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 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 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 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 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 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

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 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 each off-site shipment of airbag waste and each confirmation[**s**] of receipt from the receiving facility. For each shipment, these records 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, that is, airbag modules or airbag inflators, in the shipment. Confirmations of receipt shall include the name and address of the receiving facility; the type and quantity of the airbag waste, that is, airbag modules and airbag inflators, received; and the date which it was received. Shipping records and confirmations of receipt shall be made available for inspection and may be satisfied by routine business records 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 applicable hazardous waste rules, and the facility receiving airbag waste is considered the hazardous waste generator for the purposes of the hazardous waste rules and 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).

R315-261-7. 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) The wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container 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 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 they are discarded or intended to be discarded as described in Subsection R315-261-2(a)(2)(i), if they are mixed with waste oil or used oil or other material and applied to the land for dust suppression or road treatment, if they are otherwise applied to the land in lieu of their original intended use or if they are contained in products that are applied to the land in lieu of their original intended use, or 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 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 each formulation 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, if 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, 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, 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, if present at concentrations greater than 0.3%
P001	(1)81-81-2	Warfarin, and salts, 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-

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 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 the applicable independent requirements in Subsections R315-262-10(a)(1)(i) through R315-262-10(a)(1)(iii).

(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 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: Section R315-262-34 is applicable to the on-site accumulation of hazardous waste by generators. Therefore, Section R315-262-34 only applies 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 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 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 in a calendar	Quantity of non-acute hazardous waste generated in a	Quantity of residues from a cleanup of acute hazardous waste	Generator category

month	calendar month	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 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 Subsection R315-262-13(c)(7), the term eligible academic entity shall have the meaning as defined in Section R315-262-200;

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

(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 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 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 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), 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, 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 containers 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 characteristics, 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.

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 standards that define the acceptable management of hazardous waste.

(b) The standards in Rule R315-264 apply to each owner and operator of facilities that 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 each owner or operator of a POTW that 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 the following:

(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.

(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; or

(C) a discharge of a material that, if discharged, becomes a hazardous waste.

(ii) An owner or operator of a facility otherwise regulated by Rule R315-264 shall comply with 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 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, if handling the following 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 each owner or operator of facilities that 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 do the following:

(1) Obtain an EPA identification number by applying to the 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 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.

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 references to "Regional Administrator", and for 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 treatment, storage and disposal of hazardous waste at these facilities after the effective date of these 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, which are 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 the following:

(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: Rule R315-265 does 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 that 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 R315-15 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.

(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; or

(C) a discharge of a material that, if discharged, becomes a hazardous waste.

(ii) An owner or operator of a facility otherwise regulated by this Rule R315-265 shall comply with 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 the applicable requirements of 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, if handling the following 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 R315-273-6(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. F020, F021, F022, F023, F026, or F027 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 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) [~~F~~]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 and incorporated by reference.

(e) The requirements of Rule R315-265 apply to owners or operators of 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.

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; or

(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;

(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;

(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; 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 as follows:

(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 certain 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. A reverse distributor shall keep the following records:

(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 certain 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. A reverse distributor shall keep the following records:

(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. 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, certain hazardous wastes shall be treated by particular treatment methods before they can be land disposed and soils 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 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 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 each constituent. If each Constituent will be treated and monitored, there is no need to put each of them 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, if available	X	X	X	
6. Date the waste is subject to the prohibition			X	
7. For hazardous debris, 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	X	X		

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, 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 provided by 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 shall be kept on site in the generator's records, and the following requirements 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 the information necessary to treat the wastes 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, 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 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 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 if the hazardous characteristic is removed prior to disposal, or 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 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 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 each constituent. If each constituent will be treated and monitored, there is no need to put each of them on the LDR notice.	X
3. The notice shall include the applicable	X

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		
4. Waste analysis data, 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) 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 Subsection R315-266-20(b) regarding treatment standards and prohibition levels, the owner or operator of a treatment facility, 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.

(d) Generators or treaters who first claim that hazardous debris is excluded from the definition of hazardous waste under Subsection R315-261-3(f) 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; 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 each inspection, evaluation, 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 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 numbers;

(C) An indication of the hazards of the contents, examples include:

(I) the applicable hazardous waste characteristics, 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.

(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.

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 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 that 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, 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 the following:

(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 are not required to obtain a hazardous waste permit:

(i) A generator who accumulates hazardous waste on-site in compliance with the conditions for exemption provided in Sections R315-262-14, R315-262-15, R315-262-16, and R315-262-17.

(ii) A farmer who disposes of hazardous waste pesticides from their own use as provided in Section R315-262-

(iii) A person who owns or operates facilities solely for the treatment, storage or disposal of hazardous waste excluded from regulation under Rule R315-270 by Section R315-261-4 or Section R315-262-14, very small quantity generator exemption.

(iv) An owner or operator of totally enclosed treatment facilities as defined in Section R315-260-10.

(v) An owner and operator of one or more elementary neutralization units or wastewater treatment units as defined in Section R315-260-10.

(vi) 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.

(vii) A person adding absorbent material to waste in a container, as defined in Section R315-260-10, and a person 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 if handling the following universal wastes;]

(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; or

(C) a discharge of a material that, 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 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 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, 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-

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), any person seeking to add a hazardous waste or a category of hazardous waste to Rule R315-273 may petition for a 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 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.