off-site healthcare facility that either supplies the LTCF with its pharmaceuticals (*e.g.,* a long-term care pharmacy) or is under the control of the same person and that is operating under subpart P.[325] Note that this provision is limited to hazardous waste pharmaceuticals and not to those that are also controlled substances because the DEA allows controlled substances to be returned to a long-term care pharmacy only when they are subject to a recall.

Third, this final rule also allows a healthcare facility, including a LTCF that is a VSQG, to use an on-site DEA authorized collection receptacle to dispose of its hazardous waste pharmaceuticals (see § 266.504(c)). It could be argued that VSQGs would already be allowed to use DEA authorized collection receptacles for their hazardous waste pharmaceuticals even without this new provision, provided the waste from the DEA authorized collection receptacles is treated or disposed at one of the types of facilities identified in § 262.14(a)(5) (*e.g.,* facilities that are permitted or have interim status to manage hazardous waste and facilities that are permitted, licensed or registered by a state to manage hazardous waste, municipal waste or non-municipal waste). Nevertheless, we did propose, and are finalizing the provision in § 266.504(c) making it clear that healthcare facilities that are VSQGs can place their hazardous waste pharmaceuticals in an on-site DEA collection receptacle. DEA already allows controlled substances to be commingled with non-controlled substances. Therefore, EPA believes it is consistent to allow VSQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA collection receptacles with controlled substances. EPA believes that management of VSQGs' hazardous waste pharmaceuticals as DEA controlled substances is preferable because it provides greater protection to patients, visitors, and workers at healthcare facilities to have the hazardous waste pharmaceuticals accumulating in DEA-authorized collection receptacles rather than in the regular trash. However, it is important to note that the DEA regulations for controlled substances are much narrower in what may be placed in a collection receptacle; DEA only allows controlled substances from patients to be placed in collection receptacles that are at LTCFs. To reiterate, under the DEA regulations, if a LTCF, or any other healthcare facility, is a DEA registrant it may not place its own inventory of controlled substances in a collection receptacle, even if it is a VSQG under RCRA.

Fourth, for the LTCFs that are not VSQGs, the handful of RCRA hazardous waste pharmaceuticals that are also DEA controlled substances will not be subject to RCRA, provided they meet three conditions: (1) They are combusted at a small or large MWC, a HMIWI, a CISWI or a hazardous waste combustor (or destroyed by another method publicly approved by DEA), (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances, and (3) they are not sewered. DEA allows LTCFs to put their patients' controlled substances into an on-site collection receptacle; therefore, an LTCF could also place its patients' controlled substances that are also RCRA hazardous waste into a DEA authorized collection receptacle (alternatively, patients could use another allowable take-back method, such as mail-back envelopes) in order to meet the conditional exemption. However, we must stress that only LTCFs would be able to use collection receptacles (or another allowable take-back method) to meet the conditional exemption for RCRA hazardous wastes that are also DEA controlled substances, because they are the only type of facility that DEA allows to place their patients' wastes into an on-site collection container. Other healthcare facilities, such as hospitals, could not meet the conditional exemption by placing their DEA controlled substances that are also RCRA hazardous wastes in a collection receptacle because DEA does not allow patients at hospitals to use on-site collection receptacles. No registrant healthcare facility, including an LTCF, would be able to use the collection receptacle to meet the terms of the conditional exemption for any of its own inventory of DEA controlled substances that are also RCRA hazardous wastes because DEA does not allow registrants to use collection receptacles for their own inventory.

For those LTCFs that are not VSQGs, the hazardous waste pharmaceuticals that are not controlled substances (and therefore not conditionally exempt) will be subject to part 266 subpart P, while the other hazardous wastes will be subject to the SQG or LQG regulations, as applicable, in part 262.

See Table 7 for a summary of the intersection of RCRA and DEA regulations for the disposal of hazardous waste pharmaceuticals at LTCFs:

TABLE 7—INTERSECTION OF RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES

Types of pharmaceutical waste at long-term care facilities	RCRA regulatory requirements		
	How RCRA applies	DEA authorized collection methods allowed for HW pharmaceuticals?	Can be returned to an off-site HCF owned by the same person or LTC pharmacy?
Hazardous Waste Pharmaceuticals that are NOT Controlled Substances:			
if LTCF is a VSQG	§ 262.14 and sewer prohibition.	Yes. § 266.504(c)	Yes.
if LTCF is *not* a VSQG	part 266 subpart P	No	No.
Hazardous Waste Pharmaceuticals that are also Controlled Substances:			

[324] See the Regulatory Impact Analysis for this final rule in the docket EPA–HQ–RCRA–2007–0932.

[325] See 40 CFR 266.502(l) and 266.503(b) for non-creditable and creditable hazardous waste pharmaceuticals, respectively.

TABLE 7—INTERSECTION OF RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES—Continued

Types of pharmaceutical waste at long-term care facilities	RCRA regulatory requirements		
	How RCRA applies	DEA authorized collection methods allowed for HW pharmaceuticals?	Can be returned to an off-site HCF owned by the same person or LTC pharmacy?
if LTCF is a VSQG	§ 262.14 and sewer prohibition.	Yes. Only from patients	Only if subject to a recall.
if LTCF is *not* a VSQG	Conditionally exempt from RCRA (§ 266.506) if: • Combusted (or other DEA approved destruction method). • Comply with DEA regulations.	Yes. Only from patients (DEA collection methods meet the terms of the RCRA conditional exemption).	Only if subject to a recall.

XV. Management of Residues in Pharmaceutical Containers (§ 266.507)

A. Regulatory Background

Over the years, EPA has received numerous inquiries regarding the regulatory status of residues in various types of containers that once held pharmaceuticals that are considered hazardous waste when discarded. Stakeholders have been particularly concerned about residues in containers that once held pharmaceuticals that are on the ''P-list'' of acutely hazardous commercial chemical products in § 261.33(e) because a generator becomes an LQG if it generates more than 1 kg of acute hazardous waste per calendar month.[326] The regulatory status of acute and non-acute commercial chemical product residues remaining in a container are specifically addressed in § 261.33:

''The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded . . . (c) Any *residue* remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is *empty* as defined in § 261.7(b).''

In § 261.7(b)(1), there are two ways a container that held a non-acute hazardous waste can be considered ''empty.'' The container is considered empty if all wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, *e.g.,* pouring, pumping, aspirating, *and* (1) no more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, *or* (2) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or no more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.

Therefore, it is important to note that if the container that held the non-acute hazardous waste pharmaceutical does not have its contents removed by a commonly employed practice even though it has one inch or less of residue remaining or has 3 percent or less by weight of the total capacity of the container remaining,[327] the container is still *not* considered ''RCRA empty.'' If the container is not ''RCRA empty,'' then the residues are regulated as hazardous waste (since the residues are within the container, the container must be managed as hazardous waste, as well, even if it is not itself hazardous waste).

According to § 261.7(b)(3), there are three ways that a container that held an acute hazardous waste can be considered empty:

(1) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(2) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(3) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

According to these requirements, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered ''RCRA empty,'' even though the pharmaceutical may have been fully removed. If the container is not ''RCRA empty,'' then the residues are regulated as acute hazardous waste.

In November 2011, EPA issued guidance about containers that once held P-listed pharmaceuticals [328] that provides three possible regulatory approaches for generators:

(1) Count only the weight of the hazardous waste residues toward generator category

(2) Demonstrate an equivalent removal method to render containers RCRA empty

(3) In the case of warfarin, show that the concentration in the residue is below the P-listed concentration

This guidance was intended as a short-term solution that worked within the confines of the existing RCRA hazardous waste regulations. In 2015, we proposed to amend the regulations that pertain to residues in containers that once held pharmaceuticals that are RCRA hazardous wastes. EPA proposed different regulatory solutions for different types of containers found in healthcare settings. Specifically, the proposal addressed the following three categories of containers: (1) Unit-dose containers (*e.g.,* packets, cups, wrappers, blister packs, and delivery devices) and dispensing bottles and vials; (2) dispensed syringes; and (3) other containers, including delivery devices. Generally, commenters were supportive of the need for these new empty container standards specifically developed for the types of small containers used in the healthcare setting, although they did have suggestions for changes. Each category

[326] Additionally, acute hazardous wastes are included on the F-list of § 261.31; however, none of those acute hazardous wastes are pharmaceuticals.

[327] We are assuming that containers that hold pharmaceuticals are in containers less than 119 gallons in size.

[328] Rudzinski to RCRA Division Directors, November 11, 2011, RCRA Online #14827.

of container is discussed separately below. Today's new ''empty container'' regulations in § 266.507 will replace the November 2011 guidance as it pertained to residues of hazardous waste pharmaceuticals in containers, although the memo will remain in effect for non-pharmaceutical hazardous wastes.

B. Stock, Dispensing and Unit-Dose Containers (§ 266.507(a))

1. Summary of Proposal

We proposed that a dispensing bottle, vial, or ampule (not to exceed 1 liter or 1,000 pills) or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack or delivery device) would be considered empty and the residues would not be regulated as hazardous waste if the hazardous waste pharmaceuticals have been removed from the dispensing or unit-dose container by commonly employed methods.

This proposal applied to containers that once held acute or non-acute hazardous waste pharmaceuticals. Under the proposal, for containers that once held non-acute hazardous waste pharmaceuticals, it would not be necessary to measure the remaining contents. Likewise, under the proposal, for containers that once held acute hazardous waste pharmaceuticals, it would not be necessary to triple rinse the containers or demonstrate an equivalent removal method. Rather, we proposed that a dispensing or unit-dose container would be considered empty if all pharmaceuticals have been removed using the practices commonly employed to remove materials from that type of container—thus, the residues (and therefore the container as well) may be disposed of as non-hazardous waste.

We proposed this new ''RCRA empty'' standard for containers used within a healthcare setting for two reasons. First, this approach will help eliminate the sewering of pharmaceuticals. In a healthcare setting, if containers are triple rinsed, the rinsate will likely be poured down the drain, which is not a good environmental practice. We think it is important that the residues be managed in a more controlled manner—such as in municipal solid waste landfills— rather than poured down the drain. Second, although the ''empty container'' regulations of § 261.7 apply to all sizes of containers, they were developed with larger, industrial-sized containers in mind. For the most part, the containers that hold pharmaceuticals are smaller in size than a 55-gallon drum; therefore, the amount of residue will likely be much less in these containers. In the preamble to the proposed rulemaking, we explained that we selected the 1,000-pill/1-liter limit because, in our observation, EPA had rarely seen dispensing bottles larger than that. We specifically sought comment on whether larger containers are used for dispensing pharmaceuticals and, if so, which pharmaceuticals they are used for and what RCRA hazardous waste codes would apply.

In the proposal, EPA presented data from three stakeholders helping to confirm the assumption that very little residue remains in containers after the pharmaceuticals (*e.g.,* pills) have been removed. In addition, EPA's Office of Research and Development conducted similar research.[329] A summary of the results is in the preamble to the proposed rulemaking, while the full results from each of the four sources are included in the docket for the proposed rulemaking.[330] [331]

EPA is aware that there are certain limitations with the data from the four sources. For instance, in one of the studies, no replicate samples were tested. In another study, only warfarin residues were tested. However, given the size of the containers involved and the nominal quantities of residues involved, the Agency proposed to allow the residues in dispensing bottles, vials and ampules, and single-unit dose containers that once held hazardous waste pharmaceuticals to be managed as non-hazardous waste provided the pharmaceutical product has been removed (*e.g.,* all pills have been removed).

As part of the proposal, EPA raised the concern of potential diversion of the pharmaceutical containers that may occur when the pharmaceutical residues and containers are discarded in the municipal waste stream. The Agency proposed that RCRA-empty pharmaceutical containers that are original pharmaceutical packages (and therefore susceptible to diversion) should be destroyed prior to placing them in the trash. These types of containers would include dispensing bottles, vials, or ampules typically used in pharmacies, but would not include paper or plastic cups, or blister packs used for dispensing singles doses to patients. In the preamble to the proposal, we explained that the means of destruction could include crushing or shredding the container.

2. Summary of Comments

The comments for this section can be broken into two major groups. One group of comments expressed concern with the 1,000-pill/1-liter size limit to pharmaceutical dispensing containers and commenters asked EPA to consider allowing the new RCRA-empty standard for pharmaceutical dispensing containers to apply to larger pharmaceutical containers or even to all dispensing containers, regardless of size.

As part of its comments, CVS Health included results from an analysis conducted on containers that held warfarin.[332] Their tests included brand name and generic warfarin stock bottles, testing the largest stock bottles with the highest prescription strength warfarin typically found in a CVS Health Pharmacy, although their comments do not specify the size of the largest stock bottle, nor do they specify the highest prescription strength of warfarin. That said, their results do offer similar results as the studies used in support of the proposal, indicating the range of total residues detected was 0.0–19.8 mg (excluding outliers).

Another group of comments objected to the proposed requirement to destroy the containers before disposing of them in municipal solid waste landfills. Commenters objected to this proposed provision for several reasons. First, the most common reason given by commenters that objected to this provision was they disagreed with EPA that diversion of these containers is occurring. Many states commented that this has never been a problem in their state and that the issues with these types of containers arise from purchase of empty vials on the internet and counterfeit labels made on home computers, not from dumpster diving. Second, there was concern that this would be a costly option since many healthcare facilities would now need to hire someone or buy equipment to destroy the containers. Many commenters thought the same goals could be reached through more cost-effective means such as defacing the label to render the containers unusable for illicit purposes. Third, a few commenters were also concerned with the release of the residues in these containers upon destruction and the effect that could have on the workers. This set of commenters included the one state that favored destruction of the containers. Finally, some commenters noted that these empty containers are already being disposed of in locked

[329] Tolaymat, T. and A. El Badawy. Evaluation of P-Listed Pharmaceutical Residues in Empty Pharmaceutical Containers. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–14/167, 2015.

[330] September 25, 2018; 80 FR 58052.

[331] EPA–HQ–RCRA–2007–0932–0153 through 0156.

[332] See comment number EPA–HQ–RCRA–2007–0932–0312.

dumpsters and there are adequate institutional controls to address any public health risk from use of discarded containers in counterfeit drug sales.

3. Final Rule Provisions

In response to comments, we have made three substantive changes to the regulations proposed in § 266.507(a) that define when a dispensing or unit-dose container is empty. First, based on comments, we now recognize that we used the term ''dispensing'' bottle, vial, or ampule incorrectly. Dispensing bottles are those that are provided to patients when they get a prescription filled. Although a healthcare facility such as a pharmacy may dispose of some dispensing bottles, they are more likely to dispose of the stock bottles that they use to fill the dispensing bottles provided to the patients. As a result, we have modified the regulatory language to include stock bottles in addition to dispensing bottles, vials or ampules, and unit-dose containers.

Second, after reviewing comments and asking for additional support and clarification from commenters, including the Army Public Health Center, CVS Health and the Department of Veterans Affairs, the Agency has increased the size of the dispensing containers from 1,000 pills to 10,000 pills.[333] The Army Public Health Center states that they ''routinely procure containers containing 1K, 2K, and even 5K or 10K pill counts'' for refilling the automated dispensing machines at their facilities.[334] This exceeds the size of dispensing containers that we and others tested, but given that the contents are solid pills, capsules and tablets, and that the residues we and others detected are very small, we determined that it is appropriate to increase the size of the stock or dispensing container to 10,000 pills.

However, we have kept the maximum volume for stock and dispensing containers at a maximum of 1 liter since this volume limit would apply to liquids (and other non-pill formulations), which are harder to fully remove, and commenters did not provide sufficient information to support increasing the volume limit. Further, it is not clear from comments or subsequent correspondence whether any containers larger than 1 liter are in use for pharmaceuticals that would be hazardous waste when discarded. Stock or dispensing containers that exceed 1 liter would be considered ''other containers'' under § 266.507(d). As such, under the final rule, if they held pharmaceuticals that are non-acute hazardous waste, then they would be able to use § 261.7(b)(1) to show that they are empty.

The third substantive change is that we have removed the proposed requirement to destroy the empty pharmaceutical containers prior to disposal. We share commenters' concerns about possible worker exposure during the process of crushing or shredding the containers. However, EPA remains concerned about the diversion of the empty containers for illicit purposes. Therefore, we strongly encourage healthcare facilities to use best management practices, such as locked dumpsters and defacing labels, to prevent the diversion of these containers, but the extra step of destroying these containers will not be required.

Thus, under the final rule, a stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

In § 261.33(c), we have also added a reference to the new empty container provisions for hazardous waste pharmaceuticals in § 266.507 as a conforming change. Previously, § 261.33(c) referenced only the empty container provisions of § 261.7(b).

4. Comments and Responses

One commenter asked us to add an explicit reference to acute/P-listed hazardous waste in this section of the regulations. We believe this is unnecessary since § 261.7(c) indicates that containers of hazardous waste pharmaceuticals (which includes acute and non-acute hazardous waste pharmaceuticals) are subject to § 266.507 in lieu of § 261.7 for determining when they are empty. Nevertheless, we agree with the commenter that all of the new empty container provisions in § 266.507 apply to containers that held either non-acute or acute hazardous waste pharmaceuticals. Under the new subpart P provisions, for containers that once held non-acute waste pharmaceuticals to be considered empty, it will not be necessary to measure the remaining contents, and for containers that once held acute hazardous waste pharmaceuticals, it will not be necessary to triple-rinse the containers or demonstrate an equivalent removal method.

C. Syringes (§ 266.507(b))

1. Summary of Proposal

EPA proposed that the residues remaining in a syringe would not be regulated as hazardous waste provided the syringe had been used to administer a pharmaceutical to a patient, the syringe is placed in a sharps container (if appropriate), and is managed in accordance with all applicable federal, state, and local medical waste or regulated waste regulations. As with all of the new empty container standards proposed in § 266.507, this proposed provision applied to syringes used to administer pharmaceuticals that are acute or non-acute hazardous waste when discarded.

Prior to the proposal, EPA issued guidance regarding the regulatory status of residues in syringes in December 1994 and April 2008.[335] [336] In the December 1994 RCRA/Superfund Hotline Q&A about whether epinephrine residues in a discarded syringe would be P042, EPA stated, ''Drug residues often remain in a dispensing instrument after the instrument is used to administer medication. EPA considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. The epinephrine could be a RCRA hazardous waste, however, if it exhibits a characteristic of hazardous waste.'' [337] In the April 2008 memo, EPA clarified that the 1994 interpretation extends to other P- and U-listed pharmaceuticals that have been used to administer the pharmaceutical by syringe.

EPA thinks that it is important to clarify in regulation when syringes are considered RCRA empty as this has been a source of many questions over the years. As part of the decision making, EPA is aware of the need to

[333] See the email correspondence from Lisa Strutz (APHC); Donald Dempsey (CVS Health); and Peter Carbrey (VA) in the supporting materials of the docket for this final rulemaking (EPA–HQ–RCRA–2007–0932).

[334] See the email correspondence from Lisa Strutz (APHC) to Kristin Fitzgerald (EPA), dated February 9, 2017, in the supporting materials of the docket for this final rulemaking (EPA–HQ–RCRA–2007–0932).

[335] December 1994, RCRA Online #13718.

[336] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788.

[337] Note that since this Q&A was issued, EPA issued guidance indicating that epinephrine salts are not included in the scope of the P042 listing and therefore, most, if not all, medical applications of epinephrine are not P042 (October 15, 2007; RCRA Online #14778).

minimize the potential for exposures of healthcare workers to the sharps, which may be contaminated with bloodborne pathogens, as well as to the contents of the syringes.

The preamble to the proposed rulemaking also noted that sharps containers containing syringes are typically autoclaved prior to disposal. EPA expressed concern that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose workers to the aerosolized hazardous waste residues, posing risks via pulmonary exposure to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs.[338] As a result, EPA requested comment on whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this new provision would apply or whether any other conditions would be appropriate.

2. Summary of Comments

As noted above, commenters generally supported EPA's goal of codifying new standards for defining when containers are considered empty, including syringes. EPA received many comments requesting that the Agency clarify what it means when it uses the term ''dispensed.'' Further, they noted that although the proposed regulations used the term ''dispensed,'' in several cases in the preamble, we used the term ''fully dispensed'' and they requested clarification about which was correct. Commenters also noted that EPA used the term ''dispensed'' inappropriately and stated that the term ''administered'' was more appropriate. The Agency received mixed comments on whether any residues or contents should be left in the syringes when disposing of the syringe. In the case of autoclaving residues in syringes, almost all commenters agreed that the hazardous waste pharmaceutical residues should not be autoclaved. Some commenters believed that the contents should be disposed of in a gauze pad or equivalent while others argued that this was in contradiction to NIOSH recommendations for minimizing exposure to hazardous drugs. Some commenters were comfortable with leaving contents in the syringes, suggesting that would be in compliance with OSHA [339] and DOT.[340]

3. Final Rule Provisions

We have made two substantive changes to this section of the regulations that define when syringes are considered empty for the sake of RCRA regulation. First, EPA agrees with commenters that we used the term ''dispensed'' inappropriately in the proposed rulemaking. FDA defines ''dispense to patients to mean the act of delivering a prescription drug product to a patient or an agent of the patient.'' [341] Dispensed pharmaceuticals are then administered directly to the patient. EPA has revised the regulations to address commenters' concerns. In the final rule, to avoid confusion, when discussing syringes we do not use the term dispensed, fully dispensed, or administered. Instead, under the final rule, a syringe is considered empty and the residues are not regulated as hazardous waste provided the contents have been removed by fully depressing the plunger of the syringe. Thus, the final regulations convey an intent that is more similar to the proposed preamble use of the term ''fully dispensed.'' This reflects commenters' and EPA's desire to avoid the possibility of autoclaving syringes that may have a large portion of their hazardous waste pharmaceutical contents remaining.

Commenters affirmed EPA's concerns about aerosolizing the autoclaved hazardous waste in sharps containers and we have concluded that hazardous waste incineration of hazardous waste pharmaceuticals remaining in non-empty syringes is more appropriate. A recent literature search also supports this position. The NIOSH and the American Society of Hospital Pharmacists (ASHP) have both published articles regarding autoclaving of sharps. The 2004 NIOSH alert states, ''Do not place hazardous drug-contaminated sharps in red sharps containers that are used for infectious wastes, since these are often autoclaved or microwaved.'' [342] The ASHP article states, ''Sharps used in the preparation of hazardous drugs should not be placed in red sharps containers or needle boxes, since these are most frequently disinfected by autoclaving or microwaving, not by incineration, and pose a risk of aerosolization to waste-handling employees.'' [343]

A syringe with a fully depressed plunger will have a minute amount of residue and the syringe can be considered empty under the final rule. Thus the residue in the empty syringe (as well as the syringe) will not be regulated as hazardous waste. A syringe that does not have a fully depressed plunger could have anything from a small amount to 99% of hazardous waste pharmaceutical contents still left in it. Therefore, we have concluded that it is impracticable to impose an alternate bright line for determining whether a partially administered syringe is empty. Further, we concur with ASHP and NIOSH regarding concerns about the safety of autoclave operators and believe the standard in this final rule will help prevent exposing workers to volatilized hazardous waste pharmaceutical residues during the autoclaving process.

The second substantive change we made in the final rule is to clarify that if a syringe contains a pharmaceutical that is a hazardous waste and it is not empty because the plunger is not fully depressed, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart as well as any applicable federal, state, and local requirements for sharps containers and medical or regulated waste. We note that the new empty syringe provisions being finalized today supersedes the previous EPA interpretations expressed in guidance memos in December 1994 and April 2008.[344] [345]

We note that a syringe can become empty in three ways: (1) Fully depressing the plunger of the syringe by administering the contents of the syringes to a patient, or (2) fully depressing the plunger by injecting the contents of the syringe into another delivery device such as an IV bag, or (3) fully depressing the plunger of the syringe by emptying the remaining contents into a hazardous waste collection container.

[338] Daughton CG, Drugs and the Environment: Stewardship & Sustainability, National Exposure Research Laboratory, Environmental Sciences Division, US EPA, Las Vegas, NV; NERL–LV–ES 10/081, EPA/600/R–10/106; September 2010 (*https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=228503*).

[339] OSHA Title 29 CFR 1910.1030 Bloodborne Pathogens.

[340] DOT Title 49 CFR 172.343 subpart D—Marking; 172 subpart E—Labeling Standards; 172.432 Subpart E.

[341] See 21 CFR 208.3.

[342] NIOSH. ''Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings.'' Publication Number 2004–165, Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Cincinnati, OH, 2004. 58 pp; *http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf.*

[343] ASHP. ''ASHP guidelines on handling hazardous drugs.'' American Journal of Health-System Pharmacy 2006, 63:1172–1193; *http://dx.doi.org/10.2146/ajhp050529.*

[344] December 1994, RCRA Online #13718.

[345] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788.

4. Consultation With OSHA

As part of the final rule process, EPA consulted with OSHA to gain a better understanding of its Bloodborne Pathogens standard and how it interacts with other regulations for the disposal of sharps and the contents within the syringes. The Bloodborne Pathogens standard states that ''[u]niversal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.'' [346] It also states that disposal of a sharp shall be done ''immediately or as soon as feasible.'' [347] Further, OSHA requires that containers for contaminated sharps shall be ''easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can reasonably anticipated to be found.'' [348] When workers travel to a remote location to discard a sharp, it increases the possibility of an accidental needlestick, increases the chances that needles and other sharps will be improperly discarded, and creates potential hazards for other staff members. The determination of whether or not a sharps disposal container is as close as feasible should be made on a case-by-case basis by OSHA.[349]

Therefore, the practice of emptying the contents of the syringe would not violate the OSHA standard if the containers are as close as feasible. Any related work practices must also be such that they do not create additional hazards to workers (*e.g.,* containers are located in close proximity to the work area to avoid employees travelling with used sharps to disposal receptacles located outside the point of use). Furthermore, nothing in this new subpart requires workers to recap needles or other sharps, or otherwise manually manipulate the sharp or needle during emptying, such as unscrewing the needle from the syringe.

As part of this consultation, OSHA addressed the issue of waste disposal. OSHA's Bloodborne Pathogens compliance directive states: ''[W]hile OSHA specifies certain features of the regulated waste containers, including appropriate tagging, the ultimate disposal method (landfilling, incinerating, and so forth) for medical waste falls under the purview of the EPA and possibly State and local regulations'' (''Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories'' (1910.1030(d)(4)(iii)(C))).[350]

The Agency also received comment that we should recommend the extra protective step that all syringes/sharps be incinerated. Any sharps container that contains hazardous waste must be treated to meet the LDR requirements in part 268. In most cases, the LDR treatment standard for hazardous waste pharmaceuticals is incineration. On the other hand, if a sharps container does not contain hazardous waste pharmaceuticals because all the syringes have been emptied by fully depressing the plunger, then the RCRA hazardous waste regulations would not apply to these sharps containers (although these sharps containers are still solid wastes).

Regardless of whether sharps containers have regulated hazardous waste pharmaceutical residues, they could contain bloodborne pathogens or other infectious materials. Thus, OSHA's Bloodborne Pathogens standard requires that ''disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.'' [351] Many states have medical waste regulations that require the treatment of regulated medical waste, including sharps containers, to render it non-infectious, which is often achieved by autoclaving, prior to disposal as solid waste.

D. Other Containers, Including Delivery Devices (§ 266.507(c) & (d))

1. Summary of Proposal

EPA proposed that the residues remaining in other types of unused or used containers, including delivery devices, such as IV bags and tubing, inhalers, aerosols, nebulizers, tubes of ointments, gels, or creams, would be regulated as hazardous waste if the residues are acute or non-acute hazardous waste. In some cases, such as with IV bags, the volume of hazardous waste being disposed is much larger than with residues contained in syringes or unit-dose containers. It is extremely difficult to determine how much residue remains in tubes of ointments, gel, or cream. In the case of aerosols, it would be inadvisable to remove the contents of the container. Since EPA proposed that hazardous waste pharmaceuticals managed under subpart P would not be counted towards a facility's generator category, we argued that managing these residues and containers as hazardous waste under the proposed provisions should not pose the same burden that generators had been facing in with keeping track of the monthly amount of residues in containers that are not ''RCRA empty.''

2. Summary of Comments

Comments were mixed in this section. Some commenters agreed with EPA that it is difficult to determine if containers such as inhalers, aerosol cans, tubes of ointments, gels, or creams meet the RCRA empty standards within § 261.7 and, therefore, managing them under the streamlined requirements of subpart P would be protective. Other commenters wanted EPA to allow these other containers to continue to meet the definition of empty within § 261.7 or develop specific empty container standards for them within subpart P. One commenter recommended that EPA revise the regulations to state that IV bags and their tubing, inhalers, aerosols, nebulizers, tubes of ointments, and gels or creams are RCRA empty and not subject to hazardous waste regulations if they contain non-acute hazardous waste and their contents are fully administered.

3. Final Rule Provision

In response to comments, the final rule contains an empty container standard for IV bags separate from other containers, including delivery devices. The Agency stated in the proposal that it is very hard to determine if aerosols, tubes of ointments, gels and creams, inhalers, and nebulizers are empty due to their containers and contents. As commenters pointed out, this is not the case for IV bags and tubing since they are transparent and the liquids inside can be easily observed.

Taking approaches suggested from commenters, EPA is finalizing in § 266.507(c) that an IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. In cases where the IV bag has not been fully administered and the IV bag held non-acute hazardous waste pharmaceuticals, then IV bag can be shown to be empty and the remaining residues not regulated as hazardous waste per § 261.7(b)(1). If an IV bag is not empty through either of these means because it either has not been fully

[346] See 29 CFR 1910.1030(d)(1).

[347] See 29 CFR 1910.1030(d)(4)(iii)(A)(*1*).

[348] See 29 CFR 1910.1030(d)(4)(iii)(A)(*2*)(*i*).

[349] OSHA Compliance Directive CPL 02–02–069 Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens *https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-069.pdf.*

[350] Ibid.

[351] See 29 CFR 1910.1030(d)(4)(iii)(C).

administered or cannot meet the requirements of § 261.7(b)(1) or because it contained an acute hazardous waste pharmaceutical, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart.

In the final rule, EPA has also altered the requirements for other types of containers including delivery devices. Commenters pointed out that a healthcare facility should not be precluded from proving that these containers meet the RCRA-empty standards in § 261.7 simply due to the type of container or contents. EPA agrees with the commenters that these types of containers which held non-acute hazardous waste pharmaceuticals should be able to use the RCRA empty container standards under § 261.7 and has changed the final rule to allow this. If the containers meet the RCRA empty standard under § 261.7 then the non-acute hazardous waste pharmaceutical residues (and the container) are not regulated as hazardous waste and can be managed as solid waste.

If these other containers, a category that includes but is not limited to inhalers, aerosols, nebulizers, tubes of ointments, gels or creams, once held an acute hazardous waste pharmaceutical or if they held a non-acute hazardous waste pharmaceutical but cannot meet the RCRA empty container standard of § 261.7, then the residues of these hazardous waste pharmaceuticals (and their containers) must be managed as non-creditable hazardous waste pharmaceuticals under this subpart.

4. Comments and Responses

One commenter was concerned that managing all other containers that held hazardous waste pharmaceuticals as non-empty could cause a VSQG healthcare facility to bump up in generator category to an LQG. This will no longer be a concern since a healthcare facility now has the option to prove that their other containers that held non-acute hazardous waste pharmaceuticals meet the RCRA empty container standards in § 261.7 and they can manage the residues (and containers) as non-hazardous waste. Otherwise, if these other containers are not considered empty, then the residues (and containers) must be managed as non-creditable hazardous waste pharmaceuticals under subpart P and hazardous waste pharmaceuticals managed under subpart P do not count towards determining the generator category. Further, we note that a healthcare facility can use the new empty container provisions in § 266.507 when determining whether they generate enough hazardous waste to become subject to part 266 subpart P.

XVI. Shipping Standards for Hazardous Waste Pharmaceuticals (§§ 266.508 and 266.509)

A. Shipping Non-Creditable Hazardous Waste Pharmaceuticals From Healthcare Facilities to Treatment, Storage, and Disposal Facilities (§ 266.508(a))

1. Summary of Proposal

Under part 266 subpart P, hazardous waste pharmaceuticals generated in a healthcare facility fall into two categories: (1) Non-creditable hazardous waste pharmaceuticals (*e.g.,* partially administered for patient care), and (2) potentially creditable hazardous waste pharmaceuticals (*e.g.,* unused, unadministered). This section discusses the proposed requirements for shipping non-creditable hazardous waste pharmaceuticals. For information regarding the shipment of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and reverse distributors, see section XVI.D. of this preamble.

Generally, non-creditable hazardous waste pharmaceuticals differ from potentially creditable hazardous waste pharmaceuticals in that they have been partially administered and often are not in their original packaging. In addition, since there is not a reasonable expectation that prescription non-creditable hazardous waste pharmaceuticals are eligible to receive manufacturer credit, they are shipped off site to a TSDF rather than a reverse distributor. Due to concerns that a healthcare facility might send all of its hazardous waste pharmaceuticals to a reverse distributor even if there is not a reasonable expectation of receiving manufacturer credit—essentially using the reverse distributor as a TSDF—EPA proposed that non-creditable hazardous waste pharmaceuticals generated at healthcare facilities, when shipped off site, must be shipped to a designated facility (*e.g.,* an interim status or permitted hazardous waste TSDF), as was required under part 262 (unless the healthcare facility has interim status or a RCRA permit to store or treat hazardous waste and chooses to store or treat the non-creditable hazardous waste pharmaceuticals on site instead of shipping them to a designated facility).

Specifically, EPA proposed that healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a designated facility for treatment or disposal must continue to comply with the existing Department of Transportation (DOT) pre-transport requirements for packaging, labeling and marking, and that the non-creditable hazardous waste pharmaceuticals must continue to be shipped using a hazardous waste transporter and be tracked with a hazardous waste manifest. However, to avoid unnecessarily burdening the healthcare facility staff, who the Agency assumes are typically unfamiliar with RCRA, EPA proposed that the hazardous waste numbers (often called hazardous waste codes) are not required to be entered into the hazardous waste manifest for non-creditable hazardous waste pharmaceuticals. In lieu of hazardous waste codes, EPA proposed that the words, ''hazardous waste pharmaceuticals'' must be entered in the ''special handling and additional information'' box on the manifest (this box was called Item 14 at the time of the proposal).

We also proposed that all existing RCRA recordkeeping requirements regarding hazardous waste manifesting as well as all applicable DOT shipping requirements continue to apply to healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF for treatment or disposal (see section X.K).

2. Summary of Comments

Comments on this section of the proposed rulemaking were mixed. Commenters generally agreed with the proposed standards for packaging, labeling, marking, placarding, and shipping papers. Adverse comments were mostly in regard to the decision to not require individual waste codes on the manifest for a healthcare facility sending non-creditable hazardous waste pharmaceuticals to a TSDF for disposal. In fact, commenters were generally concerned about the proposal to not require individual waste codes anywhere in the management standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. Whether the comments were regarding waste code determinations, labeling containers with waste codes, or including waste codes on the manifest, the overarching concern was that TSDFs would not know the specific contents of shipments received, resulting in an increase to their burden, and possibly would be detrimental to human health and the environment. Therefore, the adverse comments regarding the lack of a proposed requirement to input individual waste codes on the manifest are applicable more broadly to the subject of whether or not the

information that individual waste codes convey should somehow be provided to a TSDF by the healthcare facility shipping non-creditable hazardous waste pharmaceuticals.

Some states agreed with the proposal to not require individual waste codes on the manifest, while others commented that it is important to have waste codes at all steps where they would otherwise be required under previous RCRA regulations. Comments from waste management companies were also mixed, with some supporting the proposal to not require individual hazardous waste codes on the manifest, while others agreed with the proposal but suggested including a profile of likely constituents to alert TSDFs of potential waste contents to aid in LDR compliance.

Those waste management companies that disagreed with the proposed standards cited the added burden imposed by not knowing the specific waste constituents included in a shipment, which would make compliance with LDR standards more difficult. They were primarily concerned about the added burden of having to either begin testing their ash for wastes that have a numeric treatment standard, or modify existing testing protocols. One commenter from the healthcare industry disagreed with the elimination of individual hazardous waste codes on manifests from healthcare facilities shipping non-creditable hazardous waste pharmaceuticals, arguing that healthcare workers are capable of making accurate hazardous waste determinations. They also stated that hazardous waste codes are integral to properly managing hazardous waste. One waste management commenter stated that continuing to require waste codes on LDR notices altogether negates any actual relief because healthcare facilities will have to determine appropriate waste codes before sending hazardous waste pharmaceuticals off site to a TSDF whether or not they are required on the container label or manifest.

One reverse distributor also agreed with the proposed standards under the condition that the Agency agree that pharmaceuticals being sent to a reverse distributor are not waste.

3. Final Rule Provisions

The agency is finalizing the majority of the proposed requirements in this section. Before being shipped off site, all shipments of non-creditable hazardous waste pharmaceuticals must comply with applicable DOT pre-transport requirements for packaging (49 CFR parts 173, 178, and 180), labeling (49 CFR part 172 subpart E), and marking (49 CFR part 172 subpart D). There are, however, three notable changes being finalized.

First, § 266.508(a)(1)(v) has been removed and a healthcare facility shipping hazardous waste pharmaceuticals to a TSDF for disposal must instead comply with § 266.508(a)(2)'s manifest requirement to meet DOT's shipping papers requirement.

Second, the agency has decided to modify the proposal to not require any hazardous waste codes in Item 13 (Waste Codes) of the hazardous waste manifest for shipments of non-creditable hazardous waste pharmaceuticals being sent to a TSDF, and write the words ''Hazardous Waste Pharmaceuticals'' in Item 14 (Special Handling Instructions and Additional Information). The Agency is instead finalizing a requirement to write only one waste code— ''PHARMS''—in Item 13, and not impose any requirements for what must be written in Item 14. After further consideration of the impacts this proposed requirement would impose on implementation and data collection, the Agency decided it had to be modified. During the development of this rule, the Agency has also been developing the electronic manifest system (e-Manifest) which requires that some code be written in Item 13. We chose the PHARMS code because it both meets the required number of characters and communicates the nature of the waste. Since the waste will now be sufficiently characterized in Item 13, the Agency feels there is no longer the need to require the words ''hazardous waste pharmaceuticals'' in Item 14.

This new PHARMS code is for manifesting and reporting purposes only and is not an official EPA hazardous waste code. Because it will be written in the same place as other official EPA hazardous waste codes, it may also be referred to colloquially as a ''hazardous waste code.'' However, it does not modify any existing LDR treatment standards, nor does it enact any new or alternate LDR treatment standards for hazardous waste pharmaceuticals. Many commenters throughout the proposed rulemaking suggested that EPA promulgate an alternative treatment standard of the ''CMBST'' code specifically for hazardous waste pharmaceuticals with numeric treatment standards. The agency considered incorporating these suggestions into the proposed rulemaking, but did not receive the necessary data to support such an action. The Agency does, however, generally agree that implementing a new alternative treatment standard for hazardous waste pharmaceuticals might help mitigate burden on the regulated community while remaining protective of human health and the environment. The Agency remains open to considering the addition of an alternative treatment standard for hazardous waste pharmaceuticals in future rulemakings.

Although the Agency is now requiring the PHARMS code in Item 13 for shipments of non-creditable hazardous waste pharmaceuticals from a healthcare facility to a TSDF, hazardous waste codes are not required on the manifest, which was preferred by some commenters. As a result, TSDFs treating hazardous waste pharmaceuticals will have to assume that shipments of hazardous waste pharmaceuticals contain the few that have numeric treatment standards in order to demonstrate compliance with LDRs.

The third change made to the regulations was to modify the regulatory language in § 266.508(a) slightly to clarify that shipments of non-creditable hazardous waste pharmaceuticals being sent from a healthcare facility for disposal must be sent to a designated facility and accompanied by a hazardous waste manifest. As part of the manifest requirements in 40 CFR part 262 subpart B, shipments of non-creditable and evaluated hazardous waste pharmaceuticals must be sent to a designated facility via a hazardous waste transporter. One commenter noted that the proposed language could have been interpreted to mean that such shipments are also allowed to go elsewhere, which was not the Agency's intent.

Another substantive change to the regulatory language that resulted from incorporating commenters' concerns was to remove the requirements for shipping papers in § 266.508(a)(1)(v). A commenter pointed out that the requirement is unnecessary given the requirements in § 266.508(a)(2) and the Agency agreed. Section 266.508(a)(1)(v) would have required a healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a TSDF to prepare shipping papers in accordance with 49 CFR 172 subpart C; however, the subsequent paragraph (§ 266.508(a)(2)) outlines the requirements for manifesting a shipment of non-creditable hazardous waste pharmaceuticals. Requiring both shipping papers and a manifest is redundant and could have possibly resulted in confusion and contradictory requirements. The hazardous waste manifest requirements, if complied

with, duly satisfy DOT's shipping paper requirements.

The wording in § 266.508(a) was modified slightly to clarify that healthcare facilities and reverse distributors that ship non-creditable and evaluated hazardous waste pharmaceuticals off site, respectively, are required to send them to a designated facility.

Finally, to be consistent with the Hazardous Waste Generator Improvements final rule, we have added paragraph 266.508(a)(1)(iii)(C) to mirror § 262.32(d), which addresses marking for lab packs. Specifically, lab packs of hazardous waste pharmaceuticals that will be treated using the alternative treatment standard of incineration, as allowed by § 268.42(c), do not have to marked or labeled with EPA hazardous waste numbers. However, lab packs that contain D004 (arsenic), D005 (barium), D006 (cadmium), D007 (chromium), D008 (lead), D010 (selenium) or D011 (silver), the EPA hazardous waste number must be marked or labeled with the EPA hazardous waste numbers (or electronic means may be used). These specific metals must be identified because § 268.42(c)(4) requires any incinerator residues from lab packs that contain any of these specific metals to undergo further treatment prior to land disposal.

B. Shipping Evaluated Hazardous Waste Pharmaceuticals From Reverse Distributors to Treatment, Storage, and Disposal Facilities (§ 266.508(a))

1. Summary of Proposal

For reverse distributors, once a potentially creditable hazardous waste pharmaceutical has been evaluated and it has been determined that it is not destined for another reverse distributor for further evaluation or verification of credit, EPA proposed that the hazardous waste pharmaceuticals be referred to as ''evaluated hazardous waste pharmaceuticals.'' As with shipping non-creditable hazardous waste pharmaceuticals, when evaluated hazardous waste pharmaceuticals are shipped off-site, EPA proposed that they must be shipped in accordance with the existing DOT pre-transport requirements under 49 CFR parts 172–80 for packaging, labeling, marking, placarding, and shipping papers. We also proposed that they must be shipped in accordance with the existing RCRA manifest requirements of 40 CFR part 262 subpart B, which requires all relevant waste codes be listed in Item 13 and that they be shipped via a hazardous waste transporter to a designated facility. This continues current practices under existing regulations for this type of hazardous waste pharmaceutical and does not represent an increase in burden. EPA argued that the use of a hazardous waste manifest and a hazardous waste transporter are appropriate at this point for two reasons. First, once credit for the hazardous waste pharmaceuticals has been verified, the potential for mismanagement is greater because evaluated pharmaceuticals no longer retain any value and will cost the reverse distributor money to dispose. Second, TSDFs are accustomed to receiving hazardous waste via a hazardous waste transporter with a hazardous waste manifest and it would place administrative and compliance burdens on the receiving TSDF to accept shipments of hazardous waste with alternative tracking.

EPA proposed that a reverse distributor must list all appropriate hazardous waste codes on the manifest when shipping evaluated hazardous waste pharmaceuticals to a TSDF. This differs from the requirements for a healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a TSDF. Unlike non-creditable hazardous waste pharmaceuticals generated at a healthcare facility, hazardous waste pharmaceuticals received by reverse distributors are typically in the manufacturer's original, intact, and labeled packaging (if not, they are likely non-creditable hazardous waste pharmaceuticals and should be sent to a TSDF), so the information needed to determine the appropriate hazardous waste codes once evaluated should be readily available to the reverse distributor. Also, reverse distributors are currently required to include hazardous waste codes on the manifest and it is expected that they have the necessary expertise in the management of these hazardous wastes that healthcare personnel lack. Under the reverse distributor standards in § 266.510(c)(10)(ii), EPA also proposed that reverse distributors must keep copies of hazardous waste manifests for three years from the date evaluated hazardous waste pharmaceuticals are shipped to a TSDF.

2. Summary of Comments

Comments in this section were mixed. Many commenters addressed the standards for healthcare facilities sending shipments of non-creditable hazardous waste pharmaceuticals to a TSDF but did not specifically mention the standards for shipping evaluated hazardous waste pharmaceuticals to a TSDF. Nevertheless, many of the concerns expressed by commenters with the standards for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF are relevant because the standards in § 266.508 are the same for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals as they are for reverse distributors shipping evaluated hazardous waste pharmaceuticals, with the exception of § 266.508(a)(2)(i) and (ii). The few that commented directly on the proposed shipping standards for evaluated hazardous waste pharmaceuticals being shipped from a reverse distributor to a TSDF agreed with the standards as proposed.

Reverse distributor and waste management industry commenters were in agreement with the proposed standards for shipping evaluated hazardous waste pharmaceuticals to a TSDF, but to reiterate, did not agree with the standards for shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility to a TSDF (no waste codes on the manifest). Many commenters on this section simply stated that waste codes should be included on a manifest, referring to the requirements in § 266.508(a)(2)(i) and (ii) which do not require waste codes on the manifest for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF. Since those standards only apply to healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF and not reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF, the agency assumes that those same commenters are generally in agreement with the requirement for reverse distributors shipping evaluated hazardous waste pharmaceuticals to a TSDF to comply with all of the manifest standards in 40 CFR part 262 subpart B, which includes a requirement to list all applicable EPA hazardous waste codes on the manifest.

3. Final Rule Provisions

The Agency is finalizing the standards for shipping evaluated hazardous waste pharmaceuticals from a reverse distributor to a TSDF with minor changes. First, § 266.508(a)(1)(v) has been removed. The standards for shipping papers for reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF are contained instead in subparagraph § 266.508(a)(2) (*i.e.,* the manifest).

Second, the clarification to the regulatory language mentioned previously, which specifies that non-creditable hazardous waste

pharmaceuticals must go only to a TSDF, also applies to evaluated hazardous waste pharmaceuticals. As mentioned above, commenters were concerned that the proposed regulatory language appeared to make it optional for a reverse distributor to ship evaluated hazardous waste pharmaceuticals to a TSDF for disposal, although it was not intended to read that way. The finalized regulatory language was modified to clarify that a reverse distributor shipping evaluated hazardous waste pharmaceuticals must send them to a TSDF for treatment and disposal. This change pertains to both evaluated pharmaceuticals being shipped from a reverse distributor as well as non-creditable hazardous waste pharmaceuticals being shipped from a healthcare facility.

To summarize, reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF for disposal are required to comply with all standards in § 266.508(a), which includes a requirement to list all applicable waste codes in Item 13 of the manifest, even though healthcare facilities sending non-creditable hazardous waste pharmaceuticals to a TSDF do not. They are not, however, required to write the word PHARMS in Item 13 or on the container label in addition to all other applicable waste codes.

C. Shipping Non-Creditable or Evaluated Hazardous Waste Pharmaceuticals for Import or Export (§§ 266.508(b) and 266.508(c))

1. Summary of Proposal

Under part 262, a healthcare facility or reverse distributor may not import hazardous waste pharmaceuticals unless it has a RCRA permit or interim status that allows it to accept hazardous waste from off site and complies with the requirements for importing hazardous waste in 40 CFR part 262 subpart H. Under part 266, EPA did not propose to change the regulations as they apply to the import of non-creditable or evaluated hazardous waste pharmaceuticals. Likewise, under part 262, a healthcare facility or reverse distributor may not export (non-creditable nor evaluated) hazardous waste pharmaceuticals unless it complies with requirements for exporting hazardous waste in 40 CFR part 262 subpart H. Under part 266, EPA did not propose to change the regulations as they apply to the export of (non-creditable or evaluated) hazardous waste pharmaceuticals.[352]

EPA requested comment on the likelihood that non-creditable hazardous waste pharmaceuticals that are shipped from a healthcare facility to a domestic TSDF, would then be exported to a TSDF in a foreign country. In addition, EPA did not anticipate that hazardous waste pharmaceuticals would be destined for transboundary shipments for purposes of recovery operations and therefore potentially subject to 40 CFR part 262 subpart H; however, we also requested comment on whether this is the case.

2. Summary of Comments

We received no comments on the proposed standards for importing and exporting non-creditable or evaluated hazardous waste pharmaceuticals.

3. Final Rule Provisions

Since part 266 subpart P was proposed, the hazardous waste import and export regulations under part 262 have been revised.[353] The export regulations which had been in part 262 subpart E are now in part 262 subpart H. Likewise, the import regulations which had been in part 262 subpart F are also now in part 262 subpart H. The requirements for both importing and exporting non-creditable hazardous waste pharmaceuticals are being substantially finalized as proposed. The only change being made from the proposed requirements is to update the reference to the revised part 262 regulations, in order to conform to the changes implemented in the Hazardous Waste Imports and Exports Improvement Rule. Whereas the proposed § 266.508(b) and (c) refer to the standards in 40 CFR part 262 subpart E and F, they now refer to 40 CFR part 262 subpart H.

D. Shipping Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.509).

1. Summary of Proposal

This section discusses the proposed requirements for shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility to a reverse distributor and between reverse distributors. The return of potentially creditable waste pharmaceuticals (hazardous and non-hazardous) to a reverse distributor can involve multiple shipping steps before the pharmaceuticals are transported for ultimate treatment and disposal. In comments on the 2008 Pharmaceutical Universal Waste proposal and in response to EPA's request for information,[354] reverse distributors described various scenarios. For example, a healthcare facility typically sends waste pharmaceuticals to the reverse distributor with which it has a contract. However, some manufacturers will only provide manufacturer credit after the pharmaceuticals have been returned to the reverse distributor with which the manufacturer has a contract. Thus, if the reverse distributor with which the healthcare facility has a contract differs from the reverse distributor with which the manufacturer has a contract, then the healthcare facility's reverse distributor must send the pharmaceuticals on to the manufacturer's reverse distributor for the manufacturer credit to be given to the healthcare facility. In some cases, a pharmaceutical manufacturer may require the reverse distributor to ship the pharmaceuticals back to them so they can perform the verification and issue credit themselves. The estimated amount of pharmaceuticals transported from reverse distributors to manufacturers for verification varies. Based on our request for information, reverse distributors indicated that the percent of potentially creditable hazardous waste pharmaceuticals transported to manufacturers ranged from an estimated 25 percent to 93 percent of total volume, depending on the contractual agreement between the reverse distributor and the manufacturer. The scenarios described previously occur routinely and are an integral part of the process by which manufacturers issue credit.

As explained in section IV.A, EPA proposed that all pharmaceuticals transported to reverse distributors for manufacturer credit are solid wastes, some of which would also be considered hazardous wastes. The finalized regulations have been modified, however, such that only prescription pharmaceuticals going through reverse distribution for manufacturer credit are solid wastes, while OTC pharmaceuticals going through reverse logistics are outside of this rule. Under the part 262 regulations, hazardous waste, including hazardous waste pharmaceuticals, must be manifested to a permitted or interim

[352] In the proposed rule we referenced part 262 subparts E and F when discussing this provision. Part 262 subparts E and F have since been replaced by part 262 subpart H; see the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

[353] See the final Hazardous Waste Export-Import Revisions rule, 81 FR 85696; December 31, 2016.

[354] See the survey of reverse distributors in docket number: EPA–HQ–RCRA–2007–0932–0158 through 0160.

status TSDF and shipped using a hazardous waste transporter to ensure the cradle-to-grave system of RCRA is maintained. However, compared to other hazardous wastes, EPA believes that the risk of environmental release posed by most potentially creditable hazardous waste pharmaceuticals during accumulation and transport is relatively low. The risk is low because of the form and packaging of most potentially creditable hazardous waste pharmaceuticals, which is typically in small, individually packaged doses (such as with many tablets and capsules) or small vials. These small volumes of individually wrapped or packaged pharmaceuticals, when aggregated in a larger container, are unlikely to spill or be released into the environment since they are essentially double-packed when transported to a reverse distributor. Potentially creditable hazardous waste pharmaceuticals that are in liquid and aerosol forms may pose more of a risk during accumulation and transport due to possible spillage or leakage, but the small quantities in which they are generated, along with the DOT packaging requirements of 49 CFR parts 173, 178, and 180, would likely mitigate this risk (see EPA's recommendation regarding liquids and aerosols in section XI.C.1). Further, the 2008 Pharmaceutical Universal Waste proposal specifically sought comment regarding the risks of transportation of hazardous waste pharmaceuticals and no commenters identified environmental risks.

Due to the low risk to human health and release to the environment, EPA proposed to allow potentially creditable hazardous waste pharmaceuticals to be shipped without a hazardous waste manifest and without the use of hazardous waste transporters when the healthcare facility is sending potentially creditable hazardous waste pharmaceuticals to a reverse distributor or when a reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another reverse distributor. The same DOT shipping requirements would continue to apply to shipments of potentially creditable hazardous waste pharmaceuticals (provided they are classified as DOT hazardous materials) that applied prior to this final rule. Nothing in this final rule changes how DOT shipping requirements apply to shipments of prescription pharmaceuticals to reverse distributors.

EPA proposed an alternate tracking method for potentially creditable hazardous waste pharmaceuticals—with two requirements in lieu of requiring a hazardous waste manifest and the use of hazardous waste transporters. First, EPA proposed that for each shipment, healthcare facilities and reverse distributors must provide in writing (via letter or electronic communication), advance notice of the intent to send a shipment to the receiving reverse distributor. We also proposed that the receiving reverse distributor must provide acknowledgement to the shipper that they received the advance notice. This requirement was intended to function like a manifest, tracking the potentially creditable hazardous waste pharmaceuticals en route to the reverse distributor. Second, EPA proposed that for each shipment, the receiving reverse distributor must provide confirmation to the healthcare facility or reverse distributor that initiated the shipment, that the shipment of potentially creditable hazardous waste pharmaceuticals has been received. The Agency proposed this requirement in direct response to concerns expressed by commenters over the lack of tracking of pharmaceutical waste in the 2008 Pharmaceutical Universal Waste proposal.

The Agency proposed that, if a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within seven calendar days, that the healthcare facility or reverse distributor that initiated the shipment must contact the shipper and the intended recipient promptly to (1) report that the confirmation was not received, and (2) to determine the status and whereabouts of the potentially creditable hazardous waste pharmaceuticals that were shipped.

The Agency proposed that if a healthcare facility or reverse distributor exports potentially creditable hazardous waste pharmaceuticals, it must generally comply with 40 CFR part 262 subpart E, except that it is not required to manifest the potentially creditable hazardous waste pharmaceuticals. The Agency also proposed that any person that imports potentially creditable hazardous waste pharmaceuticals, must comply with the proposed requirements for the shipment of potentially creditable hazardous waste pharmaceuticals, in lieu of the requirements for hazardous waste imports found at 40 CFR part 262 subpart F.[355]

[355] Part 262 subparts E and F have since been replaced by part 262 subpart H; see the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

EPA proposed to require healthcare facilities (§ 266.503(d)) and reverse distributors (§ 266.510(b)(4)) to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Specifically, we proposed that healthcare facilities and reverse distributors that initiate a shipment to a reverse distributor must keep (1) records of advance notification regarding shipments of potentially creditable hazardous waste pharmaceuticals, (2) delivery confirmation for three years after the shipment was initiated, and (3) shipping papers or bills of lading. The Agency argued that these records are necessary to ensure that potentially creditable hazardous waste pharmaceuticals reach their intended destination and are not diverted.

In most cases, retaining records for three years should be sufficient for inspection purposes; however, we proposed that the periods of retention would be automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator. The Agency sought comment on whether additional recordkeeping is necessary to document the cases when the reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within seven calendar days and the steps must be taken to locate the shipment.

2. Summary of Comments

The majority of comments focused on the provision to allow shipments of potentially creditable hazardous waste pharmaceuticals to be sent via carrier (*i.e.,* not by hazardous waste transporter), the requirements for advance notice of shipment and delivery confirmation, and the time frame within which delivery confirmation is received before the shipper must take action to locate a missing shipment.

Comments on whether the Agency should allow shipments of potentially creditable hazardous waste pharmaceuticals to be sent via carriers such as USPS, UPS, and FedEx without a manifest were mixed. Only a few states commented on this provision specifically. The majority of states agreed that shipping via carriers provides sufficiently low risk of release or illicit diversion. However, one state was concerned that we did not propose a requirement to reconcile the contents of what was shipped with what was received. That same commenter, as well as a handful of others, also voiced concern about whether DOT regulations would permit hazardous waste

pharmaceuticals to be lawfully shipped via carrier in the first place. Manufacturers, waste management companies, healthcare industry groups, and pharmacy trade associations were all generally in agreement with the proposed shipping standards for potentially creditable hazardous waste pharmaceuticals.

One of the primary points of contention in this subsection was the proposed standard that would require a shipper to provide advance notice of its intent to ship potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Reverse distributors objected, arguing it would impart undue financial and administrative burden, which would require them to hire additional staff to adequately process advance notices, track, and confirm the delivery of thousands of shipments per year. A national trade association of retailers expressed similar concerns. They did not support the proposed advance notice and delivery confirmation requirements and argued the requirements would add undue burden due to the high volume of shipments large retailers send per year. The commenters suggested that the proposed notification and delivery standards either be removed or modified to match current inventory and accounting practices.[356] One pharmaceutical manufacturer also disagreed with the proposed standard, but gave no reasoning as to why, other than they thought it was unnecessary. States generally agreed with the proposed standard and a few suggested the Agency finalize additional requirements like reconciling what was in the notice with the contents of the package after delivery which would also require an inventory of each container. One state was concerned about its ability to confirm that a shipment has reached its final destination (TSDF) in scenarios where a shipment is sent to an out-of-state reverse distributor or a second reverse distributor. Healthcare facilities and pharmacist trade groups either agreed with the proposed standards or did not mention these standards specifically. One pharmacist trade group said they want some clarification about what constitutes advance notice.[357]

There were numerous comments both in agreement with and opposition to the proposed requirement to take action to locate a shipment of potentially creditable hazardous waste pharmaceuticals if no delivery confirmation is received within seven days from the day the shipment leaves the shipper's facility. Most comments were related to the time frame within which the shipper must receive delivery confirmation, but a few commenters from the retail and reverse distribution industries opposed the requirement altogether because of the added financial, procedural, and administrative burden they argue it would impose. Many commenters were concerned that the proposed time frame was too short and would result in frequent situations in which the shipper would be required to undertake efforts to locate a shipment that eventually arrives without intervention sometime after the seven days. Some commenters noted that seven days is the minimum transit time for a standard cross-country shipment under ideal conditions, which provides no buffer for unforeseen circumstances that may cause delays such as inclement weather or some other service disruption. One state suggested a 35-day time frame as an alternative because it would be the same as the time frame specified for delivery confirmation of universal waste shipped via carrier per the universal waste rule.[358]

There were limited comments regarding the proposed standards for healthcare facilities and reverse distributors importing and/or exporting potentially creditable hazardous waste pharmaceuticals. The only concern raised was whether shipments sent to or received from U.S. territories (*e.g.,* Puerto Rico, Guam) are considered exports/imports, and if so, they recommended that the Agency confer with other appropriate federal agencies and their reverse distributor contractors.

3. Final Rule Provisions

In response to comments, the Agency has made several changes to the proposed standards for shipping potentially creditable hazardous waste pharmaceuticals. First, we have made a minor change to make our regulatory language more consistent with DOT's terminology and clarify to whom the regulations refer. Specifically, in § 266.509(c), we changed the word shipper to carrier. As originally proposed, the word shipper could have been interpreted to refer to the party that prepares and offers a shipment of potentially creditable hazardous waste pharmaceuticals, whereas the regulations apply to the company providing transportation of a shipment of potentially creditable hazardous waste pharmaceuticals. To clarify, a shipper is the party that prepares and offers a shipment to be transported by a carrier.

Second, we have eliminated the requirement in § 266.509(a)(1) for a healthcare facility or reverse distributor that ships potentially creditable hazardous waste pharmaceuticals to provide advance notice of the shipment. The Agency believes that the proposed advance notice requirement goes beyond the manifest requirements and would have resulted in undue burden on both the shippers and the receiving reverse distributors while only nominally more protective of human health and the environment. We would, however, recommend that, as a best practice, shippers of potentially creditable hazardous waste pharmaceuticals provide advance notice to the recipients to the extent practicable. Conforming changes have been made throughout the regulations that reflect the elimination of the requirement to provide advance notice of shipments of potentially creditable hazardous waste pharmaceuticals.

Third, the proposed requirement that a reverse distributor that receives a shipment of potentially creditable hazardous waste pharmaceuticals must provide delivery confirmation to the facility that initiated the shipment is being finalized as proposed, with the added clarification that the shipment is not considered delivered until it is under the custody and control of the receiving reverse distributor. Requiring delivery confirmation provides assurance that the shipment was actively received by the reverse distributor and the chain of custody maintained. Without this confirmation from the receiving reverse distributor personnel, it is possible for a shipment to be delivered to the destination location but not necessarily taken into their custody and control (*e.g.,* left unattended outside the building).

Under this final rule, healthcare facilities and reverse distributors may use carriers, such as USPS, UPS, and FedEx for shipments of potentially creditable hazardous waste pharmaceuticals to and between reverse distributors, as long as personnel are present to receive and take control of the shipments upon arrival. EPA believes that carriers are able to provide safe shipment since these potentially creditable hazardous waste pharmaceuticals present low risk of release during transport.

In addition, all of the carriers EPA is aware of offer services that meet the delivery confirmation requirement.

[356] See comment number EPA–HQ–RCRA–2007–0932–0295.

[357] See comment number EPA–HQ–RCRA–2007–0932–0284.

[358] See comment number EPA–HQ–RCRA–2007–0932–0238.

Delivery confirmation can be paper-based or electronic and must indicate that personnel from the receiving reverse distributor have taken the shipment into their custody and control. One way for healthcare facilities and reverse distributors sending shipments of potentially creditable hazardous waste pharmaceuticals to a reverse distributor via carrier may comply with the delivery confirmation requirement would be to utilize the delivery confirmation service provided by most carriers (*e.g.,* Return Receipt from USPS, Delivery Confirmation from UPS, or Signature Proof of Delivery from FedEx). Typically, personnel at the receiving reverse distributor will sign for a shipment confirming that it is now in their custody and control. That signature will then be made available to the shipper, which satisfies the delivery confirmation requirement.

EPA has learned that some stakeholders use alternative electronic tracking methods outside of those offered by carriers. One alternative electronic tracking method is to apply barcoding on pharmaceutical packaging or on containers containing multiple pharmaceutical packages. A barcode is a unique identifier that links the container to a database with detailed information about its contents and includes the exact quantities of each item included in the shipment (inventories). Typically, when a reverse distributor receives a barcoded shipment, it will scan the barcodes upon receipt, and the sender will receive electronic notification that the shipment has arrived at its destination and is in the custody and control of the reverse distributor. This type of barcode tracking would meet the delivery confirmation requirement of this final rule. Another type of alternative electronic tracking that would satisfy the delivery confirmation requirement is radio frequency identification (RFID). Similar to barcodes, RFID tags are placed inside a container, or integrated into the container itself, and linked to inventories and other detailed information. The RFID tags are read when they arrive at the receiving facility and that information is made available to the shipper, confirming that the shipment has been taken into the custody and control of the receiving reverse distributor.[359]

Fourth, we have eliminated the regulatory language that was proposed in § 266.509(a)(2). We had referenced the DOT pre-transport regulations that apply to shipments of non-creditable hazardous waste pharmaceuticals. However, in 2016, DOT revised the Hazardous Materials Regulations (HMR) as they apply to shipments of items in reverse logistics.[360] As a result, many of the DOT pre-transport requirements we had referenced no longer apply to shipments of hazardous materials in reverse logistics. In response, we have eliminated the reference to the DOT pre-transport requirements and instead modified our final regulations in § 266.509(a) to refer to the entire HMR, rather than specific provisions within the HMR. Healthcare facilities and reverse distributors that send shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors need only comply with the applicable sections of DOT's HMR for shipments in reverse logistics.

We note that healthcare facilities and reverse distributors must meet the applicable DOT hazardous material shipping requirements only when shipping potentially creditable hazardous waste pharmaceuticals that meet the definition of DOT hazardous material. Under the DOT regulations, a RCRA hazardous waste that requires a manifest is considered a Class 9 hazardous material. Potentially creditable hazardous waste pharmaceuticals do not require a manifest; therefore, the DOT shipping requirements will apply when potentially creditable hazardous waste pharmaceuticals are shipped to reverse distributors only when the hazardous wastes are otherwise classified as DOT hazardous materials (*i.e.,* DOT hazard class 1–8). We added regulatory language (that was adapted from the Universal Waste regulations) to reflect this.

Fifth, the Agency has finalized the requirement that the shipper of potentially creditable hazardous waste pharmaceuticals must receive a delivery confirmation from the reverse distributor, however, the Agency has extended the time frame within which the shipper must receive the delivery confirmation from the reverse distributor from the proposed seven days to 35 days, after which the shipper must begin taking actions to locate a shipment if the delivery confirmation is not received. Many commenters suggested 14 days as an alternative to the proposed seven-day time frame, while others suggested far longer or to eliminate the time frame altogether. Upon reconsideration of the issue and how it pertains more generally to other RCRA hazardous waste programs, the Agency decided that 35 days was more appropriate, while remaining duly protective of human health and the environment and reducing burden on the regulated community. The time frame to receive delivery confirmation for shipments of potentially creditable hazardous waste pharmaceuticals is also now in line with the standard for delivery confirmation under universal waste, which is also 35 days. In addition, one of the overarching goals of this rule was to enact universal waste-like standards for hazardous waste pharmaceuticals, to which this provision conforms. Some states wanted the Agency to go further and require that the EPA Regional Administrator be notified whenever a shipment has not been received within the allotted time frame. Although the Agency understands the utility of such a provision, it is not being adopted because of the added burden it would impose on both states and the regulated community. In addition, the Agency prefers, in this instance, to allow states the flexibility to implement more stringent reporting standards for missing shipments of potentially creditable hazardous waste pharmaceuticals according to their individual circumstances and preferences.

After considering these comments, the Agency determined that it is necessary to require a delivery confirmation in order to ensure shipments of potentially creditable hazardous waste pharmaceuticals have been received and taken into the custody and control of the destination facility as a way to approximate the manifest system without requiring the use of hazardous waste transporters or manifests. In response to comments, we have reconsidered the proposed seven-day time frame for the shipper to receive delivery confirmation; the Agency decided that 35 days is more appropriate. It strikes a balance between being duly protective of human health and the environment, reducing burden, and is now in line with universal waste standards.

Sixth, we have made several changes to the pre-transport requirements that we proposed in § 266.509(a)(1) and (2). Because of the removal of the requirement for advance notice of shipments of potentially creditable hazardous waste pharmaceuticals, we renumbered the section such that it all appears in § 266.509(a) now. What was proposed in § 266.509(a)(2) and is now in § 266.509(a), has been modified to reflect the removal of § 266.508(a)(1)(v) which previously contained a requirement that DOT shipping papers be generated. The Agency believes that the shipping papers requirement—

[359] See comment number EPA–HQ–RCRA–2007–0932–0268.

[360] March 31, 2016; 62 FR 18527.

although duplicative for shipments of non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor—is appropriate for shipments of potentially creditable hazardous waste pharmaceuticals given that they are not manifested. Therefore, the requirement for DOT shipping papers has been added to § 266.509(a). Language was also added to clarify that shipments of potentially creditable hazardous waste pharmaceuticals from a healthcare facility or reverse distributor to a reverse distributor do not require a manifest. This language was taken from the universal waste standards in § 273.52(a) which is consistent with the goal of developing universal waste-like shipping standards for potentially creditable hazardous waste pharmaceuticals.

As with the export of non-creditable hazardous waste pharmaceuticals, the proposed standards for healthcare facilities or reverse distributors that export potentially creditable hazardous waste pharmaceuticals to a foreign destination have also been modified to reflect the changes made to the import/export rules of part 262. Specifically, the Agency is finalizing requirements that exporters of potentially creditable hazardous waste pharmaceuticals must comply will all applicable sections of 40 CFR part 262 subpart H, except for the manifest requirements of § 262.83(c), in addition to the requirements for shipping potentially creditable hazardous waste pharmaceuticals in § 266.509(a) through (c).

Subsequent to when this rule was proposed in September 2015, the Hazardous Waste Import-Export Revisions rule was finalized in 2016.[361] As a result, the Agency has had to make conforming changes to this final rule to reflect the changes made by the Import-Export Revisions final rule. Because the regulations for importing and exporting hazardous waste were previously located in separate subparts—exports in subpart E and imports in subpart F—the proposed requirements in this rule were also separated into discreet subsections and referred to their respective subparts (exporting and importing) of 40 CFR part 262. A significant change enacted by the Import-Export Revisions Rule was to consolidate into subpart H the multiple related subparts in 40 CFR 262 regarding import, export, and transboundary movements of hazardous waste that had been in subparts E and F.

The essence of the proposed regulations has not changed in the finalized requirements. That is, a healthcare facility or reverse distributor exporting potentially creditable hazardous waste pharmaceuticals is still subject to the same or similar provisions as were proposed, only now they must comply with 40 CFR part 262 subpart H instead, except for the manifesting requirements, and paragraphs (a) through (c) of § 266.509.

For healthcare facilities and reverse distributors that import potentially creditable hazardous waste pharmaceuticals, the requirements are being finalized as proposed, except that due to the conforming changes necessitated by the Hazardous Waste Export-Import Revisions Final Rule, they must now comply with the shipping standards for potentially creditable hazardous waste pharmaceuticals in lieu of 40 CFR part 262 subpart H (instead of part 262 subpart F). One other clarification was added to the regulatory language specifying that potentially creditable hazardous waste pharmaceuticals are subject to all applicable provisions in this subpart immediately after entering the United States.

4. Comments and Responses

The commenter that requested an official definition of advance notice also requested an official definition for delivery confirmation.[362] The Agency is purposely leaving this standard sufficiently broad as to allow the implementing agencies discretion to determine the best implementation strategies on a case-by-case basis.

EPA notes that a reverse distributor is not required to segregate the potentially creditable hazardous waste pharmaceuticals from the potentially creditable non-hazardous waste pharmaceuticals when they are destined for another reverse distributor. However, if the potentially creditable pharmaceuticals are not segregated, the reverse distributor must follow the tracking procedures for the entire shipment. On the other hand, if a reverse distributor chooses to segregate the potentially creditable hazardous waste pharmaceuticals from the non-hazardous waste pharmaceuticals prior to shipping to another reverse distributor, only the potentially creditable hazardous waste pharmaceutical portion would have to be shipped according to these standards.

XVII. Standards for Reverse Distributors (§ 266.510)

A. Background on Reverse Distributor Operations

Reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. They receive shipments of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these pharmaceuticals. From stakeholder input, EPA site visits, and comments on the proposed rulemaking, EPA's understanding is that when a reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its computer system. Based on manufacturers' ''business rules'' (*i.e.,* manufacturers' return policies), the reverse distributors determine which potentially creditable hazardous waste pharmaceuticals can receive manufacturer credit, as well as which must be sent on to another reverse distributor for completion of the crediting process. ''Business rules'' (*i.e.* manufacturers' return policies) refers to the rules that govern the disposition of retail items agreed to by the manufacturer, retailer, and reverse distributor or reverse logistics center.[363]

In many cases, there is more than one reverse distributor involved in establishing and verifying manufacturer credit for a particular potentially creditable hazardous waste pharmaceutical. For instance, reverse distributors may have contracts with specific pharmaceutical manufacturers such that only a specific reverse distributor may facilitate credit for a particular manufacturer's pharmaceuticals. If the receiving reverse distributor has a contract with the healthcare facility, but not with the pharmaceutical manufacturer, then the receiving reverse distributor sends the returned pharmaceutical on to the reverse distributor that has a contract with the pharmaceutical manufacturer in order to facilitate the manufacturer credit process.

Because manufacturers' business rules change over time, sometimes a reverse distributor receives a potentially creditable hazardous waste

[361] See the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

[362] See comment number EPA–HQ–RCRA–2007–0932–0284.

[363] This definition is derived from the definition of ''business rules'' in the ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

pharmaceutical that is not eligible for credit immediately, and the reverse distributor retains the potentially creditable hazardous waste pharmaceutical on site until it is credit eligible (often called ''aging'' a pharmaceutical). For example, manufacturers only issue credit for expired pharmaceuticals. As a result, sometimes a reverse distributor receives an unexpired hazardous waste pharmaceutical that is otherwise creditable but awaiting its expiration date. The reverse distributor then retains the potentially creditable hazardous waste pharmaceutical on site until after it has expired and thus becomes eligible for manufacturer credit. In some cases, even after the reverse distributor has awarded manufacturer credit, a pharmaceutical manufacturer may request that the hazardous waste pharmaceuticals be transported back to the manufacturer to verify the amount of pharmaceuticals and manufacturer credit.

On the other hand, if the potentially creditable hazardous waste pharmaceuticals are not sent on to another reverse distributor and the reverse distributor awards the manufacturer credit to the healthcare facility itself, it then manages the hazardous waste pharmaceuticals on site until they are sent off site for treatment and disposal. As discussed previously, after a potentially creditable hazardous waste pharmaceutical has been evaluated and no additional reverse distributors will be involved in the manufacturer's crediting process, EPA uses the term ''evaluated hazardous waste pharmaceutical.'' This is to distinguish between the potentially creditable hazardous waste pharmaceuticals awaiting determination within the reverse distribution system versus the evaluated hazardous waste pharmaceuticals that will not be sent to another reverse distributor for evaluation. Both are considered hazardous waste pharmaceuticals, but they are managed differently under this subpart.

EPA is not aware of any reverse distributor that facilitates manufacturer credit that also has interim status or a permit to treat or dispose of hazardous waste on-site.[364] Therefore, EPA anticipates that reverse distributors eventually send all evaluated hazardous waste pharmaceuticals off site for treatment and disposal.

[364] Several DEA reverse distributors have RCRA interim status or a permit to treat or dispose of hazardous waste, but these DEA reverse distributors do not facilitate manufacturer credit.

B. EPA's Rationale for Finalizing New RCRA Management Standards for Reverse Distributors

This final rule establishes standards for the management of both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that reverse distributors receive and manage. The management standards discussed in this section apply only to reverse distributors of prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. The management standards discussed in this section do not apply to the reverse logistics systems that may exist for other retail items. In response to comments, EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed (see the definition of hazardous waste pharmaceutical under section VIII and section IX, the applicability section). Additionally, EPA is establishing a policy that other retail items that are sent through reverse logistics are not solid waste at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed (see section VI). Therefore, reverse logistics centers that receive and manage nonprescription pharmaceuticals will not be regulated under this subpart and will not be subject to the standards for reverse distributors.

The current federal RCRA hazardous waste generation regulations at 40 CFR part 262 provide that only designated facilities, such as RCRA-permitted and interim status TSDFs, may receive hazardous waste from off site for treatment, storage, or disposal. However, the Agency does not believe it is necessary for reverse distributors to obtain permits or have interim status to store hazardous waste pharmaceuticals in order to protect human health and the environment. Thus, EPA is finalizing a new category of hazardous waste management facilities under RCRA called a ''reverse distributor,'' which is defined as any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. The definition specifies that any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription hazardous waste pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. EPA is finalizing that reverse distributors are not required to have interim status or a RCRA permit to accumulate hazardous waste pharmaceuticals and they may only accept potentially creditable hazardous waste pharmaceuticals from off site provided they comply with the standards in this final rule. Reverse distributors may not treat or dispose of hazardous waste on-site unless authorized to do so as a RCRA-permitted or interim status TSDF.

As discussed earlier in this document, EPA's previous interpretation allows reverse distributors to be generators of hazardous waste pharmaceuticals after a decision is made about whether the pharmaceuticals will be repurposed. As a hazardous waste generator, a reverse distributor had to comply with the LQG, SQG, or VSQG generator regulations, depending on the total volume of hazardous waste generated in a calendar month. Some smaller reverse distributors might have stayed under the hazardous waste quantity limits for VSQGs, which would mean that under the federal RCRA regulations, these VSQG reverse distributors would not have had to notify EPA as a generator and their hazardous waste pharmaceuticals could be disposed of with municipal and non-municipal solid waste (see § 262.14). However, the Agency has concerns with VSQG reverse distributors not notifying EPA that they are managing hazardous waste. EPA is even more concerned about reverse distributors that currently qualify as VSQGs placing the hazardous waste pharmaceuticals into the municipal and non-municipal solid waste stream and sending them to non-hazardous waste landfills. Some studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems.[365] [366] Landfill leachate is generally transported to a wastewater treatment

[365] Barnes, K.K., Christenson, S.C., Kolpin, D.W., Focazio, M.J., Furlong, E.T., Zaugg, S.D., Meyer, M.T. and Barber, L.B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. Groundwater Monitoring & Remediation, 24: 119–126.

[366] Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. Bulletin of Environmental Contamination and Toxicology, 82.6:635–659.

plant to be treated before discharge; however, some pharmaceutical compounds pass through treatment and are discharged, becoming a potential contributor of the pharmaceutical compounds detected in our nation's waters.

In this final rule, EPA is revising its position regarding prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals, such that they will be considered discarded at the healthcare facilities, not at the reverse distributors. This revision is based on new information demonstrating to EPA that prescription pharmaceuticals returned to a reverse distributor are rarely, if ever, recycled or reused, and therefore the decision to send a potentially creditable hazardous waste pharmaceutical to a reverse distributor is a decision to discard the pharmaceutical (as discussed previously in section VI). Comments on the December 2008 Pharmaceutical Universal Waste proposal indicated that notification to EPA by reverse distributors and tracking of shipments of potentially creditable hazardous waste pharmaceuticals are critical and must be included in any regulatory scheme to ensure the safe management of potentially creditable hazardous waste pharmaceuticals.

Although EPA maintains its position as stated in the proposed rulemaking preamble that hazardous waste pharmaceuticals going to reverse distributors are solid wastes at the healthcare facility, there are important differences between reverse distributors and traditional TSDFs. Only between 2–6 percent of the potentially creditable pharmaceuticals that are received by reverse distributors are listed or characteristic hazardous wastes.[367] Therefore, the vast majority of the potentially creditable pharmaceutical waste that a reverse distributor receives is not considered a characteristic or listed hazardous waste pharmaceutical under the existing definition of hazardous waste. This stands in contrast to a typical TSDF, whose primary function is to manage hazardous waste. As a result, a reverse distributor generally manages a smaller volume of hazardous waste than a typical permitted TSDF.

In addition, because the pharmaceuticals in the reverse distribution system are receiving manufacturer credit, they are moved through the system efficiently. In fact, one national pharmacy retail chain informed EPA that the value of the credit they receive from manufacturers for returned pharmaceuticals is approximately $1 billion a year.[368] Healthcare facilities and reverse distributors have a vested interest in having potentially creditable hazardous waste pharmaceuticals processed and credited quickly and managed appropriately so money is not lost in the process.

Furthermore, potentially creditable hazardous waste pharmaceuticals generally present a low risk of release to the environment as they typically are still in the manufacturer's packaging, which in some cases includes inner and outer packaging (*e.g.,* plastic bottle inside a box). Since there is a relatively low human health and environmental risk of release associated with the low volumes of potentially creditable hazardous waste pharmaceuticals shipped to reverse distributors for crediting purposes, and because EPA is not aware of any incidents of mismanagement resulting in environmental harm or releases of hazardous waste pharmaceuticals by reverse distributors, EPA believes that it is not necessary to require reverse distributors to obtain RCRA hazardous waste storage permits with respect to typical reverse distribution operations, such as receiving, sorting, consolidating, and reshipping potentially creditable hazardous waste pharmaceuticals.

Thus, EPA is taking a tailored approach to regulating reverse distributors by regarding them as a new type of RCRA hazardous waste entity—a reverse distributor. This approach balances EPA's revised interpretation that the point of generation for prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, not the reverse distributor, with the fact that potentially creditable hazardous waste pharmaceuticals have value which provides an incentive for proper management.

EPA is establishing new management standards for reverse distributors in 40 CFR part 266 subpart P. These entities will not be subject to 40 CFR parts 262, 264, 265, or 270. Generally, EPA is finalizing that reverse distributors comply with standards that are similar to the current federal LQG standards, in combination with certain requirements that permitted or interim status hazardous waste TSDFs must meet. We are establishing one set of requirements for all reverse distributors, regardless of the amount of potentially creditable hazardous waste pharmaceuticals they receive. EPA believes this uniform set of standards will make it easier for reverse distributors to comply with the new subpart, in part because the burden of having to count hazardous waste pharmaceuticals on a monthly basis, especially the 1 kg of acute hazardous waste pharmaceuticals, will be removed.

EPA is finalizing that a reverse distributor will not be required to have a hazardous waste permit or interim status for on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals provided it follows the final reverse distributor standards. As mentioned previously, the on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals generally presents low risk of release to the environment because they are typically in the manufacturer's packaging. However, for activities such as treatment or disposal of hazardous waste pharmaceuticals or other hazardous waste, a reverse distributor must either obtain a RCRA permit or have interim status, as these activities pose a higher risk of release. EPA has determined that requirements similar to LQG standards for on-site accumulation of hazardous waste that are found in § 262.17 are appropriate. As discussed previously, the value of the potentially creditable pharmaceuticals creates an incentive for proper management and the risk of release is low. Furthermore, many reverse distributors are already LQGs and, therefore, this final rule should not represent a large shift in current practices or increased burden.[369] However, once credit is provided, the value of the pharmaceuticals is eliminated and therefore the evaluated hazardous waste pharmaceuticals have a greater potential for mismanagement. As a result, EPA is finalizing additional standards for the management of evaluated hazardous waste pharmaceuticals at reverse distributors.

EPA received numerous comments that expressed concern that the standards for reverse distributors would be burdensome for reverse logistics

[367] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932–0157, EPA–HQ–RCRA–2007–0932–0158, EPA–HQ–RCRA–2007–0932–0159, EPA–HQ–RCRA–2007–0932–0160, EPA–HQ–RCRA–2007–0932–0161, EPA–HQ–RCRA–2007–0932–0162, EPA–HQ–RCRA–2007–0932–0163, EPA–HQ–RCRA–2007–0932–0164.

[368] Meeting with representatives from CVS (August 11, 2012); see the docket for meeting notes (EPA–HQ–RCRA–2007–0932–0188).

[369] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

centers that handle nonprescription pharmaceuticals. For example, one commenter expressed concern that the reverse distributor inventory requirements for both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals would be burdensome for facilities that receive and manage nonprescription pharmaceuticals because these reverse logistics centers do not currently maintain an inventory for these retail items.[370] EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed (see section VI for more discussion). Therefore, reverse logistics centers will not be regulated under part 266 subpart P and will not be subject to the standards for reverse distributors. As a result, comments received on the impact of the reverse distributor standards on reverse logistics centers that receive and manage nonprescription pharmaceuticals are outside the scope of the final rule and are not discussed in this section. EPA also received numerous general comments expressing concern that finalizing new RCRA management standards for reverse distributors would be burdensome. However, some specific provisions included in the proposed reverse distributor standards received few comments.

C. Detailed Discussion of Final Reverse Distributor Standards

The final standards for reverse distributors are organized into three sections. The first section applies to the reverse distributor for the management of all potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals (§ 266.510(a)). The second section includes additional standards that would apply to the management of the potentially creditable hazardous waste pharmaceuticals that will be sent to another reverse distributor for further evaluation or verification of credit and therefore continue to be regulated as potentially creditable hazardous waste pharmaceuticals (§ 266.510(b)). The third section includes additional standards that apply to the management of the evaluated hazardous waste pharmaceuticals that will not be sent to another reverse distributor, but instead will be sent to a permitted or interim status TSDF (§ 266.510(c)).

1. Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals (§ 266.510(a))

This portion of the preamble discusses the standards that apply to reverse distributors for the management of all hazardous waste pharmaceuticals on site, including potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Unlike the following two sections, the standards discussed in this section apply to all prescription hazardous waste pharmaceuticals at a reverse distributor, regardless of the subsequent destination of the hazardous waste pharmaceuticals. We note that a reverse distributor must follow these standards for the management of hazardous waste pharmaceuticals even if it generates other, non-pharmaceutical hazardous waste that is managed under 40 CFR part 262. Note that we have reorganized § 266.510(a) since the proposal to more accurately reflect the flow of hazardous waste pharmaceuticals at a reverse distributor. The subsequent preamble section follows the organization of the final regulations.

a. Notification

Summary of Proposal. EPA proposed that a reverse distributor must notify EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12). Under the RCRA Subtitle C program, SQGs, LQGs, and TSDFs must submit a Site ID Form to EPA. EPA proposed that a reverse distributor that does not have an EPA ID number will be required to submit the Site ID Form to obtain one and that a reverse distributor that already has an EPA ID number will need to notify EPA as a reverse distributor.

Summary of Comments. EPA received two comments in support of the proposed notification requirements. One state supported all of the proposed notification requirements.[371] Inmar, Inc. supported the requirement that reverse distributors must notify EPA using EPA Form 8700–12.[372]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(1) that a reverse distributor must notify EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12). The Agency will revise the Site ID Form to include a box to allow notifications by reverse distributors. EPA believes it is appropriate, and in line with comments received on the proposal, to require reverse distributors to notify EPA. Under the final rule, a reverse distributor that does not have an EPA ID number will be required to submit the Site ID Form to obtain one. A reverse distributor that already has an EPA ID number will need to notify EPA as a reverse distributor. The time frame in both cases is within 60 days of the effective date of this subpart or within 60 days of becoming subject to this subpart. Some reverse distributors may also be generators of other types of hazardous waste (*e.g.,* from cleaning and maintenance operations). Therefore, it is possible that a reverse distributor may notify on the same notification form as both a generator of hazardous waste and as a reverse distributor.

b. Inventory

Summary of Proposal. EPA proposed that reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. EPA proposed that the inventory must include the identity (*e.g.,* name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical. EPA also proposed that a reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the reverse distributor.

Summary of Comments. EPA received comments from states and industry in support of the proposed inventory requirement.[373] One state suggested that EPA also require reverse distributors to include the name of the healthcare facility that shipped the potentially creditable hazardous waste pharmaceuticals to the reverse distributor.[374]

Retail Industry Leaders Association argued that the inventory requirements for reverse distributors should be reduced.[375] Inmar, Inc. did not support the inventory requirements and argued

[370] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[371] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[372] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[373] See comment numbers EPA–HQ–RCRA–2007–0932–0235, EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, EPA–HQ–RCRA–2007–0932–0300, and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[374] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

[375] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

that they are duplicative because reverse distributors must already inventory and track prescription pharmaceuticals.[376] Inmar, Inc. wrote that at least four states currently require the maintenance of drug inventories by law.[377] Both Inmar, Inc. and RILA expressed concern that the inventory requirements would be particularly burdensome for their facilities that handle nonprescription pharmaceuticals. Inmar, Inc. pointed out that their reverse logistics centers do not maintain an inventory for nonprescription pharmaceuticals.[378]

EPA received multiple comments from industry that expressed concern that the reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival.[379] One commenter expressed concern that the reverse distributor must complete an inventory upon arrival because packages of potentially creditable hazardous waste pharmaceuticals can remain unopened for up to 5 business days.[380] Healthcare Distribution Management Association [381] pointed out that reverse distributors sometimes receive tens of thousands of products in a day and do individual product accounting when the credit determination is made.[382]

Commenters on the proposed rulemaking also pointed out that reverse distributors are already required to inventory and track prescription pharmaceuticals under licensing and accreditation programs overseen by the National Association of Boards of Pharmacy.[383]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(2) that reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. In response to comments, we have made several changes to what was proposed but have determined that an inventory is a key requirement to protect public health by helping to prevent the diversion of hazardous waste pharmaceuticals. An inventory will allow the reverse distributor to know which hazardous waste pharmaceuticals they have on-site at any time. Based on stakeholder input and site visits, the Agency believes that in many cases, reverse distributors already maintain inventories of pharmaceuticals and this requirement is not expected to be burdensome for the reverse distributors to implement. According to responses from reverse distributors to a 2011 request for information, four out of eight of them indicated that they already keep inventories as best management practices or because it is required by the Board of Pharmacy in their state.[384] The inventory must include the identity (*e.g.,* name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals. In response to commenter concern that the inventory requirement would be duplicative, EPA clarified in the regulatory language of the final rule that if the reverse distributor already meets the inventory requirements because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory.

EPA proposed that a reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the reverse distributor. The final rule has been revised to state that reverse distributors must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of arriving at the reverse distributor. EPA made this change in response to commenter concern that the Agency did not provide enough time for reverse distributors to inventory potentially creditable hazardous waste pharmaceuticals. As previously mentioned, comments pointed out that reverse distributors sometimes receive tens of thousands of products in one day and need additional time to inventory each potentially creditable hazardous waste pharmaceutical.[385] EPA is also aware that many reverse distributors inventory the potentially creditable hazardous waste pharmaceutical at the same time that they evaluate the potentially creditable hazardous waste pharmaceutical to determine if it will receive manufacturer credit. When a reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its system and make a credit determination. EPA believes that 30 days is an adequate amount of time for the reverse distributor to sort through shipments of hazardous waste pharmaceuticals and inventory the potentially creditable hazardous waste pharmaceuticals. The Agency has determined that because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, increasing the amount of time reverse distributors have to complete the inventory will not increase risk of release to the environment.

c. Evaluating Potentially Creditable Hazardous Waste Pharmaceuticals Within 30 Days

Summary of Proposal. The key role the reverse distributor plays in managing the issuing of credit from a manufacturer to a healthcare facility is sorting through shipments of potentially creditable hazardous waste pharmaceuticals and evaluating them to determine which must be transported to another reverse distributor for further evaluation of manufacturer credit and which will be sent off site for treatment and disposal. The reverse distributors often use barcodes to scan items into their systems.

EPA proposed that this evaluation process must be completed within 21 days of arriving at the reverse distributor. Likewise, EPA proposed that if the reverse distributor is a manufacturer, the manufacturer must finish verifying the appropriate credit within 21 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals. The Agency proposed that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that each reverse distributor is allowed to accumulate hazardous waste pharmaceuticals on site.

Summary of Comments. The most frequent comment EPA received on the proposed requirement that reverse distributors complete the evaluation process within 21 days of arriving at the reverse distributor is that the proposed time frame was too short. Waste Management National Services, Inc.

[376] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[377] See the EPA correspondence with Inmar dated March 29, 2017 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

[378] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[379] See comment numbers EPA–HQ–RCRA–2007–0932–0295, EPA–HQ–RCRA–2007–0932–0276, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0340 in the docket for this rulemaking.

[380] See comment number EPA–HQ–RCRA–2007–0932–0278 in the docket for this rulemaking.

[381] Now renamed Heathcare Distribution Alliance.

[382] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[383] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[384] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932–0157, EPA–HQ–RCRA–2007–0932–0158, EPA–HQ–RCRA–2007–0932–0159, EPA–HQ–RCRA–2007–0932–0160, EPA–HQ–RCRA–2007–0932–0161, EPA–HQ–RCRA–2007–0932–0162, EPA–HQ–RCRA–2007–0932–0163, EPA–HQ–RCRA–2007–0932–0164.

[385] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

requested that EPA allow additional time for reverse distributors to evaluate potentially creditable hazardous waste pharmaceuticals.[386] One state requested that EPA allow reverse distributors to have 30 days to complete the evaluation process.[387] RILA and PharmaLink, Inc. requested that EPA allow reverse distributors to have 60 days to complete the evaluation process.[388] GENCO, Qualanex, LLC, and Healthcare Waste Institute of the National Waste and Recycling Association requested that there be no time limit set for reverse distributors to complete the evaluation process.[389] One state suggested that it is not critical to require the evaluation to take place in a certain number of days if the days count toward the total number of days that hazardous waste pharmaceuticals are allowed to accumulate on site.[390]

EPA also received multiple comments in support of the requirement that reverse distributors complete the evaluation process in a short time frame. One state supported the requirement that reverse distributors complete the evaluation process in a short time frame.[391] Clean Harbors Environmental Services argued that 21 days is more than adequate for a reverse distributor to evaluate potentially creditable hazardous waste pharmaceuticals.[392]

Final Rule Provisions. Under the final rule, EPA is requiring in § 266.510(a)(3) that reverse distributors evaluate potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Likewise, EPA is finalizing in § 266.510(a)(4) that if the reverse distributor is a manufacturer, the manufacturer must finish verifying the appropriate credit within 30 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals.

EPA is now aware that reverse distributors sometimes receive tens of thousands of products in one day and that sometimes reverse distributors need more than 21 days to evaluate the potentially creditable hazardous waste pharmaceuticals.[393] As mentioned previously, commenters pointed out that many reverse distributors inventory the potentially creditable hazardous waste pharmaceuticals at the same time that they evaluate the potentially creditable hazardous waste pharmaceuticals to determine if they will be credited.[394] Therefore, the Agency is finalizing that both the inventory and the evaluation process must be completed in 30 days to ensure that reverse distributors have adequate time to sort through shipments of potentially creditable hazardous waste pharmaceuticals.[395] In the case where healthcare facilities do not segregate hazardous waste pharmaceuticals from non-hazardous waste pharmaceuticals as part of the evaluation process, reverse distributors will effectively make a hazardous waste determination in order to determine which pharmaceuticals are hazardous waste pharmaceuticals and thus subject to this subpart.

The Agency is finalizing that the 30 calendar days for evaluating the potentially creditable hazardous pharmaceuticals do not count as part of the total 180 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on site at the reverse distributor. The Agency has determined that because of the value of the potentially creditable hazardous waste pharmaceuticals and the low risk these materials present, increasing the amount of time reverse distributors have to evaluate shipments of potentially creditable hazardous waste pharmaceuticals will not increase risk of release to the environment. Additionally, because most potentially creditable hazardous waste pharmaceuticals are in their original packaging, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard, and therefore EPA has determined that having a longer accumulation time is not a hazard to human health and the environment.[396]

EPA is finalizing that once an evaluation is made on the incoming potentially creditable hazardous waste pharmaceuticals, if they are destined for another reverse distributor, they are still considered potentially creditable hazardous waste pharmaceuticals. There are additional regulations in this subpart at § 266.510(b) that pertain to these potentially creditable hazardous waste pharmaceuticals. If, however, they are destined for an interim status or permitted TSDF, they are considered ''evaluated hazardous waste pharmaceuticals.'' There are additional regulations in this rule at § 266.510(c) that pertain to these evaluated hazardous waste pharmaceuticals.

d. Accumulation Time Limit

Summary of Proposal. EPA proposed that, like LQGs, reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days without having interim status or a permit. However, because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present because they are in original manufacturer's packaging that would meet our typical requirement for closed containers, the Agency decided not to propose specific container management standards.

The Agency proposed that the 90-day time limit begin when the potentially creditable hazardous waste pharmaceuticals initially arrive at the reverse distributor. The Agency also proposed that there is a 90-day accumulation limit for the hazardous waste pharmaceuticals at each reverse distributor. Some potentially creditable hazardous waste pharmaceuticals travel through more than one reverse distributor to receive manufacturer credit. The Agency proposed that in such cases, each reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a 90-day accumulation limit.

EPA did not propose a specific method that reverse distributors must use to document that accumulation does not exceed 90 calendar days. EPA

[386] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[387] See comment number EPA–HQ–RCRA–2007–0932–0313 in the docket for this rulemaking.

[388] See comment numbers EPA–HQ–RCRA–2007–0932–0295 and EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[389] See comment numbers EPA–HQ–RCRA–2007–0932–0336, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[390] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

[391] See comment number EPA–HQ–RCRA–2007–0932–0315 in the docket for this rulemaking.

[392] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[393] See comment numbers EPA–HQ–RCRA–2007–0932–0276 and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[394] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[395] Although RILA requested that EPA allow reverse distributors to have 60 days to complete the evaluation process, RILA was primarily concerned that it would be difficult for reverse distributors to sort through over-the-counter pharmaceuticals and dietary supplements within the proposed time frame (see comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking). However, the Agency thinks that 30 days is a sufficient amount of time for reverse distributors to sort through shipments of potentially creditable hazardous waste pharmaceuticals, which does not include over-the-counter pharmaceuticals and dietary supplements under the final regulations (see the definition of ''potentially creditable hazardous waste pharmaceuticals'' in 266.500).

[396] For more discussion of the closed container standard see memo from Devlin to RCRA Division Directors, November 3, 2011 (RCRA Online #14826).

anticipated that most reverse distributors would use the inventory system to verify the 90-calendar day time frame rather than taking the extra step of labeling containers with dates for verification. EPA also proposed to allow a reverse distributor to request from EPA an extension of the 90-day accumulation time limit for situations when the hazardous waste pharmaceuticals are involved in litigation, a recall, or in unforeseen circumstances beyond the control of the reverse distributor. Under the part 262 generator regulations, the extension of time typically allowed is limited to an extra 30 days for LQGs. However, due to the complex nature of pharmaceutical litigation and recalls, EPA proposed to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis.

Summary of Comments. The most frequent comment EPA received on the proposed on-site accumulation time limit was that the 90-day accumulation limit was too short. Waste Management National Services, Inc. did not support the 90-day accumulation limit, arguing that there are many reasons why a reverse distributor would experience significant changes in the volumes of returns it receives, including recalls.[397] Inmar, Inc. did not support the 90-day accumulation limit, arguing that its facilities receive thousands of shipments every day and it would be impractical to ensure a 90-day accumulation limit.[398] Healthcare Distribution Management Association pointed out that the 90-day accumulation limit is too short because manufacturers frequently take longer than 90 days to make credit determinations.[399] Waste Management National Services, Inc., Qualanex, LLC, and PharmaLink, Inc. requested that EPA not require the 90-day accumulation to begin until the potentially creditable hazardous waste pharmaceuticals become evaluated hazardous waste pharmaceuticals.[400] Stericycle, Inc. requested that EPA extend the accumulation time limit from 90 days to 180 days and suggested that there should not be an accumulation time limit for hazardous waste pharmaceuticals being held due to recall.[401] GENCO and Healthcare Waste Institute of the National Waste and Recycling Association also requested that EPA extend the accumulation time limit from 90 days to 180 days.[402] RILA Association requested that EPA extend the accumulation time limit from 90 days to one year.[403] National Pharmaceutical Returns requested that EPA place no accumulation time limit on potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.[404]

EPA received multiple comments suggesting that the accumulation time limits did not accommodate situations where reverse distributors receive unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date or situations where reverse distributors ''age'' potentially creditable pharmaceuticals until they are eligible for manufacturer credit.[405]

One state supported the 90-day accumulation limit.[406] One state agreed that the 90-day accumulation limit is reasonable but did not support allowing each reverse distributor to have a 90-day accumulation period because it increases the potential for mismanagement.[407]

Final Rule Provisions. In response to comments, EPA is providing additional time for reverse distributors accumulating hazardous waste pharmaceuticals. Specifically, EPA is finalizing in § 266.510(a)(5) that reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for up to 180 calendar days without having interim status or a permit as long as they meet the conditions of this subpart. The Agency is finalizing that the 180-day time limit begins once the reverse distributor evaluates the potentially creditable hazardous waste pharmaceutical and determines if the potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor for further evaluation of manufacturer credit or if it will be sent off site for treatment and disposal. As mentioned in the previous section, reverse distributors are required to inventory and evaluate potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Therefore, the potentially creditable hazardous waste pharmaceuticals can be accumulated at each reverse distributor for no more than 210 days in total after arrival.

The Agency is finalizing that there is a 180-day accumulation limit for the hazardous waste pharmaceutical at each reverse distributor. Some potentially creditable hazardous waste pharmaceuticals travel through more than one reverse distributor to receive manufacturer credit. Under the final rule, each reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a new 180-day accumulation limit. Under the final rule, the 180-day time limit begins when the reverse distributor evaluates potentially creditable hazardous waste pharmaceuticals and to determine which potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor and which ones will be sent off site for treatment and disposal.

Under the final rule, EPA is not requiring a specific method that reverse distributors must use to document that accumulation does not exceed 180 calendar days. EPA anticipates that most reverse distributors will use the inventory system to verify the 180-calendar day time frame rather than taking an addition step of labeling containers with dates for verification. As discussed previously, EPA is finalizing that a reverse distributor must inventory potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Many reverse distributors utilize barcoding and scanners to log potentially creditable pharmaceuticals into a database upon arrival or soon after a shipment arrives.

Because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, the Agency is not requiring specific container management standards in the final rule. Furthermore, potentially creditable hazardous waste pharmaceuticals are typically still in the manufacturer's packaging, which would meet our typical requirement for closed containers.

Under the final rule, EPA has eliminated the proposed provision allowing reverse distributors to request an extension of the accumulation time limit. In order to accommodate situations where hazardous waste

[397] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[398] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[399] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[400] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[401] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[402] See comment numbers EPA–HQ–RCRA–2007–0932–0336 and EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[403] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[404] See comment number EPA–HQ–RCRA–2007–0932–0310 in the docket for this rulemaking.

[405] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[406] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[407] See comment number EPA–HQ–RCRA–2007–0932–0300 in the docket for this rulemaking.

pharmaceuticals are involved in unforeseen circumstances beyond the control of the reverse distributor, the Agency increased the accumulation time limit from 90 days to 180 days. As discussed previously, the Agency also increased the amount of time reverse distributors can take to evaluate potentially creditable hazardous waste pharmaceuticals from 21 to 30 days. Additionally, in order to accommodate situations when hazardous waste pharmaceuticals are involved in litigation or a recall, under the final rule, the Agency decided that hazardous waste pharmaceuticals that are either involved in an investigation or judicial proceeding or are subject to a voluntary or federally-mandated recall are not required to be managed under subpart P (see section IX for a detailed discussion). As a result, we do not anticipate the need for reverse distributors to seek accumulation time extensions and therefore we have deleted proposed § 266.510(a)(5).

In order to accommodate situations when reverse distributors receive unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (*i.e.,* aging in a holding morgue), EPA has added a provision in § 266.510(a)(5)(ii) to allow reverse distributors to accumulate these unexpired pharmaceuticals for up to 180 days after the expiration date provided that the unexpired pharmaceuticals are managed in accordance with the container labeling and management standards for evaluated hazardous waste pharmaceuticals found at § 266.510(c)(4)(i)–(vi) while they are aging. This includes labeling containers with the words ''hazardous waste pharmaceuticals;'' ensuring the containers are in good condition, managed to prevent leaks and compatible with the contents; and keeping containers closed.

Once a reverse distributor evaluates a hazardous waste pharmaceutical and determines that it is not destined for another reverse distributor, the reverse distributor must manage that hazardous waste pharmaceutical according to the standards for evaluated hazardous waste pharmaceuticals (unless, as previously mentioned, the hazardous waste pharmaceuticals are unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date). The evaluated hazardous waste pharmaceuticals can be accumulated for up to 180 calendar days without having interim status or permits and they must be managed in accordance with the standards for evaluated hazardous waste pharmaceuticals in § 266.510(c). Although reverse distributors must manage the hazardous waste pharmaceuticals that are not destined for another reverse distributor in accordance with the standards for evaluated hazardous waste pharmaceuticals, the reverse distributor can decide at any point during the accumulation time that the evaluated hazardous waste pharmaceuticals have become eligible for manufacturer credit. If the evaluated hazardous waste pharmaceuticals become eligible for manufacturer credit, the reverse distributor does not get additional calendar days beyond the 180-day accumulation time limit to accumulate the hazardous waste pharmaceuticals. If the evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit, and the hazardous waste pharmaceutical will still not be sent to another reverse distributor for further evaluation, the reverse distributor must continue to manage the hazardous waste pharmaceutical in accordance with the standards for evaluated hazardous waste pharmaceuticals.

EPA does not anticipate a scenario where an evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit and the reverse distributor needs to send the hazardous waste pharmaceutical to another reverse distributor for further evaluation. A reverse distributor is unlikely to utilize resources to accumulate a pharmaceutical that another reverse distributor is required to evaluate due to contractual arrangements with pharmaceutical manufacturers. Although EPA does not anticipate this scenario, if an evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit and the reverse distributor determines that it should go to another reverse distributor to be further evaluated for manufacturer credit, the reverse distributor can then resume managing the hazardous waste pharmaceutical pursuant to the standards for potentially creditable hazardous waste pharmaceuticals that are going on to another reverse distributor (§ 266.510(b)). However, the reverse distributor does not get additional time to accumulate the hazardous waste pharmaceuticals. That is, the reverse distributor can only accumulate the hazardous waste pharmaceuticals for a total of 180 days after the initial evaluation process is complete. Overall, this approach balances the requests from commenters to accommodate situations where reverse anticipate that a manufacturer's policy might change and that evaluated hazardous waste pharmaceuticals might become eligible for manufacturer credit with EPA's belief that it is necessary to limit total accumulation time to 180 days.

e. Security

Summary of Proposal. EPA proposed that reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. Due to increased thefts of pharmaceuticals from pharmacies reported in recent years in major media outlets, EPA was concerned that reverse distributors could face such thefts since they accumulate unused pharmaceuticals.[408] Further, commenters on the 2008 Pharmaceutical Universal Waste proposal suggested that pharmaceutical universal waste handlers should meet the TSDF facility security requirement. EPA agreed with the commenters that the requirements in the interim status TSDF security regulations would be appropriate to adopt and apply to reverse distributors to prevent the illicit use of these pharmaceuticals, thereby safeguarding human health. EPA's proposal required that they must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (*e.g.,* a receiving area and accumulation area).

Summary of Comments. Inmar, Inc. and RILA did not support the proposed security requirements and argued that they are duplicative because protective security measures are already required by other state and federal laws.[409] One state and two industry commenters expressed support that reverse distributors must meet a performance-based security standard.[410] One industry commenter pointed out that this requirement should not be an added burden since reverse distributors should already have significant security systems in place and one industry commenter pointed out that the requirements are consistent with the

[408] ''Pharmacies Besieged by Addicted Thieves'' by Abby Goodnough Published: February 6, 2011 *http://www.nytimes.com/2011/02/07/us/07pharmacies.html.*

[409] See comment numbers EPA–HQ–RCRA–2007–0932–0377 and EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[410] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0280, and EPA–HQ–RCRA–2007–0932–0315 in the docket for this rulemaking.

way that reverse distributors operate.[411] [412]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(6) that reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. EPA believes that the requirements that appear in the interim status TSDF security regulations are appropriate to adopt and apply to reverse distributors to prevent the illicit use of these pharmaceuticals thereby safeguarding human health. The security requirement of § 265.14(a) requires a facility to ''prevent the unknowing entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the active portion of his facility.'' EPA is finalizing a similar requirement for reverse distributors: they must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (*e.g.,* a receiving area and accumulation area).

Based on site visits and comments received on the proposed rulemaking, EPA recognizes that many reverse distributors may already meet the proposed security standard through the use of key cards that allow only authorized personnel into specific areas of the reverse distributor, camera surveillance systems, and cages for storing pharmaceuticals. Some reverse distributors may use fences and signs. EPA is including several examples of acceptable security measures in the regulatory text, but reverse distributors are not limited to the examples provided. Further, EPA does not believe this requirement is duplicative because we included a provision in the regulations that if a reverse distributor already meets the performance-based security standard by complying with other regulations, such as DEA's regulations, then the reverse distributor would not need to install additional security. Furthermore, in response to comments we added a reference to the State Board of Pharmacy regulations as a second example of other regulations that could be used to fulfill the performance based security requirement.

f. Contingency Plan and Emergency Procedures

Summary of Proposal. The Agency proposed to require that reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures at 40 CFR part 265 subpart D. EPA noted in the proposal that a reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Since many reverse distributors are already LQGs, they should already have contingency plans to address the hazards on site. It may be possible that the reverse distributors would have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but the Agency pointed out in the proposal that such modifications should not impose much burden.

Summary of Comments. One state and two industry commenters supported the requirement that reverse distributors meet the same contingency planning standards as LQGs at 40 CFR part 265 subpart D.[413] Inmar, Inc. supported the proposed contingency plan and emergency procedures requirements and pointed out that most of their facilities are LQGs and already follow these requirements.[414] RILA argued that the contingency planning and emergency procedures requirements should not apply to reverse distributors that handle lower volumes of hazardous waste than an SQG generates because the nature of the waste does not warrant the more stringent requirements.[415]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(7) that reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures. Since this rule was proposed, the 2016 Hazardous Waste Generator Improvements rule has been finalized and has placed the contingency plan and emergency procedures for LQGs in part 262 subpart M, entitled ''Preparedness, Prevention and Emergency Procedures for Large Quantity Generators.'' As a result, this final rule now references the LQG standards in part 262 subpart M rather than the interim status TSDF standards part 265 subpart D. EPA believes that a reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Reverse distributors that are LQGs should already have contingency plans to address the hazards on-site. Commenters pointed out that reverse distributors that currently operate as SQGs will face a burden under this requirement, but EPA's data shows that most reverse distributors are already LQGs.[416] It is possible that the reverse distributors will have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but EPA does not believe that such modifications will impose much burden.

Comments and Responses. One state recommended that EPA establish a similar requirement to 40 CFR 264.31 (failure of a facility owner or operator to maintain or operate facility to minimize possibility of fire, explosion or releases of hazardous waste or hazardous waste constituents) for reverse distributors.[417] EPA included similar language in the regulations at § 266.510(c)(4)(v).

g. Closure

Summary of Proposal. Due to the generally low risk of release to the environment of the hazardous waste pharmaceuticals that reverse distributors will accumulate on site, as well as the value of the hazardous waste pharmaceuticals, EPA proposed a performance-based closure standard for reverse distributors that incorporated the federal LQG closure standard found at § 265.111. Specifically, when a reverse distributor closes its operations related to hazardous waste pharmaceuticals, EPA proposed that it must control or minimize post-closure releases of hazardous waste into the environment. EPA expected that this would entail removing the containers of both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals from the facility before closure.

Summary of Comments. Waste Management National Services, Inc., the California Department of Toxic Substances Control, and the Connecticut Department of Energy and Environmental Protection support the requirement for a performance-based closure standard that is based on the

[411] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[412] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[413] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0341, and EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[414] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[415] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[416] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[417] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

federal LQG closure standard.[418] Inmar, Inc. requested that EPA clarify that the reverse distributor closure requirement only apply to the closure of the facility and not to the closure of accumulation areas.[419]

Final Rule Provisions. Under the final rule at § 266.510(a)(8), EPA is requiring a performance-based closure standard that is based on the federal LQG closure standard. Since the rule was proposed, the 2016 Hazardous Waste Generator Improvements rule has been finalized and has incorporated the LQG closure standards into the new LQG regulations in § 262.17. As a result, this final rule now references the LQG closure standard in §§ 262.17(a)(8)(ii) and (iii) rather than incorporating the regulatory language of § 265.111. The LQG closure standards are substantially the same as before. Therefore, when a reverse distributor closes its operations related to hazardous waste pharmaceuticals, it must control or minimize post-closure releases of hazardous waste constituents into the environment. This will entail removing the containers of both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals from the facility before closure. The closure standards apply when the reverse distributor closes its operations related to hazardous waste pharmaceuticals rather than when the reverse distributor closes an accumulation area.

h. Reporting

Summary of Proposal. In some instances, a shipment arriving at a reverse distributor may inadvertently include items that are not potentially creditable pharmaceuticals. These shipments can include wastes that are clearly not eligible to receive credit, such as patient care waste (*e.g.,* IV bags and tubing), contaminated personal protective equipment (PPE), medical waste, or other inappropriate wastes. Reverse distributors are not the appropriate waste management facility for medical or infectious wastes and these wastes must be managed and transported from the healthcare facility to an appropriate waste disposal facility. In some cases, these non-creditable wastes may be hazardous waste. These non-creditable hazardous wastes are prohibited from being transported from a healthcare facility to a reverse distributor and should have been manifested from the healthcare facility to a designated facility, such as a permitted or interim status TSDF.

EPA proposed that if a shipment including these unauthorized wastes arrives at a reverse distributor from a healthcare facility, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 15 days. EPA adapted the existing requirement for situations when permitted and interim status TSDFs receive unmanifested hazardous waste (§ 264.76 and § 265.76, respectively) to make it appropriate for situations when unauthorized waste arrives at a reverse distributor. EPA also proposed additional requirements for when inappropriate hazardous waste arrives at a reverse distributor.

First, EPA proposed that the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility that sent the unauthorized waste. This requirement was intended to alert the healthcare facility of its mistake in order to prevent further shipments of non-creditable hazardous waste or non-pharmaceutical hazardous waste.

Second, EPA proposed that the reverse distributor must manage the unauthorized waste that it receives in accordance with all applicable regulations. Third, the Agency proposed that the EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Summary of Comments. The most frequent comment that EPA received on the proposed reporting requirements is that 15 days is not enough time to submit an unauthorized waste report to the EPA Regional Administrator. Four commenters argued that 15 days is not enough time to submit an unauthorized waste report to the EPA Regional Administrator.[420] Two industry commenters pointed out that it may take up to 30 days for shipments to be processed.[421] Healthcare Waste Institute of the National Waste and Recycling Association suggested that reverse distributors be required to submit an unauthorized waste report within 15 days of processing a shipment of hazardous waste rather than within 15 days of receiving the hazardous waste.[422]

CT DEEP supported the reporting requirements and wrote that the requirement might incentivize healthcare facilities not to ship unauthorized wastes to reverse distributors.[423] RILA did not support the reporting requirements and wrote that reverse distributors should not be required to submit an unauthorized waste report when shipments of non-creditable hazardous waste pharmaceuticals arrive at the reverse distributors because the healthcare facilities are not capable of evaluating creditworthiness.[424] Waste Management National Services, Inc. requested that EPA only require reverse distributors to send a copy of the unauthorized waste report to a specific healthcare facility three times, arguing that it is not the reverse distributor's responsibility to continue this reporting.[425] National Pharmaceutical Returns pointed out that reverse distributors receive a large amount of unauthorized waste pharmaceuticals that healthcare facilities think are potentially creditable and therefore the reporting requirements will be time consuming.[426] One state requested the EPA clarify if a reverse distributor may refuse to take a shipment.[427]

Final Rule Provisions. In response to comments, EPA is finalizing at § 266.510(a)(9) that if a shipment from a healthcare facility arrives at a reverse distributor that includes hazardous waste that it is not authorized to receive, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 45 days of receiving the hazardous waste rather than the proposed 15 days. However, EPA is finalizing, as proposed, the additional requirements for when shipments of unauthorized waste arrive at reverse distributors. First, the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility that sent the unauthorized waste. Second, the reverse distributor cannot reject the shipment of non-creditable hazardous waste and must manage the unauthorized waste in accordance with all applicable

[418] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0315, and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[419] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[420] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0278, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0352 in the docket for this rulemaking.

[421] See comment numbers EPA–HQ–RCRA–2007–0932–0257 and EPA–HQ–RCRA–2007–0932–0352 in the docket for this rulemaking.

[422] See comment number EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[423] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[424] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[425] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[426] See comment number EPA–HQ–RCRA–2007–0932–0310 in the docket for this rulemaking.

[427] See comment number EPA–HQ–RCRA–2007–0932–0259 in the docket for this rulemaking.

regulations (*e.g.,* part 262 or medical waste regulations). Healthcare facilities are not equipped as well as reverse distributors to manage the hazardous waste and EPA is concerned that rejecting shipments of non-creditable hazardous waste will prolong mismanagement. Third, the Agency is finalizing as proposed that the EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. This provides the Agency with some flexibility in what reports may be required.

Comments and Responses. The Agency believes that commenters understood this provision to apply more broadly than we intended. We are aware that healthcare facilities often do not know whether a hazardous waste pharmaceutical will receive manufacturer credit at the reverse distributor. EPA did not intend for a reverse distributor to generate an unauthorized waste report each time a hazardous waste does not receive credit. Rather, a reverse distributor must generate an unauthorized waste report when it receives waste that it is not authorized to receive or manage. EPA reworded the regulations to include better examples of unauthorized waste, which includes, but is not limited to, non-pharmaceutical hazardous waste and medical or infectious waste.

In order to prevent exposing employees to unnecessary risk, EPA recommends as a best management practice that reverse distributors keep to a minimum the sorting of shipments that contain unauthorized waste since the shipment may include hazardous waste, including infectious or radioactive healthcare waste. As a result, it is possible that a reverse distributor that receives a shipment that includes non-creditable waste may be unsure whether the shipment includes hazardous waste. In such cases, EPA recommends that the reverse distributor assume the shipment includes hazardous waste and submit an unauthorized waste report. Further, we recommend that reverse distributors work with their clients to reduce the occurrence of further inappropriate shipments.

i. Recordkeeping

Summary of Proposal. EPA proposed three recordkeeping requirements to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, EPA proposed that a reverse distributor must keep a copy of its notification (EPA Form 8700–12) to EPA to indicate that it is a reverse distributor operating under 40 CFR part 266 subpart P. EPA proposed that a reverse distributor must keep the record of notification for as long as it is subject to these requirements. Second, EPA proposed that a reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This included a copy of the proposed advance notification from the healthcare facility or other reverse distributor, a copy of delivery confirmation, shipping papers or bills of loading, and any unauthorized waste reports. The Agency proposed that these shipping records must be kept for three years from the date the reverse distributor receives the shipment. Third, EPA proposed that a reverse distributor must keep a copy of its inventory at all times as long as the reverse distributor remains subject to this subpart. Finally, EPA proposed that periods of record retention indicated previously for a reverse distributor will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

Summary of Comments. EPA received multiple comments on the recordkeeping requirements. GENCO did not support the recordkeeping requirements, arguing the requirements would impose burden.[428] Inmar, Inc. argued that reverse distributors are already required to keep records under other regulatory requirements related to receipt, storage, duration, and shipping of controlled and uncontrolled substances.[429]

Stericycle, Inc., the Healthcare Waste Institute of the National Waste and Recycling Association, and Waste Management National Services, Inc. expressed concern about the requirement that a reverse distributor must keep a copy of its inventory for as long as the facility is subject to this subpart.[430] Stericycle, Inc. argued that it is not reasonable to require the inventory be maintained for the life of the facility.[431] The Illinois Council of Health-System Pharmacists requested that EPA clarify whether reverse distributors must maintain only a current inventory or that all inventories as they change must be maintained.[432]

Final Rule Provisions. EPA is finalizing the proposed recordkeeping requirements at § 266.510(a)(10) with some minor changes in order to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, EPA is finalizing that a reverse distributor must keep a copy of its notification (EPA Form 8700–12) to EPA to indicate that it is a reverse distributor operating under 40 CFR part 266 subpart P. A reverse distributor must keep the record of notification for as long as it is subject to these requirements.

Second, EPA is finalizing that a reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This includes a copy of delivery confirmation, shipping papers or bills of lading, and any unauthorized waste reports. We have revised the regulation language such that these shipping records must be kept for three years from the date the shipment arrives at the reverse distributor rather than when the reverse distributor ''receives'' the shipment since this standard is more precise.

Third, EPA is finalizing that a reverse distributor must keep a copy of its current inventory at all times as long as the reverse distributor remains subject to this subpart. The inventory is a living document that will constantly be updated and must be available for inspection. In order to clarify that a reverse distributor must maintain only a current inventory rather than all inventories even if they have changed, EPA revised the final regulatory language in § 266.510(a)(2) such that a reverse distributor must keep a copy of its current inventory. This recordkeeping change is being made to be consistent with that change in § 266.510(a)(2).

Finally, EPA is finalizing that periods of record retention referred to in this section are automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any

[428] See comment number EPA–HQ–RCRA–2007–0932–0336 in the docket for this rulemaking.

[429] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[430] See comment numbers EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[431] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[432] See comment number EPA–HQ–RCRA–2007–0932–0228 in the docket for this rulemaking.

enforcement action. The Agency recommends reverse distributors keep electronic versions of these records rather than paper or hard copy versions of these records.

Note that additional recordkeeping requirements may also pertain to reverse distributors. For example, a reverse distributor that manifests its non-pharmaceutical hazardous waste is subject to the manifest recordkeeping requirements of § 262.40. Further, as discussed in subsequent sections, there are additional recordkeeping requirements that apply to reverse distributors for the management of potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor (§ 266.510(b)) and others that apply to reverse distributors for the management of evaluated hazardous waste pharmaceuticals (§ 266.510(c)).

2. Additional Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Reverse Distributor (§ 266.510(b))

This section discusses the additional standards that apply to a reverse distributor for the management of potentially creditable hazardous waste pharmaceuticals that require further evaluation or verification of manufacturer credit at another reverse distributor. Since these pharmaceuticals retain their value and there is greater incentive to manage them carefully in order to receive full manufacturer credit, EPA is requiring few regulatory standards for the management of the potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor.

a. *Where potentially creditable hazardous waste pharmaceuticals can be sent.*

Summary of Proposal. EPA proposed a limit of three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are ultimately transported to a permitted or interim status TSDF. The Agency proposed that the three possible types of transfers were: [433]

(1) A healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a reverse distributor, which may or may not be a manufacturer;

(2) the first reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another reverse distributor, which may or may not be a manufacturer;

(3) the second reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a reverse distributor that is a manufacturer.

Because EPA proposed that each reverse distributor could accumulate hazardous waste pharmaceuticals up to 90 days after arriving at the reverse distributor, this proposed chain of transfers ensured that the potentially creditable hazardous waste pharmaceuticals would be accumulated for no more than 270 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal.[434] As described previously, this is consistent with current practice among reverse distributors because of the contractual arrangements that reverse distributors have with specific manufacturers.

Summary of Comments. One state did not support allowing three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are required to be transported to a TSDF and requested that EPA consider a maximum of two transfers prior to transportation to a TSDF.[435] Two industry commenters opposed EPA's proposed limit on the number of times a potentially creditable hazardous waste pharmaceutical may be transferred before it must be transported to a TSDF.[436] One of the industry commenters argued that reverse distributors have no knowledge about the pedigree of products prior to receipt and as such cannot be held accountable as to how many times a product is handled before transport to a TSDF.[437]

Final Rule Provisions. The final regulations for reverse distributors continue to be structured so that there is a limit to the number of transfers of potentially creditable hazardous waste pharmaceuticals that may occur before they are ultimately transported to a TSDF for treatment and disposal. Stakeholders expressed concern that the 2008 Pharmaceutical Universal Waste proposal would have allowed hazardous waste pharmaceuticals to be shipped repeatedly and indefinitely from one universal waste handler to another. From discussions with reverse distributors and reviewing comments received on the proposed rulemaking, the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceutical is ultimately transported to a TSDF. The three possible types of transfers are: [438]

(1) A healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a reverse distributor, which may or may not be a manufacturer;

(2) the first reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another reverse distributor, which may or may not be a manufacturer (§ 266.510(b)(1)); and

(3) the second reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a reverse distributor that is a manufacturer (§ 266.510(b)(2)).

Therefore, if a reverse distributor receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility, the reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor (which may or may not be a manufacturer) or must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c). However, a reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor is more limited in where it can send the potentially creditable hazardous waste pharmaceuticals. It can send potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is the manufacturer or else must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c).

The Agency disagrees with the commenter who argued that reverse distributors cannot be accountable for how many times a hazardous waste pharmaceutical is transferred because reverse distributors do not have a record of transfers of the potentially creditable hazardous waste pharmaceuticals prior to receipt.[439] It is not necessary for a reverse distributor to have a record of previous transfers. It is only necessary for a reverse distributor to know

[433] A healthcare facility or reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA-permitted or interim status TSDF.

[434] Although the proposal did allow for the possibility to request an accumulation time limit, the final rule does not.

[435] See comment number EPA–HQ–RCRA–2007–0932–0261 in the docket for this rulemaking.

[436] See comment numbers EPA–HQ–RCRA–2007–0932–0349 and EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[437] See comment number EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[438] A healthcare facility or reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA-permitted or interim status TSDF.

[439] See comment number EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

whether a shipment of potentially creditable hazardous waste pharmaceuticals originated from a healthcare facility or another reverse distributor. EPA believes it is reasonable for a reverse distributor to know the origin of a shipment that arrives at their facility.

Regardless of the origin or the destination of the potentially creditable hazardous waste pharmaceuticals, each reverse distributor must make an evaluation of them within 30 calendar days and may only accumulate the hazardous waste pharmaceuticals on site for no more than 180 calendar days after the evaluation before it ships them off-site to another reverse distributor or a RCRA-permitted or interim status TSDF (resulting in a maximum of 210 days). The 180 calendar day accumulation time starts after the 30 calendar days to make an evaluation. In the proposal, reverse distributors only had 90 days to accumulate hazardous waste pharmaceuticals on-site, including the 21 calendar days to make an evaluation. EPA made this conforming change to align with the change in § 266.510(a)(5) that allows reverse distributors to accumulate hazardous waste pharmaceuticals on-site for up to 180 calendar days without having interim status or a permit. In addition, all shipments of evaluated hazardous waste pharmaceuticals are subject to § 266.508 and shipments of all potentially creditable hazardous waste pharmaceuticals are subject to § 266.509.

Although this chain of transfers will allow potentially creditable hazardous waste pharmaceuticals to be accumulated for up to 630 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal, EPA does not expect that potentially creditable hazardous waste pharmaceuticals will be accumulated for this time period in practice. First, it is unlikely that a reverse distributor will expend resources to accumulate potentially creditable hazardous waste pharmaceuticals on site for the full 180 calendar days if the potentially creditable hazardous waste pharmaceuticals are destined for another reverse distributor. Second, the desire to receive manufacturer credit in a timely manner will also make it unlikely that reverse distributors will accumulate potentially creditable hazardous waste pharmaceuticals for the full 180 days.

EPA anticipated that some healthcare facilities that are VSQGs will send their potentially creditable hazardous waste pharmaceuticals directly to reverse distributors. We allow for this under § 266.504(a). On the other hand, healthcare facilities that are VSQGs may choose to consolidate all their hazardous waste pharmaceuticals (both creditable and non-creditable) at an off site healthcare facility, as allowed by § 266.504(b). In this later case, the consolidated potentially creditable hazardous waste pharmaceuticals at an off-site VSQG in § 266.504(b) are not counted as one of the 3 allowable transfers of potentially creditable hazardous waste pharmaceuticals under § 266.510(b).

Under the final rule, manufacturers cannot send hazardous waste pharmaceuticals to a reverse distributor because the hazardous waste pharmaceuticals are no longer considered potentially creditable hazardous waste pharmaceuticals. Since manufacturers are unable to issue credit to themselves, it is not possible for the hazardous waste pharmaceuticals to be considered potentially creditable hazardous waste pharmaceuticals.

b. *Recordkeeping for reverse distributors shipping potentially creditable hazardous waste pharmaceuticals to another reverse distributor.*

Summary of Proposal. EPA proposed that reverse distributors must keep records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor (whether it is a manufacturer or not). This included a copy of the advance notification provided to the other reverse distributor, a copy of delivery confirmation, as well as shipping papers or bill of lading. EPA proposed that the reverse distributor must keep these shipping records for three years from the date it initiates the shipment.

Summary of Comments. EPA received few comments on the recordkeeping requirements for reverse distributors that ship potentially creditable hazardous waste pharmaceuticals to another reverse distributor. One state asked EPA to clarify what it means by ''shipping papers.'' [440]

Final Rule Provisions. EPA is finalizing in § 266.510(b)(4) that reverse distributors must keep records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor (whether it is a manufacturer or not). This includes a copy of delivery confirmation, as well as DOT shipping papers. EPA has clarified in the regulations that it is the DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C we are referring to as ''shipping papers''; EPA is not adding a requirement for additional shipping papers. The regulations do not specifically mention that reverse distributors keep a copy of a bill of lading, as this is only one type of shipping paper that reverse distributors can use to comply with 49 CFR part 172 subpart C. EPA is finalizing that these shipping records must be kept for three years from the date of shipment.

3. Additional Standards for Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals (§ 266.510(c))

This section discusses the additional standards that apply to a reverse distributor for the management of evaluated hazardous waste pharmaceuticals. In general, the term evaluated hazardous waste pharmaceuticals refers to hazardous waste pharmaceuticals that were potentially creditable hazardous waste pharmaceuticals but have been evaluated by a reverse distributor to establish whether they are eligible for manufacturer credit and will not be sent to another reverse distributor for further evaluation or verification. While potentially creditable hazardous waste pharmaceuticals have value in the form of manufacturer credit, evaluated hazardous waste pharmaceuticals do not. Therefore, in order to minimize the potential for their mismanagement, EPA believes it is necessary to have additional standards for the evaluated hazardous waste pharmaceuticals. These standards generally resemble the standards for LQG CAAs.

a. *Accumulation area.*

Summary of Proposal. EPA proposed that once a reverse distributor completes its evaluation of a potentially creditable hazardous waste pharmaceutical and the reverse distributor knows that the hazardous waste pharmaceutical is destined for treatment and disposal at a RCRA-permitted or interim status TSDF, rather than another reverse distributor, the pharmaceutical is considered an evaluated hazardous waste pharmaceutical. EPA proposed that a reverse distributor must establish an on-site accumulation area where it will accumulate these evaluated hazardous waste pharmaceuticals. An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the

[440] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

potentially creditable hazardous waste pharmaceuticals.

Summary of Comments. One state supported the requirement for reverse distributors to establish on-site accumulation areas for evaluated hazardous waste pharmaceuticals.[441]

Final Rule Provisions. EPA is finalizing as proposed that a reverse distributor must establish an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals in § 266.510(c)(1). An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals that have fewer requirements and are destined for another reverse distributor.

b. *Weekly inspections.*

Summary of Proposal. EPA proposed that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least weekly to ensure containers are not leaking and that diversion of the evaluated hazardous waste pharmaceuticals is not occurring. Under the recordkeeping requirements for reverse distributors, the Agency proposed that a reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

Summary of Comments. One state commented that weekly inspections are not sufficient to determine whether or not diversion of evaluated hazardous waste pharmaceuticals is occurring and requested EPA require additional security provisions.[442] Washington State Department of Ecology requested that EPA clarify the intent of ''at least weekly'' and argued that they interpret ''at least weekly'' to mean once within every seven days.[443]

Final Rule Provisions. In response to comments, EPA is finalizing that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least once every seven days to ensure containers are not leaking and that diversion of the hazardous waste pharmaceuticals is not occurring. We agree with the commenter that phrasing the standard as ''at least once every seven days'' is more precise than ''at least weekly'' and will avoid the situation where a reverse distributor could inspect early in one week and late the following week and still claim it is inspecting weekly. Under the recordkeeping requirements for reverse distributors in § 266.510(c)(10), the Agency is finalizing that a reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

c. *Personnel training.*

Summary of Proposal. EPA proposed to require that reverse distributors meet the same federal classroom or on-the-job personnel training regulations that LQGs must meet (§ 265.16). However, the Agency specified in the proposal that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals in the on-site accumulation area. EPA argues that these personnel are the individuals handling and managing the evaluated hazardous waste pharmaceuticals and must have appropriate hazardous waste training.

Summary of Comments. Two industry commenters and one state supported the personnel training criteria for reverse distributors.[444] One state argued that the training requirements should be applied to the personnel who handle potentially creditable hazardous waste pharmaceuticals in addition to the personnel who handle evaluated hazardous waste pharmaceuticals on site.[445] Inmar, Inc. pointed out that personnel at reverse distributors are already required to receive training under other regulatory requirements.[446]

Final Rule Provisions. Under the final rule, reverse distributors must meet the same classroom or on-the-job personnel training requirements that LQGs must meet. EPA is finalizing that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals. Since these personnel are the individuals handling and managing the hazardous waste pharmaceuticals, they must have appropriate hazardous waste training. As mentioned previously, EPA received multiple comments in support of the training requirements for reverse distributors. Additionally, EPA does not believe the training requirements will add burden because EPA believes most reverse distributors currently operate as LQGs.[447] Since the proposed rulemaking, the 2016 Hazardous Waste Generator Improvement rule was finalized. As part of its reorganization, the personnel training regulations for LQGs are now incorporated into § 262.17(a)(7) and no longer refer to § 265.16. As a result, the § 266.510(c)(3) training requirements for personnel managing evaluated hazardous waste pharmaceuticals at reverse distributors now reference § 262.17(a)(7) instead of § 265.16.

d. *Labeling and management of containers in on-site accumulation area.*

Summary of Proposal. EPA proposed that while containers of evaluated hazardous waste pharmaceuticals are in the on-site accumulation area, they must be marked with the words, ''hazardous waste pharmaceuticals.'' EPA proposed this term in order to distinguish them from the non-hazardous waste pharmaceuticals and from the hazardous waste pharmaceuticals that are still considered potentially creditable. The Agency did not propose to require an accumulation start date on the label for the containers of evaluated hazardous waste pharmaceuticals.

In terms of container management standards, the Agency proposed requirements that are similar to the container management standards for LQGs, but the Agency proposed to include some requirements specific to evaluated hazardous waste pharmaceuticals. For example, LQGs must keep all containers of hazardous waste closed. However, EPA proposed to require that only containers with hazardous waste pharmaceuticals that are liquids or gels be kept closed during accumulation due to the low potential for release to the environment for those hazardous waste pharmaceuticals that are in a solid form. The Agency did not propose to require other containers of evaluated hazardous waste pharmaceuticals to be closed during accumulation, although we expect that reverse distributors would choose to do so as a best management practice. Further, because most evaluated hazardous waste pharmaceuticals are in their original packaging, we proposed that if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are

[441] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[442] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[443] See comment number EPA–HQ–RCRA–2007–0932–0272 in the docket for this rulemaking.

[444] See comment numbers EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0304 in the docket for this rulemaking.

[445] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[446] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[447] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

considered to meet the proposed closed container standard.

As with LQGs, EPA proposed that containers of evaluated hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the evaluated hazardous waste pharmaceuticals placed in the container. Another requirement that was tailored to reverse distributors was the proposal that reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals.

The LQG regulations in part 262 include management standards for several types of accumulation units that EPA did not propose to include for the management of evaluated hazardous waste pharmaceuticals. For instance, the proposal only set standards for the accumulation of evaluated hazardous waste pharmaceuticals in containers. EPA did not think it was necessary to include standards for accumulation units such as tanks, containment buildings, or drip pads because reverse distributors do not currently use these types of accumulation units. In addition, the Agency did not propose to require reverse distributors to meet the air emission standards found in 40 CFR part 265 subpart CC as required in § 262.34(a)(1)(i) for LQGs because the Agency anticipated that they will not be applicable. Additionally, 40 CFR part 265 subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are not applicable to the activities of a reverse distributor.

Summary of Comments. EPA received numerous comments on the proposed requirements for labeling and management of containers of evaluated hazardous waste pharmaceuticals in on-site accumulation areas at reverse distributors. One state supported that containers be marked with the words ''hazardous waste pharmaceuticals,'' but three states and one industry commenter requested that EPA require reverse distributors to label containers with the accumulation start date.[448] Stericycle, Inc. agreed that there is not a need to include standards for accumulation units such as tanks, containment buildings, or drip pads.[449] Clean Harbors argued that the only way to prevent diversion of hazardous waste pharmaceuticals is for all containers to be closed and sealed.[450] One state requested that EPA prohibit reverse distributors from mixing or commingling incompatible hazardous waste pharmaceuticals in the same container rather than only requiring reverse distributors to manage containers to prevent dangerous situations, such as fire explosion or release of toxic fumes.[451] One commenter agreed that the 40 CFR part 265 subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are not applicable to the activities of a reverse distributor and its management of hazardous waste pharmaceuticals.[452]

Final Rule Provisions. Final standards for labeling and management of containers at an on-site accumulation area are found at § 266.510(c)(4). EPA is finalizing that while containers of evaluated hazardous waste pharmaceuticals are in the accumulation area, they must be marked with the words, ''hazardous waste pharmaceuticals.'' Under the final rule, reverse distributors are not required to mark an accumulation start date on the label for the containers, because the reverse distributor's inventory will likely be used to verify the accumulation start date. However, a reverse distributor may choose an alternate method, such as marking the date on each container, to ensure that the containers of evaluated hazardous waste pharmaceuticals are not accumulated at the reverse distributor for more than 180 days. As explained previously, EPA prefers to allow a performance-based standard that allows flexibility to verify the 180-day accumulation time rather than require dating on the container labels. Most of the commenters that requested accumulation start dates on labels were states. Although the requirement is not being finalized at the federal level, any authorized state has the ability to impose more stringent regulations. If a state chooses to require the accumulation start date on the container label, that would be considered more stringent and permissible under RCRA.

In terms of container management standards, the Agency is finalizing the proposed requirements that are similar to the container management standards for LQGs as well as the additional management requirements specific to evaluated hazardous waste pharmaceuticals. Specifically, only containers with evaluated hazardous waste pharmaceuticals that are liquids or gels must be kept closed during accumulation, although EPA expects that all containers of evaluated hazardous waste pharmaceuticals will be closed given that evaluated hazardous waste pharmaceuticals are in their original packaging. As with the proposal, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard.

EPA is also finalizing that containers of evaluated hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container. In addition, a reverse distributor that manages any container of ignitable or reactive evaluated hazardous waste pharmaceuticals or any container of commingled incompatible evaluated hazardous waste pharmaceuticals must manage the container to prevent dangerous situations, such as fire, explosion, or release of toxic fumes. These regulations are consistent with the LQG container management regulations in part 262 and already apply to LQG reverse distributors accumulating hazardous waste on site. The Agency is also finalizing that reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals. The dilution prohibition of § 268.3(c) already prohibits the incineration of some hazardous waste pharmaceuticals. This new provision highlights this prohibition to the reverse distributors accumulating the hazardous waste pharmaceuticals prior to sending off site for treatment and disposal.

Comments and Responses. EPA is finalizing management standards only for containers used to accumulate evaluated hazardous waste pharmaceuticals because commenters

[448] See comment numbers EPA–HQ–RCRA–2007–0932–0211, EPA–HQ–RCRA–2007–0932–0235, EPA–HQ–RCRA–2007–0932–0341, and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[449] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[450] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[451] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[452] See comment number EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

confirmed that reverse distributors do not use other types of hazardous waste accumulation units, such as tanks, containment buildings, or drip pads.

In addition, the Agency is not requiring reverse distributors to meet the air emission standards found in 40 CFR part 265 subpart CC as required for LQGs in § 262.17(a)(1)(i) because the Agency anticipates that they will not be applicable. Specifically, § 265.1083(c) of subpart CC exempts tanks, surface impoundments, and containers from the organic air emission standards if the hazardous waste entering the accumulation unit has an average volatile organic concentration of less than 500 parts per million by weight, while § 265.1080(b)(2) of subpart CC exempts containers with a capacity of less than 0.1 m^3 (26 gallons) from the standards. EPA understands that the only evaluated hazardous waste pharmaceuticals that have the potential for air emissions are liquids and gels, but they generally do not contain volatile organics. Thus, they do not release organic air emissions, which is what the 40 CFR part 265 subpart CC air emission standards for tanks, surface impoundments, and containers were promulgated to control. Moreover, because evaluated hazardous waste pharmaceuticals are often in their original packaging, and EPA is requiring that liquid and gel evaluated hazardous waste pharmaceuticals must be in intact, sealed packaging or otherwise in closed containers, EPA believes that the container air emission standards are unnecessary. In addition, the Agency anticipates that the packaging and containers for hazardous waste pharmaceuticals will have a capacity of less than 0.1 m^3 (26 gallons) further limiting the applicability of the container air emission standards. Similarly, EPA does not anticipate that the 40 CFR part 265 subpart AA (air emissions standards for process vents) and subpart BB (air emission standards for equipment leaks) are applicable to the activities of a reverse distributor and its management of evaluated hazardous waste pharmaceuticals. Therefore, like 40 CFR part 265 subpart CC discussed previously, EPA is not requiring that 40 CFR part 265 subparts AA and BB apply to reverse distributors.

e. *Hazardous waste numbers (codes).*

Summary of Proposal. EPA proposed that RCRA hazardous waste numbers (commonly called ''hazardous waste codes'') must be marked on the container label in order to ensure that they are readily visible and cannot be separated from the hazardous waste. In the proposal, the Agency did not require that the reverse distributor be the party that adds the hazardous waste codes to the containers. The proposed regulations allowed a vendor to perform this duty on behalf of the reverse distributor.

Summary of Comments. Two states supported the requirement that hazardous waste codes be placed on containers of evaluated hazardous waste pharmaceuticals.[453] Waste Management National Services, Inc. argued that it is not practical to include all hazardous waste codes on each container label and instead suggested that codes be listed on the hazardous waste profile developed with the TSDF and on the manifest.[454]

Final Rule Provisions. Under the final rule, EPA is requiring that the containers of evaluated hazardous waste pharmaceuticals be marked with the applicable RCRA hazardous waste numbers (codes) at § 266.510(c)(5). The hazardous waste codes must be added prior to shipping evaluated hazardous waste pharmaceuticals off site, although they may be placed on the container label at any time during on-site accumulation. The hazardous waste numbers must be marked on the container label in order to ensure that it is readily visible and cannot be separated from the hazardous waste. It is necessary that the hazardous waste numbers are on the containers so that transporters, transfer facilities, and TSDFs know how to properly transport, consolidate, treat, store and dispose of the hazardous waste in compliance with the applicable RCRA regulations. In the final rule, the Agency is not requiring that the reverse distributor be the party that adds the hazardous waste numbers to the containers. The regulations allow a vendor to perform this duty on behalf of the reverse distributor. In practice, however, if a vendor is responsible for assigning hazardous waste numbers, personnel from the reverse distributor may need to assist in the process. To be consistent with the Hazardous Waste Generator Improvements final rule, we have added a sentence to § 266.510(c)(5) indicating that a nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste number(s).

f. *Shipping evaluated hazardous waste pharmaceuticals.*

Summary of Proposal. Although it is already stated in § 266.508(a) under the section of the regulations that pertains to shipping standards, for clarity, EPA proposed to repeat in the § 266.510 the reverse distributor regulations that reverse distributors that ship evaluated hazardous waste pharmaceuticals off site must do so in accordance with the proposed shipping requirements in § 266.508(a). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a designated facility.

Summary of Comments. Two states generally supported the shipping requirements for evaluated hazardous waste pharmaceuticals.[455] One state supported that EPA repeat in § 266.510 the requirements pertaining to shipping standards although it is already stated in § 266.508(a).[456]

Final Rule Provisions. For clarity, the final reverse distributor regulations state that a reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a permitted or interim status TSDF.

g. *Procedures for managing rejected shipments.*

Summary of Proposal. The Agency proposed to require that reverse distributors meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Specifically, if a designated permitted or interim status TSDF identified on the hazardous waste manifest cannot accept a shipment of evaluated hazardous waste pharmaceuticals from a reverse distributor and the TSDF returns the shipment to the reverse distributor, EPA proposed that the reverse distributor must sign either item 18c of the original manifest or item 20 of a new manifest. In addition, the proposal allowed the reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on site for up to 90 days provided they were managed in the on-site accumulation area and in accordance with the reverse distributor standards for evaluated hazardous waste pharmaceuticals. EPA also proposed that reverse distributors send a copy of

[453] See comment numbers EPA–HQ–RCRA–2007–0932–0300 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[454] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[455] See comment numbers EPA–HQ–RCRA–2007–0932–0261 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[456] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

the manifest to the designated facility that returned the shipment to the reverse distributor within 30 days of delivery.

Summary of Comments. One state requested the EPA clarify that a reverse distributor that receives a rejected shipment does not have to transport it off site upon receipt by the reverse distributor.[457] One state argued that a reverse distributor does not need 90 days to accumulate rejected hazardous waste pharmaceuticals in the on-site accumulation area and argued that 30 days is sufficient.[458]

Final Rule Provisions. The Agency is finalizing in § 266.510(c)(7) that reverse distributors must meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Under part 262, these rejected shipment procedures already apply to LQG reverse distributors. Furthermore, EPA anticipates that a rejected shipment is a relatively infrequent occurrence and therefore should not be a burden to reverse distributors. In addition, the final rule allows the reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on site for up to 90 days provided they are managed in the on-site accumulation area and in accordance with the reverse distributor standards for evaluated hazardous waste pharmaceuticals. Although one state requested EPA only allow accumulation for 30 days, any authorized state has the ability to impose more stringent regulations. If a state chooses to shorten the accumulation time, that would be considered more stringent and permissible under RCRA.

h. *Land disposal restrictions.*

Summary of Proposal. EPA proposed that reverse distributors are subject to the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA proposed to amend the testing, tracking, and recordkeeping requirements for generators, treaters and disposal facilities at § 268.7 to add the words, ''pharmaceutical reverse distributors'' to the title of that section to make the applicability of the treatment standards clear.

Summary of Comments. EPA received multiple comments in support of the requirement that reverse distributors meet the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals, including two states.[459] The Oregon Association of Clean Water Agencies wrote that applying the LDRs will reduce mobility of pharmaceutical constituents in landfill leachate, which is frequently routed to POTWs in Oregon.[460]

Final Rule Provisions. As required by HSWA, EPA is finalizing that reverse distributors are subject to the same land disposal restrictions that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA is amending the titles at §§ 268.7 and 268.7(a) to add the words, ''reverse distributors'' to make the applicability of the land disposal restrictions clear. SQG and LQG reverse distributors are already subject to LDRs for their hazardous waste pharmaceuticals. Therefore, this provision does not impose additional burden on reverse distributors.

i. *Reporting.*

Summary of Proposal. EPA proposed that reverse distributors submit a biennial report (BR) for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. The Agency proposed that the BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a reverse distributor sends to another reverse distributor. Specifically, EPA proposed that a reverse distributor comply with the LQG BR requirements in § 262.41, except for § 262.41(a)(7), which included the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. The Agency did not propose that a reverse distributor provide such information because it does not have control of the volume or toxicity of the hazardous waste pharmaceuticals it receives from healthcare facilities, and thus has no ability to reduce the volume or toxicity of the hazardous waste pharmaceuticals.

EPA proposed that reverse distributors provide an exception report when a TSDF does not return the hazardous waste manifest to the reverse distributor for shipments of evaluated hazardous waste pharmaceuticals. Likewise, EPA proposed that reverse distributors meet LQG exception reporting when a shipment from a reverse distributor is rejected by the designated facility and forwarded onto an alternate facility. These proposed standards were adapted from the exception reporting for LQGs in § 262.42(a).

Summary of Comments. One state supported both of the proposed reporting requirements for reverse distributors managing evaluated hazardous waste pharmaceuticals that are transported to a TSDF.[461] RILA argued that the requirement that reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF is effectively more stringent than current generator requirements that only require generators to submit a biennial report if they generate over 1000 kg of hazardous waste in a month.[462]

Final Rule Provisions. EPA is finalizing at § 266.510(c)(9)(i) that reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. The BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a reverse distributor sends to another reverse distributor. EPA does not expect that requiring reverse distributors to submit a BR for evaluated hazardous waste pharmaceuticals will be burdensome because most reverse distributors currently operate as LQGs and already submit a BR.[463] Specifically, under the final rule, reverse distributors must comply with the LQG BR requirements in § 262.41. EPA proposed that reverse distributors had to comply with the LQG BR requirements in § 262.41 except § 262.41(a)(7), which included the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. However, since the proposed rulemaking, the 2016 Hazardous Waste Generator Improvement rule was finalized. As part of that final rule, § 262.41(a)(7) was removed from the generator requirements. Thus, the final rule only states that reverse distributors must

[457] See comment number EPA–HQ–RCRA–2007–0932–0231 in the docket for this rulemaking.

[458] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[459] See comment numbers EPA–HQ–RCRA–2007–0932–0315 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[460] See comment number EPA–HQ–RCRA–2007–0932–0288 in the docket for this rulemaking.

[461] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[462] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[463] See the Regulatory Impact Analysis in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

comply with the LQG BR requirements in § 262.41.

Consistent with the LQG regulations in part 262, EPA is finalizing at § 266.510(c)(9)(ii) that reverse distributors must provide an exception report when a TSDF does not return the signed hazardous waste manifest to the reverse distributor for shipments of hazardous waste pharmaceuticals to a designated facility within 45 days of shipment. Likewise, EPA is finalizing that reverse distributors must provide an exception report when a shipment from a reverse distributor is rejected by the designated facility and forwarded onto an alternate facility and the reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days. These standards were adapted from the exception reporting for LQGs in § 262.42(a), while the standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals were adapted from the exception reporting for SQGs § 262.42(b). EPA is finalizing that a reverse distributor that does not receive a copy of the manifest within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or TSDF to determinate the status of the evaluated hazardous waste pharmaceuticals. EPA is also finalizing that a reverse distributor must submit a copy of an exception report if it has not received a copy of the manifest within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The exception report must include a legible copy of the manifest for which the reverse distributor does not have confirmation of delivery and a cover letter explaining efforts taken to locate the evaluated hazardous waste pharmaceuticals.

j. *Recordkeeping.*

Summary of Proposal. In total, EPA proposed five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at reverse distributors. First, EPA proposed that a reverse distributor keep a log (written or electronic) of its weekly inspections of the on-site accumulation area. The other four recordkeeping requirements that EPA proposed for reverse distributors are the same as the LQG recordkeeping requirements that appear in §§ 262.17(a)(7)(iv) and (v), 262.40, and 262.42; these include training documentation, hazardous waste manifest records, records of biennial reports, and exception reporting.

Summary of Comments. Hennepin County supported the requirement for reverse distributors to document training.[464]

Final Rule Provisions. Many of the final recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals have been discussed in the sections previously, but for clarity, it is useful to restate them in this recordkeeping section, so that reverse distributors can refer to one section to determine their recordkeeping requirements related to evaluated hazardous waste pharmaceuticals. In total, EPA is finalizing five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at reverse distributors that can be found listed at § 266.510(c)(10). First, EPA is requiring that a reverse distributor keep a log (written or electronic) of its inspections of the on-site accumulation area. The other four recordkeeping requirements that EPA is requiring under the final rule for reverse distributors are the same as the LQG recordkeeping requirements in part 262. These include hazardous waste manifest records, records of biennial reports, exception reporting and training documentation.

4. When a Reverse Distributor Must Have a RCRA Hazardous Waste Permit (§ 266.510(d))

a. *Summary of proposal.* In the proposed rulemaking, EPA did not require that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510. However, EPA proposed that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site.

b. *Summary of comments.* One state supported the proposed requirement that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site.[465] Clean Harbors argued that EPA's rationale for not requiring a hazardous waste storage permit is flawed and argued that the requirement for obtaining a full RCRA permit be based on the amount of time a potentially creditable hazardous waste pharmaceutical is stored.[466] The Environmental Technology Council argued that reverse distributors should be required to obtain permits or interim status for storage.[467]

c. *Final rule provisions.* Under the final rule, EPA is not requiring that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510. In other words, a reverse distributor will be subject to regulation as a TSDF and require a RCRA permit (or interim status) if it does not meet the conditions of § 266.510. In addition, EPA is finalizing that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site. A reverse distributor is required to reject shipments of manifested hazardous waste that it may inadvertently receive from off site because a reverse distributor is not a designated facility and therefore is not eligible to receive hazardous waste shipped with a manifest. EPA believes that this approach to regulation of reverse distributors that accumulate potentially creditable and evaluated hazardous waste pharmaceuticals strikes an appropriate balance because it recognizes that reverse distributors are different from typical hazardous waste TSDFs for permitting purposes, while it still imposes certain conditions for exemption from permitting requirements that provide the necessary environmental protection.

XVIII. Amendments to the Part 268 Prohibitions on Storage

The Agency is finalizing conforming changes that we proposed to the prohibitions on storage of restricted waste in § 268.50. We are finalizing two new subparagraphs in § 268.50(a) to make it clear that the storage prohibitions apply to both healthcare facilities and reverse distributors operating under part 266 subpart P. Specifically, we are adding paragraph (4) for healthcare facilities and paragraph (5) for reverse distributors to extend the application of the existing storage prohibition to facilities operating under subpart P. Under the LDR storage prohibition the storage of restricted hazardous wastes is

[464] See comment number EPA–HQ–RCRA–2007–0932–0386 in the docket for this rulemaking.

[465] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[466] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[467] See comment number EPA–HQ–RCRA–2007–0932–0297 in the docket for this rulemaking.

prohibited unless certain conditions are met. Healthcare facilities must comply with the applicable requirements in §§ 266.502 and 266.503 and reverse distributors must comply with § 266.510 when accumulating hazardous waste pharmaceuticals on site.

XIX. Implementation and Enforcement

A. Healthcare Facilities

1. Determining Whether a Healthcare Facility Is Subject to Part 266 Subpart P

EPA is finalizing that healthcare facilities that are currently considered LQGs or SQGs are subject to the final 40 CFR part 266 subpart P requirements for the management of hazardous waste pharmaceuticals. Thus, a healthcare facility that generates more than 100 kg of hazardous waste per month, or more than 1 kg of acute hazardous waste per calendar month, or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute wastes listed in §§ 261.31, or 261.33(e), must manage its hazardous waste pharmaceuticals in compliance with the 40 CFR part 266 subpart P requirements. In addition, healthcare facilities that are VSQGs are subject to the prohibition on sewering hazardous waste pharmaceuticals in § 266.505, the empty container standards in § 266.507, and the optional standards of § 266.504.

To determine whether a healthcare facility is subject to 40 CFR part 266 subpart P or is a VSQG regulated under § 262.14, a healthcare facility must count all the hazardous waste—pharmaceutical and non-pharmaceutical—it generates in a calendar month. Note that in the final rule EPA has revised which pharmaceuticals are considered hazardous wastes. Specifically, EPA is finalizing that potentially creditable hazardous waste pharmaceuticals transported to a reverse distributor are considered a solid and hazardous waste from the point of generation at the healthcare facility and therefore must be counted when determining whether the healthcare facility is a VSQG regulated under § 262.14 or whether it is regulated under 40 CFR part 266 subpart P for its hazardous waste pharmaceuticals. This differs from previous healthcare facility practice of not counting the potentially creditable hazardous waste pharmaceuticals it sends to a reverse distributor towards its hazardous waste generator category. Therefore, although a healthcare facility may have been considered a VSQG under that previous practice, when it begins counting its potentially creditable hazardous waste pharmaceuticals, it may no longer be a VSQG. In that case, the healthcare facility would be subject to the 40 CFR part 266 subpart P requirements for its hazardous waste pharmaceuticals.

2. Healthcare Facilities Managing Hazardous Waste Pharmaceuticals Under Part 266 Subpart P

EPA is finalizing that all healthcare facilities operating Under part 266 subpart P will be subject to the same regulations for the management of their hazardous waste pharmaceuticals, regardless of the quantity of hazardous waste pharmaceuticals generated. A healthcare facility that generates both pharmaceutical and non-pharmaceutical hazardous waste must manage the non-pharmaceutical hazardous waste pursuant to part 262, but need not count its hazardous waste pharmaceuticals toward determining the facility's monthly hazardous waste generator category. Therefore, although a facility that previously may have been considered an LQG, once it no longer counts its hazardous waste pharmaceuticals towards its monthly hazardous waste generator category, it may no longer be an LQG. As a result, it is possible that the healthcare facility may not need to manage its non-pharmaceutical hazardous waste pursuant to the LQG regulations in § 262.17, but rather can operate under the reduced regulations for SQGs in § 262.16 or for VSQGs in § 262.14. In addition, if a healthcare facility that is a VSQG does not want to keep track of the amount of hazardous waste pharmaceuticals it generates to ensure it does not exceed the VSQG quantity limits, it can choose to operate under this final rule. If it chooses to operate under this final rule, however, a healthcare facility must comply with all the requirements of this subpart for the management of its hazardous waste pharmaceuticals.

Following publication of the final rule, EPA plans extensive outreach to educate healthcare facilities and reverse distributors on the provisions of this final rule.

B. Reverse Distributors and Reverse Logistics Centers

1. Prescription Pharmaceuticals Sent to Reverse Distributors Are Solid Wastes

EPA proposed to change how RCRA would apply to pharmaceuticals returned to reverse distributors to obtain manufacturers credit. EPA proposed that the decision by a healthcare facility to send a pharmaceutical to a reverse distributor is the decision to discard the pharmaceutical. Due to many comments on this proposed change, the Agency is now making a clear distinction in the final rule between reverse distribution, in the case of prescription pharmaceuticals, and reverse logistics in the case of all other pharmaceuticals—including over-the counter pharmaceuticals and dietary supplements, as well as other unsold consumer items (see section VI for a discussion of the comments). EPA is finalizing that the decision by a healthcare facility to send a prescription pharmaceutical to a reverse distributor is the decision to discard the prescription pharmaceutical. Therefore, under this final rule, once the healthcare facility makes the decision to send a prescription pharmaceutical to a reverse distributor for credit, it is a solid waste at the healthcare facility. A portion of the potentially creditable solid waste prescription pharmaceuticals at healthcare facilities that are destined for a reverse distributor will also meet the definition of hazardous waste and as a result, these potentially creditable hazardous waste prescription pharmaceuticals would need to be managed in accordance with the final 40 CFR part 266 subpart P requirements.

In addition, the Agency notes that the change in EPA's position concerning reverse distribution and the management standards discussed in this final rule pertain only to the reverse distribution of prescription hazardous waste pharmaceuticals and does not apply to the reverse logistics of other pharmaceuticals or to the reverse logistics systems that may exist for other unsold consumer items.

2. Nonprescription Pharmaceuticals Sent to Reverse Logistics Centers Are Not Solid Wastes

EPA proposed that the decision by a healthcare facility to send any pharmaceutical to a reverse distributor is the decision to discard the pharmaceutical, but is now making a clear distinction in the final rule between reverse distribution of prescription pharmaceuticals and reverse logistics of nonprescription pharmaceuticals and other unsold retail items. In response to comments, EPA is codifying our previous policy that the decision by a healthcare facility to send nonprescription pharmaceuticals to a reverse logistics center is not a decision to discard if the nonprescription pharmaceuticals have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed. In other words, EPA is finalizing that nonprescription pharmaceuticals are not

solid wastes, and therefore not hazardous waste pharmaceuticals if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

3. Reverse Distributors Managing Hazardous Waste Pharmaceuticals Under Part 266 Subpart P

EPA is finalizing that all reverse distributors are subject to 40 CFR part 266 subpart P and will be subject to the same standards with respect to their hazardous waste pharmaceuticals, regardless of the amount of hazardous waste pharmaceuticals they manage. Even reverse distributors that are currently VSQGs will be regulated under 40 CFR part 266 subpart P for the management of their hazardous waste pharmaceuticals. Therefore, a reverse distributor subject to 40 CFR part 266 subpart P will no longer have to keep track of the amount of hazardous waste pharmaceuticals that it generates on a monthly basis.

C. Healthcare Facilities and Reverse Distributors Managing Non-Pharmaceutical Hazardous Waste in Accordance With 40 CFR Part 262 or Part 273 (i.e., Complying With ''More Than One RCRA'')

Most, if not all, healthcare facilities and reverse distributors generate at least some hazardous wastes other than pharmaceuticals. These non-pharmaceutical hazardous wastes will continue to be regulated under 40 CFR part 262 (and other applicable Subtitle C regulations). The standards established by this rulemaking apply only to the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. Healthcare facilities and reverse distributors likely generate or manage other types of hazardous wastes. For example, hospitals may generate non-pharmaceutical hazardous wastes, such as solvents in their diagnostic laboratories; those hazardous wastes must still be managed in accordance with the part 262 generator regulations (such as the RCRA SAA regulations (§ 262.15)), or if it is a teaching hospital, the Academic Laboratories Rule (if it has opted into part 262 subpart K). Retail stores, including pharmacies and grocery stores, may have non-pharmaceutical hazardous wastes on-site as well, which must be managed in accordance with the 40 CFR part 262 regulations and all other applicable RCRA Subtitle C regulations. For example, fluorescent bulbs may be managed under the universal waste program (40 CFR part 273). For reverse distributors, this rule only applies to the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Some reverse distributors may generate other non-pharmaceutical hazardous wastes from activities, such as cleaning and maintenance; other RCRA Subtitle C regulations will apply to those non-pharmaceutical hazardous wastes.

D. State Enforcement Activities and Interpretations

States have taken a variety of approaches regarding hazardous waste pharmaceuticals. One major goal of this final rule is to provide clarity on this topic, and thereby promote national consistency, which should promote better compliance among healthcare facilities, including pharmacies.

In 2012, Connecticut's Department of Energy and Environmental Protection (DEEP) took enforcement actions at seven CVS stores for violations of the RCRA hazardous waste regulations. Consent orders from CT DEEP direct CVS stores in the state to follow a set of best management practices.[468] A number of the practices developed in these consent orders mirror some of the practices EPA is finalizing in this rule, particularly with regard to pharmaceuticals destined for a reverse distributor. CT DEEP asserts RCRA jurisdiction over the pharmaceuticals destined for reverse distributors by applying specific management practices. For example, CVS must maintain records of each shipment of non-dispensable pharmaceuticals to a reverse distributor, including confirmation of receipt of the non-dispensable pharmaceuticals from the receiving reverse distributor. The best practices also include procedures for addressing situations when CVS does not receive delivery confirmation of shipment to a reverse distributor. Further, the consent order sets out separate, more comprehensive practices for the non-dispensable pharmaceuticals that are not suitable for reverse distribution.

Aside from best management practices developed by Connecticut as part of a consent order, at least two other states have developed guidance documents that apply conditions to the management of hazardous wastes pharmaceuticals in exchange for enforcement discretion. In particular, in 2008, the Washington State Department of Ecology issued guidance titled, Interim Enforcement Policy: Pharmaceutical Waste in Healthcare.[469] This interim enforcement discretion policy had some elements in common with this final rule for hazardous waste pharmaceuticals. For instance, a healthcare facility was required to notify the Department of Ecology that it was operating under the policy and had to train its staff involved in pharmaceutical waste management. Only a time limit, rather than a quantity limit, applied to the accumulation of the hazardous waste pharmaceuticals on site. Of particular note is that Washington State prohibited disposing of most hazardous waste pharmaceuticals down the toilet or drain. In anticipation of this final rule, Washington State updated the interim policy in June 2017 to provide regulated facilities with the opportunity to use some of the provisions outlined in the proposed rulemaking, such as allowing facilities to send creditable pharmaceuticals to a reverse distributor for evaluation without providing hazardous waste codes.[470]

In 2011, Minnesota's Pollution Control Agency (MPCA) issued a fact sheet titled Reverse Distribution of Pharmaceuticals: Guidance for Minnesota Healthcare Providers.[471] In this guidance, Minnesota states, ''Whether a pharmaceutical is eligible for return credit does not affect its product or waste status. In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a waste. The MPCA considers health care practitioners and pharmacies to be generators of these pharmaceutical wastes. Nevertheless, the MPCA believes that the established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, it will allow Minnesota health care practitioners and pharmacies to manage certain pharmaceuticals through reverse distribution, subject to additional requirements discussed in this fact sheet.'' This is similar to the approach that EPA is finalizing for potentially creditable hazardous waste pharmaceuticals. For example, like EPA's final rule, MPCA does not require hazardous waste pharmaceuticals destined for a reverse distributor to be

[468] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0173.

[469] See the 2008 interim enforcement policy in the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0181.

[470] See the 2017 interim enforcement policy at *https://fortress.wa.gov/ecy/publications/documents/0704024.pdf* or in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[471] See the guidance document in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932–0178).

counted toward determining a healthcare facility's generator category. In addition, MPCA does not require hazardous waste pharmaceuticals to be accompanied by a hazardous waste manifest when shipped to a reverse distributor. By finalizing a rule that is consistent with state approaches, EPA is bringing national consistency to the management of hazardous waste pharmaceuticals, while avoiding disruption to practices already in place.

E. Intersection of Part 266 Subpart P With the Hazardous Waste Generator Improvements Rule

The Hazardous Waste Generator Improvements rule was finalized on November 28, 2016.[472] This rule finalized a much-needed update to the hazardous waste generator regulations in part 262 to make the rules easier to understand, facilitate better compliance, provide greater flexibility in how hazardous waste is managed and close important gaps in the regulations. This section of preamble discusses three portions of the Hazardous Waste Generator Improvements final rule that might impact healthcare facilities and reverse distributors that are subject to part 266 subpart P.

1. Episodic Generation

One of the key provisions with which EPA added regulatory flexibility allows a hazardous waste generator to avoid increased burden of a higher generator category when generating episodic waste provided the episodic waste is properly managed in accordance with part 262 subpart L. Healthcare facilities and reverse distributors will be able to take advantage of this added regulatory flexibility (assuming their state has adopted this provision).

A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste can use the episodic generation provision of part 262 subpart L for all of its hazardous waste, including its hazardous waste pharmaceuticals. If a healthcare facility is generally operating under § 262.14 as a VSQG, but has an episodic event, it would be far less burdensome to comply with part 262 subpart L than to come into compliance with all the provisions of part 266 subpart P for the short duration of the episodic event. For example, if a VSQG healthcare facility is directed to dispose of recalled pharmaceuticals, it could use the episodic generator provisions of part 262 subpart L to avoid an increase in hazardous waste generator category. However, if a healthcare facility that is a VSQG generates hazardous waste in excess of the allowable amounts as a VSQG,[473] and it chooses not to use the episodic generator provisions in part 262 subpart L, it would become subject to part 266 subpart P for its hazardous waste pharmaceuticals.

As discussed previously, healthcare facilities and reverse distributors that are subject to part 266 subpart P for their hazardous waste pharmaceuticals may still be subject to part 262 for the management of their non-pharmaceutical hazardous waste. A healthcare facility or reverse distributor operating under part 266 subpart P for its hazardous waste pharmaceuticals may not use the episodic generator standards of part 262 subpart L with respect to its hazardous waste pharmaceuticals. Under part 266 subpart P, all healthcare facilities are regulated the same regardless of amounts of hazardous waste pharmaceuticals generated and all reverse distributors are regulated the same, regardless of amounts of hazardous waste pharmaceuticals managed, making the need for episodic generation provisions unnecessary. On the other hand, if a healthcare facility or reverse distributor is generally operating as a VSQG or SQG for its non-pharmaceutical hazardous waste, but has an episodic event, the healthcare facility may use the provisions in part 262 subpart L for its non-pharmaceutical hazardous waste.

2. Small Quantity Generator Re-Notification

The 2016 Hazardous Waste Generator Improvements final rule added a new requirement for periodic re-notification by SQGs.[474] Under this new provision, SQGs must re-notify EPA starting in 2021 and every four years thereafter using EPA Form 8700–12. This re-notification must be submitted by September 1st of each year in which re-notifications are required.[475] Healthcare facilities and reverse distributors operating under part 266 subpart P may also be subject to part 262 for the management of its non-pharmaceutical hazardous waste. If a healthcare facility or reverse distributor is an SQG for its non-pharmaceutical hazardous waste, then it will be subject to this re-notification requirement under part 262. Therefore, in order to avoid duplicative notification requirements, under part 266 subpart P, EPA is not requiring re-notification by healthcare facilities and reverse distributors.

3. Very Small Quantity Generators That Accumulate More Than 1 Kg of Acute Hazardous Waste

The 2016 Hazardous Waste Generator Improvements final rule clarified in § 262.14(a)(3) that if a VSQG accumulates at any time greater than 1 kg of acute hazardous waste,[476] all quantities of that acute hazardous waste are subject to the additional conditions for exemption for LQGs. More specifically, the acute hazardous waste must be held on site for no more than 90 days beginning on the date when more than 1 kg is exceeded, and the acute hazardous waste is subject to the LQG conditions for exemption in § 262.17(a) through (g). In other words, while the acute hazardous waste becomes subject to the stricter standards for LQGs when the accumulation limits are exceeded, the generator continues to be considered a VSQG, provided the generator continues to generate within the VSQG thresholds identified in the definition of VSQG in § 260.10.

If a healthcare facility that is a VSQG accumulates more than 1 kg of acute hazardous waste,[477] then it will remain subject to § 262.14(a)(3); the healthcare facility will not become subject to part 262 subpart P.

XX. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize states to administer the RCRA Subtitle C hazardous waste program. Following authorization, the authorized state program operates in lieu of the federal regulations. EPA retains authority to enforce the authorized state Subtitle C program, although authorized states have primary enforcement authority. EPA also retains its authority under RCRA sections 3007, 3008, 3013, and 7003. The standards and requirements for state authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a state with final RCRA authorization administered its hazardous waste program entirely in

[472] See November 28, 2016; 81 FR 85732.

[473] See the definition of very small quantity generator in 40 CFR 2601.10.

[474] See 40 CFR 262.18(d)(1).

[475] See 81 FR 85777–8; November 28, 2016 for the preamble discussion explaining the need for re-notification.

[476] Or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or 261.33(e).

[477] Or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or 261.33(e).

lieu of EPA administering the federal program in that state. EPA did not issue permits for any facilities in that state, since the state was now authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the state was obligated to enact equivalent authorities within specified time frames. However, the new requirements did not take effect in an authorized state until the state adopted the equivalent state requirements.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized states at the same time that they take effect in unauthorized states. While states must still adopt HSWA-related provisions as state law to retain authorization, EPA implements the HSWA provisions in authorized states, including the issuance of any permits pertaining to HSWA requirements, until the state is granted authorization to do so.

Authorized states are required to modify their programs only when EPA promulgates federal requirements that are more stringent or broader in scope than existing federal requirements.[478] RCRA section 3009 allows the states to impose standards more stringent than those in the federal program (see 40 CFR 271.1). Therefore, authorized states may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

B. Effect on State Authorization

This action adds a new subpart P to 40 CFR part 266, and it is being finalized in part under the authority of HSWA and in part under non-HSWA authority. The bulk of 40 CFR part 266 subpart P is being finalized under non-HSWA authority. Thus, the amendments promulgated under non-HSWA authority are applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. Only the prohibition of sewering hazardous waste pharmaceuticals (§ 266.504) is being finalized under HSWA authority in section 3018 of RCRA. The amendments promulgated under the authority of HSWA (*i.e.,* the prohibition on sewering hazardous waste pharmaceuticals) are applicable on the effective date of the final rule in all states. Moreover, authorized states are required to modify their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. For those changes that are less stringent, states are not required to modify their programs.

While some provisions of part 266 subpart P are considered less stringent than the current federal standards, other provisions of the final rule are considered more stringent than the current federal standards. Taken as a whole, we consider the entire new subpart P under 40 CFR part 266 entitled ''Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities'' (sections VIII–XVII of this preamble) to be more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt these revisions. When a state adopts this new subpart, if elements of the state program are more stringent than this new subpart, the state has the option of retaining those more stringent elements. Likewise, when a state adopts this new subpart, the state has the option of adding elements that are more stringent or broader in scope than this new subpart.

On the other hand, one final revision is less stringent than the current hazardous waste regulations. The amendment to exempt from the P075 listing the nicotine patches, gums and lozenges that are FDA-approved OTC nicotine replacement therapies is less stringent that the current hazardous waste regulations (section V of this preamble). Thus, authorized states may, but are not required to, adopt the change to the P075 listing.

C. Effect on State Authorization in States That Have Added Pharmaceuticals to the Universal Waste Program

The Universal Waste program allows states to add waste streams to their own state program, even when the waste stream has not been added to the federal Universal Waste program, provided the state has adopted and been authorized for the petition process in §§ 260.20 and 260.23. Two states have added hazardous waste pharmaceuticals to their Universal Waste programs: Florida and Michigan. Because the added subpart P under CFR part 266 is considered more stringent than either the ''traditional RCRA'' standards or the Universal Waste program, both Florida and Michigan will be required to modify their programs to adopt an approach at least as stringent as the amendments. Furthermore, because the Agency has determined that it is not appropriate to add hazardous waste pharmaceuticals to the Universal Waste program, both Florida and Michigan must remove hazardous waste pharmaceuticals from their Universal Waste program when they adopt this new subpart, although they may continue to regulate non-hazardous waste pharmaceuticals under the Universal Waste program, to the extent allowed under state law. In addition, states may choose to add non-hazardous waste pharmaceuticals to their Universal Waste program or may regulate them more stringently as part of their hazardous waste program but states may not add hazardous waste pharmaceuticals to their Universal Waste program in the future. Accordingly, we have amended the regulations in § 273.80(a) and added § 273.80(d) to reflect this decision that states may not add hazardous waste pharmaceuticals to their Universal Waste program.

XXI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Pursuant to the terms of Executive Order 12866, as affirmed in Executive Order 13563, the Agency has determined that this rule is a significant regulatory action because it contains novel policy issues, as defined under section 3(f)(4) of the Order. Any changes made in response to OMB recommendations have been documented in the docket.

As discussed in section I above, EPA prepared an economic analysis of the potential costs and benefits associated with this action. This analysis, *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals,* indicates that the rule is projected to result in net annual cost savings of approximately $12.99 million to $14.96 million based on a discount rate of 7 percent or $12.98 to $14.95 million based on a discount rate of 3 percent. The full analysis is available in the docket for this rule.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory

[478] EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes a state program for a particular rule.

action. Details on the estimated cost savings of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 2486.02, OMB control number 0250–0212. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

EPA is finalizing in this rule, under a new subpart P to 40 CFR part 266, new and revised reporting and recordkeeping requirements for healthcare facilities and reverse distributors. These requirements, which are also identified in the ICR supporting this action, will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals. In addition, the requirements include provisions for tracking of hazardous waste pharmaceuticals that are sent to reverse distributors.

EPA will use the collected information to ensure that hazardous waste pharmaceuticals are being managed in a protective manner. The tracking requirements ensure that these wastes arrive at their intended destinations rather than diverted for illicit purposes or managed at facilities not equipped to manage these wastes. These tracking requirements will also help facilities identify shipments that do not arrive at their destination as planned, allowing generators to take corrective action that will ensure that future shipments are transported to the appropriate location. Information marked on containers of hazardous waste pharmaceuticals will assist handlers and transporters in ensuring proper management during storage and shipment.

Respondents/affected entities: Drug wholesalers, supermarkets and other grocery stores, pharmacies and drug stores, warehouse clubs and supercenters, veterinary clinics, physicians' offices, dentists' offices, other health practitioners, outpatient care centers, other ambulatory health care services, hospitals, nursing care facilities, continuing care retirement communities, and reverse distributors.

Respondent's obligation to respond: The recordkeeping and notification requirements are mandatory and are being promulgated under section 3001 of RCRA.

Estimated number of respondents: 13,373.

Frequency of response: The frequency of response varies.

Total estimated burden: EPA estimated the total annual burden to respondents to be approximately 43,577 hours. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: EPA estimated the total estimated annual cost of this paperwork burden to respondents to be approximately $2,543,409.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. As documented in the Regulatory Impact Analysis found in the docket for this proposal, EPA does not expect the rule to result in an adverse impact to a significant number of small entities. EPA estimates that there are at least 10,481 to 15,114 small entities that will be impacted by this rule. However, small entities are expected to experience a net cost savings under the final rule, and for the small entities that are expected to experience a net cost under the final rule, the RIA estimates the costs, at most, to represent 0.013 percent of annual revenues for small entities. We have therefore concluded that this action will either relieve regulatory burden or have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As indicated previously, the annual net cost savings is estimated to be between approximately $13 million and $15 million (based on a discount rate of 7%). Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. While some hospitals are publicly owned, the requirements affecting those facilities are not unique in that they are the same as those affecting all facilities in the proposed rulemaking. Also, using data on revenues of hospitals owned by state and local governments, EPA estimated that the costs of the rule borne by state and local governments represent less than 0.001% of their revenues. Therefore, the costs incurred by small governments are not expected to be significant.

F. Executive Order 13132: Federalism

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation With Tribal Governments

This action may have tribal implications as specified in Executive Order 13175. The final rule will neither impose substantial direct compliance costs on tribal government, not preempt tribal law. Under the RCRA statute, the federal government implements hazardous waste regulations directly in Indian Country. Thus, the final rule would not impose any direct costs on tribal governments.

To assess the potential tribal implications of the action, EPA compiled data on the number of tribally run healthcare facilities in the U.S. and estimated the costs of this action for these facilities. As documented in the Regulatory Impact Analysis in the docket for this rule, the rule is not expected to impose a substantial burden on tribal governments.

EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its

development. A summary of that consultation is provided in the docket for this rule (see EPA–HQ–RCRA–2008–0932).

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

H. Executive Order 13045: Children's Health

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the EPA does not believe the environmental health or safety risks addressed by this proposed action present a disproportionate risk to children. This action's health and risk assessments are contained in the *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals,* found in the docket for this action.

I. Executive Order 13211: Energy Supply

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. The final rule does not directly regulate energy production or consumption. Changes in the management of hazardous waste pharmaceuticals stipulated in this action are not expected to impact energy production or distribution and will have minimal impact on energy consumptions.

J. National Technology Transfer and Advancement Act

This final rulemaking does not involve technical standards.

K. Executive Order 12898: Environmental Justice

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the Regulatory Impact Analysis, which can be found at regulations.gov under docket number EPA–HQ–RCRA–2007–0932.

To meet the requirements of Executive Order 12898, EPA analyzed potential environmental justice impacts associated with the diversion of hazardous waste pharmaceuticals from sewer disposal to hazardous waste combustion facilities. Populations living near and downstream from wastewater treatment plants may also benefit from the elimination of sewering of hazardous waste pharmaceuticals. To the extent that minority and/or low-income populations near or downstream from wastewater treatment plants make up a disproportionately high portion of the overall population, this final action may result in positive environmental justice impacts.

Overall, EPA expects that this action may positively affect U.S. environmental justice populations, although the size of the impact will vary by wastewater treatment plant. A reduction in sewering expected under the final rule may benefit relatively large minority and low-income populations in close proximity to or downstream from wastewater treatment plants. The diversion of hazardous waste pharmaceuticals from wastewater treatment plants to combustion facilities, however, may increase the environmental burden borne by environmental justice populations near these combustion facilities. Although these effects offset each other to a certain degree, the number of minority and low-income individuals near wastewater treatment facilities exceeds the number near hazardous waste combustion facilities. This suggests that, on the whole, the final action may benefit environmental justice populations.

L. Congressional Review Act

EPA will submit a report containing this rule and other information required by the Congressional Review Act (5 U.S.C. 801 *et seq.*) to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until sixty (60) days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This final authorization will be effective August 22, 2019.

List of Subjects

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 264

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 266

Environmental protection, Energy, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 270

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: December 11, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons stated in the preamble, Title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 2. Section 261.4 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 261.4 Exclusions.

(a) * * *

(1) * * *

(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, except as prohibited by § 266.505 and Clean Water Act requirements at 40 CFR 403.5(b). ''Domestic sewage'' means

untreated sanitary wastes that pass through a sewer system.

* * * * *

■ 3. Section 261.7 is amended by adding paragraph (c) to read as follows:

§ 261.7 Residues of hazardous waste in empty containers.

* * * * *

(c) Containers of hazardous waste pharmaceuticals are subject to § 266.507 for determining when they are considered empty, in lieu of this section, except as provided by § 266.507(c) and (d).

■ 4. Section 261.33 is amended by:

■ a. Revising paragraph (c); and

■ b. Revising the four entries for ''P075'' in the table in paragraph (e).

The revisions read as follows:

§ 261.33 Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof.

* * * * *

(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is empty as defined in § 261.7(b) or § 266.507 of this chapter.

[*Comment:* Unless the residue is being beneficially used or reused, or legitimately recycled or reclaimed; or being accumulated, stored, transported or treated prior to such use, re-use, recycling or reclamation, EPA considers the residue to be intended for discard, and thus, a hazardous waste. An example of a legitimate re-use of the residue would be where the residue remains in the container and the container is used to hold the same commercial chemical product or manufacturing chemical intermediate it previously held. An example of the discard of the residue would be where the drum is sent to a drum reconditioner who reconditions the drum but discards the residue.]

* * * * *

(e) * * *

Hazardous waste No.	Chemical abstracts No.	Substance
*	*	* * * * *
P075	[1] 54–11–5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * *
P075	[1] 54–11–5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * *
P075	[1] 54–11–5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * *
P075	[1] 54–11–5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * *

* * * * *

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 5. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, 6938, and 6939g.

■ 6. Section 262.10 is amended by adding paragraphs (m) and (n) to read as follows:

§ 262.10 Purpose, scope and applicability.

* * * * *

(m) All reverse distributors (as defined in § 266.500) are subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

(n) Each healthcare facility (as defined in § 266.500) must determine whether it is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste). A healthcare facility that generates more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in § 261.31 or § 261.33(e), is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part. A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to part 266 subpart P, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

■ 7. Section 262.13 is amended by adding paragraph (c)(9) to read as follows:

[1] CAS Number given for parent compound only.

§ 262.13 Generator category determination.

* * * * *

(c) * * *

(9) Is a hazardous waste pharmaceutical, as defined in § 266.500, that is subject to or managed in accordance with 40 CFR part 266 subpart P or is a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under § 266.506.

* * * * *

■ 8. Section 262.14 is amended by adding paragraphs (a)(5)(ix) and (x) to read as follows:

§ 262.14 Conditions for exemption for a very small quantity generator.

(a) * * *

(5) * * *

(ix) A reverse distributor (as defined in § 266.500), if the hazardous waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical generated by a healthcare facility (as defined in § 266.500).

(x) A healthcare facility (as defined in § 266.500) that meets the conditions in §§ 266.502(l) and 266.503(b), as applicable, to accept non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.

* * * * *

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 9. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6939g.

■ 10. Section 264.1 is amended by adding paragraph (g)(13) to read as follows:

§ 264.1 Purpose, scope and applicability.

* * * * *

(g) * * *

(13) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

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PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 11. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, 6937, and 6939g.

■ 12. Section 265.1 is amended by adding paragraph (c)(16) to read as follows:

§ 265.1 Purpose, scope, and applicability.

* * * * *

(c) * * *

(16) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

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PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

■ 13. The authority citation for part 266 continues to read as follows:

Authority: 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 3017, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

Subpart O—[Reserved]

■ 14. Add reserved subpart O.

■ 15. Add subpart P, consisting of §§ 266.500 through 266.510, to read as follows:

Subpart P—Hazardous Waste Pharmaceuticals

Sec.

Subpart P—Hazardous Waste Pharmaceuticals

§ 266.500 Definitions for this subpart.

The following definitions apply to this subpart:

Evaluated hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

Hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (*e.g.,* lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

Healthcare facility means any person that is lawfully authorized to—

(1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Household waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).

Long-term care facility means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

Non-creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

Non-pharmaceutical hazardous waste means a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical, as defined in this section.

Pharmaceutical means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (*e.g.,* electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (*e.g.,* pre-filled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

Potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is—

(1) In original manufacturer packaging (except pharmaceuticals that were subject to a recall);

(2) Undispensed; and

(3) Unexpired or less than one year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

Reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

§ 266.501 Applicability.

(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is *not* subject to this subpart, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with § 266.501(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with § 262.14 and the optional provisions of § 266.504.

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in paragraph (a) of this section, a healthcare facility is subject to the following in lieu of parts 262 through 265:

(1) Sections 266.502 and 266.505 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

(2) Sections 262.502(a), 266.503, 266.505 through 266.507, and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to §§ 266.505 through 266.510 of this subpart in lieu of parts 262 through 265 with respect to the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (*e.g.,* pharmaceutical manufacturers and reverse logistics centers) are not subject to this subpart. Other generators are subject to 40 CFR part 262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) The following are not subject to 40 CFR parts 260 through 273, except as specified:

(1) Pharmaceuticals that are not solid waste, as defined by § 261.2, because they are legitimately used/reused (*e.g.,* lawfully donated for their intended purpose) or reclaimed.

(2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as

defined by § 261.2, because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

(3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 subpart C. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(5) Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.

(6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. This subpart does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

(7) Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in §§ 266.506(a)(2) and 266.506(b).

§ 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

(a) *Notification and withdrawal from this subpart for healthcare facilities managing hazardous waste pharmaceuticals*—(1) *Notification.* A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA identification number.

(i) A healthcare facility that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) *Withdrawal.* A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a very small quantity generator under § 262.14, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA Form 8700–12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA identification number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of § 262.14.

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) *Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) *Hazardous waste determination for non-creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (*i.e.,* it exhibits a characteristic identified in 40 CFR part 261 subpart C or is listed in 40 CFR part 261 subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this subpart.

(d) *Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) must be accumulated in separate containers and

labeled with all applicable hazardous waste numbers (*i.e.,* hazardous waste codes).

(e) *Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase ''Hazardous Waste Pharmaceuticals.''

(f) *Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) *Land disposal restrictions for non-creditable hazardous waste pharmaceuticals.* The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 40 CFR part 268. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (*i.e.,* hazardous waste codes) on the land disposal restrictions notification.

(h) *Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals.* A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter may accumulate the returned non-creditable hazardous waste pharmaceuticals on site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(i) *Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals*—(1) *Biennial reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) *Exception reporting by healthcare facilities for a missing copy of the manifest*—(i) *For shipments from a healthcare facility to a designated facility.* (A) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(ii) *For shipments rejected by the designated facility and shipped to an alternate facility.* (A) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(3) *Additional reports.* The EPA Regional Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) *Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.* (1) A healthcare facility must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with § 262.11(f), for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages all of its non-creditable non-hazardous waste pharmaceuticals as

non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(5) All records must be readily available upon request by an inspector.

(k) *Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this subpart.

(l) *Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.* A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person (as defined in § 260.10) as the very small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site (''control,'' for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person as defined in § 260.10 of this chapter shall not be deemed to ''control'' such healthcare facilities) or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) *Hazardous waste determination for potentially creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.,* it is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subpart.

(b) *Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.* A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

(c) *Prohibition.* Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) *Biennial Reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(e) *Recordkeeping by healthcare facilities.* (1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(i) The confirmation of delivery; and

(ii) The shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(3) All records must be readily available upon request by an inspector.

(f) *Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this subpart.

§ 266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

(a) *Potentially creditable hazardous waste pharmaceuticals.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) The receiving healthcare facility meets the conditions in § 266.502(l) of this subpart and § 266.503(b), as applicable; or

(2) The very small quantity generator healthcare facility meets the conditions in § 262.14(a)(5)(viii) and the receiving large quantity generator meets the conditions in § 262.17(f).

(c) *Long-term care facilities that are very small quantity generators.* A long-

term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(d) *Long-term care facilities with 20 beds or fewer.* A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to § 262.14 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and *not* subject to this subpart, except for §§ 266.505 and 266.507 and the other optional provisions of this section. The EPA Regional Administrator has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in § 260.10. A long-term care facility with more than 20 beds that operates as a very small quantity generator under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by § 260.10.

§ 266.505 Prohibition of sewering hazardous waste pharmaceuticals.

All healthcare facilities—including very small quantity generators operating under § 262.14 in lieu of this subpart—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).

§ 266.506 Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.

(a) *Conditional exemptions.* Provided the conditions of paragraph (b) of this section are met, the following are exempt from 40 CFR parts 262 through 273:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) *Conditions for exemption.* The hazardous waste pharmaceuticals must be:

(1) Managed in compliance with the sewer prohibition of § 266.505; and

(2) Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

(3) Destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(i) A permitted large municipal waste combustor, subject to 40 CFR part 62 subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR part 60 subparts Eb for new large municipal waste combustors; or

(ii) A permitted small municipal waste combustor, subject to 40 CFR part 62 subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR part 60 subparts AAAA for new small municipal waste combustors; or

(iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62 subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60 subpart Ec for new hospital, medical and infectious waste incinerators.

(iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62 subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR part 60 subpart CCCC for new commercial and industrial solid waste incinerators.

(v) A permitted hazardous waste combustor subject to 40 CFR part 63 subpart EEE.

§ 266.507 Residues of hazardous waste pharmaceuticals in empty containers.

(a) *Stock, dispensing and unit-dose containers.* A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) *Syringes.* A syringe is considered empty and the residues are not regulated as hazardous waste under this subpart provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) *Intravenous (IV) bags.* An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1).

(d) *Other containers, including delivery devices.* Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subpart, unless the container held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1) or (2). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

(a) *Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-

site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) *Packaging.* Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) *Labeling.* Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172 subpart E.

(iii) *Marking.* (A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation (DOT) regulations on hazardous materials under 49 CFR part 172 subpart D;

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse distributor's Name and Address _____

Healthcare Facility's or Reverse distributor's EPA Identification Number _____

Manifest Tracking Number _____

(C) Lab packs that will be incinerated in compliance with § 268.42(c) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(iv) *Placarding.* Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172 subpart F.

(2) The manifest requirements of 40 CFR part 262 subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (*i.e.,* hazardous waste codes) in Item 13 of EPA Form 8700–22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word ''PHARMS'' in Item 13 of EPA Form 8700–22.

(b) *Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H.

(c) *Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off site.

§ 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.

(a) *Shipping potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8. For purposes of the Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the U.S. Environmental Protection Agency specified in 40 CFR part 262. Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

(b) *Delivery confirmation.* Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) *Procedures for when delivery confirmation is not received within 35 calendar days.* If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (*i.e.,* the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) *Exporting potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of 40 CFR part 262 subpart H, except the manifesting requirement of § 262.83(c), in addition to paragraphs (a) through (c) of this section.

(e) *Importing potentially creditable hazardous waste pharmaceuticals.* Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of 40 CFR part 262 subpart H. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this subpart.

§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that it complies with the following conditions:

(a) *Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals*—(1) *Notification.* A reverse distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse distributor operating under this subpart.

(i) A reverse distributor that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse

distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(2) *Inventory by the reverse distributor.* A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on site.

(i) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of each waste arriving at the reverse distributor.

(ii) The inventory must include the identity (*e.g.,* name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(iii) If the reverse distributor already meets the inventory requirements of this paragraph because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory pursuant to this section.

(3) *Evaluation by a reverse distributor that is not a manufacturer.* A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a ''potentially creditable hazardous waste pharmaceutical'' and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an ''evaluated hazardous waste pharmaceutical'' and must be managed in accordance with paragraph (c) of this section.

(4) *Evaluation by a reverse distributor that is a manufacturer.* A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section.

(5) *Maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor.* (i) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 calendar days or less. The 180 days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether they are destined for another reverse distributor (*i.e.,* potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (*i.e.,* evaluated hazardous waste pharmaceuticals).

(ii) *Aging pharmaceuticals.* Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (*i.e.,* aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with paragraph (a) of this section and the container labeling and management standards in 266.510(c)(4)(i) through (vi).

(6) *Security at the reverse distributor facility.* A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(A) A 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) A means to control entry, such as keycard access.

(ii) If the reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration or State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to this section.

(7) *Contingency plan and emergency procedures at a reverse distributor.* A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must prepare a contingency plan and comply with the other requirements of 40 CFR part 262 subpart M.

(8) *Closure of a reverse distributor.* When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with § 262.17(a)(8)(ii) and (iii).

(9) *Reporting by a reverse distributor*—(i) *Unauthorized waste report.* A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (*e.g.,* non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the EPA Regional Administrator within 45 calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the reverse distributor;

(B) The date the reverse distributor received the unauthorized waste;

(C) The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(D) A description and the quantity of each unauthorized waste the reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) *Additional reports.* The EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(10) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date the shipment arrives at the reverse distributor;

(iii) A copy of its current inventory for as long as the facility is subject to this subpart.

(b) *Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with § 266.509.

(4) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(i) The confirmation of delivery; and

(ii) The DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable

(c) *Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) *Accumulation area at the reverse distributor.* A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) *Inspections of on-site accumulation area.* A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) *Personnel training at a reverse distributor.* Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of § 262.17(a)(7).

(4) *Labeling and management of containers at on-site accumulation areas.* A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, ''hazardous waste pharmaceuticals'';

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) (*e.g.,* arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) *Hazardous waste numbers.* Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (*i.e.,* hazardous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(6) *Shipments.* A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b).

(7) *Procedures for a reverse distributor for managing rejected shipments.* A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned evaluated hazardous waste pharmaceuticals on

site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with § 266.510(a) and (c). Upon receipt of the returned shipment, the reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(iv) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of § 266.508(a) or (b).

(8) *Land disposal restrictions.* Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 40 CFR part 268. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must comply with the land disposal restrictions in accordance with § 268.7(a) requirements.

(9) *Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals*—(i) *Biennial reporting by a reverse distributor.* A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with § 262.41.

(ii) *Exception reporting by a reverse distributor for a missing copy of the manifest.*

(A) *For shipments from a reverse distributor to a designated facility.* (*1*) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(*2*) A reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(*i*) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B*) For shipments rejected by the designated facility and shipped to an alternate facility.* (*1*) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(*2*) A reverse distributor must submit an Exception Report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 45-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The Exception Report must include:

(*i*) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) *Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

(ii) A reverse distributor must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A reverse distributor must keep records to document personnel training, in accordance with § 262.17(a)(7)(iv).

(vi) All records must be readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(d) *When a reverse distributor must have a permit.* A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of 40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270, if the reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off site; or

(3) Treats or disposes of hazardous waste pharmaceuticals on site.

PART 268—LAND DISPOSAL RESTRICTIONS

■ 16. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

■ 17. Section 268.7 is amended by revising the section heading and the paragraph (a) subject heading to read as follows:

§ 268.7 Testing, tracking, and recordkeeping requirements for generators, reverse distributors, treaters, and disposal facilities.

(a) *Requirements for generators and reverse distributors.* * * *

* * * * *

■ 18. Section 268.50 is amended by adding paragraphs (a)(4) and (5) to read as follows:

§ 268.50 Prohibitions on storage of restricted wastes.

(a) * * *

(4) A healthcare facility accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the applicable requirements in §§ 266.502 and 266.503 of this chapter.

(5) A reverse distributor accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the reverse distributor complies with § 266.510 of this chapter.

* * * * *

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

■ 19. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

■ 20. Section 270.1 is amended by adding paragraph (c)(2)(x) to read as follows:

§ 270.1 Purpose and scope of these regulations.

* * * * *

(c) * * *

(2) * * *

(x) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

* * * * *

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

■ 21. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

■ 22. Section 273.80 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 273.80 General.

(a) Except as provided in paragraph (d) of this section, any person seeking to add a hazardous waste or category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 40 CFR 260.20 and 260.23.

* * * * *

(d) Hazardous waste pharmaceuticals are regulated by 40 CFR part 266 subpart P and may not be added as a category of hazardous waste for management under this part.

[FR Doc. 2019–01298 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

WASTE MANAGEMENT AND RADIATION CONTROL BOARD
Executive Summary
REQUEST FOR A SITE-SPECIFIC TREATMENT VARIANCE
Energy*Solutions* LLC
July 9, 2020

What is the issue before the Board?	On April 29, 2020, Energy*Solutions* LLC submitted a request for a site-specific treatment variance from the Utah Hazardous Waste Management Rules to dispose of waste containing hazardous constituents and PCBs as Underlying Hazardous Constituents.
What is the historical background or context for this issue?	EnergySolutions requests approval to dispose of waste that has been chemically treated to meet regulatory treatment standards for all contaminants except PCBs. This request is for approximately 1,000 cubic feet from Energy*Solutions* generator 9105, waste streams 9105-08 and 9105-09. The waste consists of non-liquid characteristically hazardous soils and sludges that are also contaminated with PCB remediation waste at concentrations exceeding the UTS for PCBs. Treatment standards in R315-268-40 (40 CFR 268.40, 2015 Edition, incorporated by reference) require waste containing characteristic codes be treated to applicable UTS for their specific constituents and for all Underlying Hazardous Constituents (UHCs) listed in R315-268-48. The UTS for the PCBs UHC is 10 mg/kg. Therefore, these regulations require PCBs within waste that is characteristically hazardous be treated to less than 10 mg/kg prior to disposal. Further, the Environmental Protection Agency (EPA) has clarified the disposal of PCB remediation waste in the Toxic Substance Control Act (TSCA) regulations at 40 CFR 761. Disposal criteria for PCB remediation waste is specifically described in 40 CFR 761.61(a)(5)(i)(B)(2)(iii) as follows: "Bulk PCB remediation wastes with a PCB concentration ≥50 ppm shall be disposed of in a hazardous waste landfill permitted by EPA under section 3004 of RCRA, or by a State authorized under section 3006 of RCRA, or a PCB disposal facility approved under this part."

	The MWLC is a permitted hazardous waste landfill permitted by the State of Utah. Consequently, if the PCB waste did not contain RCRA hazardous waste codes, but contained the same PCB concentrations, it could be disposed in the MWLC without additional treatment. Therefore, treatment of the PCBs within this waste stream is technically inappropriate and not required for final disposal of the waste form. A notice for public comment was published in the *Salt Lake Tribune*, the *Deseret Morning News* and the *Tooele County Transcript Bulletin* on May 12, 2020. The comment period began May 13, 2020 and ended June 12, 2020. No comments were received.
What is the governing statutory or regulatory citation?	Variances are provided for in 19-6-111 of the Utah Solid and Hazardous Waste Act. This is a one-time site-specific variance from an applicable treatment standard as allowed by R315-268.44 of the Utah Administrative Code.
Is Board action required?	Yes, this is an action item before the Board.
What is the Division/Director's recommendation?	The Director recommends approval of this variance request. The Director's recommendation is based on the following findings: the proposed alternative treatment method meets the regulatory basis for a variance and will be as safe to human health and the environment as the required method.
Where can more information be obtained?	For technical questions, please contact Otis Willoughby at (801) 536-0220. For legal questions, please contact Bret Randall at (801) 536-0284.

WASTE MANAGEMENT AND RADIATION CONTROL BOARD

Executive Summary

Tooele Army Depot South Area (TEAD-S)

July 9, 2020

What is the issue before the Board?	A Stipulation and Consent Order (SCO), No. 2001003, to resolve Notice of Violation (NOV) No. 1911117, was issued to the TEAD-S on November 26, 2019.
What is the historical background or context for this issue?	The NOV was based on information documented during an inspection at the facility on August 6-7, 2019, and a self-reported notice of non-compliance submitted on August 27, 2019. TEAD-S had discontinued open detonation operations for several years while they were destroying the chemical agent stockpile. They received authorization to begin open detonation operations again on October 9, 2018. The violations included failing to calculate potential emission levels for detonations on several days. When the calculations were done, it showed that they had exceeded the emission limit for nickel on seventeen days. The violations have been resolved. A proposed SCO was brought before the Board as an informational item during the public comment period on March 12, 2020. It included a penalty of $25,662. During the comment period, TEAD-S submitted a comment indicating that they had used the wrong munition in calculating the emission limits. Therefore, although they had violated the permit by not calculating the emissions prior to the detonations, they did not exceed the nickel emission limits. As a result, TEAD-S requested a reduction in penalty. Based on the new information, a revised penalty of $7,753 has been calculated and agreed upon. A new public comment period is being conducted for the revised SCO.
What is the governing statutory or regulatory citation?	§ 19-6-107(3)(a) of the Utah Solid and Hazardous Waste Act authorizes the Director to issue orders and approve or disapprove settlements with a civil penalty under $25,000.
Is Board action required?	No. This is an informational item only. The SCO will not require approval by the Board.
What is the Division Director's recommendation?	N/A
Where can more information be obtained?	For technical information, please contact Rick Page at (801) 536-0230. For legal information, please contact Connie Nakahara at (801) 536-0285

WASTE MANAGEMENT AND RADIATION CONTROL BOARD
Executive Summary
Thermo Fluids Inc.
Proposed Stipulation and Consent Order No. 1909097
July 9, 2020

What is the issue before the Board?	Proposed Stipulation and Consent Order (SCO), No. 1909097, issued to the Thermo Fluids Inc. (TFI), a used oil processor and used oil marketer located at 3545 West 500 South in Salt Lake City, Utah. This SCO was issued to resolve the TFI's Notice of Violation and Compliance Order (NOV/CO) No. 1909088.
What is the historical background or context for this issue?	The Division documented compliance issues during inspections conducted at TFI on May 1, 2, and May 9 of 2019. The Division issued TFI a NOV/CO on November 19, 2019, based on these compliance issues. TFI failed to comply with regulatory requirements of TFI's Used Oil Processor Permit, Used Oil Marketer Registration, the Utah Used Oil Management Act, and the Utah Solid and Hazardous Waste Act when conducting used oil operations. TFI has since resolved these specific violations and returned to compliance. The SCO includes a monetary penalty of $42,906.00.
What is the governing statutory or regulatory citation?	Utah Code §19-6-104(1)(e) authorizes the Board to review and approve or disapprove settlements negotiated by the Director with a civil penalty over $25,000.
Is Board action required?	No, this is an informational item only. A 30-day public comment period began on May 27, 2020 and ended on June 26, 2020.
What is the Division Director's recommendation?	N/A
Where can additional information be found?	For technical information contact, Michelle Weis at (801) 536-0256. For legal information contact, Paul McConkie at (801) 536-0288.

DSHW-2020-007466
Attachments: Proposed Stipulation and Consent Order (DSHW-2020-003162)
Narrative Explanation (DSHW-2020-002942)
Notice of Violation Number 1909088 (DSHW-2019-010922)

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In the Matter of:	:	**PROPOSED STIPULATION AND**
	:	**CONSENT ORDER**
Thermo Fluids Inc.	:	**No. 1909097**
Notice of Violation and Compliance Order	:	
No. 1909088		
UTR000008458		

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This proposed **STIPULATION AND CONSENT ORDER (CONSENT ORDER)** is issued by the DIRECTOR OF THE UTAH DIVISION OF WASTE MANAGEMENT AND RADIATION CONTROL (Director) pursuant to the Utah Used Oil Management Act (the Act), Utah Code §19-6-701, *et seq*. and the Utah Solid and Hazardous Waste Act, Utah Code §19-6-101, et seq.

JURISDICTION

1. The Director has jurisdiction over the subject matter of this **CONSENT ORDER** pursuant to Utah Code §19-6-705(2)(c), §19-6-721, §19-6-107, and §19-6-112 and jurisdiction over Thermo Fluids Inc. owned and operated by Thermo Fluids Inc. . Thermo Fluids Inc. and the Director are the parties to this agreement.

2. The Waste Management and Radiation Control Board (Board) has authority to review this **CONSENT ORDER** pursuant to Utah Code §19-6-104(e) and jurisdiction over Thermo Fluids Inc.

FINDINGS

3. Thermo Fluids Inc. ("TFI") is a Delaware corporation licensed to do business in the State of Utah and is the owner and operator of the Thermo Fluids Inc., used oil processing facility located at 3545 West 500 South in Salt Lake City, Utah. TFI is a "used oil processor" and a "used oil marketer" within the meaning of Utah Code §19-6-703 (26) and §19-6-703(23), respectively.

4. TFI conducts used oil processing operations at its facility located at 3545 West and 500 South, in Salt Lake City, Utah. TFI operates the Salt Lake City facility under the provisions of its Used Oil Processor Permit (Permit) (#UOP-0095 and Used Oil Marketer Registration (Registration) (UOR-0060) issued by the Director to TFI on July 16, 2005 and September 17, 1996, respectively. The Division renewed and reissued the Permit and Registration to TFI effective May 10, 2018 and May 23, 2018, respectively.

5. The TFI is a "person" as defined in Utah Code §19-1-103(4) and is subject to all applicable provisions of the Utah Administrative Code (the Rules), the Act, the Permit and the Registration.

6. Authorized representatives of the Director (inspectors) conducted a compliance evaluation and used oil inspection at the TFI facility on May 1-2, and May 9 of 2019 (the FY2019 inspection).

7. Based on findings documented during the FY2019 inspection, the Director issued **NOTICE OF VIOLATION and COMPLIANCE ORDER** No. 1909088 (NOV/CO) on November 19, 2019, alleging violations by TFI of its Permit, the Act and the Utah Administrative Code.

8. TFI filed a response to the NOV/CO on February 12, 2020.

STIPULATION AND CONSENT ORDER

9. The parties now wish to fully resolve Notice of Violation/Compliance Order No. 1909088 without further administrative or judicial proceedings.

10. In full settlement of the violations alleged in NOV/CO No. 1909088, TFI shall pay a penalty of $42,906.00. Payment shall be made within 30 days of the effective date of this **CONSENT ORDER**. Payment shall be made to the State of Utah, Department of Environmental Quality, Utah Division of Waste Management and Radiation Control, c/o Ty L. Howard, Director, P.O. Box 144880, Salt Lake City, Utah 84114-4880. This amount has been determined in accordance with the Division's Civil Penalty Policy (R315-102 of the Rules), which considers such factors as the gravity of the violations, the extent of deviation from the rules, the potential for harm to human health and the environment, good faith efforts to comply, and other factors.

EFFECT OF CONSENT ORDER

11. For the purpose of this **CONSENT ORDER**, the parties agree and stipulate to the above stated facts. The stipulations contained herein are for the purposes of settlement and shall not be considered admissions by any party and shall not be used by any person related or unrelated to this **CONSENT ORDER** for purposes other than determining the basis of this **CONSENT ORDER**. Nothing contained herein shall be deemed to constitute a waiver by the State of Utah of its right to initiate enforcement action, including civil penalties, against TFI in the event of future non-compliance with this **CONSENT ORDER**, with the Act, with the Rules, or with the Permit; nor shall the State of Utah be precluded in any way from taking appropriate action should such a situation arise again at the TFI facility. However, entry into this **CONSENT ORDER** shall relieve TFI of all liability for violations, which did arise or could have arisen with respect to the allegations contained in the NOV/CO.

(Intentionally left blank)

EFFECTIVE DATE

12. This **CONSENT ORDER** shall become effective upon execution by Thermo Fluids Inc. and the Director.

Dated this_____day of_____, 2020.

Thermo Fluids Inc.	**Division of Waste Management and Radiation Control**
Billy Ray Ross, Senior Vice President Compliance, Safety-Kleen Systems Inc. (Authorized signatory for Thermo Fluids Inc.)	Ty L. Howard, Director

Narrative Explanation to Support Penalty Amount

Thermo Fluids, Inc. – Used Oil Processor

Draft Proposed Stipulation and Consent Order No. 1909097

Notice of Violation No. 1909088

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 1

Violation Description: Utah Code § 19-6-113(3) by knowingly making false representations on seventeen Bills of Lading (BOL) documents dated from April 17, 2019 through May 1, 2019, for shipments of oily-water to a facility located at 1141 South 3200 West, Salt Lake City, Utah.

1. **Gravity Based Penalty: $10,000.00**

   (a) **Potential for Harm – Major**

   The used oil Bill of Lading (BOL) and Manifest systems create a written record of the chain of custody from the time a material leaves a generator until it reaches its final destination and is a critical regulatory component of the Used Oil Program. Record falsification is viewed as major because it goes to the heart of the integrity of the Used Oil Program as the Division relies upon truthful recordkeeping. In this instance, the false representations made on shipping records by Thermo Fluids, Inc. (TFI) were reportedly done for business interests. It also achieved an unfair competitive advantage (economic benefit) over other companies that comply with used oil regulations, along with reliance upon and potential liability for the destination facility accepting the shipments.

   (b) **Extent of Deviation – Major**

   The extent of the deviation is major as TFI disregarded the regulatory requirement for BOL/manifest requirements. TFI has operated as a permitted Used Oil Processor in Utah for fifteen years and is a subsidiary of Safety-Kleen who is currently the leading recycler of used oil in the U.S.A.

   TFI false representations of who generated the oily water on shipping records delivered to a processing facility started on April 17, 2019 and only discontinued the practice after the discovery of this violation by the Division on May 1, 2019.

   (c) Multiple Events -NA

2. **Adjustment Factors:**

   (a) Good faith - NA
   (b) **Willfulness/Negligence – 20% Increase** @ $2,000.00 - Management was aware of this practice.
   (c) History of Noncompliance - NA
   (d) Ability to pay - NA
   (e) Other Unique Factors - NA

3. **Economic Benefit:** The Division did not calculate economic benefit for this specific violation due to the difficulty in accurately quantifying this parameter's impact on the competitive advantage.

4. **Recalculation of Penalty based on New Information:** NA

Violation 1 –Penalty Total: **$12,000.00**

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 2

Violation Description: By failing to submit a permit modification and receive approval from the Director prior to modifying tanks and ancillary equipment specified in the permit.

1. **Gravity Based Penalty: $8,000.00**

   (a) **Potential for Harm – Major**

   The failure of TFI to submit a permit modification to the Director for approval prior to a major upgrade of the equipment in the tank farm and changes in the type of material stored in permitted used oil storage tanks has a high adverse effect on the Division's implementation of the used oil program.

   During an inspection conducted on August 8, 2018, TFI's environmental compliance manager and branch manager discussed the upcoming renovations planned for tank farm. The inspectors explained the importance of coordination and communication would be needed once the modification was submitted to facilitate the approval process.

   TFI delayed and avoided costs associated with the permit modification process which is a critical component of the Used Oil Program.

   (b) **Extent of Deviation – Major**

   TFI deviated from the regulatory requirements to such an extent that none of the requirements were met resulting in substantial noncompliance.

   (c) Multiple Events -NA

2. **Adjustment Factors:**

   (a) Good faith - NA

   (b) **Willfulness/Negligence – 20% Increase** @ $1,600.00 - Management was aware of the requirement to submit the Permit modification.

   (c) **History of Noncompliance – 20% Increase** @ $1,600.00 - The Division documented this same violation during a CEI conducted at the facility on August 8, 2018 and issued TFI a NOV/CO (#1810087).

   (d) Ability to pay - NA

   (e) Other Unique Factors - NA

3. **Economic Benefit:** The Division did not calculate economic benefit for this specific violation due to the difficulty in accurately quantifying this parameter.

4. **Recalculation of Penalty based on New Information:** NA

Violation 2 –Penalty Total: **$11,200.00**

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 3

Violation Description: By allowing transportation of eleven shipments of oily water by a non-permitted Utah used oil transporter.

1. **Gravity Based Penalty: $400.00**

   (a) **Potential for Harm – Minor**

   TFI used Clean Harbors Industrial Services (CHIS) to transport used oil in Utah. Clean Harbors Industrial Services is not a permitted used oil transporter in Utah.

   CHIS (EPA ID No. TXR000025791) is a hazardous waste transporter and transported the oily water to a facility that could process the oily water, therefore the risk to human health and the environment is low.

   (b) **Extent of Deviation – Moderate**

   TFI significantly deviated from this Permit requirement by allowing non-permitted used oil transporters to transport used oil in Utah.

   (c) **Multiple Events – 10 (11-1) events** @ $40.00/event = $400.00

2. **Adjustment Factors:**
   (a) Good faith - NA
   (b) Willfulness/Negligence – NA
   (c) History of Noncompliance - NA
   (d) Ability to pay - NA
   (e) Other Unique Factors - NA

3. **Economic Benefit:** The Division did not calculate economic benefit for this specific violation due to the difficulty in accurately quantifying this parameter.

4. **Recalculation of Penalty based on New Information:** NA

Violation 3 – Penalty Total: **$800.00**

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 4

Violation Description: Weekly Inspection Documentation

1. **Gravity Based Penalty: $0.00**
   (a) **Potential for Harm –**
   (b) **Extent of Deviation –**
   (c) Multiple Events -NA
2. **Adjustment Factors:**
   (a) Good faith - NA
   (b) Willfulness/Negligence – NA
   (c) History of Noncompliance - NA
   (d) Ability to pay - NA
   (e) Other Unique Factors - NA
3. **Economic Benefit:**
4. **Recalculation of Penalty based on New Information:** NA

Violation 4 - Penalty Total: **$00.00**

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 5

Violation Description: By transferring off-specification used oil into an on-specification used oil tank.

1. **Gravity Based Penalty: $100.00**

   (a) **Potential for Harm – Minor**

   TFI transferred off-specification used oil, exceeding the chromium concentration limit of 10 part per million, into the on-specification used oil tank RFO-26. The potential for harm is minor due to the act of blending the contaminated used oil with the large volume of on-specification used oil in tank thereby diluting the chromium concentration.

   (b) **Extent of Deviation – Minor**

   TFI met the used oil on-specification regulatory limits prior to transferring used oil into the on-specification tank the majority of the time.

   (c) **Multiple Events – 2 (3-1) events** @ $40.00/event = $80.00

2. **Adjustment Factors:**

   (a) Good faith - NA
   (b) Willfulness/Negligence – NA
   (c) History of Noncompliance - NA
   (d) Ability to pay - NA
   (e) Other Unique Factors - NA

3. **Economic Benefit:** The Division did not calculate economic benefit for this specific violation due to the difficulty in accurately quantifying this parameter.

4. **Recalculation of Penalty based on New Information:** NA

Violation 5 Penalty Total: **$180.00**

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 6

Violation Description: By using a laboratory not Utah certified for the methods specified in the Used Oil Marketer Registration.

1. **Gravity Based Penalty: $600.00**

   (a) **Potential for Harm – Minor**

   The laboratory did have Utah certification but not for the required methods specified in the marketer registration. The samples were tested by other certified methods, so this violation poses a minor risk to human health or the environment.

   (b) **Extent of Deviation – Major**

   TFI has substantial non-compliance by sending all samples collected from August 9, 2018 until February 5, 2019, to a laboratory that did not have Utah laboratory certification for the EPA Methods required by TFI's Marketer Registration.

   (c) **Multiple Events – 49 (50-1) events** @ $40.00/event = $1,960.00

2. **Adjustment Factors:**

   (a) Good faith - NA

   (b) **Willfulness/Negligence – 30% Increase** @ $768.00 - Management was aware that laboratories were not certified for methods specified in the Marketer Registration.

   (c) History of Noncompliance - NA

   (d) Ability to pay - NA

   (e) Other Unique Factors - NA

3. **Economic Benefit:** The Division did not calculate economic benefit for this specific violation due to the difficulty in accurately quantifying this parameter.

4. **Recalculation of Penalty based on New Information:** NA

Violation 6 Penalty Total: **$3,328.00**

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 7

Violation Description: By management failing to verify the analytical data met the on-specification concentration limits prior to transferring to the on-specification tank

1. **Gravity Based Penalty: $2,600.00**
   (a) **Potential for Harm – Moderate**
   TFI's non-compliance with this regulation has a moderate adverse impact on the regulatory purposes and procedures for implementing the used oil program.
   (b) **Extent of Deviation – Moderate**
   TFI significantly deviated from the requirements of the regulation.
   (c) Multiple Events – NA
2. **Adjustment Factors:**
   (a) Good faith - NA
   (b) **Willfulness/Negligence – 10% Increase** @ $260.00 - Management was negligence as they were aware of this requirement.
   (c) History of Noncompliance - NA
   (d) Ability to pay - NA
   (e) Other Unique Factors - NA
3. **Economic Benefit:** The Division did not calculate economic benefit for this specific violation due to the difficulty in accurately quantifying this parameter.
4. **Recalculation of Penalty based on New Information:** NA

Violation 7 - Penalty Total: **$2,860.00**

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 8

Violation Description: By failing to have readily accessible records for inspection by authorized representatives of the Director.

1. **Gravity Based Penalty: $560.00**

   (a) **Potential for Harm – Minor**

   TFI's non-compliance with this regulation has a minor adverse impact on the regulatory purposes and procedures for implementing the used oil program.

   (b) **Extent of Deviation – Moderate**

   TFI significantly deviated from the requirements of the regulation as all requested records on May 2, 2019 were not accessible to the inspectors. However, some of the records were available on May 9, 2019.

   (c) **Multiple Incident – 1 (2-1) events** @ $40.00/event = $40.00

2. **Adjustment Factors:**

   (a) Good faith - NA
   (b) Willfulness/Negligence – NA
   (c) History of Noncompliance - NA
   (d) Ability to pay - NA
   (e) Other Unique Factors - NA

3. **Economic Benefit:** The Division did not calculate economic benefit for this specific violation due to the difficulty in accurately quantifying this parameter.

4. **Recalculation of Penalty based on New Information:** NA

Violation 8 - Penalty Total: **$600.00**

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 9

Violation Description: By failing to properly document the delivery or removal of used oil from the facility's used oil/oily-water storage tanks.

1. **Gravity Based Penalty: $2,600.00**
   (a) **Potential for Harm – Moderate**
   TFI's non-compliance with this regulation has a moderate adverse impact on the regulatory purposes and procedures for implementing the used oil program, as accurate records are critical in evaluating the Permittee's regulatory compliance.
   (b) **Extent of Deviation – Moderate**
   TFI significantly deviated from the requirements of the regulation; approximately 50% of the records reviewed had the information required by the Permit.
   (c) Multiple Incident – NA
2. **Adjustment Factors:**
   (a) Good faith - NA
   (b) Willfulness/Negligence – NA
   (c) **History of Noncompliance - 20% Increase** @ $520.00 - The Division documented this same violation during a CEI conducted at the facility on August 8, 2018 and the Division issued TFI NOV/CO (#1810087).
   (d) Ability to pay - NA
   (e) Other Unique Factors - NA
3. **Economic Benefit:** The Division did not calculate economic benefit for this specific violation due to the difficulty in accurately quantifying this parameter.
4. **Recalculation of Penalty based on New Information:** NA

Violation 9 - Penalty Total: **$3,120.00**

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 10

Violation Description: By failing to keep records/documentation of the removal of stormwater from the facility's secondary containment system.

1. **Gravity Based Penalty: $1,200.00**

   (a) **Potential for Harm – Minor**

   TFI stated they removed stormwater from the facility's secondary containment but failed to keep records; this noncompliance posed minor harm to human health or the environment.

   (b) **Extent of Deviation – Major**

   TFI had substantial noncompliance, as no records were obtainable from August 11, 2018 through May 1, 2019.

   (c) Multiple Incident – NA

2. **Adjustment Factors:**

   (a) Good faith - NA
   (b) Willfulness/Negligence – NA
   (c) History of Noncompliance - NA
   (d) Ability to pay - NA
   (e) Other Unique Factors - NA

3. **Economic Benefit:** The Division did not calculate economic benefit for this specific violation due to the difficulty in accurately quantifying this parameter.

4. **Recalculation of Penalty based on New Information:** NA

Violation 10 - Penalty Total: **$1,200.00**

Total Proposed Stipulation and Consent Order Penalty Amount: $42,906.00

Violation Number 11

Violation Description: By failing to determine if the used oil met the specification requirements, prior to shipment to a facility utilizing the used oil as burner fuel.

1. **Gravity Based Penalty: $5,200.00**

   (a) **Potential for Harm – Major**

   TFI could not provide documentation that four out the five shipments of used oil had been tested as on-specification used oil; therefore this violation posed or may have posed a relatively high risk of exposure to humans or other environment receptors.

   In addition, used oil burners received inaccurate information creating potential liability by burning this fuel.

   (b) **Extent of Deviation – Minor**

   TFI could document that the majority of burner fuel shipments met the regulatory requirements for on-specification used oil fuel.

   (c) **Multiple Event – 3 (4-1) events** @ $220.00/event = $660.00

2. **Adjustment Factors:**

   (a) Good faith - NA
   (b) Willfulness/Negligence – NA
   (c) **History of Noncompliance - 30% Increase** @ $1,758 -The Division documented this same violation during a CEI conducted at the facility on August 8, 2018 and issued Thermo a NOV/CO (#1810087).
   (d) Ability to pay - NA
   (e) Other Unique Factors - NA

3. **Economic Benefit:** The Division did not calculate economic benefit for this specific violation due to the difficulty in accurately quantifying this parameter.

4. **Recalculation of Penalty based on New Information:** NA

Violation 11 - Penalty Total: **$7,618.00**

State of Utah

GARY R. HERBERT
Governor

SPENCER J. COX
Lieutenant Governor

Department of
Environmental Quality

L. Scott Baird
Interim Executive Director

DIVISION OF WASTE MANAGEMENT
AND RADIATION CONTROL
Ty L. Howard
Director

November 19, 2019

Joe Dwyre, Branch General Manager
Thermo Fluids Inc.
3545 West 500 South
Salt Lake City, UT 84014

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
70005 0390 0000 7508 6460

RE: Notice of Violation and Compliance Order Number 1909088
UTR000008458

Dear Mr. Dwyre:

Enclosed is a **NOTICE OF VIOLATION AND COMPLIANCE ORDER (NOV/CO)** Number **1909088**, based on findings documented by Division of Waste Management and Radiation Control inspectors regarding operations related to the storage, processing and marketing of used oil at Thermo Fluid Inc.'s facility. Please be advised that compliance with this **ORDER** is mandatory and will not relieve Thermo Fluid Inc. of liability for past violations.

This **ORDER** requires you to provide certain information to the Division within 30 days of the date of this NOV/CO and other information/records on specific dates required in the **ORDER**. Your response to this request will not constitute an administrative contest to the attached NOV.

You have 30 days from the date of the attached NOV/CO to contest it in the manner and within the time-period prescribed by R305-7-303 of the Utah Administrative Code.

If you have any questions, please call Michelle Weis at (801) 536-0256.

Sincerely,

Ty L. Howard, Director
Division of Waste Management and Radiation Control

(Over)

DSHW-2019-010922

195 North 1950 West • Salt Lake City, UT
Mailing Address: P.O. Box 144880 • Salt Lake City, UT 84114-4880
Telephone (801) 536-0200 • Fax (801) 536-0222 • T.D.D. (801) 536-4284
www.deq.utah.gov

TLH/MAW/kl

Enclosure: Notice of Violation & Compliance Order Number 1909088

c: Gary Edwards, MS, Health Officer, Salt Lake County Health Dept.
Dorothy Adams, Deputy Director, Salt Lake County Health Dept.
Royal DeLegge, MPA, EHS, Environmental Health Director, Salt Lake County Health Dept.
Michelle Lackman, Senior Environmental Compliance Manager, Thermo Fluids, Inc. (Email)
Annette Maxwell, U.S. EPA, Region VIII, ENF-R

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In the Matter of:	:	**NOTICE OF VIOLATION and COMPLIANCE ORDER**
Thermo Fluids Inc. UTR000008458	:	**No. 1909088**

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This **NOTICE OF VIOLATION AND COMPLIANCE ORDER (NOV/CO)** is issued by the Director of the Utah Division of Waste Management and Radiation Control pursuant to the Utah Used Oil Management Act Utah Code Ann. § 19-6-701, *et seq.* and the Utah Solid and Hazardous Waste Act, Utah Code Ann. § 19-6-101, *et seq.* The Director has authority to issue such NOTICES and ORDERS in accordance with § 19-6-705 and 721, and § 19-6-112.

FINDINGS

1. Thermo Fluids Inc. ("TFI") is a Delaware corporation licensed to do business in the State of Utah and is the owner and operator of the Thermo Fluids Inc. facility located at 3545 West 500 South, Salt Lake City, Utah. TFI is a "used oil processor" and a "used oil marketer" within the meaning of Utah Code Ann. § 19-6-703(26) and § 19-6-703(23), respectively.

2. TFI is a "person" as defined in Utah Code Ann. § 19-1-103(4) and is subject to all applicable statutory provisions, the Utah Administrative Code (Rules), the Used Oil Processor Permit (UOP-0095) and Used Oil Marketer Registration (UOR-060) issued to Thermo Fluids Inc. as owner and operator of the TFI processing facility.

3. The Director issued a Used Oil Processor Permit (Permit) and a Used Oil Marketer Registration (Registration) to TFI on July 16, 2005 and September 17, 1996, respectively. The Division renewed and reissued the Permit and Registration to TFI effective May 10, 2018 and May 23, 2018, respectively.

4. On May 1, May 2, and May 9 of 2019, authorized representatives of the Division of Waste Management and Radiation Control conducted a compliance evaluation inspection at TFI's facility located at 3545 West and 500 South, Salt Lake City, Utah and documented the following compliance issues as noted below:

5. Utah Code Ann. § 19- 6-113(3)(c) states that no person shall knowingly omit material information or make any false material statement or representation in any application, label, manifest, record, report, permit, operation plan, or other document filed, maintained, or used for purposes of compliance with this part or RCRA.

   The inspection revealed that TFI had generated 17 shipping documents (Bill of Lading ("BOL")), for oily-water, with dates ranging from April 17, 2019 through May 1, 2019, on which TFI knowingly made false representations on the BOLs. On these 17 BOLs, the generator name and address is TFI's facility, but the TFI facility was not the actual generator of the oily-water. An authorized representative of TFI's processor facility signed these "virtual" shipping documents as the generator releasing the oily-water to a used oil transporter for delivery. TFI informed the inspectors that these BOLs were "virtual" shipping records

created to protect TFI's client list. An authorized representative for the transporters then signed these TFI "virtual" shipping documents as "Transporter 1" certifying that they collected the oily-water from TFI's processor facility. The transporters had actually collected the oily-water from other Utah generators and then delivered the oily-water directly to a facility located at 1141 South and 3200 West, Salt Lake City, Utah. The used oil transporters did not provide the receiving facility with the original shipping documents that had the correct generator information (name and address), but with the shipping documents, generated by the TFI processor facility, that had a false representation that TFI's facility was the generator of this oily-water.

The shipping document numbers on which TFI made false representations were on BOLs #1171457, #1171458, #1171459, #1171467, #1171466, #1171465, #1171464, #1171463, #1171462, #1171401, #1171405, #1171514, #1171402, #1171513, #1171400, #1171515 and #1171404.

6. Permit Condition I.C. requires approval from the Director to modify the permit for the type or number of facility storage tanks, facility piping, or other equipment at the facility prior to implementation of that change.

   TFI implemented the following changes at the facility without prior approval from the Director:

   a. TFI changed the type of storage tanks and installed new piping and auxiliary equipment in the facility tank farm. TFI retained a contractor to complete an upgrade of the piping and other auxiliary equipment in TFI's tank farm in October of 2018. The contractor began construction in the first week of January 2019. The installation of the new piping and auxiliary equipment at TFI's facility was completed and in use by TFI as of January 30, 2019.

   b. TFI's Permit allows only the storage of used oil in tanks DT-5 and DT-6. TFI began storing universal waste antifreeze in used oil storage tank DT-5 on January 24, 2019 without submitting a modification request to the Director for approval. TFI is currently storing universal waste antifreeze in used oil storage tank DT-6 but the Division could not determine the actual date TFI began using tank DT-6 for the storage of antifreeze, as tank records for DT-6 were missing or not available at the time of inspection for review by inspectors.

7. Permit Condition II.A.9. requires that TFI only deliver shipments of used oil for transport from their processor facility to a Utah permitted used oil transporter.

   TFI delivered 11 shipments of oily-water to Clean Harbors Industrial Services (CHIS TX) operating under EPA ID # TXR000025791, on dates that range from October 15, 2018 through November 1, 2018. These loads of oily-water were then transported to another Utah permitted used oil processor. CHIS TX does not have a Used Oil Transporter Permit issued by the Director.

8. Permit Condition II.E. requires that TFI conduct weekly inspections of used oil storage containers, tanks and secondary containment systems in accordance with the facility inspection form in Attachment 2 of the Permit. TFI is required to document in the inspection

log any issues discovered during the inspections (e.g. leaking tanks or water accumulation) and any actions taken by TFI to resolve these issues.

TFI personnel failed to document and report to TFI management deficient facility conditions on Section B (Pipelines) of the weekly inspection logs/reports, conducted in January of 2019 as follows:

Section B (Pipelines) of TFI's inspection report requires that the inspector verify that there are no signs of corrosion or other damage to the pipes and to check each valve, flange and other fittings for leaks.

TFI conducted inspections on January 4, January 11, January 18, and January 25 of 2019 but failed to record any deficiencies related to the condition of the piping, pumps or valves in the tank farm. A TFI contractor demolished and installed new piping, valves and pumps in the tank farm during January of 2019, but TFI inspectors failed to document construction demolition activities occurring on the tank system components during the weekly inspections.

9. Permit Condition II.F.6. requires that TFI determine that the used oil stored in facility tanks meets the specification requirements of R315-15-1.2 of the UAC (specification requirements), prior to transfer into the facility's "on-specification" oil storage tank RFO-26.

TFI failed to meet the specification requirements of Permit Condition II.F.6 as listed below:

a. TFI transferred used oil from tank DT-19 into on-specification used oil tank RFO-26 on September 11, 2018 and again on October 31, 2018 (21,095 total gallons), that failed to meet the used oil on-specification requirements due to chromium concentrations in the oil exceeding the regulatory limit of 10 ppm.

b. TFI transferred used oil from tank DT-20 into tank RFO-26 on November 15, 2018 (16,120 total gallons), that failed to meet the used oil specification requirements as required by Permit Condition II.F.6, as the chromium concentrations in the oil exceeded the regulatory limit of 10 ppm.

c. TFI failed to make a determination if the used oil stored in tanks DT-18, DT-19, DT-22, and DT-24 met the used oil on-specification requirements prior to transfer into tank RFO-26 at least 17 times, between February 4, 2019 and May 9, 2019.

10. TFI's Marketer Registration, Condition B.5 and Condition B.1 of Attachment 1, requires that the laboratory analyses used to satisfy the requirements of R315-15 of the UAC be performed by a laboratory that holds a current Utah Certification for environmental laboratories issued by the Utah Department of Health Laboratory Improvement under R444-14 of the UAC. The laboratory shall have Utah Certification for the sample preparatory methods and analytical methods, specified in the Sampling and Analysis Plan in the Marketer Registration, that are used by the laboratory to analyze all collected samples for the constituents specified by R315-15-1.2 of the UAC when determining if used oil meets the on-specification requirements.

TFI sent 100 samples of used oil for analysis from August 13, 2018 through April 30, 2019, to two different laboratories that did not have the required Utah Certification for either a preparatory method or an analytical method required by TFI's Marketer Registration as follows:

a. Precision Petroleum Labs Inc. (Precision) analyzed 65 used oil samples for TFI between August 13, 2018 and December 27, 2018 to determine if the oil met the on-specification requirements without the required Utah Certification for metals analysis preparatory Methods 3031 or 3051A and the PCB analysis preparatory Methods 3580A or 3665A.

b. Pace Analytical Nation Center for Testing & Innovation (Pace) analyzed 34 used oil samples for TFI between January 17, 2019 and April 30, 2019 to determine if the oil met the on-specification requirements without the required Utah Certification for halogen Method 9076.

11. Permit Condition B.2 of Attachment 5 requires that TFI's management review and approve the analytical results for samples used to determine if the used oil meets the on-specifications requirements prior to operators removing the lock, on the "locked down" tank, and transferring the used oil into TFI's "on-specification" oil tank RFO-26.

TFI's facility branch manager stated to the inspector on May 9, 2019, that he failed to review and approve the laboratory analytical data prior to transferring the used oil into tank RFO-26. A TFI employee/operator stated that he did not get approval from management or review the analytical data, prior to transferring the oil to tank RFO-26.

12. Permit Condition I.F. requires TFI to maintain for a minimum of three years, all applicable used oil processor tracking records required by R315-15 of the UAC and their Permit at their facility located at 3545 West 500 South, Salt Lake City, Utah. Records may be in hard copy or in an electronic format and shall be readily accessible for inspection by authorized representatives of the Director

TFI failed to have all of the facility records assessable for inspection by authorized representatives of the Director at the time of inspection on May 2, 2019 and May 9, 2019 as follows:

a. Requested tank records on May 2, 2019 were inaccessible at the time of inspection, as TFI had placed them into shrink-wrapped boxes stored in the warehouse and could not provide them during the inspection.

b. TFI failed to provide tank logs for all of the facility's' used oil/oily water tanks during the inspection ending on May 9, 2019 even though the Division inspectors had requested these records on May 2, 2019. The following records were not provided at the time of inspection or prior to this NOV.

   i. Tank DT-17 records are missing or were not provided to the Division from February 9, 2019 through February 17. 2019.

   ii. Tank DT-18 records are missing or were not provided to the Division from January 30, 2019 through February 17, 2019.

   iii. Tank DT-19 records are missing or were not provided to the Division from January 30, 2019 through May 1, 2019.

   iv. Tank DT-20 records are missing or were not provided to the Division from February 15, 2019 through May 1, 2019.

   v. Tank DT-21 records are missing or were not provided to the Division from December 13, 2019 through April 7, 2019.

vi. Tank DT-23 records are missing or were not provided to the Division from April 4, 2019 through April 15, 2019.

vii. Tank DT-24 records are missing or were not provided to the Division from March 9, 2019 to April 15, 2019.

13. Permit Condition I.F.3.b. requires that TFI record the date, time, operator (initials), source and volume of the used oil delivered into each used oil/oily-water tank and the date, time, operator (initials), and destination of the used oil removed from each tank (including inter-tank transfers).

TFI failed to comply with the requirements of Permit Condition I.F.3.b. as follows:

a. TFI failed to record the required information on 53% of the incoming oil entries on the facilities tank log sheets, dated from August 2018 through May 2019.

b. Tank DT-17 log sheet records indicate that on January 30, 2019 and February 8, 2019 that the volume of used oil in the tank was 28,879 gallons and 30,309 gallons, respectively. The maximum capacity of tank DT-17 is 19,905 gallons.

c. Tank DT-20 log sheet records indicate that on February 4, 2019 and February 15, 2019 that the volume of used oil in the tank was 27,949 gallons and 31,834 gallons, respectively. The maximum capacity of tank DT-20 is 19,905 gallons.

14. Permit Condition I.F.3.d. requires that TFI document the volume of used oil, water or other liquids (including storm water) removed from the secondary containment system, the date of removal, the operator's signature and how the Permittee managed these liquids. The record shall also document that the operator visually inspected the storm water for oil contamination prior to transfer to the facility's storm water evaporation pond.

From August 11, 2018 through May 1, 2019, TFI failed to keep records/documentation of the removal of stormwater from the facility's secondary containment system as required by Permit Condition I.F.3.d. These records are required to provide documentation that TFI has removed any liquids accumulating in the secondary containment within 24 hours of discovery in accordance with Permit Condition I.E.8.

15. Permit Condition A.1 of Attachment 5 requires that TFI determine that used oil fuel meets the on-specification levels prior to shipment to facilities that burn the used oil as fuel.

TFI sent five shipments totaling 32,800 gallons of used oil, from tanks DT-22 and DT-24, to used oil burners, without valid analytical test data to determine if the used oil met the on-specification requirements as follows:

a. The TFI facility shipped 9,400 gallons of burner fuel to Clean Harbors Aragonite, LLC on April 14, 2019 from tank DT-22.

b. The TFI facility shipped 7,200 gallons of burner fuel to Nielson Construction on April 16, 2019 from tank DT-22.

c. The TFI facility shipped 4,700 gallons of burner fuel to Nielson Construction on April 30, 2019 from tank DT-24.

d. The TFI facility shipped 5,750 gallons of burner fuel to Clean Harbors Aragonite, LLC on May 7, 2019 from tank DT-24.

e. The TFI facility shipped 5,750 gallons of burner fuel to Nielson Construction on May 8, 2019 from tank DT-22.

DETERMINATION OF VIOLATIONS

Based on the foregoing FINDINGS, Thermo Fluids Inc. has violated Utah law and its Permit and Registration. Specifically, Thermo Fluids Inc. has violated the following:

1. Utah Code Ann. § 19-6-113 (3)(c) by knowingly making false representations on 17 Bills of Lading dated from April 17, 2019 through May 1, 2019, for shipments of oily-water to a facility located at 1141 South and 3200 West in Salt Lake City, Utah.

2. Permit Condition I.C. by failing to submit a Permit modification and receive approval from the Director, prior to the removal and installation of new piping, pumps and other auxiliary equipment in the tank farm and before storing antifreeze in tanks DT-5 and DT-6 which are only permitted for the storage of used oil.

3. Permit Condition II.A.9. by delivering 11 shipments of oily-water to a transporter without a Used Oil Transporter Permit issued by the Director.

4. Permit Condition II.E. by failing to document and report to TFI management, any deficient conditions for the piping, pumps or other auxiliary equipment in the tank farm in January of 2019.

5. Permit Condition II.F.6. by transferring used oil from tank DT-19 on September 11, 2018 and October 31, 2018 and from tank DT-20 on November 15, 2018 into tank RFO-26, that failed to meet the used oil on-specification requirements for chromium.

6. TFI Marketer Registration Condition B.5 and Condition B.1 of Attachment 1, by sending 100 samples of used oil for on-specification analysis, from August 13, 2018 through April 30, 2019, to laboratories that did not have the required Utah Certification for either a preparatory method or an analytical method.

7. Permit Condition B.2. of Attachment 5 by failing to have management review and approve the laboratory analytical data, used to determine if used oil meets the specification requirements, prior to operators transferring the used oil into the "on-specification" oil tank RFO-26.

8. Permit Condition I.F. by failing to have records, hard copy or electronic, readily accessible for inspection by authorized representatives of the Director on May 2, 2019 and May 9, 2019.

9. Permit Condition I.F.3.b. by failing to properly record or failing to record the information required by Permit Condition I.F.3.b. to document the delivery or removal of used oil from the facility's used oil/oily-water storage tanks.

10. Permit Condition I.F.3.d. by failing to keep records/documentation of the removal of stormwater from the facility's secondary containment system, from August11, 2018 through May 1, 2019.

11. Permit Condition A.1. of Attachment 5 by failing to determine if the used oil met the specification requirements, prior to shipment, for five shipments of used oil sent to facilities that utilized the used oil as burner fuel.

ORDER

TFI is hereby ordered to submit the following information, to the Director, within 30 days from the date of this NOV/CO.

1. TFI shall submit a list of TFI's employees or other individuals (e.g. Emerald employees) that TFI has authorized to conduct used oil operations at TFI's processing facility under Permit UOP-0095 and documentation that these individuals received used oil training required by the TFI's Permit in 2018 and 2019.

2. TFI shall provide a list of Utah permitted used oil transporters that utilize TFI's facility as a base for used oil operations conducted in Utah. Include a detailed description of operations conducted at TFI's facility by these companies and if any of these other transporters store used oil/oily-water for longer than 24 hours in vehicles at TFI's facility.

3. TFI shall provide specific steps implemented for each violation in this NOV/CO, to assure future compliance with TFI's Permit, R315-15 UAC, Utah Code Ann. § 19-6-701, *et seq.* and Utah Code Ann. § 19-6-101, *et seq.*

4. TFI shall locate and correct all shipping documents that TFI provided to the facility located at 1141 South and 3200 West, Salt Lake City, Utah which do not accurately identify the generator, and verify such actions to the Director.

TFI is hereby ordered to submit, to the Director for review, hard copies of future facility records listed below, for the calendar months of December of 2019, and January, February and March of 2020. TFI shall submit records for each of these months to the Director, within 10 days from the end of the calendar month in which the records were generated.

5. Tank log sheets for all used oil and oily-water tanks OW-1, OW-2, OW-3, OW-4, DT-1, DT-5, DT-6, DT-17, DT-18, DT-19, DT-21, DT22, DT-23, DT-24, and RFO-26.

6. All sampling and analytical data used to determine if used oil meets the on-specification requirements. Analytical data must have the facility manager's signature with the date that the manager reviewed and approved the analytical data.

7. Shipping records (e.g. manifest/BOL) for shipments of on-specification used oil to burners using this oil as a fuel.

8. Weekly inspection logs/reports with the facility manager's signature and the date that the manager reviewed the inspection report.

9. TFI records documenting the volume of used oil, water or other liquids (includes storm water) removed from the secondary containment system, the date of removal, the operators signature and how the Permittee managed these liquids.

EFFECTIVE DATE

This NOTICE OF VIOLATION AND COMPLIANCE ORDER is effective on the date of signature, below. It remains effective unless a stay is issued or unless it is rescinded, vacated or otherwise terminated.

OPPORTUNITY FOR HEARING

This NOTICE OF VIOLATION AND COMPLIANCE ORDER is effective immediately and shall become final unless Thermo Fluids Inc. administratively contests it. Failure to contest this NOTICE OF VIOLATION AND COMPLIANCE ORDER in the manner and within the time period prescribed by Utah Admin. Code R305-7-303 constitutes a waiver of any right of administrative contest, reconsideration, review, or judicial appeal.

Utah Code Ann. § 19-6-721 provides that violation of any order, plan, rule, or other requirement issued or adopted under this part may be subject to a civil penalty of up to $10,000 per day for each day of violation.

Utah Code Ann. § 19-6-113(2) provides that violation of any order, plan, rule, or other requirement issued or adopted under this part may be subject to a civil penalty of up to $13,000 per day for each day of violation.

Dated this 19th day of **November, 2019**

By: _____

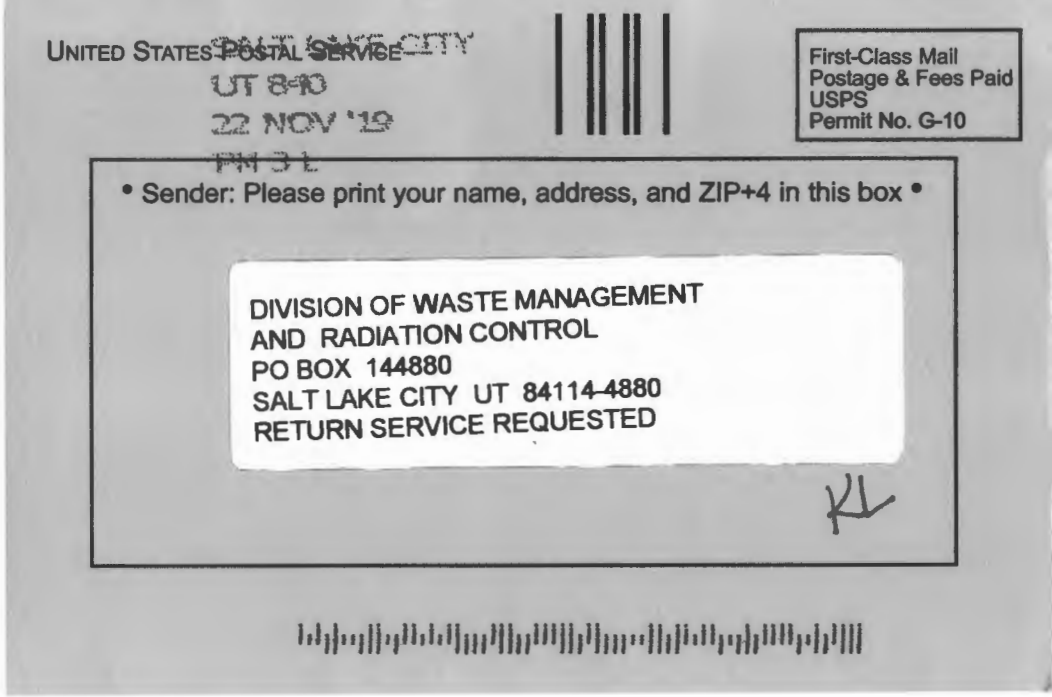
Ty L. Howard, Director
Division of Waste Management and Radiation Control

CERTIFICATE OF MAILING

I HEREBY CERTIFY that I mailed a true and correct copy of the foregoing **NOTICE OF VIOLATION AND COMPLIANCE ORDER on the 19 day of November 2019 by US Certified Mail, Return Receipt Requested, to:**

Joe Dwyre, Branch General Manager
Thermo Fluids Inc.
3545 west 500 south
Salt Lake City, UT 84014

Kathy Lundy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SENDER: *COMPLETE THIS SECTION*

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

Joe Dwyre, Branch General Manager
Thermo Fluids Inc.
3545 West 500 South
Salt Lake City, UT 84014

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X ☐ Agent ☐ Addressee

B. Received by *(Printed Name)*

C. Date of Delivery 11/22

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☑ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

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