NUREG-1556
Volume 20, Rev. 1

Consolidated Guidance About Materials Licenses

Guidance About Administrative Licensing Procedures

Final Report

Office of Nuclear Material Safety and Safeguards

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Protecting People and the Environment

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Consolidated Guidance About Materials Licenses

Guidance About Administrative Licensing Procedures

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ABSTRACT

This technical report contains information intended to document the materials licensing process and provide licensing guidance for the U.S. Nuclear Regulatory Commission staff. This report will be available to Agreement States, applicants, licensees, and the general public.

FOREWORD

The U.S. Nuclear Regulatory Commission's (NRC's) NUREG–1556 technical report series provides a comprehensive source of reference information about various aspects of materials licensing and materials program implementation. These reports, where applicable, describe a risk-informed, performance-based approach to licensing consistent with the current regulations. The reports are intended for use by applicants, licensees, license reviewers, and other NRC personnel. The NUREG–1556 series currently includes the following volumes:

Volume No.	Volume Title
1	Program-Specific Guidance About Portable Gauge Licenses
2	Program-Specific Guidance About Industrial Radiography Licenses
3	Applications for Sealed Source and Device Evaluation and Registration
4	Program-Specific Guidance About Fixed Gauge Licenses
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers
8	Program-Specific Guidance About Exempt Distribution Licenses
9	Program-Specific Guidance About Medical Use Licenses
10	Program-Specific Guidance About Master Materials Licenses
11	Program-Specific Guidance About Licenses of Broad Scope
12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses
18	Program-Specific Guidance About Service Provider Licenses
19	Guidance for Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)
20	Guidance About Administrative Licensing Procedures
21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator

The current document, NUREG–1556, Volume 20, Revision 1, "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures," is intended for use by the NRC staff. This revision provides a general update to the previous information contained in NUREG–1556, Volume 20, issued December 2000.

A team composed of staff from NRC Headquarters and regional offices prepared this document, drawing on their collective experience in the materials licensing programs and processes. NUREG–1556, Volume 20, Revision 1, is not a substitute for NRC regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable.

No public comments were received during the public comment period for NUREG–1556, Volume 20, Revision 1.

Michael C. Layton, Director
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Office of Nuclear Material Safety and Safeguards

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ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
ALARA	as low as is reasonably achievable
AU	authorized user
CFR	*Code of Federal Regulations*
CRCPD	Conference of Radiation Control Program Directors
Ci	curie
Cs-137	cesium-137
CUI	Controlled Unclassified Information
DCGL	derived concentration guidelines level
DOE	U.S. Department of Energy
DP	decommissioning plan
DRG	Desk Reference Guide
EA	environmental assessment
EPACT	Energy Policy Act
FONSI	finding of no significant impact
Ga-68	gallium-68
Ge-68	germanium-68
GLTS	General License Tracking System
HQ	Headquarters
I-125	iodine-125
I-131	iodine-131
IAEA	International Atomic Energy Agency
IMC	Inspection Manual Chapter
IN	Information Notice
Ir-192	iridium-192
LA	Licensing Assistant
mCi	millicurie
MD	Management Directive
MML	Master Materials License
mrem	millirem
MSST	Division of Materials Safety, Security, State, and Tribal Programs
NARM	Naturally Occurring and Accelerator-Produced Radioactive Material
NIST	U.S. National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
NORM	Naturally Occurring Radioactive Material
NRC	U.S. Nuclear Regulatory Commission
NSIR	Office of Nuclear Security and Incident Response
NSTS	National Source Tracking System
OAR	Official Agency Record
OCFO	Office of the Chief Financial Officer
OE	Office of Enforcement
OGC	Office of the General Counsel
OMB	U.S. Office of Management and Budget
PII	personally identifiable information
PLG	Pre-Licensing Guidance

PM	Project Manager
POC	point of contact
Ra-226	radium-226
RA	Regional Administrator
RAI	request for additional information
RIS	Regulatory Issue Summary
RSAO	Regional State Agreement Officer
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RSRM	risk-significant radioactive material
SA	State Agreement
SCATR	Source Collection and Threat Reduction
SER	safety evaluation report
SUNSI	Sensitive Unclassified Non-Safeguards Information
TAR	technical assistance request
TBq	terabecquerel
U.S.C.	United States Code
WBL	Web-based Licensing

1 PURPOSE OF REPORT

This report provides guidance to both the U.S. Nuclear Regulatory Commission (NRC) license reviewers and Licensing Assistants (LAs) on administrative licensing procedures. This document includes procedures for acknowledging requests for specific or general licensing actions, tracking the progress of actions, maintaining files electronically in the Agencywide Documents Access and Management System (ADAMS), preparing licenses or registration certificates, processing general licenses under reciprocity, distributing documents, and other miscellaneous administrative matters. It is specifically intended for the NRC staff; however, Agreement States may find the information useful in implementing their radiation protection programs. This document contains information on license fees and other matters that are subject to change and beyond the control of NRC licensing staff. This information is provided for convenience only. Any questions or issues concerning these matters will be referred to the responsible NRC program office.

The applicability of this report is limited to the materials program area currently overseen by the Division of Materials Safety, Security, State, and Tribal Programs (MSST) in the Office of Nuclear Material Safety and Safeguards (NMSS). This NUREG is intended for use by the materials program area only. Although some information in this report is applicable to other program areas within NMSS, such as decommissioning and environmental assessments, it is not intended to supersede administrative licensing procedures established by other technical divisions.

Much of the information in this NUREG needed by NRC licensing staff is provided in the appendices. Readers should note the following information:

- Appendix A contains checklists that are helpful for documenting the acceptance review of certain categories of licensing actions.
- Appendix B contains standard letters that may be edited to meet case-by-case requirements.
- Appendix C contains a link to the standard license conditions.
- Appendix D contains examples of routine exemptions that the Regions may authorize without approval from NRC Headquarters (HQ).
- Appendix E contains examples of non-routine exemptions that require coordination with the Office of the General Counsel (OGC) and NMSS.
- Appendix F contains a checklist that provides information for NRC personnel for evaluating requests to withhold information from public disclosure under Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390.

Additionally, the NRC recognizes the importance of maintaining a healthy safety culture at the agency and the need to continuously improve its internal organizational effectiveness. This is done by including safety culture, along with the agency's values and Principles of Good Regulation, in the NRC's overall organizational culture. The NRC strives to create a work environment that focuses on safety and security and encourages all employees to raise and listen to concerns.

The NRC's Leadership Model contains additional information on internal safety culture at the NRC. This information is available at the "NRC Leadership Model" (ADAMS Accession No. ML18166A139).

2 AGREEMENT STATES

2.1 Jurisdiction Determination

Certain States, called Agreement States (see Figure 2-1), have entered into agreements with the U.S. Nuclear Regulatory Commission (NRC) that give them the authority to license and inspect byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass, which are used or possessed within their borders. Any applicant, other than a Federal entity, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with the NRC. In areas under exclusive Federal jurisdiction within an Agreement State, NRC continues to be the regulatory authority.

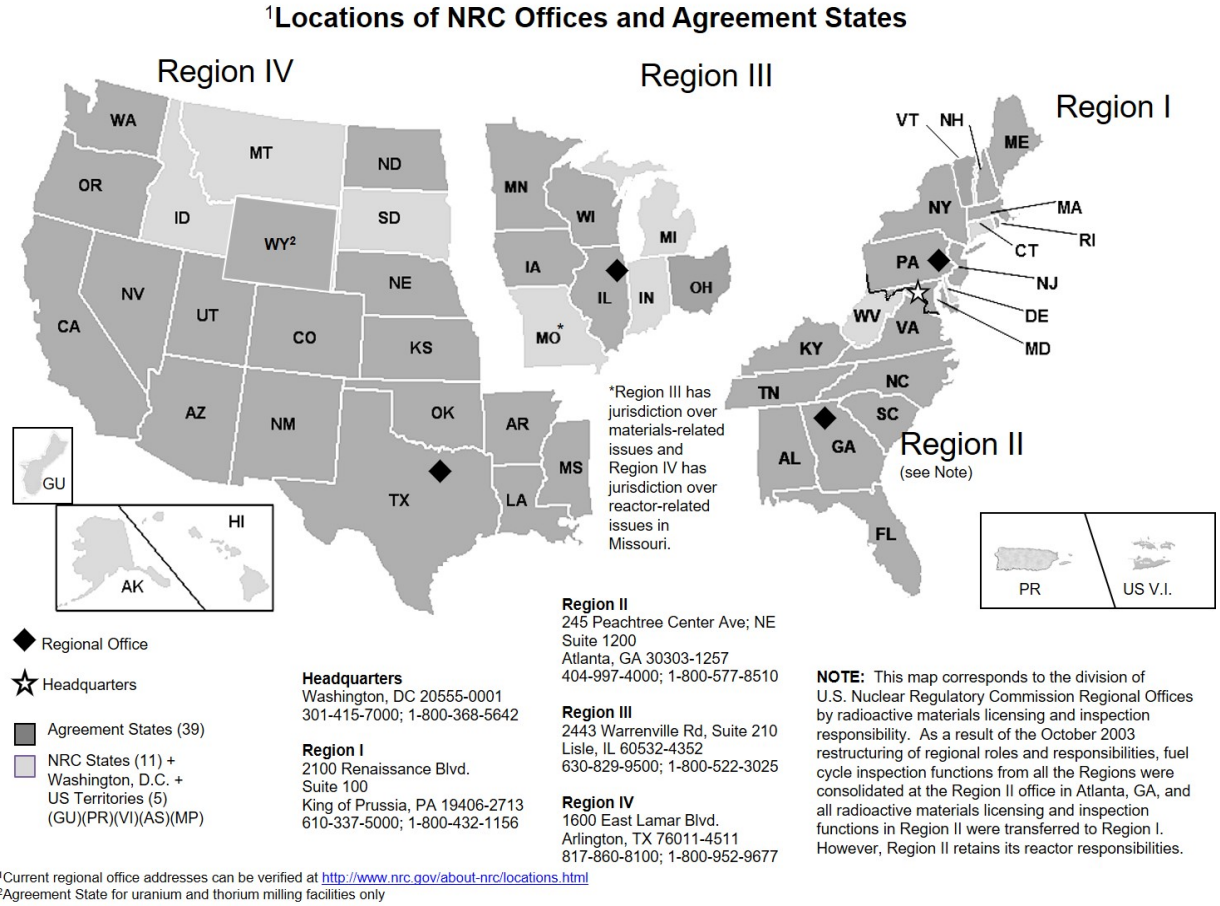


Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

In the special situation of work at federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement State has regulatory authority. These areas can also include Tribal lands of federally recognized Indian Tribes.[3] The NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State may have jurisdiction over nonexclusive Federal jurisdiction land. Applicants are responsible for determining, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. Additional guidance on determining jurisdictional status is found in the Office of Nuclear Material Safety and Safeguards (NMSS) procedures in the State Agreement series, SA-500, "Jurisdiction Determination," which is available at https://scp.nrc.gov. Once on the Web site, use the link for "NMSS Procedures" in the left-hand column under "Resources & Tools."

Table 2-1 provides a quick way to evaluate whether the NRC or an Agreement State has regulatory authority.

Table 2-1. Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency, regardless of location (except that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.12, "Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts;" also, see 10 CFR 40.11.	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or Tribal member on Indian Tribal land	NRC
Non-Federal entity on federally recognized Indian Tribal land	NRC[4]
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State.	Agreement State

[3]For the purposes of this guidance, an "Indian Tribe" is defined as an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994. A list of federally recognized tribes is available at www.bia.gov.

[4]The NRC can exercise jurisdiction as the regulatory authority on Tribal land of a federally recognized Indian Tribe. Section 274b. agreements do not give States the authority to regulate nuclear material in these areas. However, there may be States that exercise regulatory authority over these areas, based on treaties or agreements with specific tribes. Companies owned or operated by federally recognized Indian Tribe members or non-Indians that wish to possess or use licensed material on Tribal lands should contact the appropriate NRC regional office to determine the jurisdictional status of the Tribal lands and identify the appropriate regulatory agency for licensing and reciprocity.

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	**Regulatory Agency**
Non-Federal entity in Agreement State	Agreement State[5]
Non-Federal entity in Agreement State at federally controlled site **not** subject to exclusive Federal jurisdiction	Agreement State[5]
Non-Federal entity in Agreement State at federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	NRC
Non-Federal entity in Agreement State using radioactive materials **not** directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	Agreement State[5]

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) is available at the NMSS public Web site at https://scp.nrc.gov. A request for the list can also be made to an NRC regional office.

2.2 Reciprocal Recognition of Specific Licenses

Performing licensed activities in other jurisdictions is possible through reciprocal recognition of specific licenses (i.e., reciprocity). Agreement States have reciprocity provisions that permit NRC licensees to perform licensed activities under circumstances when an Agreement State is the regulatory authority (see Section 2.1). NRC licensees and Agreement State licensees are subject to the regulations of the regulatory authority, as indicated in Section 2.1. To ensure compliance with an Agreement State's reciprocity requirements, licensees are advised to request authorization from the appropriate Agreement State radiation control program office well in advance of the scheduled use of licensed material.

Agreement State licensees that wish to conduct licensed activities in areas under NRC jurisdiction must either obtain a specific NRC license or file for reciprocity with the appropriate NRC regional office for the Agreement State that issued their license. Failure to file for reciprocity or obtain a specific NRC license before working in areas under NRC jurisdiction can result in NRC enforcement action, which may include civil penalties. The reciprocity filing must be renewed annually.

[5]Section 274m. of the Atomic Energy Act (AEA) withholds to the NRC regulatory authority over radioactive materials covered under the Section 274b. agreements when the activity can affect the Commission's authority to protect the common defense and security, to protect restricted data, or guard against the loss or diversion of special nuclear material. (This is an uncommon situation that NRC usually evaluates on a case-by-case basis.) Individuals or companies wishing to possess or use licensed material should contact the licensee to determine the jurisdictional status for specific AEA radioactive materials they intend to possess or use.

Specific guidance regarding NRC licensees filing for reciprocity in Agreement States and Agreement State licensees filing for reciprocity with the NRC or another Agreement State are provided in NUREG–1556, Volume 19, "Consolidated Guidance About Materials Licenses: Guidance for Agreement State Licensees About NRC Form 241 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters' and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)."

Additionally, guidance for the NRC staff regarding processing of reciprocity applications (NRC Form 241) is contained in Section 3.2.10 of this NUREG.

3 LICENSING ASSISTANT GUIDANCE

The purpose of this chapter is to provide Licensing Assistants (LAs) and other appropriate staff members with basic administrative procedures for processing, managing, and tracking licensing actions from the time each action is received by the agency until the action is issued. The information provided in this chapter is not comprehensive, and it does not fully describe the duties of the LA.

Note: For convenience, the term LA is used in this NUREG to refer to both the LA and other staff members designated to perform LA duties and responsibilities. The term "license reviewer" refers to a staff member tasked with the review of a specific license.

3.1 Web-Based Licensing (WBL) System

The Web-Based Licensing (WBL) System is the computer system for tracking each license issued by the U.S. Nuclear Regulatory Commission (NRC) for nonreactor activities. In addition to maintaining an electronic record of each license, WBL is used to individually track each license application from its receipt to completion. WBL supports a standardized review process and provides licensing and inspection management reports. Each license application is tracked using a variety of methods in WBL to support different reports and queries.

3.1.1 WBL Guidance

NRC users should follow the guidance in the current WBL User Guide. The User Guide is available online upon entry into WBL. For questions about the WBL User Guide or other WBL issues, contact a LA or the WBL System Administrator at NRC Headquarters (HQ) [Division of Materials Safety, Security, State, and Tribal Programs (MSST), Office of Nuclear Material Safety and Safeguards (NMSS)]. The WBL Help Desk can also be contacted at 877-671-6787.

When a request for a licensing action is received, the LA will generate a unique WBL record to track it through the licensing process. A WBL worksheet may be printed for each licensing action request for use by the LA or license reviewer. WBL identifies and tracks the various operations performed on a license and documents the assigned primary and secondary program codes. Program code descriptions and definitions are provided on the NRC's public Web site: https://www.nrc.gov/materials/miau/mat-toolkits.html.

3.1.2 Notice of License Expiration

A Notice of License Expiration letter is sent to each licensee 60 days before its license expires. The HQ LA should routinely generate a standard form letter using WBL. A sample letter is provided in Appendix B, Sample Letter B.1.1 of this NUREG. The form letters are addressed to the attention of the Radiation Safety Officer (RSO) or licensee contact person listed in WBL.

3.2 Administrative Procedures

3.2.1 Acceptance of Documents by the NRC

The NRC may accept several different methods of authentication for initial applications, amendment requests, or renewals. All initial applications and renewals should include with the submittal an NRC Form 313, "Application for Materials License." License amendment requests

may be submitted using an NRC Form 313, or in a letter on company letterhead, which may be submitted by mail, facsimile, or e-mail. However, e-mail may be accepted provided the document is signed by the applicant, licensee, or a duly authorized person. Paper documents received by the NRC are scanned through an optical character reader and converted to an electronic format. To ensure a smooth transfer to an electronic format, applicants and licensees should do the following:

- Submit all documents, typed, on 8½ × 11-inch or legal-sized paper that will feed easily into a document scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura.
- Use 11-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

Pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 30.32(c), 40.31(b), and 70.22(d), each application must be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee. If it is not clear whether the application was signed by someone duly authorized to act for and on behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual who signed the application is duly authorized to act for and on behalf of the applicant or licensee. By signing the application, the duly authorized individual acknowledges the licensee's commitments and responsibilities.

Applications may be submitted in electronic form via the NRC's Electronic Information Exchange or CD-ROM. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at https://www.nrc.gov/site-help/e-submittals.html. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of non-public information. Additionally, license reviewers should refer to NRC Management Directive (MD) 2.9, "Use and Acceptance of Electronic Signatures" (Agencywide Document Access and Management System (ADAMS) Accession No. ML17283A173) for additional information about understanding and implementing electronic signatures at the NRC.

The NRC will accept both handwritten and digital signatures on applications. NRC will accept a handwritten signature on the NRC Form 313 or company letterhead, which is submitted by mail, faxed, or scanned and attached to an e-mail. In addition, the NRC will accept a digital signature for electronic requests.

3.2.2 Initial Processing of Incoming Licensing Actions

All incoming licensing documents, with the exception of Classified or Safeguards Information, will be entered into ADAMS as Non-Publicly Available Pending Review. Documents are made available to the public in accordance with current procedures. Documents may be processed using MD 3.4, "Release of Information to the Public" (ADAMS Accession No. ML080310417),

which is subject to change. The LA should watch for change notices issued in ADAMS and periodically review and confirm that the licensing staff is using the latest version of templates issued by the NRC's Office of Information Services.

Documents containing information restricted under the provision of 10 CFR 2.390 as proprietary should be entered into ADAMS in their entirety, but the file should be profiled in ADAMS as non-publicly available (see Section 4.17 of this NUREG). Documents containing information that meets one of the Sensitive Unclassified Non-Safeguards Information (SUNSI)[1] criteria (see Section 4.22 of this NUREG) should be entered into ADAMS in their entirety, but the file should be profiled in ADAMS as non-publicly available and with the corresponding sensitive value code.

The LA is responsible for the processing of all materials license applications. All materials licenses are assigned unique license and docket numbers that are tracked in WBL for the life of the license. In addition, each licensing action is assigned a unique mail control number that is generated by WBL and tracked in WBL from receipt of a request for licensing action to completion. All documents associated with the licensing action should be profiled in ADAMS and include the same unique mail control number, docket number, and license number.

To process the large number of requests for licensing actions effectively and efficiently, each licensing action should receive an initial administrative completeness review using NRC Form 532, "Acknowledgement—Receipt of Correspondence" (ADAMS Accession No. ML18200A140), at the time of its receipt, but not later than 30 days after receipt. The LA should send a copy of NRC Form 532 to the applicant or licensee via mail or other methods (e.g., facsimile, scanned and attached to an e-mail). The LA can routinely perform the administrative completeness review. This administrative completeness review performed by the LA is different from a technical Acceptance Review performed by a license reviewer (see Sections 4.2.1 or 4.3 of this NUREG). Both the administrative completeness review and technical Acceptance Review precede the technical review (see Sections 4.4.2 and 4.4.3) performed by the license reviewer.

For new licensing actions from existing licensees, the LA will enter information into WBL, and a mail control number will be generated by WBL. For new applicants who do not have a license, the LA will enter the information into WBL, assign a unique institution code, and enter a primary program code upon initial entry. WBL will generate a mail control number and assign a unique docket number for the new application. After completing entries into WBL, the LA will create an action package or document the file in ADAMS containing all the scanned or electronically added documents for a license reviewer's use in completing the licensing action. License reviewers can obtain WBL worksheets electronically from the Reports section of WBL. The technical review starting date in WBL should be the date of the completion of the technical Acceptance Review. The technical Acceptance Review should be completed within 30 days of receipt of the licensing action.

Use NRC Form 580 to add a new or modify an existing program code. NRC Form 580 is <u>not</u> used to change a program code on a license. Assign a five-digit program code number to each license to designate the major activity or principal use authorized in the license. The assignment of an appropriate program code to a license activity affects the fee and inspection

[1]SUNSI will be replaced at the NRC by Controlled Unclassified Information (CUI) around the end of 2021. The CUI program will change how the NRC currently marks, handles, safeguards, and disseminates sensitive information.

priority for that license. Licenses with multiple activities may be assigned multiple program codes. Program code descriptions and definitions are provided on the NRC's public Web site: https://www.nrc.gov/materials/miau/mat-toolkits.html.

For complex licensing actions, the LA may wish to confer with a member of the technical staff while performing the administrative completeness review. This initial administrative processing does not in any way replace the technical Acceptance Review or the required technical review specified in the NUREG–1556 series. After the LA conducts an administrative completeness review, the licensing request is ready for the license reviewer to conduct the technical Acceptance Review (see Chapter 4 of this NUREG). If the licensing action does not contain sufficient administrative information to proceed with the requested action, the LA should discuss the licensing action with the assigned license reviewer and cognizant Branch Chief. The LA should include on the NRC Form 532 any administrative omissions.

Responsibility for Review of License Applications

To ensure uniform handling of license applications between licensees and Regions and to minimize licensing and inspection conflicts, the responsibility for reviewing a license application and issuing the license should be assigned to the Region where the licensed activities are inspected. In most cases, the mailing address and the place of use are located in the same Region.

When a mailing address is located in one Region and the field offices are located in another Region, the licensee should be assigned to the Region where the majority of field offices are located. In most cases where an application or license authorizes the use of material in multiple Regions, the mailing address of the parent company should be used to determine the Region that will conduct the review and issue the license.

Certain types of licenses and certificates are reviewed and issued by NMSS staff at HQ (e.g., exempt distribution licenses, Sealed Source and Device registration certificates, a few source materials licenses, registration certificates for *in vitro* testing with byproduct material under general licenses, and certain source and special nuclear materials licenses in quantities that exceed the requirements of 10 CFR 150.11). Contact NMSS/MSST if it is unclear who has responsibility for the review.

3.2.3 Processing Misdirected Materials Licensing Applications

Applications that licensees mistakenly send to HQ, either to NMSS or to the Office of the Chief Financial Officer (OCFO), will be handled in the following manner:

1. Original applications will be entered into ADAMS by an HQ LA with a preliminary profile in the HQ Central Mail Room.

2. Applications that NMSS receives will be discussed with the Regions to determine who should take the lead for the licensing action. NMSS will designate the proper licensing Region that should receive the application if the application will not be reviewed and approved by NMSS. If NMSS is to take the lead for an application, then the LA will enter the application into WBL and process it through milestone 02 and forward a copy of the payment to OCFO.

3. If the misdirected application is for an action that does not require a fee (e.g., amendments and renewals), NMSS will forward the application directly to the licensing Region. If the license reviewer determines there is a change in the scope of existing license that increases the annual fee, the Region will notify OCFO.

4. Applications that OCFO receives will be processed by OCFO for fee purposes. If the applicant has submitted the proper fee, or if the licensee is fee exempt, OCFO will then forward the application to the appropriate Region for entry into WBL. The Region, normally the regional LA, will call OCFO to let them know when milestones 01 and 02 have been entered into WBL so that OCFO can enter the fee milestones. (See Chapter 5 of this NUREG for fees processing.)

5. If OCFO receives an application without the proper fee, or with no fee, they will send the application to NMSS for entry into WBL, and then NMSS will determine who will take the lead for the application.

Applications that are mistakenly directed to the incorrect Region should be handled in a similar manner, whether they are the responsibility of HQ or another Region, including general license registration certificates (see Section 3.2.9 of this NUREG) and any other submittal that should go to another office. The appropriate licensing office should contact the licensee to remind them to send future correspondence to the proper address.

The above procedures should ensure that the original misdirected application or amendment request is forwarded to the appropriate office within 5 to 7 days.

3.2.4 Follow-Up on Mail Returned From Licensees

A small fraction of mail sent to licensees is returned to NRC marked ‘undeliverable.’ It is extremely important that the LA follow up on these cases. Mail returned to NRC may indicate a number of problems, ranging from a clerical error to loss of control of a licensed program. The procedure listed below should be followed with regard to returned mail:

1. Mail returned to NRC as undeliverable should be checked by the LA against the license file to ensure that the address on the envelope corresponds with the address the licensee provided on the last licensing action completed. If the mailing address differs from the license file due to an NRC clerical error, WBL should be checked and corrected, as needed. Correct the mailing address and re-send the documents. Otherwise, contact the licensee via telephone or e-mail to determine the correct mailing address, and request a letter from the licensee documenting the change. An administrative corrected copy of the license should be sent to the licensee.

2. Any pending application related to the license should be checked for the correct mailing address.

3. For mail returned to NRC for any reason other than an NRC clerical error, the regional licensing staff should coordinate with the inspection staff to ensure that the matter is evaluated, and (if necessary) the inspection staff should conduct a site visit. This is especially important for licenses that involve large quantities of radioactive materials. The regional licensing staff should inform the licensee to submit a change of address request, along with any amendment requests associated with the change of address.

4. When the licensee can be located through telephone contact or other sources, the LA or NRC staff may notify the licensee by sending a Returned Mail Follow-up Letter using the template in Appendix B, Sample Letter B.1.4 of this NUREG ; however, a documented telephone conversation record may also serve as record of notification (see NRC Form 699 in Appendix B, Sample Letter B.2.2 of this NUREG).

5. If the attempts to reach the licensee by telephone indicate that the number has been disconnected or is no longer in service, a reactive inspection or site visit should be considered. The reactive inspection or site visit should follow the direction provided in NRC Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program," to ensure that licensed material is safe and secure.

6. If the LA or designee believes the licensee possesses radioactive material but cannot be located, and the NRC staff suspects wrongdoing by the licensee, the allegation process should be followed.

3.2.5 Expired Materials Licenses

The identification and review of expired licenses is an important part of the material licensing and inspection program, as shown in Checklist A.1. A license is considered pending expiration if a renewal application has not been received or postmarked on or before 30 days prior to the expiration date posted on the license. The following procedure for expired licenses should be followed:

1. On or about the fifth of each month, the Regions and HQ staff should identify from WBL Management Report No. 15 (Expired License Report) all materials licenses issued by the Regions and HQ that expired the previous month.

2. WBL automatically distinguishes between licenses that are considered under timely renewal and licenses that are expired, provided the regional offices and HQ have correctly classified the Action Type as Renewal and the status as Pending Renewal. Licensing staff should note that a license pending expiration and an expired license cannot be renewed; however, it can be superseded by a new license.

3. If a termination request is pending for a license, WBL will designate it as "Pending Termination" from the beginning of the process until final action has been taken on the termination request, even if the action extends beyond the actual expiration date. When the license is terminated, then an NRC Form 314 (a copy of the form is available at https://www.nrc.gov/reading-rm/doc-collections/) or equivalent is filed in the official docket file, along with supporting documentation verifying the disposition of the material and that the facility is free of contamination in excess of regulatory requirements. Step 3 does not apply to licenses that only allow distribution.

4. The regional licensing staff should coordinate with the inspection staff and take appropriate follow-up action on expired licenses. If the license includes large quantities of radioactive materials, then follow-up action should be prompt. This follow-up action may include a visit to the facility to ensure that radioactive materials are not possessed by the licensee or that significant contamination does not exist in the facilities where radioactive materials were used or stored. The results of the inspection should be forwarded to the regional licensing staff.

5. The regional and HQ licensing staff, under most circumstances, should make the final decision on license retirement. A license is considered retired after an expired license has been terminated. Before the license is retired, the NRC staff should ensure that there is sufficient documentation in the file to demonstrate (i) that a new license has been issued superseding the expired license or (ii) that the licensee has ceased operations, properly transferred or disposed of all radioactive material, and provided documents demonstrating that the facility is suitable for release for unrestricted use, if applicable.

6. For expired licenses for which the Region has licensing responsibility, the regional licensing staff should retire the licenses, as appropriate, in accordance with current records retirement procedures outlined in the latest revision of NUREG–0910, Revision 4, "NRC Comprehensive Records Disposition Schedule" (ADAMS Accession No. ML051390495), and change the license in WBL to retired status. For all licenses that are retired and where the licensing staff has issued a new license related to the retired license, there should be a statement in the retired docket file indicating that a new license has been issued.

7. Questions concerning proper document retirement procedures and disposition of retired docket files may be directed to the Office of Chief Information Officer, Governance and Enterprise Management Services Division. Also, see Section 4.23 to ensure proper license status change when a license is retired.

3.2.6 Preparation and Distribution of Completed Licensing Documents

Completed licensing documents will be prepared and distributed per ADAMS Document Submission Guidelines (available in the WBL User Guide). These instructions are subject to change, so the LA should watch for change notices and periodically confirm that the licensing staff is using the latest version of the instructions.

1. Currently, all licenses are amended in their entirety (i.e., supersedes the previous license). This process will assist inspectors and provide a complete, up-to-date license in ADAMS. **If the license under review is not being renewed, be careful that the expiration date is not changed.** After the license is mailed to the licensee, the licensing staff should ensure that the license and all supporting documents for the current action are placed into ADAMS, unless they are already in the system. Be sure to follow appropriate SUNSI guidance (see Section 4.22 of this NUREG) for release or nonrelease of documents in ADAMS.

2. The license reviewer should ensure that the correct program code is assigned to the license in WBL.

   ***Note**:* It is imperative that program codes are correct because the fee billing process is based on the correct codes being assigned to each license issued. When it becomes necessary to assign more than one program code to a license, the code with the highest inspection priority (shortest inspection cycle) should be designated the primary code.

3. The docket number, license number, and mail control number should be included on all outgoing correspondence to assist in the identification of documents being processed.

4. Historically, after issuing the final licensing action to the applicant, distribution was limited to the docket file and the Public Document Room for most materials licenses. For distribution using ADAMS, consult the ADAMS Document Submission Guidelines for the distribution instructions.

5. Completed materials licensing documents should be saved in ADAMS folders. For licensing staff convenience, ADAMS packages may be created and used to associate documents that are dispatched or linked together as part of a physical package.

6. Do not scan classified or safeguards information into ADAMS. Classified or safeguards information should be handled in accordance with MD 12.2, "NRC Classified Information Security Program" (ADAMS Accession No. ML14142A085), and MD 12.7, "NRC Safeguards Information Security Program" (ADAMS Accession No. ML14142A166). Nonsensitive transmittal letters should be separated from sensitive attachments, the markings defaced (normally strikeout), and then added to ADAMS as a public record of the licensing action. Documents containing information restricted under the provision of 10 CFR 2.390 as proprietary should be entered into ADAMS in their entirety, but the file should be profiled in ADAMS as non-publicly available (see Section 4.17 of this NUREG). Documents containing information that meets one of the SUNSI criteria (see Section 4.22 of this NUREG) should be entered into ADAMS in their entirety, but the file should be profiled in ADAMS as non-publicly available and with the corresponding sensitive value code.

7. All correspondence addressed to, or that involves activities of, the NRC Advisory Committee on the Medical Uses of Isotopes should be marked Official Use Only. These documents and the associated package will be profiled in ADAMS as non-publicly available.

8. Regional Offices should coordinate with the States in their Regions and determine what licensing documents they wish to receive. If a State requests to receive licensing documents issued by NMSS (e.g., exempt distribution licenses), the Region should inform NMSS of the request.

3.2.7 Availability, Security, and Integrity of Materials License Files

Prior to 2000, the Agency's hard copy docket files were maintained in the HQ File Center for licenses issued by NMSS and in the regional docket file rooms for licenses issued by the Regions. Starting in April 2000, NRC began managing all official docket files in ADAMS. ADAMS is now NRC's official electronic records storage and retrieval system and should reduce the need to maintain paper-based record collections. ADAMS also replaces the Nuclear Documents System, the Public Document Room's Bibliographic Retrieval System, and the Regulatory Information Distribution System.

The historical Nuclear Documents System information can be obtained from ADAMS legacy library. The profile in ADAMS will provide the microfiche and page number for the document.

Most of NRC's Official Agency Records (OARs) and other nonrecord reference materials will be maintained in ADAMS. ADAMS will store OARs, including programmatic and administrative records that were kept in paper recordkeeping systems, with the exception of unclassified safeguards information and other sensitive records determined to be inappropriate for electronic

maintenance. The NRC staff will add records to ADAMS using the guidance provided in the appropriate final ADAMS Document Templates located in the ADAMS Document Manager.

The term OAR has the same meaning and definition for "records" as defined in Title 44 of the United States Code (44 U.S.C.) 3301. In 44 U.S.C. 3301, the term "records" includes the following:

> all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them.

Some examples of documents that contain OARs requiring preservation under Federal regulations are as follows:

- documents related to NRC programs, policies, organizations, decisions, decision making, minutes, or agendas
- documents containing unique information that explains why the agency made a decision or took an action
- documents that direct one to take an action or that one uses to direct another to act
- information that NRC creates or acquires via e-mail, facsimile, telephone record, or meeting notes about a licensing matter or an inspection of a licensee's facility that contains (i) unique information, (ii) the rationale for an NRC decision, or (iii) guidance that is not documented in the OAR

The partial listing of materials and publications below will provide further information on this subject:

> Management Directive 3.1, "Freedom of Information Act"
>
> Management Directive 3.4, "Release of Information to the Public"
>
> Management Directive 12.2, "NRC Classified Information Security Program"
>
> Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program"
>
> Management Directive 12.7, "NRC Safeguards Information Security Program"
>
> 10 CFR 2.390 "Public Inspections, Exemptions, Requests for Withholding"
>
> NRC SUNSI Web site available on the NRC Office of Information Services Web site (on the NRC internal Web site)

3.2.8 Coordinators for Certain Federal Organizations

Certain Federal organizations coordinate licensing actions through a central office. These coordinators may support single licenses, multisite licenses, master materials licenses, or a license that controls several, specific licenses issued to the same Federal organization. In the case of the Department of the Interior, Bureau of Indian Affairs, the Federal organization holds

lands in trust for federally recognized Indian Tribes and may be useful to determine exclusive Federal jurisdiction on Indian lands. The current coordinator information for these Federal organizations can be obtained through NMSS.

3.2.9 Processing General License Registration Certificates

This section provides guidance for processing NRC Form 244, "Registration Certificate—Use of Depleted Uranium Under General License," and NRC Form 483, "Registration Certificate—*In Vitro* Testing With Byproduct Material Under General License." For annual registration of generally licensed devices under 10 CFR 31.5, see NRC Form 664, "General Licensee Registration." Copies of these forms are provided at https://www.nrc.gov/reading-rm/doc-collections/.

NRC Form 244: The regulations in 10 CFR 40.25 grant a general license to persons who receive, acquire, possess, use, or transfer depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device. Such use only applies to industrial products or devices that have been manufactured or initially transferred under a specific license issued pursuant to 10 CFR 40.34(a) or under an equivalent Agreement State license. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license under 10 CFR 40.25 must register with the NRC by filing NRC Form 244 by an appropriate method listed in 10 CFR 40.5, with a copy to the appropriate NRC Regional Administrator (RA), within 30 days after first receipt or acquisition of such depleted uranium.

NRC Form 483: The regulations in 10 CFR 31.11 grant a general license to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital for receipt, acquisition, possession, transfer, or use of specified byproduct material "in prepackaged units" not exceeding certain quantities for any regulatory authorized *in vitro* (outside the body) clinical or laboratory testing. Such testing, under the provisions of a general license, must not involve the direct administration of this type of byproduct material to human beings or animals. A person must not receive, acquire, possess, use, or transfer byproduct material under the 10 CFR 31.11 general license unless that person has registered with the NRC by filing NRC Form 483 and received an acknowledgment of the registration from the NRC with a registration number assigned.

NMSS/MSST/Branch with Licensing Responsibilities

1. Provide on request a copy of NRC Form 244 or 483 to new applicants requesting a general license for the use of certain industrial products or devices containing depleted uranium (a source material) or the use of certain byproduct material for *in vitro* clinical or laboratory testing.

2. Review NRC Forms 244 and 483 when received to ensure that the applicant is eligible for a general license and that the proposed activities are in accordance with the provisions of 10 CFR 40.25 and 10 CFR 31.11, as appropriate. If activities are not in accordance with these regulations, contact the applicant regarding the lack of conformance with the NRC general license regulations.

3 Mail the signed NRC Form 244 or 483 to the applicant with a registration number assigned to the applicant. Signature authority for the reviewing official of generally licensed activities should be designated according to NMSS policy.

4. Place NRC Forms 244 and 483 in ADAMS. These records are unscheduled and are retained according to NUREG–0910, "NRC Comprehensive Records Disposition Schedule."

Registration Requirements

NRC Form 244

1. A person who receives, acquires, possesses, uses, or transfers depleted uranium is subject to the regulations in 10 CFR 40.25. Within 30 days of first receipt or acquisition of such depleted uranium under a general license, a general licensee must file NRC Form 244 with the Director, NMSS, with a copy to the appropriate NRC RA.

   ***Note**:* There is no fee for filing a registration for a general license under 10 CFR 40.25.

2. A person who receives, acquires, possesses, uses, or transfers depleted uranium contained in industrial products or devices for mass-volume applications under a general license must comply with the regulations in 10 CFR 40.25.

   ***Note**:* This general license applies only to industrial products or devices that have been manufactured or initially transferred under a specific license issued pursuant to 10 CFR 40.34(a) or under a specific license issued by an Agreement State that authorizes manufacture of the products or devices for distribution to persons generally licensed by the Agreement State.

NRC Form 483

1. Any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital requesting a general license for the receipt, acquisition, possession, use, or transfer of a specified byproduct material not exceeding certain quantities in "prepackaged units" for *in vitro* clinical or laboratory testing is subject to 10 CFR 31.11. Before receiving, acquiring, possessing, using, or transferring byproduct material under a general license, a general licensee (with the exception of Part 35 medical use licensees) must register by filing NRC Form 483 with the Director of NMSS and must receive an acknowledgment of the registration by way of a validated NRC Form 483 with a registration number assigned.

   ***Note**:* There is no fee for filing a registration for a general license under 10 CFR 31.11.

2. A person who receives, acquires, possesses, uses, or transfers byproduct material under a general license for use for certain *in vitro* clinical or laboratory testing must comply with the regulations in 10 CFR 31.11 (included on NRC Form 483).

   ***Notes**:* 10 CFR 32.71 authorizes the issuance of specific licenses for the manufacture and distribution of byproduct material for use under general license pursuant to 10 CFR 31.11 provided that specific requirements are satisfied.

   General licensees operating under 10 CFR 31.11 are limited to specific radioisotopes and unit quantities of radioactive material.

Persons authorized by a specific license under the provisions of 10 CFR Part 35 for the medical use of byproduct material may receive, acquire, possess, use, or transfer byproduct material under a general license without filing NRC Form 483.

The *in vitro* testing must not involve the internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

"Prepackaged units" include individual reagent vials, radio assay kits, and/or calibration sources.

Processing of NRC Forms 244 and 483

The branch with licensing responsibilities in NMSS will process NRC Forms 244 and 483 as follows:

1. Receipt—The HQ Document Control Desk will forward the hard copy of the request directly to the Licensing Branch for processing without scanning the document into ADAMS.

2A. Processing Form 244 Requests—Search in ADAMS to determine whether the applicant has a valid form on file. If there is a record for the applicant, enter the file number from the initial filing in General License Tracking System (GLTS) database onto the revised Form 244. Otherwise, obtain the next file number from GLTS database, and enter it onto the hard copy Form 244.

2B. Processing Form 483 Requests—Verify that the applicant is a physician, a veterinarian in the practice of veterinary medicine, a clinical laboratory, or a hospital. Search the existing document submitted to determine if the applicant has a valid form on file. If there is a record for the applicant, enter the validation number from the initial filing onto the revised Form 483. Otherwise, obtain the next validation number from the GLTS database and enter it onto the hard copy Form 483.

3. Approval and Distribution—A licensing staff member will sign and date the hard copy form, scan the completed form into ADAMS, complete the profile, and declare it an OAR. The licensing staff should mail the signed, original form with an acknowledgment letter back to the applicant. A sample acknowledgment letter is provided in Appendix B, Sample Letter B.1.3 of this NUREG. The licensing staff member should notify the applicable regional office regarding the approval of the NRC Form 244 or 483 request.

   ***Note**:* All new NRC Form 244 and 483 requests will be maintained in ADAMS. The historical hard copy requests are maintained by the branch with licensing responsibilities in NMSS. These historical hard copy files (received before April 2000) are not currently scanned into ADAMS; therefore, these hard copy records should be searched for previously submitted forms. This preliminary review, in addition to searching ADAMS, should be conducted before completing the request and adding the file/validation number.

4. Deficiencies—If an NRC Form 244 or 483 is found deficient (i.e., does not contain the required information or indicates that the applicant would not qualify under the provisions of a general license), the license reviewer will attempt to resolve the deficiencies through e-mail, facsimile, or telephone contact with the applicant. If the deficiencies can be resolved in this manner, then the license reviewer will mark the form with the corrections

the applicant provided. If the deficiencies cannot be resolved, then send a formal letter to the applicant requesting the necessary information.

5. Termination—If a licensee requests the termination of an NRC Form 244 or 483 registration certificate, the termination will be processed through the NMSS licensing staff by mailing a termination letter to the general licensee. The letter should include the validation number previously assigned to the general licensee. The licensing staff should also notify the appropriate regional office regarding the termination of the NRC Form 244 or 483 registration certificate.

3.2.10 Processing Reciprocity Applications (Form 241)

This section provides guidance to licensing staff on processing the initial NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters," and licensee-requested changes to NRC Form 241. Agreement State licensees wishing to perform licensed activities in Non-Agreement States, areas of exclusive Federal jurisdiction in Agreement States, Federal offshore waters, or Tribal lands (i.e., areas of NRC jurisdiction) are subject to the general license regulations in 10 CFR 150.20. Under this provision, the NRC recognizes and allows certain Agreement State licensees to work in areas of NRC jurisdiction under their Agreement State license, provided the Agreement State license does not limit the authorized activity to a specific installation or location. Specifically, the general license under 10 CFR 150.20 only applies if the Agreement State license authorizes temporary jobsites or alternate locations for the requested activity.

Agreement State licensees are required to report their proposed activities in areas of NRC jurisdiction to the NRC RA of the Region in which the Agreement State is located. Every calendar year the NRC must receive, from the Agreement State licensee, consistent with 10 CFR 150.20, the initial request of the NRC Form 241 at least 3 calendar days prior to the proposed work date.

Jurisdiction

In certain situations, NRC or Agreement State jurisdictions can be very complex. Reviewers should refer to the definitions and guidance in Volume 19 of NUREG–1556, "Consolidated Guidance About Materials Licenses: Guidance for Agreement State Licensees About NRC Form 241 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters' and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)," and NMSS procedure (State Agreements) SA-500,"Jurisdiction Determinations," to assess whether NRC has jurisdiction over the proposed activity.

In general, the Federal Government exercises various kinds of jurisdiction over lands that are federally owned. Over some such lands, the Federal Government exercises exclusive Federal jurisdiction. Over certain other federally owned lands, the Federal Government exercises lesser degrees of jurisdiction, which have been commonly designated as concurrent, partial, or proprietorial interest, where certain state laws may still be applicable. Private sector licensees performing work on federally owned or federally controlled lands within Agreement States are covered by one of the forms of jurisdiction noted in the "Definitions" below. If the jobsite is identified as falling under Exclusive Federal Jurisdiction, then the activity is under the regulatory authority of the NRC. However, if the jobsite is identified as other than Exclusive

Federal Jurisdiction, then the regulatory authority is under the Agreement State's jurisdiction, as applicable. The "Definitions" below can be found in SA-500, "Jurisdiction Determinations."

Definitions—Categories of Legislative Jurisdiction

1. Exclusive Federal Jurisdiction—This term is applied in those instances where only Federal laws are applicable, pursuant to the U.S. Constitution or through cession by a State.

2. Concurrent Legislative Jurisdiction—This term is applied in those instances where the State concerned has reserved the right to exercise, concurrently with the Federal Government, all of the same authority.

3. Partial Legislative Jurisdiction—This term is applied in those instances where the State concerned has granted the Federal Government certain portions of the State's authority but has reserved the right to exercise, by itself or concurrently with the Federal Government, other authority (e.g., the right to tax private property).[2]

4. Proprietorial Interest—This term is applied to those instances wherein the Federal Government has acquired some right of title to an area in a State but has not obtained any measure of the State's authority over the area.

On federally recognized Tribal land, there is a presumption that the Section 274b Agreement, as implemented by 10 CFR Part 150, does not transfer regulatory authority to the States for either:

1. American Indian owned companies operating on federally recognized Tribal lands or

2. Private (non-American Indian owned) companies operating on federally recognized Tribal lands.

Consequently, absent NRC-written approval, a State may not regulate activities on federally recognized Tribal lands.

If a State desires to exercise jurisdiction over activities on federally recognized Tribal lands, it must apply, in writing, to the NRC staff providing the basis that it has the requisite legal authority to regulate Atomic Energy Act materials on these Tribal lands. The NRC staff may receive inquiries or questions on the jurisdictional status of activities on federally recognized Tribal lands. NRC will entertain requests from States for determinations as to whether the State may regulate such activities. NRC does not intend to revisit State or NRC decisions, made prior to the issuance of SA-500 (September 25, 2007), on jurisdiction on federally recognized Tribal lands unless a written request is made.

Persons intending to use byproduct, source, or special nuclear material in Antarctica should contact the National Science Foundation at: https://www.nsf.gov, which has management

[2]When property falls within this category (sometimes called Joint Jurisdiction), the Office of the General Counsel (OGC) must make a determination as to the type of authority reserved to the State (e.g., authority for public health protection).

responsibility for the United States Antarctic Program. The Memorandum of Understanding between the NRC and the National Science Foundation is available at: https://www.federalregister.gov/documents/1999/09/15/99-24058/memorandum-of-understanding-between-the-nuclear-regulatory-commission-and-the-national-science.

NRC cannot effectively maintain accurate information regarding jurisdictional status of Federal lands or facilities throughout the country because of the large number of sites and the fact that their status frequently changes. It is the responsibility of the licensee to ask a representative (e.g., contract officer, base environmental health officer, district office staff, Judge Advocate General) of the respective Federal agency whose responsibility it is to exercise Federal control over the site to help determine the jurisdictional status of the land. A written statement concerning the jurisdictional status is not required for the licensee to file reciprocity. If there is any question, then the regional staff should make their own determination by contacting the Federal or state agency with control over the site.

Responsibilities and Authorities

Division of Materials Safety, Security, State, and Tribal Programs, NMSS

NMSS/MSST is responsible for maintaining WBL. WBL contains reciprocity information. WBL is necessary for tracking reciprocity activities, assisting in the planning of inspections of reciprocity activities, and providing summaries of reciprocity activities and inspections on an agencywide basis. NMSS/MSST is also responsible for establishing the procedures and guidelines for processing NRC Form 241.

Regional Offices

1. Before January 1 of each year, issue a procedures letter (see Appendix B, Sample Letter B.5.1 of this NUREG) to all reciprocity licensees who filed during the previous year.

2. Provide a procedures letter or equivalent to new applicants requesting reciprocity.

3. Review each submitted NRC Form 241 to ensure that the requested activity of the Agreement State licensee is in accordance with 10 CFR 150.20 and is authorized under the Agreement State license at a temporary jobsite or alternate location. If the activity requested is not in accordance with the provisions of 10 CFR 150.20, then contact the Agreement State licensee regarding the lack of conformance with the NRC general license requirements.

4. Enter the licensee information from the NRC Form 241 into WBL (Reciprocity module).

5. Profile all reciprocity documents as non-publicly available in ADAMS.

6. Distribute the signed NRC Form 241, and provide notification to the appropriate authorities, including the NRC regional office having jurisdiction in the area(s) where the Agreement State licensee intends to operate under reciprocity. Signature authority for the reviewing officials of the reciprocity activities requested on NRC Form 241 should be designated according to regional policy.

NRC Form 241 Requirements

1. Agreement State licensees requesting reciprocity for activities conducted in areas of NRC jurisdiction are subject to the provisions of 10 CFR 150.20. Under 10 CFR 150.20, the first time within a calendar year that an Agreement State licensee conducts reciprocity activities, it must file a completed NRC Form 241, provide one copy of its Agreement State license, and the appropriate fee, as specified in fee category 16 of 10 CFR 170.31, unless one or more of the exemptions in 10 CFR 170.11(a)(4) are applicable. See 10 CFR 150.20(b)(1) for further details; the licensee must submit the required documentation at least 3 days before performing any work activities.

   ***Note**:* Verify that those licensees engaging in radiography activities are registered as a user for each approved transport package issued a Certificate of Compliance number.

   ***Note**:* If a company has more than one Agreement State license, a separate NRC Form 241 must be submitted for work conducted under each Agreement State license used during the calendar year.

2. All questions concerning reciprocity fees should be referred to OCFO. According to 10 CFR 171.11(b)(1), fees will not be assessed for a license applied for, by, or issued to, a nonprofit educational institution for the possession and use of byproduct material, source material, or special nuclear material.

3. In completing NRC Form 241, the Agreement State licensee should provide sufficient information to enable NRC to conduct unannounced inspections at the location provided. It is important that the information submitted on the NRC Form 241 be specific regarding the location(s) and date(s) of use as well as the activity requested. If it is not possible to provide complete addresses for the locations of work, the licensee should provide as much information as possible concerning the work site(s) or client location(s) such as the town, county, or area. In addition, applicants are encouraged to provide global positioning system coordinates, as appropriate. The licensee is responsible for providing new or additional information concerning addresses or locations of work as soon as such information becomes available.

   ***Note**:* If an applicant or licensee submits documents that give the exact location of use and storage for any amount of radioactive material, the applicant should mark these documents as “Security-Related Information—Withhold Under 10 CFR 2.390.”

4. The Agreement State licensee should only identify work to be conducted during a calendar year.

5. In general, applicants prefer to file for reciprocity by using facsimile transmissions or e-mail to the electronic mailbox established by each region, if available. Either of these electronic methods is acceptable and avoids any possible delays because of the mail system.

6. The initial NRC Form 241 must be received by NRC at least 3 days before the licensee engages in each proposed activity. A copy of the Agreement State license and the check or credit card application on NRC Form 629 should accompany NRC Form 241. A copy of the check serves as a promissory note from the applicant to NRC. It is the

responsibility of the applicant to ensure that the NRC regional office receives the documentation within the specified 3-day time frame.

7. If the electronic method for filing the required NRC Form 241 information is not available to the licensee as a result of an emergency or for other unforeseen reasons, then the RA (or the RA's designee) can waive the time requirements specified in 10 CFR 150.20(b)(1) for the initial and subsequent filing of NRC Form 241, provided the Agreement State licensee requesting reciprocity performs the following actions:

   a. Informs the Region by telephone, facsimile, an NRC Form 241, or a letter of initial activities or revisions to the information submitted on the initial NRC Form 241 (e.g., additional locations of work or changes to the radioactive material or work activities)

   b. Receives oral or written authorization for the activity from the Region

   c. Files NRC Form 241, one copy of the Agreement State license, and the check or credit card application for the fee payment within 3 days after the telephone or facsimile notification

Processing Initial NRC Form 241 (Refer to NUREG–1556, Volume 19)

1. Upon receipt of initial NRC Form 241, stamp or otherwise note the date of receipt on the NRC Form 241 to verify that it is timely filed. The electronic date on the form is sufficient to reflect the receipt date. The initial NRC Form 241 should be received at least 3 calendar days before the licensee begins work, unless the waiver is extended and the provisions stipulated in Item 7 above are met.

   ***Note**:* The initial NRC Form 241 may be submitted with the location and dates of work still to be determined. This is acceptable; however, the general licensee will have to submit a *change* to the NRC Form 241 with the specific location and dates of work when activities are to commence. *Changes* include identifying previously unidentified work locations, changing the radioactive material authorization, adding or deleting dates of work activities, or specifying work activities different from the activities identified on the initial NRC Form 241. See "Processing Changes to NRC Form 241" in this section.

2. Upon receipt of initial NRC Form 241, verify that the applicant has provided the required information on the form and that the certification block for the certifying entity has been signed and dated by the RSO or a management representative.

   ***Note**:* Confirm that none of the licensee's staff members are banned from NRC-licensed activities by checking the escalated enforcement actions issued to individuals. Go to the Office of Enforcement (OE) page for current issues and actions on the external Web site located at https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/. Search for the individual's last name under Individual Actions. If an Order was issued to the individual, read the Order and confirm whether the restrictions still apply. Consult with the OE *before* taking any action for an individual who appears to be banned from NRC activities.

3. Verify that the NRC Form 241 package contains a check or credit card payment using NRC Form 629 for the required fee payment specified in 10 CFR 170.31; one

complete copy of a valid, active Agreement State license; and the initial NRC Form 241, properly signed.

***Note**:* For an NRC Form 241 received without a fee payment, notify the licensee by telephone that the required fee (10 CFR 170.31) must be provided prior to conducting activities under reciprocity. In cases where the Agreement State licensee seeks a waiver of the time requirements in 10 CFR 150.20 from the RA, the reviewing official in the Region may authorize reciprocity activities prior to receipt of the fee. However, the licensee must provide proof of payment (pending the actual receipt of the check or payment by credit card on NRC Form 629). If no proof of payment is available, authorization can only be granted after OCFO has been contacted and OCFO has granted approval. A copy of the check for reciprocity activities serves as a promissory note.

4. Review the Agreement State license that was submitted with NRC Form 241 to verify that the license authorizes the proposed activities. In addition, verify that the license will remain in effect and not expire during the time of the proposed activities. A timely renewal letter issued by the licensee's Agreement State is sufficient for the licensee to continue work under the NRC general license.

   ***Note**:* An Agreement State licensee cannot qualify for a general license under the provisions of 10 CFR 150.20 if the license the Agreement State issued limits the activity authorized by the license to specific installations or locations. The license must authorize temporary jobsites or alternate locations for the general license to be applicable under 10 CFR 150.20.

5. If the NRC Form 241 is found deficient (e.g., does not contain the required information, or the information provided indicates that the applicant does not qualify), the licensing staff should refer to the procedure for handling deficient forms below.

6. When it is determined that the applicant has provided the required information and the correct fee payment, an authorized staff member will sign and date NRC Form 241 as the reviewing official.

   ***Note**:* Signature authority for the reviewing official for reciprocity activities requested by NRC Form 241 should be designated according to regional policy.

7. For an initial NRC Form 241, enter the Agreement State licensee information, work location, and dates of work activity into WBL. The entire calendar year may be entered for each offshore location because there is not a 180-day time limit for the work activity.

   ***Note**:* For offshore waters, the description should include: (i) oil field, (ii) block number, (iii) platform or laybarge, and (iv) the name of the laybarge, as applicable.

8. A unique WBL number is generated for each location entered into the system. For offshore waters, a unique number is assigned to the entire Gulf or Ocean in lieu of a specific location of work. This unique number should be entered on NRC Form 241 under the Location Reference Number, for use by the licensee on subsequent changes to the NRC Form 241. Additionally, the WBL number is updated to ADAMS as the "Case/Reference Number" by Document Process Center.

9. Generate an Acknowledgment Letter [refer to Appendix B, Sample Letter B.5.2 of this NUREG]. Additionally, print a copy of the "Information Notice: Information Needed by the NRC from Caller Concerning Incident Involving Radiation Sources" [refer to Appendix B, Sample Letter B.5.2 of this NUREG].

10. The approved copy of NRC Form 241, Acknowledgment Letter, and the Information Notice may be transmitted via facsimile, e-mail, or other available and efficient method of transmission to the licensee. The original should be placed in the mail to the licensee.

11. Licensing staff should promptly notify, via facsimile or e-mail, the appropriate regional office that has the responsibility for inspecting the reciprocity activities. The licensing staff should annotate "copy to Region ____," indicating the appropriate Region for distribution.

12. A copy of the completed reciprocity package should be scanned into ADAMS as non-publicly available and sensitive (Item Code A.3) and declared as an OAR.

13. A copy of the approved NRC Form 241 and Acknowledgment Letter should be provided to the appropriate Agreement State.

14. Generate a Fee Transmittal sheet to OCFO (refer to Appendix B, Sample Letters B.5 of this NUREG). Make one copy of the check or NRC Form 629, attach it to the Fee Transmittal sheet, and send it to OCFO at NRC HQ in Rockville, Maryland. For additional information about fees, call NRC's toll-free number, 800-368-5642, extension 415-7554. The e-mail address is: Fee.Resource@nrc.gov.

The regional office should not upload the fee sheet to ADAMS. The regional office may choose to maintain a copy of the Fee Transmittal sheet and a copy of payment for their records.

Processing Changes to NRC Form 241

1. Subsequent filings of NRC Form 241 or equivalent documents are considered *changes*. *Changes* include identifying previously unidentified work locations, changing the radioactive material authorization, adding or deleting dates of work activities or work site contacts, or specifying work activities different from the activities identified on the initial NRC Form 241.

2. The amended NRC Form 241 should be submitted to the NRC prior to the licensee engaging in the work activity. The 3-day limit is not applicable for changes to NRC Form 241, but only for the initial NRC Form 241.

3. An Agreement State licensee that is operating under an amended NRC Form 241 general license authorization pursuant to the general license provisions of 10 CFR 150.20 does not have to obtain a "signature review" from NRC before performing reciprocity activities requested on the amended NRC Form 241.

   ***Note**:* Confirm that none of the licensee's staff members are banned from NRC-licensed activities by checking the escalated enforcement actions issued to individuals. Go to the OE page for current issues and actions on the external Web site located at https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/. Search for the individual's last name under Individual Actions. If an Order was issued to the individual,

read the Order and confirm whether the restrictions still apply. Consult with OE *before* taking any action for an individual who appears to be banned from NRC activities.

4. Verify that the applicant has filed the initial NRC Form 241 and is currently authorized in WBL. Check that the information in WBL is current and correct before revising the licensee's reciprocity record in WBL. Confirm that the RSO or a management representative has signed and dated the certification block.

   ***Note**:* It is not necessary for the general licensee to resubmit the Agreement State license unless that license has been amended since the filing of the initial NRC Form 241.

5. If NRC Form 241 is found deficient (e.g., does not contain the required information, has no specific work location provided, or the information provided indicates that the applicant does not qualify as a general licensee), refer to the procedure outlined below for handling a deficient NRC Form 241.

6. An authorized staff member should sign and date the amended NRC Form 241 as the reviewing official. This signature indicates that the revision provided has been reviewed and found sufficient.

7. For new locations of work or different activities, enter the new information into WBL, which will assign a new WBL Location Reference Number. Record the WBL Location Reference Number on the amended NRC Form 241 or equivalent. If the revision is to add or delete dates for an existing location in WBL, then update WBL appropriately.

   ***Note**:* For offshore waters, the description should include (i) oil field, (ii) block number, (iii) platform or laybarge, and (iv) the name of the laybarge, as applicable.

8. The signed copy of NRC Form 241 may be transmitted via facsimile, e-mail, or other available and efficient method of transmission to the general licensee.

9. Licensing staff should promptly notify the appropriate regional office staff, via facsimile or e-mail, who has the responsibility for inspecting the reciprocity activities. The licensing staff should annotate "copy to Region ___," indicating the appropriate Region for distribution.

10. The original signed revision to the amended NRC Form 241 should be scanned into ADAMS as non-publicly available and sensitive (Item Code A.3) and declared as an OAR.

11. On a routine basis, the NRC staff should verify the number of total days of reciprocity charged to date to the general license based on WBL to confirm that the 180-day time limit in 10 CFR 150.20(b)(4) has not been exceeded. This may be accomplished by generating a report from the system, which summarizes the total number of days for each general licensee. The total number of days is the number of days that licensed material was used or stored in areas of NRC jurisdiction. The general licensee may work at multiple jobsites in 1 day. This is calculated as 1 day in determining the number of total days of reciprocity.

Deficient NRC Form 241

1. If either the initial or amended NRC Form 241 contains omissions or errors, first attempt to resolve these items by telephone contact with the Agreement State licensee within 3 days of receipt of the NRC Form 241 request. If the deficiencies can be resolved by telephone contact, mark the NRC Form 241 with the corrections, annotating per telephone call with specific individual, or request that the licensee resubmit the documentation, and emphasize to the licensee the need to comply with the requirements of 10 CFR 150.20.

2. If the deficiencies cannot be resolved by telephone, send a letter to the licensee identifying the errors, omissions, or deficiencies and requesting the necessary additional information. The letter should emphasize the need to comply with the requirements of 10 CFR 150.20 prior to conducting activities under reciprocity. In the deficiency letter, notify the applicant that the review process will continue upon receipt of the requested information.

3. If the applicant does not resolve the deficiencies in its response to the deficiency letter, notify the licensee by telephone and send a follow-up letter within 3 days of receipt of the applicant's response. This letter should specifically explain that the applicant has not submitted the required information and thus does not qualify for a general license under 10 CFR 150.20. Inform the licensee that work is not to be performed in areas of NRC jurisdiction until NRC receives the required information.

4. Inform OCFO regarding the status of the general license, especially if the Agreement State licensee is not authorized to conduct activities in areas of NRC jurisdiction. OCFO should make the determination for handling of the fee payment.

5. If the reciprocity package is approved, then process the package as indicated above. If the reciprocity package is disapproved, then document the decision on the NRC Form 241 or by separate letter. The documentation package should be scanned into ADAMS as non-publicly available and sensitive (Item Code A.3) and declared as an OAR.

Potentially Exceeding 180-day Limit

Under 10 CFR 150.20(b)(4), proposed reciprocity for Agreement State licensees, other than those using materials in Federal offshore waters, must not exceed 180 days in any calendar year. For licensees whose proposed reciprocity activities are approaching or would exceed the 180-day limit, the licensee should be notified by telephone or in writing that a specific NRC license must be applied for and obtained if activities are to be conducted in areas of NRC jurisdiction in excess of 180 days within the calendar year.

Apparent Noncompliance with 10 CFR 150.20

1. If the NRC Form 241 describes activities that appear to be in noncompliance with the Agreement State specific license or other regulatory requirements, take the following actions:

    a. Where the Agreement State license limits use to a specific address or location, advise the licensee, by telephone or in writing, within 3 days of receipt of the

initial NRC Form 241 request, that reciprocity cannot be granted under the current license. Suggest that the applicant apply to the Agreement State licensing authority for a license amendment permitting temporary jobsites or alternate locations on its Agreement State License, or in the alternative, apply to the appropriate NRC regional office for a specific NRC license authorizing the activity requested.

b. In cases where general license activities are considered potential violations of 10 CFR 150.20 (e.g., activities were started prior to when the initial NRC Form 241 was submitted, the Agreement State license has expired, the Agreement State license limits locations of use, the 180-day land-based limit in a calendar year is exceeded, or failure to comply with NRC regulations while conducting activities in exclusive Federal jurisdiction) that may result in NRC enforcement action(s) against the licensee, these violations should be treated in accordance with the NRC Enforcement Policy, which is available at https://www.nrc.gov/reading-rm/doc-collections/enforcement/.

c. Cases where activities, because of their nature or necessity (e.g., emergencies, weekends), were started before changes to the initial NRC Form 241 were phoned in or submitted (but the initial NRC Form 241 was submitted) should be reviewed on a case-by-case basis when determining compliance with 10 CFR 150.20.

***Note**:* Staff should consider other instances of failure to change NRC Form 241 as noncompliance with the general license provisions of 10 CFR 150.20.

NRC Form 241—Equivalence or Misdirection

1. Equivalence—There may be cases where the Agreement State licensee submits a letter in lieu of NRC Form 241 (i.e., submittal cannot be filed at least 3 days before engaging in activities under reciprocity or requests of approval of changes different from the information contained on the initial NRC Form 241). This process is acceptable per 10 CFR 150.20. Changes to the NRC Form 241 may be provided on company letterhead with the revised information provided and signed by the RSO or management representative.

2. Misdirection of NRC Form 241—If an Agreement State licensee inadvertently submits an NRC Form 241 to NMSS, another regional office, etc., then the receiving office will promptly notify the appropriate regional office and immediately forward the submittal via facsimile or e-mail and send the hardcopy by interoffice mail.

Retention and Disposal of Reciprocity Licensing Documents

All reciprocity licensing documents, including the initial NRC Form 241, authorized revisions, supporting documentation, and 10 CFR 2.390 requests, must be retained and/or destroyed in accordance with the approved records disposition schedules contained in NUREG–0910, "NRC Comprehensive Records Disposition Schedule." NUREG–0910 requires that license files be retained for 20 years after license termination. Documents associated with an NRC Form 241 should be retained for 20 years following the year the Form 241 was in effect. ADAMS is the official agency record; therefore, hardcopy records may be destroyed in accordance with regional policy.

4 LICENSE REVIEWER GUIDANCE

4.1 Introduction

4.1.1 NUREG–1556 Series

This chapter provides guidance and criteria to the license reviewer for processing license applications for new applicants, amendments, and renewals. To standardize and simplify the review processes, reviewers should use the available NUREG–1556 tools, including processes, criteria, and checklists, and the risk-informed information provided below, as a roadmap for reviewing license applications. The NUREG–1556 series applies to a broad range of applications, and reviewers should determine the relevant aspects of these guidance documents that apply to a particular application. An applicant may request authorization to use licensed materials in more than one program type. In this case, the reviewer would use more than one NUREG volume to review the application. A complete list of the documents in the NUREG–1556 series is located in the FOREWORD to this document. Most of these volumes have been revised, and the reviewer should verify the current version on the U.S. Nuclear Regulatory Commission (NRC) Web site. In addition, the current guidance for medical uses, including emerging technologies and Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000 modalities, training and experience forms, etc., is located on the medical licensee tool kit at https://www.nrc.gov/materials/miau/med-use-toolkit.html and should be used in conjunction with the license review process, as applicable.

The reviewer should review and compare the specific licensing criteria for each program type to identify the common criteria and the unique issues. The applicant's radiation safety program should adequately address all of the criteria for each program type to be authorized. When adding new or multiple program types to a single license, the reviewer should refer to the NRC's public Web site at https://www.nrc.gov/materials/miau/mat-toolkits.html to identify the program code with the highest inspection priority (shortest inspection cycle). The program code with the highest inspection priority should be identified as the primary program code in Web-Based Licensing (WBL), as this program code will dictate the inspection frequency for this license.

If the NUREG–1556 series or other previously issued directives or guidance does not request information that the reviewer deems is critical to the review of a particular licensing action, NRC Headquarters (HQ) should be informed. If additional guidance beyond the information provided in the NUREG series is needed, this information should be requested in a technical assistance request (TAR). License reviewers should refer to Section 4.16 for specific guidance about TARs.

Also, the Office of Nuclear Material Safety and Safeguards (NMSS)/Division of Materials Safety, Security, State, and Tribal Programs (MSST) branch with licensing responsibilities maintains a link on the MSST Sharepoint site for submitting feedback on any of the NUREG–1556 volumes. This link provides information on the feedback process and allows NRC staff and management to identify any suggested improvements to the NUREG–1556 volumes.

On January 15, 2019, a memorandum was issued (Agencywide Document Access and Management System (ADAMS) ML19015A290) on "Key Principles for Nuclear Material Safety and Safeguards Reviews." The memorandum referenced a May 23, 2018, Commission paper entitled, "Achieving Modern Risk-Informed Regulation." One of the overarching themes discussed in the paper and reiterated in Commission and senior leadership communications is

the need for systematic and expanded use of risk and safety insights in decision making, including the need to appropriately scale the scope of staff review and level of detail needed from an applicant for licensing decisions, consistent with NRC regulations and the overall standard of reasonable assurance of adequate protection.

Consistent with the memorandum and observations identified in the Commission paper noted above, use of this guidance should adhere to the following key principles:

- The scope of the review should reflect a focus on the most risk-significant aspects of an application. As each license application or amendment has the potential to present new and unique issues, the scope and depth of the staff's review should be customized to reflect the specifics of the licensing request. Reviewers should identify as early as possible if there are unique or complex aspects to the licensing review. Unique or complex aspects of a design or activity referenced in an application may require, in coordination with management, NMSS, the Office of General Counsel (OGC), and potentially the Commission, special consideration about the best application of the existing regulatory framework.

- Reviewers should adjust the scope and depth of their review to reflect the stage of the licensing process. For example, in the review of a license renewal application, if the staff concisely documents why its prior reasoning remains applicable to the renewal period, a detailed review of unchanged design features or of programs that were previously reviewed and approved would typically not be needed.

- Reviewers should determine as early as possible if the information in the application is sufficient to make the necessary regulatory finding. Clarifications and validation of staff understanding can be obtained through multiple means, such as telephone contacts, public meetings, or audits, and can be documented in telephone conversation records, meeting summaries, and audit reports, consistent with Management Directive 3.53, "NRC Records and Document Management Program." Requests for additional information (RAIs) should be pursued if the submitted and docketed information is not sufficient for the staff to make a finding, and such requests should provide the regulatory basis for why the information is needed.

- Many review findings are associated with, or predicated on, the licensee or applicant properly implementing various management controls or programs that are identified as license conditions or are separately required by the regulations [e.g., 10 CFR 30.34, 10 CFR 30.38, 10 CFR 40.41, 10 CFR 40.44, 10 CFR 70.32, 10 CFR 70.34, 10 CFR 20.1101(b)]. After determining that the licensee's or applicant's program meets the regulatory requirement(s), the staff should give appropriate credit to the implementation of these programs as part of their review.

Requests to license naturally occurring radioactive material (NORM) should be made to the appropriate regulatory agency. As a result of the Energy Policy Act of 2005 (EPAct), the NRC and the Agreement States, through their agreements with the NRC, regulate discrete sources of radium (Ra)-226, accelerator-produced radioactive materials, and other discrete sources of NORM that pose a threat similar to that of a discrete source of Ra-226, as described in the definition of byproduct material in 10 CFR 30.4. Notwithstanding the EPAct, most NORM continues to be regulated by the States. The NRC will only license NORM if it is a discrete source. Further information on NORM can be found in the Naturally Occurring and

Accelerator-Produced Radioactive Material (NARM) Web link on the NRC's public Web site: https://www.nrc.gov/materials/miau/mat-toolkits.html.

4.1.2 Enhanced Security and Control Through Licensed Activities

Following September 11, 2001, NRC took several measures to upgrade and enhance the control of radioactive materials. NRC issued additional requirements, in the form of Orders and new or amended rules, requiring licensees who possess risk-significant radioactive materials to implement increased security and control measures to reduce the risk of malevolent use and intentional unauthorized access to radioactive material. In response to a 2007 Government Accountability Office investigation, the NRC and Agreement States issued pre-licensing guidance to require on-site visits of unknown applicants prior to issuing a license authorizing possession of any radioactive material (see SECY–07–0147) (ADAMS Accession No. ML072360062). In addition, the NRC specified a possession limit on nearly all types of materials licenses.

The NRC, in coordination with the U.S. Department of Energy (DOE), developed a national, web-based system to track high-risk sources called the National Source Tracking System (NSTS). This system allows State and Federal agencies to track transactions of International Atomic Energy Agency (IAEA) Code of Conduct Category 1 and Category 2 sources from origin (manufacture or import) to disposition (disposal, export, and decay below Category 2 level). NSTS is considered a national resource that includes sources held by NRC and Agreement State licensees and by DOE.

Also, as a result of recommendations from a 2001 Licensing Task Force and the 2003 NRC/DOE Interagency Working Group on Radiological Dispersal Devices, the NRC developed WBL, which is integrated with NSTS and the License Verification System. The License Verification System is intended to provide an automated capability for external stakeholders (licensees and other government users) to verify the legitimacy of a license, license authorization, and possession limit information.

The NRC has developed many elements of security and control for the licensing of radioactive material that are mentioned in this guidance document. Many of the specific documents contain Sensitive Unclassified Non-Safeguards Information (SUNSI)[1] and that information must be redacted before the documents are disclosed to the public.

4.2 Processing New License Applications

4.2.1 Application Package

Applicants for new licenses are expected to provide all the information specified on NRC Form 313, "Application for Materials License." A copy of this form is available at https://www.nrc.gov/reading-rm/doc-collections/. All items in the application should be completed in enough detail for the reviewer to determine if the materials will be used as requested and whether the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect public

[1]SUNSI will be replaced at the NRC by Controlled Unclassified Information (CUI) around the end of 2021. The CUI program will change how the NRC currently marks, handles, safeguards, and disseminates sensitive information.

health and minimize danger to life and property. See Section 4.1.1 for information on performing risk-informed licensing reviews.

The license reviewer performs a technical Acceptance Review of a new application, as described below. The technical review starting date should be the date of the completion of the technical Acceptance Review. The technical Acceptance Review should be completed within 30 days of receipt of the licensing action. If the licensing action does not contain sufficient information, an Acceptance Review Discontinuation letter should be issued. Otherwise, start the normal review of the application. An example of the Acceptance Review Discontinuation letter is contained in Appendix B, Sample Letter B.1.5 of this NUREG. Each Acceptance Review Discontinuation letter should be entered into ADAMS.

Technical Acceptance Review Procedure

Within 30 days of the receipt of a new application, the NRC regional office or HQ performs a technical Acceptance Review of the licensing request and take the following actions:

1. Confirm that all necessary information needed for the application form, NRC Form 313 (available at https://www.nrc.gov/reading-rm/doc-collections/) or a licensing action request letter, are complete and that the form or letter has been signed and dated by the applicant's certifying official. In general, a license reviewer performs this step.

2. Confirm that attachments identified by the applicant are, in fact, included in the submittal.

3. Identify any requests for expedited review for safety-significant concerns (e.g., medical use) or business reasons (e.g., change in ownership, bankruptcy).

4. Identify if the licensee requests any exemptions from the regulations. (This should be only specific licensee requests. The technical Acceptance Review need not identify if a specific procedure submitted would require an exemption.)

Technical Review Process

The reviewer should perform a comprehensive review of the application against the checklists/suggested format in the appropriate NUREG–1556 volume(s). This review should consist of a comparison of all material the applicant submitted against the requirements in the regulations, guidance provided in the appropriate NUREG–1556 volume, and any specific policy guides.

Confirm that none of the applicants are banned from NRC-licensed activities by checking the escalated enforcement actions issued to individuals. Go to the external Web site at https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/individuals/ for escalated enforcement actions issued to individuals. If an Order was issued to the individual, read the Order, and confirm whether any restrictions still apply. Consult with the Office of Enforcement (OE) before taking any action for an individual who appears to be banned from NRC activities.

If the applicant intends to take possession of an aggregated Category 1 or Category 2 quantity of radioactive material upon issuance of their license, an on-site security review [referenced in the risk-significant radioactive material (RSRM) checklist] should be conducted prior to issuance of the license. 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," provides the requirements for any licensee that possesses an aggregated

Category 1 or Category 2 quantity of radioactive material listed in Appendix A of 10 CFR Part 37. The RSRM checklist and guidance are available in the Material Security Toolbox at https://scp.nrc.gov/controls.html. Under 10 CFR Part 37, security plans are not submitted to the NRC during licensing but may be subject to review and inspection.

4.2.2 Deficiencies

If in the process of evaluating an application the NRC determines that insufficient information has been submitted, the license reviewer should contact the applicant to obtain the necessary information. Also, sections of the application that do not conform to, or fail to adequately address, areas in the appropriate guidance should be identified as deficiencies that must be resolved before the license is issued. Reviewers should apply the guidance in the NUREG–1556 series to the extent suitable to the applicant's proposed activities. The reviewer should request any further commitments from the applicant needed to facilitate the review and enable the reviewer to determine whether the license should be issued. The reviewer should not apply any standards or criteria for which there is no specific regulatory basis. Reviewers should only accept procedures or proposals that result in a level of safety commensurate with the activity requested and equivalent to that provided for in NRC guidance.

All deficiencies should be clearly documented and communicated to the applicant. The reviewer may obtain the information by sending a formal written request to the applicant or by notifying the applicant of the need for information via telephone or e-mail. Submittal of an inadequate or deficient application may delay the issuance of the license. If the applicant does not provide a response within the specified timeframe or the response is inadequate, the license reviewer should contact the applicant and discuss the option of withdrawing the application. (See Section 4.11.1.1 of this NUREG.) A withdrawal of the application means that the applicant has given up pursuit of the requested action. However, it does not preclude the applicant from resubmitting their application at a later date.

Normally, the NRC expects the applicant to respond within 30 days of the date of the RAI. Applicants may request an extension of time in order to respond to any correspondence or RAI about its application, provided the NRC determines that there is good cause and the additional time requested is reasonable. Applicants may make these requests in writing or via telephone. Typically, the reviewer notifies the applicant by telephone that an extension has been granted and gives the applicant the new proposed response date.

4.2.3 Pre-Licensing Guidance and Risk-Significant Radioactive Material Checklist

The Pre-Licensing Guidance (PLG) was developed to provide a basis for confidence that radioactive material will be used for the purposes authorized under the license. This guidance applies to (i) a new applicant (i.e., an entity that has never had a license or is unknown to the licensing authority) requesting a specific license or (ii) a new applicant requesting the transfer of control from a known licensee. The PLG is available in the Material Security Toolbox at https://scp.nrc.gov/controls.html.

The RSRM checklist and guidance are used to identify licensing actions that may require additional security measures. They also contain information about the on-site security review. An on-site security review (i.e., a review of on-site security measures) is conducted prior to an applicant or licensee taking possession of an aggregated Category 1 or Category 2 quantity of

radioactive material. The purpose of the on-site security review is to verify whether the new applicant or licensee requesting aggregated Category 1 or Category 2 quantities of radioactive material has a thorough understanding of or has implemented the applicable 10 CFR Part 37 Physical Protection Program prior to taking possession of these radioactive materials. The RSRM checklist and guidance are available in the Material Security Toolbox at https://scp.nrc.gov/controls.html.

4.2.4 National Source Tracking System

The NSTS is a secure web-based database designed to identify the initial receipt and disposition of Category 1 and 2 radioactive sources that are regulated by the NRC and Agreement States. The regulation under 10 CFR 20.2207 applies to each licensee who manufacturers, transfers, receives, disassembles, or disposes of a nationally tracked source to another person. The licensee is required to submit an NRC Form 748, "National Source Tracking Transaction Report." Because licensees have limited access to the database, license reviewers will ensure that the licensee information in the NSTS is as accurate as possible. This is especially important so that the annual reconciliation may be mailed to the correct primary contact person. Credentials are required to have access to NSTS and are available at https://www.nrc.gov/security/byproduct/ismp/nsts/credentialing.html.

The reviewer should initiate Checklist A.2, "National Source Tracking System (NSTS) Update," in Appendix A of this NUREG. A credentialed NSTS user should update the following information in NSTS for a new application, renewal, or amendment action associated with Category 1 or Category 2 quantities of concern:

1. NSTS Contact Name and Title (at a minimum should be the RSO)

2. NSTS Contact Telephone Number

3. NSTS Contact Facsimile Number

4. NSTS Contact E-mail Address

5. Licensee Name

6. Licensee Mailing Address

7. Add Locations of Use (Street, City, State, Zip Code)

For those licenses that authorize temporary jobsites, NSTS should reflect "temporary jobsite" as the location of use.

The NRC has established a Help Desk to assist users by answering questions and resolving issues related to credentialing, login procedures, system use, transaction reporting, and any problems encountered in using the NSTS. Reviewers can e-mail NSTSHelp@nrc.gov or call 1-877-671-6787 to contact the NSTS Help Desk.

4.2.5 Processing a New Master Materials License (MML) Application

Upon receiving an application for an MML license:

- NRC HQ will assign a region to manage the MML application and program.
- Regional management will appoint a regional MML project manager (PM) to the application and program.
- NRC will establish an MML application review team, which consists of HQ and regional staff.

The appointed regional PM will lead the application review team and ensure that the following items are performed:

- Establish a full cost billing action to recover the cost of reviewing the new application.
- Process and track all actions, including licensing, inspections, incidents or events, allegations, investigations, and enforcement.
- Identify MML licensees with a history of health and safety issues or programmatic concerns.
- Transfer or archive NRC license docket folders for terminated MML facility licenses.

Note: See NUREG–1556, Volume 10, for more information on MML licensing.

4.3 Processing Amendments

The licensee is obligated to keep the license current. If any of the information provided in the original application changes in a way that requires an amendment to the license, as required by the regulations, or in any way affects specific items concerning NRC jurisdiction, then the licensee must submit an application for a license amendment to reflect the change, prior to the change taking place. The licensee should identify the specific changes in the amendment request and discuss the basis for the changes. The reviewer should focus their evaluation on only those areas that the licensee indicates need revision. If the licensee completely resubmits the entire application, the reviewer should request that the licensee specifically identify the requested changes. The licensee may opt to resubmit the request and only discuss the specific changes, or the licensee may identify the changes by marking or highlighting the modified text. See Section 4.1.1 for information on performing risk-informed licensing reviews.

The license reviewer performs a technical Acceptance Review of a license amendment, as described below. The technical review starting date in WBL should be the date of the completion of the technical Acceptance Review. The technical Acceptance Review should be completed within 30 days of receipt of the licensing action. If the licensing action does not contain sufficient information, an Acceptance Review Discontinuation letter should be issued. Otherwise, start the normal review of the application. An example of the Acceptance Review Discontinuation letter is contained in Appendix B, Sample Letter B.1.5 of this NUREG. Each Acceptance Review Discontinuation letter should be entered into ADAMS.

Technical Acceptance Review Procedure

Within 30 days of the receipt of a license amendment application, the NRC regional office or HQ should perform a technical Acceptance Review of the licensing request and take the following actions:

1. Confirm that all necessary information needed for the application form, NRC Form 313 (available at https://www.nrc.gov/reading-rm/doc-collections/) or a licensing action request letter, are complete and that the form or letter has been signed and dated by the applicant's certifying official. In general, a license reviewer performs this step.

2. Confirm that attachments identified by the applicant are, in fact, included in the submittal.

3. Identify any requests for expedited review for safety-significant concerns (e.g., change in the RSO, medical use, or amendment requests resulting from identification of safety-significant violations) or business reasons (e.g., change in ownership, bankruptcy).

4. Identify if the licensee requests any exemptions from the regulations. (This should be only specific licensee requests. The technical Acceptance Review need not identify if a specific procedure submitted would require an exemption.)

Technical Review Process

The reviewer should perform a comprehensive review of the license amendment against the applicable checklists/suggested format in the appropriate NUREG–1556 volume(s). This review should consist of a comparison of all material the licensee submitted against the applicable requirements in the regulations, guidance provided in the appropriate NUREG–1556 volume, and any specific policy guides.

If the license amendment meets any of the significant licensing actions identified on Checklist A.3, "Identification of Significant Licensing Action and/or Program Code Change," or authorizes any activity that the reviewer determines the inspection staff should be aware of, complete Checklist A.3.

If the license amendment request requires implementation of 10 CFR Part 37, refer to Section 4.2.3 for guidance.

If the license amendment changes, modifies, or adds to any of the administrative fields that the NRC is required to maintain in NSTS, then the reviewer should follow the guidance in Section 4.2.4 to update or delete the administrative license information in NSTS. This is especially important for the primary contact information and RSO designation because the annual reconciliation letters are sent to the primary contact during the last quarter of the calendar year.

4.4 Processing Renewals

NRC developed a four-part materials license renewal process that provides a platform for a complete review of the license renewal package. To complete a review of the renewal package, the reviewer should:

1. Review licensee records for the previous 5 years against the performance indicators discussed in Section 4.4.1 to determine the licensee's effectiveness against the performance indicators.

2. Review the renewal package to ensure that all areas of the appropriate NUREG–1556 volume(s) are addressed and to determine if any significant changes have been requested, as described in Sections 4.4.2 (Technical Review) or 4.4.3 (Limited Reviews). See Section 4.1.1 for information on performing risk-informed licensing reviews (supports Limited Reviews).

3. Evaluate the RSRM checklist available in the Material Security Toolbox at https://scp.nrc.gov/controls.html, if the licensee is requesting aggregated Category 1 or Category 2 quantities of radioactive material. (See Section 4.4.4.)

4. Determine whether conditions exist to necessitate an expiration date of less than 15 years, as described in Section 4.6.3 of this NUREG.

In line with risk-informed policy noted in Section 4.1.1 of this NUREG, the scope of the review of a renewal application should reflect a focus on the most risk-significant aspects of the application. Each application should be screened against performance indicators to determine whether the application will receive a comprehensive or limited review. The reviewer should assess applications on a case-by-case basis. For example, in the review of a license renewal application, if the staff concisely documents why its prior reasoning remains applicable to the renewal period, a detailed review of unchanged design features or of programs that were previously reviewed and approved would typically not be needed. See Section 4.4.3 of this NUREG for information regarding limited reviews of renewal applications.

4.4.1 Performance Indicator Review

The reviewer should review records, including the following: ADAMS records for the licensee, NRC databases such as the Nuclear Materials Events Database and the Licensee Event Reports for the 5 years preceding the renewal application. Assess the performance indicators below, and if the answer is YES to any of the performance indicators, document how the issues were addressed during the renewal process. Document the findings on Checklist A.4, Part 1.

1. Enforcement History

   Determine if the licensee is or has been the subject of an ongoing investigation by the Office of Investigations or an escalated enforcement action within the last 5 years. Escalated enforcement action includes any Order, civil penalty, or Notice of Violation issued at Severity Levels I, II, or III, except for those escalated enforcement actions that would be non-escalated under the current Enforcement Policy [e.g., 10 CFR 30.34(i)]. The reviewer should review the corrective actions for applicability to any license renewal commitments.

***Note**:* A license should not be renewed if the licensee is the subject of an ongoing investigation or pending enforcement action without the written concurrence of the OE and responsible program office. If necessary, a denial letter should be prepared, as described in Section 4.11.2. A denial would require divestiture of all material in the licensee's possession upon expiration of the license. The reviewer should review corrective actions, Alternative Dispute Resolution, Confirmatory Action Letters, or Orders as applicable to any license renewal commitments.

2. Loss of Material

   Determine if the licensee had a loss of control of licensed material that was reportable or resulted in a violation within the last 5 years. The reviewer should review the corrective actions for applicability to any license renewal commitments.

3. Unauthorized Disposal or Release of Material

   Determine if the licensee disposed of or released licensed materials that were reportable or resulted in a violation within the last 5 years. The reviewer should review the corrective actions for applicability to any license renewal commitments.

4. Overexposure

   Determine if the licensee has been cited for a radiation exposure in excess of regulatory requirements in the last 5 years. Exposures would include those to members of the public as well as to occupationally exposed individuals. The reviewer should review the corrective actions for applicability to any license renewal commitments.

***Note**:* Regional license reviewers should determine from the review of the licensee's ADAMS records the scope of the focus for the performance indicators. The licensee's submission of an application that does not rely on the NUREG–1556 series is not a performance indicator, and failure to use NUREG–1556 does not determine the level of review necessary. Although the application may take longer to review, it does not preclude the licensing review from being accomplished with an in-depth review on those areas that depart from the NUREG–1556 guidance.

4.4.2 Technical Review

The following areas should be reviewed as part of the technical review of a license renewal application to ensure the application conforms to the guidance from the appropriate NUREG–1556 volume(s), as applicable. Document the review on Checklist A.4, Part 2 of this NUREG.

1. Administrative Items

   a. Verify the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material. A division or department within a legal entity should not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Verify the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address.

Pursuant to 10 CFR 30.32(c), 40.31(b), and 70.22(d), each application must be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee. If it is not clear whether the application was signed by someone duly authorized to act for and on behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual who signed the application is duly authorized to act for and on behalf of the applicant or licensee. The signature on an application acknowledges the licensee's commitments and responsibilities. NRC staff should confirm that the NRC Form 313 is signed and dated by an individual authorized to make binding commitments and sign official documents on behalf of the licensee.

***Note**:* In accordance with 10 CFR 30.34(b), 10 CFR 40.46, and 10 CFR 70.36, the NRC must be notified and the transfer approved before control of the license is transferred. Change of control (ownership) must conform to the applicable regulations.

b. For each location of use and storage, verify the street address, city, and State or other descriptive address (e.g., Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State). The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable for the address where licensed material will be used or possessed. In addition, applicants are encouraged to provide global positioning system coordinates, as appropriate, for each permanent storage or use facility and field station located in a remote area. A field station is a location in which licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. If devices will not be stored at a field station, the license reviewer should indicate this on Checklist A.4.

***Note**:* If an applicant or licensee submits documents that give the exact location of use and storage for any amount of radioactive material, the applicant should mark these documents as "Security-Related Information—Withhold Under 10 CFR 2.390."

2. Financial Assurance

NUREG–1757, Volume 3, Rev. 1, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," provides guidance to the NRC staff on the information to be provided for establishing financial assurance for decommissioning and a standard format for presenting the information. Review the possession limits to ensure decommissioning financial assurance requirements remain adequate or are not required. If changes to the licensee's possession limits invoke new requirements, ensure that the application contains the required documents. For those licensees that must provide a financial assurance instrument, ensure the instrument is adequate for the current scope of the program.

***Note**:* Licensees that have a Decommissioning Funding Plan are required by 10 CFR 30.35(e) to resubmit the Decommissioning Funding Plan with adjustments, as necessary, to account for changes in costs and the extent of contamination, at the time of renewal and at intervals not to exceed 3 years. A Decommissioning Funding Plan must include a means for adjusting the cost estimates and associated funding levels periodically over the life of the facility [see 10 CFR 30.35(e), 40.36(d), and 70.25(e)].

3. Emergency Plan

Review the quantities of radioactive materials to determine whether the licensee is required to submit an emergency plan in accordance with 10 CFR 30.32(i), 40.31(j), or 70.22(i). Information regarding the need for an emergency plan is described in the NUREG–1556 volumes for various material applications.

4. Program Management

Review those portions of the application that address program management, including:

a. organizational structure (assure that appropriate elements are present and are assigned necessary authority and responsibility)

b. changes to key staff members [e.g., RSO, authorized users (AUs)] who are directly responsible for the radiation safety program

c. the qualifications of key personnel, such as the RSO, AUs, radiographers, well loggers, irradiator operators, authorized medical physicists, and authorized nuclear pharmacists

Note: Confirm that none of the licensee's staff members are banned from NRC-licensed activities by checking https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/individuals/. Search by the individual's last name. If an Order was issued to the individual, read the Order to confirm whether the restrictions still apply. Consult with the OE *before* taking any action for an individual who appears to be banned from NRC activities.

5. Equipment and Facilities

Review the application to determine if equipment and facilities are adequate to protect public health and safety.

6. Environmental Assessments

Review those portions of the application that need an environmental assessment (EA) because they do not conform to the categorical exclusions in 10 CFR Part 51. (See Section 4.10 of this NUREG for more information regarding categorical exclusions and EAs.)

7. Sealed Sources and Devices

Review applicable Sealed Source and Device registration certificates to verify manufacturer and model numbers for all sealed sources and devices listed in the application.

8. Major Program Changes

Determine whether the requested major program change(s) conform to the applicable regulations and NUREG–1556 guidance. Examples may include a new broad-scope authority; introduction of iodination with millicurie (mCi) quantities of iodine (I)-131 or

I-125 requiring major facility additions or changes; additional research and development activities (human and nonhuman); additional medical therapy modalities; naturally-occurring and accelerator-produced radioactive material uses.

9. New and/or High-Risk Technology

Determine if new technologies, including high-risk technologies, requested by the licensee conform to applicable regulations, NUREG–1556 guidance, and NRC Web site guidance for 10 CFR 35.1000. Examples may include new license categories, use of yttrium-90 microspheres, or use of a gamma stereotactic radiosurgery unit (e.g., Perfexion™, Icon™).

10. Change of Control

Determine if a change of control conforms to the regulations and NUREG–1556 guidance and whether the new entity is known or had a pre-licensing visit, as required. The reviewer should also verify whether any financial assurance documents are affected by the change of control. See Regulatory Issue Summary (RIS) 2014-08, Rev. 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licensees" (ADAMS Accession No. ML15181A223), dated May 5, 2016, for further information on change of control. This RIS can also be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": https://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Additional information regarding change of control is also available through the "Change of Control" link provided on the MSST Sharepoint site.

11. Unsealed Transuranic Radioactive Material

If the licensee is proposing to use unsealed transuranic radioactive material, the reviewer should be cognizant of the lessons learned from two U.S. National Institute of Standards and Technology (NIST) events (ADAMS Accession Nos. ML093080053 and ML18173A278). The first event resulted from a glass bottle of mixed isotopes of plutonium that was broken while conducting an experiment using a newly developed detector system at a NIST laboratory. The second event resulted from a broken vial of americium-241 that was discovered during the search for a lost source in a NIST laboratory.

12. Major Areas

Each volume of the NUREG–1556 series includes guidance regarding major areas to be discussed in the application, as applicable to that NUREG–1556 volume. Conduct a review of the application in accordance with the appropriate NUREG–1556 volume. Also, the reviewer should ensure that the general requirements in 10 CFR 30.33 are met. Document any deficiencies in an RAI. Reviewers should note that procedures and other information documented in the NUREG–1556 volumes may not be the only mechanism for meeting the regulatory requirements. Any questions should be directed to an HQ or Regional manager, as applicable. If a reviewer finds that more than one area is not addressed or contains significant deficiencies, then the reviewer should follow the Deficiency process in Section 4.5.

13. Document whether a licensing visit was performed. Refer to Section 4.9.2 for additional guidance on licensing visits.

4.4.3 Limited Reviews

Reviewers should use the limited review checklist (Checklist A.5 in Appendix A) to document the review. A limited review of a renewal application will only evaluate the following areas for conformance with the guidance from the appropriate NUREG–1556 volume(s), as applicable, on the content of the application:

1. Administrative Items

   Review administrative items, including the licensee's name and address and other items, such as the RSO's name. Also, ensure the renewal application is signed and dated by an individual authorized to make binding commitments and sign official documents on behalf of the licensee.

2. Financial Assurance

   Reviewers should check the possession limits and confirm that decommissioning financial assurance requirements have not changed. If new possession limits invoke new requirements, ensure that the application contains the required documents. For those licensees that must provide a financial assurance instrument, ensure the instrument is adequate for the current scope of the program.

   ***Note**:* If the licensee submitted a Decommissioning Funding Plan, it must include a means for adjusting the cost estimates and associated funding levels periodically over the life of the facility [see 10 CFR 30.35(e), 40.36(d), and 70.25(e)]. Periodic adjustments are expected to range from 1 to 3 years. Any proposal to wait more than 3 years before adjusting cost estimates and funding levels should be coordinated with NMSS management (branch level or above) before it is approved.

3. Program Management

   Review those portions of the application that address program management, including:

   a. Organizational structure (assure that appropriate elements are present and are assigned necessary authority and responsibility);

   b. The qualifications of key personnel, such as the RSO, authorized users, radiographers, well loggers, irradiator operators, authorized medical physicists, and authorized nuclear pharmacists; and

   c. The licensee's radiation safety audit program.

4. Equipment and Facilities

   Review those portions of the application that address equipment and facilities.

5. Environmental Assessments

Review those portions of the application that need an EA because they do not qualify as a categorical exclusion under 10 CFR Part 51.

6. Unreviewed Requests

Review any new authorizations, requested by the licensee, that have not been previously reviewed, and review any major program elements that require change as a result of the new authorization. Also review the licensee's inspection reports for changes in the licensee's scope of operations that are not referred to in the renewal package. These areas should undergo a concentrated review, as opposed to a comprehensive review of the entire application. Some examples of requests that should receive concentrated reviews are:

a. New broad scope authority; introduction of iodination with mCi quantities of I-131 or I-125 requiring major facility additions or changes; additional research and development activities (human and nonhuman); additional medical therapy modalities.

b. Any new high-risk technology uses being added to an existing license, to ensure that the licensed program can safely manage and use the new technology. Specific conditions and requirements associated with new technologies may be added to the license. Examples include new license categories, use of intravascular brachytherapy, or Boron Neutron Capture Therapy in humans.

7. Change of Control

Determine if a change of control conforms to the regulations and NUREG–1556 guidance and whether the new entity is known or had a pre-licensing visit, as required. The reviewer should also verify whether any financial assurance documents are affected by the change of control. See Regulatory Issue Summary (RIS) 2014-08, Rev. 1, “Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licensees” (ADAMS Accession No. ML15181A223), dated May 5, 2016, for further information on change of control. This RIS can also be found on the NRC’s Generic Communications Web page under “Regulatory Issue Summaries”: https://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Additional information regarding change of control is also available through the “Change of Control” link provided on the MSST Sharepoint site.

8. Change in Key Staff Members

If there has been a change in key staff members directly responsible for the radiation safety program, conduct a concentrated review of the affected area.

***Note**:* Confirm that none of the licensee’s staff members is banned from NRC-licensed activities by checking the escalated enforcement actions issued to individuals. Go to the OE page on the external Web site (https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/). Select "Enforcement Actions" from the buttons on the left side of the screen. Select "Escalated Enforcement Actions Issued to Individuals" from the links at the bottom of the page. Go to the Edit drop-down menu and select

"Find in Frame." Search for the individual's last name. If an Order was issued to the individual, read the Order to confirm whether the restrictions still apply. Consult with OE before taking any action for an individual who appears to be banned from NRC activities.

9. Major Areas

A brief overview is made of the remainder of the application to determine if the major areas discussed in the guidance on the contents of the application from the appropriate NUREG–1556 volume are present. If detected, an obvious failure or a deficiency in a significant area should result in a thorough review of that area. A finding that more than one area is not addressed or contains a significant deficiency could result in a comprehensive review of the license application. Change to a comprehensive review should be approved by licensing management, and the reason for changing from a limited review to a comprehensive review should be clearly documented on the limited review checklist in Appendix A.

***Note**:* Each Region determines from its review of the ADAMS records for the licensee and NRC databases whether a comprehensive review is necessary. The licensee's submission of an application that does not use the NUREG–1556 series is not a performance indicator, and failure to use NUREG–1556 does not determine the level of review necessary. Although the application may take longer to review, it does not preclude a limited review with an in-depth review on those areas that depart from the NUREG guidance.

10. Licensing Visit

Document whether a licensing visit was performed. Refer to Section 4.9.2 for additional guidance on licensing visits.

4.4.4 Risk-Significant Radioactive Material Review

The reviewer should initiate the RSRM checklist available in the Material Security Toolbox at https://scp.nrc.gov/controls.html. The RSRM checklist and guidance should be used as part of every applicable renewal review to document whether the licensee (i) is already subject to the requirements in 10 CFR Part 37; (ii) plans to obtain aggregated Category 1 or Category 2 quantities of radioactive material, as defined in 10 CFR 37.5; or (iii) is reducing possession limits below RSRM. If the license renewal requires implementation of 10 CFR Part 37, then refer to Section 4.2.3 for the appropriate guidance. The RSRM checklist and guidance are used to verify that licensees requesting aggregated Category 1 or Category 2 quantities of radioactive material have implemented or are prepared to implement the applicable 10 CFR Part 37 security requirements prior to taking possession or using these radioactive materials.

4.4.5 Expiration Date Review

See Section 4.6.3 of this NUREG for information involving license expirations shorter than 15 years.

4.5 Deficiency Letters, Calls, Facsimiles, and E-Mails

After identifying issues and deficiencies in an application, the license reviewer should use the most efficient process available to fully communicate issues and deficiencies to applicants or licensees, document any information requests, and elicit the appropriate applicant or licensee response. The reviewer should communicate with the applicant or licensee via telephone, facsimile, e-mail, or formal deficiency letters. All substantive communications should be clearly documented. *Draft* documents and e-mails transmitting *draft* documents from the applicant should not be accepted or scanned into ADAMS and cannot be used as the basis for a licensing action. However, e-mail that includes the applicant's or licensee's *final* clarifications or commitments on an issue or deficiency may be accepted as a binding license document and scanned into ADAMS, provided the document is signed by the applicant, licensee, or a duly authorized person, as required by 10 CFR 30.32(c), 10 CFR 40.31(b), or 10 CFR 70.22(d), as applicable.

Reviewers should document RAIs in a manner to improve the response from the applicant or licensee and reduce or eliminate the need for subsequent RAIs. Ensure that each requested item for additional information is clear (i.e., provides a description of the deficiency and a statement of what is needed); is essential to protect public health, safety, the environment, or security; and is linked to regulatory requirements and NUREG–1556. After a request for information (deficiency letter, telephone call, facsimile, or e-mail) is sent to the applicant or licensee, the action is to be tracked in WBL with a milestone to acknowledge the request, and the status of the applicant's or licensee's response should also be entered and tracked.

A request from an applicant or licensee for an extension of time to respond to any correspondence about its application or amendment request may be granted if it is determined that there is good cause to grant an extension. Appropriate WBL milestone date changes should be made by the LA or license reviewer to track each application properly and record extensions of time for responses. The reviewer should keep NRC management informed of continued requests for extensions.

4.5.1 Application for a New License or for an Amendment

Deficiencies

1. Any simple, significant, or complex deficiencies in an application for either a new license or license amendment should be described in a telephone call, e-mail, facsimile, or deficiency letter to the applicant or licensee. Telephonic discussions of deficiencies should be limited to simpler requests and should be documented on NRC Form 699, "Conversation Record" (see Appendix B, Sample Letter B.2.2 of this NUREG). The reviewer is encouraged to use the most expedient process available to communicate issues fully to the applicant or licensee. A sample deficiency letter is provided in Appendix B, Sample Letter B.2.1 of this NUREG. Deficiency letters may be sent by regular mail, e-mail, or facsimile. The letter to the applicant or licensee should contain a statement that specifies that NRC will assume the applicant or licensee does not wish to pursue its application if NRC does not receive a reply within a specified timeframe (e.g., 30 calendar days) from the date of the deficiency letter.

2. If a response to the deficiency letter is received within the specified timeframe (e.g., 30 calendar days) from the date of the letter, then proceed with the review of the response.

3. If a response to the deficiency letter is not received within the specified timeframe (e.g., 30 calendar days) from the date of the deficiency letter, then the reviewer should reach out again to the applicant or licensee to try and obtain the necessary information. If the applicant or licensee does not provide adequate information after such an exchange, the reviewer may partially complete the licensing action, as applicable. If incomplete information or no response is received, the reviewer should discuss the option of withdrawing the application with the applicant or licensee. The withdrawal should be made in writing or verbally with written follow-up, as necessary. A withdrawal of the application is done without prejudice to the resubmission of the application or amendment. If the applicant or licensee does not request withdrawal of the application, the reviewer should discuss with their management regarding whether the application should be administratively closed or denied, as appropriate. (See Section 4.11 of this NUREG.) If the applicant or licensee does not request withdrawal of the application and indicates to the reviewer that they need additional time to address any deficiencies in the deficiency letter, the reviewer may also discuss with their management whether review of the application should be suspended (see Section 4.12 of this NUREG).

4. If a response to the deficiency letter is received after an application has been administratively closed, and the response is received not more than 1 year from the original submission date for a new application, the application should be assigned a new mail control number, and review should proceed. Typically, no additional fee for a new license is necessary unless the application was subject to full cost recovery. Associated cost with this new license application should be closely coordinated with the Office of the Chief Financial Officer (OCFO).

4.5.2 Application for License Renewal

Deficiencies

1. Any simple, significant, or complex deficiencies in an application for license renewal should be described in a deficiency letter, by telephone call, facsimile, or e-mail to the licensee. Telephonic discussions of deficiencies should be limited to simpler requests and should be documented on NRC Form 699, “Conversation Record” (see Appendix B, Sample Letter B.2.2 of this NUREG). The reviewer is encouraged to use the most expedient process available to communicate issues fully to licensees. A sample deficiency letter is provided in Appendix B, Sample Letter B.2.1 of this NUREG. Deficiency letters may be sent by regular mail, e-mail, or facsimile. The deficiency letter should request the licensee to respond within 30 calendar days from the date of the deficiency letter or within such other time as may be specified.

2. If a response to the deficiency letter is received within the specified timeframe (e.g., 30 calendar days) from the date of the letter, then proceed with the review of the response.

3. If an adequate response to the deficiency letter has not been received within 30 calendar days or as specified from the date of the deficiency letter, subsequent deficiency letters or contacts with the licensee via telephone or e-mail should be considered. The

reviewer should reach out again to the licensee to try and obtain the necessary information during the review period. If the licensee indicates to the reviewer that they need additional time to address any deficiencies in the deficiency letter, the reviewer may discuss with their management whether the renewal review should be suspended (see Section 4.12 of this NUREG).

If the licensee does not provide an adequate response to the deficiencies, then the reviewer, with approval of the appropriate branch chief, should initiate a denial letter, as described in Section 4.11.2. A denial would require divestiture of all material in the licensee's possession upon expiration of the license (see Section 4.23 of this NUREG for additional information regarding license expiration). Cognizant inspection management and staff should be notified of the initiation of a denial letter.

4.6 Creating the License

4.6.1 Standard Licenses and Standard License Conditions

For consistency within NRC Regions and HQ, the reviewer should use the standard license conditions in WBL when creating a license for an applicant. **WBL contains the most current standard license conditions.** See Appendix C of this NUREG for more information regarding standard license conditions. Some instances may exist where the reviewer may need to authorize nonstandard license conditions. (See Section 4.6.2 regarding approvals for nonstandard license conditions.)

An applicant may request authorization to use licensed materials in more than one program type; therefore, the reviewer may need to review the guidance documents from more than one NUREG–1556 series volume and combine the pertinent license conditions into a single license, where appropriate. In some complex licensing cases (e.g., waste broker activities), it is best to issue separate licenses.

In some specific instances, an applicant may request authorization to conduct special activities in a program that is non-routine. The reviewer should refer to the approved list of standard license conditions in WBL. Use of standard license conditions should not substitute for obtaining information from applicants and licensees.

For licenses involving special nuclear material less than critical mass, the maximum possession limit of special nuclear material listed on the license should include the percentage of enrichment and the quantity of material in grams (or milligrams). (See NUREG–1556, Volume 17.)

The reviewer should also refer to the program code descriptions and inspection priorities provided on the NRC's public Web site at https://www.nrc.gov/materials/miau/mat-toolkits.html to identify the program code with the highest priority for inspection. The program code that identifies the highest inspection priority (shortest inspection cycle) should be the primary program code in WBL, as this program code will dictate the inspection frequency for the license. The other program codes should be assigned as secondary program codes.

The reviewer should be diligent about assigning correct program codes initially and whenever the scope of the license changes.

The reviewer should evaluate the license against the latest SUNSI requirements. If the license meets any of the SUNSI requirements, then reviewer will incorporate appropriate markings on the license. Section 4.22 provides SUNSI guidance.

For a new applicant, the Region should assign a new radioactive materials license number based on the State code; followed by the assigned institution code from WBL; followed by an incremental number for the respective institution code; and a license suffix, if applicable. For example, a new license in Michigan would be 21-12345-01. However, if the new license was the second license issued to the same institution, then the license number would be 21-12345-02. Additional guidance is provided in https://www.nrc.gov/materials/miau/mat-toolkits.html. The State codes are also available in https://www.nrc.gov/materials/miau/mat-toolkits.html. Note, the license number and docket number should not be changed after the licensee moves to a different State.

4.6.2 Nonstandard License Conditions

When reviewing applications, if there are essential issues that the licensee did not address, even after being asked to provide the information in a deficiency request, then the reviewer may use nonstandard license conditions to achieve closure rather than protracted negotiations with the applicant. Essential issues are provided in the "Response from Applicant" portions of various sections in the NUREG–1556 series. The reviewer should use standard license conditions whenever possible; however, nonstandard license conditions may be used when necessary. The license reviewer should write the nonstandard license condition to state the requirement clearly and simply. Nonstandard license conditions should be coordinated with OGC or a Regional Counsel before use. Nonstandard license conditions should also be approved by the appropriate branch chief and documented under the docket number in ADAMS. This strategy is intended to streamline the licensing process to be more responsive to licensees and provide more flexibility to the NRC staff. If the license condition requires a recordkeeping response by the applicant or licensee, then the license condition may require U.S. Office of Management and Budget clearance.

Issues not currently addressed in the NUREG–1556 series and thought to be critical to a specific type of licensing action should continue to be coordinated with HQ. If the Region believes that a nonstandard license condition is appropriate, then it should also be coordinated through HQ. In addition, license reviewers should explain these nonstandard license conditions to inspection staff and licensees to ensure that all parties have the same understanding, especially those unique to a specific type of licensee. The license reviewer should provide an explanation in the cover letter issuing the license and, if appropriate, call the licensee before issuing a license with nonstandard license conditions.

4.6.3 Establishing License Expiration Dates

As a matter of NRC policy, materials licenses will generally be approved for a 15-year license authorization limit. License authorizations shorter than 15 years may be approved on a case-specific basis, including license authorizations for Possession and Standby licenses. Except for Possession and Storage-Only and Possession and Storage in Standby licenses issued for a 2-year period, NRC management approval is required for all other license

authorizations that are shorter than 15 years. The following are some examples of conditions that may exist for licenses issued for shorter than 15 years:

- **New Technology**: The license authorizes a new high-risk technology that the industry, the particular licensee, or NRC has not had extensive experience in using or regulating.

- **Enforcement History**: The licensee, in the last inspection or past 5 years (whichever is longer), had a Severity Level I, II, or III violation.

- **Early Termination of a License Renewal**: In the case that early termination is expected after a license renewal.

- **Other**: Other situations that would warrant increased attention. These conditions will be addressed by the licensing staff on a case-specific basis.

See memorandum dated August 18, 2017, "Procedure for Implementing the 15 Year Materials Licenses Term" (ADAMS Accession No. ML17200D112) for additional expiration date information.

Possession and Storage-Only and Possession and Storage in Standby licenses should have a 2-year expiration date and may be renewed if the licensee continues to demonstrate that they have taken all reasonable efforts within their ability to divest themselves of the material and yet have been unsuccessful in these efforts. Further information is provided in Section 4.18 of this NUREG.

Use Checklist A.6 in Appendix A entitled, "New and Renewal and Possession-Only–License Term of Less than 15 Years," to document the license authorization period, the basis for the decision, and the basis for an exemption, if required. This checklist is designated an Official Agency Record (OAR) because the basis of a decision is not documented elsewhere. If the license reviewer recommends that the license authorization period should be shorter than 15 years, then a period of 5 years is typically used. Other authorization periods may be approved on a case-specific basis.

4.6.4 Issuance of Final Licensing Action

1. For all completed licensing actions, the license reviewer should send the licensee a cover letter and the original signed license.

2. If there may be information in the cover letter that is considered SUNSI or the cover letter may be transmitting SUNSI material in the enclosure, then the cover letter and enclosure must be marked appropriately, in accordance with agency policy. Refer to Section 4.22 for additional guidance regarding SUNSI.

3. The cover letter may be a form letter or individual letter, depending on the individual case and the practice of the Region. Sample cover letters are provided in Appendix B, Sample Letters B.3 of this NUREG. Many licensing actions require specific information to be included in the cover letter related to the individual case. All information may be combined into a single cover letter, or license reviewers may elect to use attachments.

4. For licenses that are amended frequently, it is acceptable to include the standard information with every licensing action; however, if deemed appropriate by the

Region, the standard information may be deleted if it was provided recently in a previous communication.

5. Cover letters are OARs and will be maintained in ADAMS.

6. Appendix B, Sample Letter B.3.4 of this NUREG also provides a sample cover letter for terminating a license.

4.7 Guidance for Multi-Site Licenses

The purpose of this section is to ensure that applications requesting authorization for multiple locations of use under one license (including amendment requests that expand a licensed program to multi-site) are identified and have radiation safety programs that are adequate, both in scope and in depth, to oversee safe use of licensed material at each facility. This section **does not** apply to certain categories of licenses that, by license condition, routinely authorize multiple locations of use (e.g., broad-scope, mobile medical service, master materials licenses) or licenses authorizing temporary jobsites.

Furthermore, this section highlights general radiation safety management concerns specific to multi-site licenses and in no way attempts to define necessary radiation safety management structures for every type of licensed activity. During the review of the licensee's radiation safety program and management oversight, the reviewer should pay particular attention to delegation of responsibility and established reciprocal lines of communication between users and management. Regardless of the number of sites authorized under one license or the geographic distance between these sites, the adequacy of the overall radiation safety management structure should be reviewed to ensure safe operations at each site. The license reviewer will tailor the review to the type of license under consideration.

An individual building or facility at one address can be a "location of use." Also, a contiguous licensee-controlled geographic area, such as a campus or licensee-owned/operated/controlled business campus or park, is considered a single "location of use" and only one address is listed on the license. Sites that are not contiguous but are located in separate parts of a city, different city or state, are separate "locations of use" and separate addresses are listed on the license.

A temporary jobsite is not a "location of use" (except for NSTS information if the license authorizes temporary jobsites). In addition, use of licensed materials at sea or on board a ship may be a separate location, specifically listed on the license, if it is a permanent jobsite. If use at sea is not a permanent location but is a temporary jobsite, then it is not a separate "location of use" and its address will not be listed on the license.

The address of each "location of use" must be listed on the license and must be listed in WBL, with exception of Federal facilities as described in the next paragraph. It is acceptable to list the address as "… [insert name of the licensee] campus [insert physical address – street number and name, city, state]…" if it is a contiguous licensee-controlled geographic area. For licenses where the locations of use are missing in WBL, the license docket files (inspection and licensing history) should be reviewed to identify where the licensed activities are authorized to take place. WBL should be updated with the correct list of authorized locations.

Licensees such as the U.S. Army that request the flexibility to use or store licensed materials at any of their locations in the United States would be considered to have more than 20 locations. These locations do not have to be listed individually on the license or in WBL. However, these

locations must be tracked by the licensee and the list of locations must be available for inspection. The locations of use condition on the license should include, for example, that the licensee "…may use or store material at any Department of Defense installation…" or other appropriate description, and an entry needs to be created in WBL to indicate that this licensee may have more than 20 locations. If these locations are in multiple regions, the appropriate program code should be used.

4.7.1 Description of Multi-Site License

A multi-site license is one that includes two or more locations of use identified on the license and the nature of licensed activities (medical vs. industrial) are the same at each site. Such locations will typically include (i) stand-alone facilities that would otherwise be licensed individually; or (ii) satellite facilities that are not located within the principal jobsite and for which NRC-licensed material use is ongoing (excluding temporary jobsites, broad-scope licenses, or mobile nuclear medicine services). A multi-site facility may also include those licensees for which the addresses of use are geographically separated. Locations of use may be under the direction of a single corporate RSO, or each facility may have a site RSO who reports to the corporate RSO. The corporate RSO is usually the RSO of record on the license. The license commitments serve to document how the specific locations of use and/or facilities are permitted and controlled. How the locations are permitted is necessary in order for the NRC to conduct unannounced inspections, as required by Inspection Manual Chapter (IMC) 2800. Examples of multi-site licenses include radiopharmacies with multiple pharmacy locations; radiographers, well-loggers, or moisture density gauge operators with multiple permanent work sites; large manufacturers with facilities at more than one geographic location; and medical licensees with facilities at more than one geographic location. (See 10 CFR 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended," and 10 CFR 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC," for additional information regarding locations of use for multi-site licenses.)

A specific limit to the number of sites permitted on a multi-site license is not practical for generic application to all licensees; rather, the reviewer should assess applications on a case-by-case basis. The basis for determining the appropriate number of sites for a specific licensee should include the following considerations: (i) past inspection history and (ii) adequacy of licensee management structure for the type, scope, and geographic distribution of the program.

4.7.2 Program Management

4.7.2.1 General Information

1. The licensee should document an administrative structure, organization, and procedures adequate to ensure safe operation by users at all facilities.

2. The application should include an organizational chart depicting the licensee's management structure, reporting pathways, and flow of authority from the corporate level to on-site management.

3. In cases where licensees unite their programs, the application should provide a clear picture of the management structure and clearly define how the radiation safety program will be implemented at each facility. Particular attention should be paid to facilities that

previously operated under their own NRC license to ensure that voids created by the elimination of a radiation safety program are identified and addressed. In situations where a change of control may have taken place, the license reviewer should refer to the latest revision to NUREG–1556, Volume 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses" for additional guidance.

4.7.2.2 Corporate Management

1. Senior Management

   The licensee's senior management is ultimately responsible for the safe use of licensed material and implementation of an effective radiation safety program at all licensee facilities. The application should discuss the following:

   a. management oversight and mechanisms used to ensure adequate control over day-to-day licensed activities at each site, including the assignment of duties and allocation of necessary resources

   b. statement of delegation of authority to the RSO and the Radiation Safety Committee (RSC), when applicable, signed by senior management. This statement should include provisions for the RSO to carry out his or her authority over each site's operations without interference by site management

   c. assurance that the RSO has sufficient time to perform duties, appropriate staff support, and provisions for RSO absence

   d. periodic site tours and meetings with site management, the RSO, and RSC, when established

   e. mechanisms for reporting to management unsafe practices and incidents, and the management role in responding to such circumstances

   f. methods and checks established to ensure that the RSO possesses and reviews current regulations

   g. chain of authority for ensuring compliance with regulatory requirements

   h. assurance that senior management has an active role in sharing program responsibilities with the RSO when an RSC is not established

   i. review of and involvement with program audits and evaluations, through membership on the RSC or otherwise

2. Site Management

   The licensee should provide a written explanation of the role of site management to assist with the tasks of program management as outlined above for senior management.

4.7.2.3 Radiation Safety Officer

The RSO's primary responsibility is to implement the radiation safety program with the support of management. The licensee should provide a written description of the RSO's role and duties to ensure compliance with regulations, license conditions, and good radiation safety practices. Although the tasks of the RSO may be delegated to other personnel, the responsibility and authority over the tasks remain with the RSO. The duties and responsibilities of the RSO should be specified in writing and should include the following:

1. frequency of reporting to, and meetings with, executive and site management

2. regular site visits, monitoring (e.g., facility/site surveys and review of reports and records for each site), and feedback to site personnel, as well as support staff, to ensure that daily operations at each site include radiation safety activities, approved procedures, safe practices, and compliance with regulations and license conditions

3. periodic, interactive (i.e., with feedback) program audits at each site, indicating audit frequency and reporting commensurate with site operations

4. mechanisms for being alerted and responding to unsafe practices and urgent situations that may occur at any site

5. authority to make decisions and terminate unsafe practices and activities jeopardizing the safety of workers, the public, or environment

Applicants should provide the office address and contact information (telephone and e-mail address) of the location where the RSO is physically located.

***Note**:* For medical use licensees, information regarding an Associate RSO is available in NUREG–1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses."

4.7.2.4 Radiation Safety Support Staff

The RSO may be supported by staff who assist in the maintenance and control of the radiation safety program at each site or a number of sites. The RSO may delegate radiation safety tasks to these individuals; however, the authority and responsibility remains with the RSO. Support staff duties, including provisions for reporting to the RSO, should be clearly specified, in writing, with sufficient time allotted for completion. Provisions for regular interaction and feedback from the RSO, Management, and the RSC (where applicable) should be specified.

4.7.2.5 Radiation Safety Committee

The necessity for an RSC should be assessed by the license reviewer on the basis of program scope and the need for assistance with radiation safety program oversight from a committee of individuals with varied specializations. However, the RSC will be limited to assistance with management oversight. Specific areas that applicants should address include:

1. appointment of representatives from each site, as well as the RSO and senior management

2. establishment of a routine meeting schedule

3. review of program audits and evaluations

4. statement of duties emphasizing program development, implementation, and oversight

5. quorum requirements

License reviewers should direct applicants to the information contained in NUREG–1556, Volume 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," for a more detailed description of the responsibilities of individuals and the RSC, if applicable, for the radiation safety program.

4.7.3 Communication

In those cases where there are multiple oversight levels proposed, the applicant should clearly address communication and accountability systems, including the following:

1. Delegation of clear and appropriate levels of authority within the licensed entity, indicating that sufficient organizational freedom exists, and that management has prerogative to communicate with, train, and direct personnel according to NRC regulations and/or license provisions.

2. Descriptions of program reviews or audits and the reporting of such activities on a regular basis.

3. Mechanisms for addressing urgent situations.

4. Mechanisms in place to inform all personnel of radiation safety program changes.

5. Provisions to make personnel aware of the appropriate representatives to contact at each level of authority.

6. Assurance provided in the application that each level of oversight is available to interact with other levels, AUs, and supervised workers, both as needed and on a regular basis.

7. Attention to contracted services in each level of program oversight.

Records

As provided for in 10 CFR 30.52, each licensee must make its radiation safety records available for NRC review, after receiving reasonable notice from NRC. The license application should specify point-of-contact information for NRC notifications and inquiries about records. The licensee may also choose to identify locations where the records will be maintained for NRC review.

4.7.4 Additional Program Areas for Review

The licensee should provide specific information about the following program areas:

1. transportation of licensed material (including radioactive waste) between authorized sites

2. applicability of decommissioning requirements

3. sharing of safety equipment between sites

4. coordination among sites for inventory control of licensed material, with the intended focus of continually monitoring types and quantities of material to ensure that the total possession limits specified in the license are not exceeded

5. informing the NRC of the permitted locations of use so that unannounced inspections may be performed as required by IMC 2800, "Materials Inspection Program"

6. implementing the radiation safety program at the permitted site and the level of oversight by the licensee for activities such as self-assessments and periodic review of the radiation protection program content and implementation

4.7.5 Master Materials License

An MML is a multi-site, multi-regional license that is issued to a Federal organization that authorizes the licensee to undertake a limited number of activities normally performed by the NRC, including permitting, inspection, decommissioning, and enforcement actions. Information about licensing an MML is provided in NUREG–1556, Volume 10, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Master Materials Licenses."

4.8 Opportunity for an Informal Hearing—Materials Licensing

The purpose of this section is to provide license reviewers with basic information relevant to hearing rights associated with materials licensing actions. Under the Atomic Energy Act of 1954, as amended (AEA), an aggrieved member of the public has the right to request a hearing on any materials licensing action. The AEA does not, however, require that formal notice (in the *Federal Register*) be given for materials licensing actions or that hearings held on materials licensing actions be of a formal nature. Specifically, reviewers should be aware that in many materials licensing actions, notices are not published in the *Federal Register*. In such instances, a member of the public may request a hearing under Subpart C of 10 CFR Part 2, "Rules of General Applicability: Hearing Requests, Petitions To Intervene, Availability of Documents, Selection of Specific Hearing Procedures, Presiding Officer Powers, and General Hearing Management for NRC Adjudicatory Hearings." Most hearings are conducted under the procedures of Subpart L of 10 CFR Part 2, "Simplified Hearing Procedures for NRC Adjudications."

The regulations set forth in 10 CFR 2.309(b)(4) generally allow a member of the public to file a request and/or petition and the list of contentions not later than 60 days after (1) publication of notice on the NRC Web site or (2) after the requester receives actual notice of a pending application, but not more than 60 days after the NRC issues an action on a materials application in which a *Federal Register* notice is not published. If a *Federal Register* notice is published for an NRC action, then under 10 CFR 2.309(b)(3) the petition must be filed within the time period specified in the notice. If a period is not specified, then the petition must be filed within 60 days from the date of publication of the notice. The regulations in 10 CFR 2.310 state, in part, that the Commission, the presiding officer, or the Atomic Safety and Licensing Board designated to rule on the request/petition will determine and identify the specific hearing procedures to be used. As noted in 10 CFR 2.107, if an application is withdrawn prior to issuance of a notice of

hearing, the Commission shall dismiss the proceeding. If a licensing action is withdrawn after a notice of hearing has been issued, the presiding officer may prescribe the terms of the hearing.

The procedures under Subpart L provide a less formal hearing process that balances the need for formal procedures and the expeditious resolution of contested matters. Although the NRC is under no specific regulatory requirement to publish a *Federal Register* notice of a materials licensing action, in most cases, such a notice is published whenever the NRC staff makes an environmental assessment (see Section 4.10 of this NUREG). After NRC's technical review, any draft or final finding of no significant impact (FONSI) with respect to a proposed action must be published in the *Federal Register* [see 10 CFR 51.33 and 51.35(a)]. The *Federal Register* notice should include a specific reference to Subpart L, as applicable, and the opportunity for the public to request a hearing.

Direct or indirect transfer of control of an NRC materials license requires prior approval of the NRC under the Commission's regulations, governing statute, or pursuant to a license condition. A petition for hearing must be filed within 20 days from the date of publication of the notice in the *Federal Register*, as specified in 10 CFR 2.309(b)(1). For further information, see RIS 2014-08, Rev. 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licensees," dated May 5, 2016. This RIS can also be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": https://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Pursuant to 10 CFR 2.310(g), hearings related to such direct or indirect transfers of control are conducted under Subpart M of 10 CFR Part 2, unless the Commission determines otherwise in a case-specific Order.

Although unusual, reviewers should be aware that there have been occasions where members of the public have filed a request for a hearing with the NRC's Executive Director for Operation's staff but have failed to file (i.e., submit) the hearing request with the Secretary of the Commission. On becoming aware of a hearing request filed with the Executive Director for Operation's staff, the reviewer should determine whether the request has also been filed with the Secretary. If the license reviewer determines that the request from a member of the public was not filed with the Secretary of the Commission, the license reviewer should discuss the matter with the Office of the Secretary and OGC before proceeding with any additional activities or notifications.

4.9 Licensing Site Visits

There are two types of site visits: (i) pre-licensing site visits and (ii) licensing site visits. These site visits are not considered inspections. A pre-licensing site visit is a face-to-face meeting with an entity to provide the reviewer with a basis for confidence that radioactive material will be used as specified, prior to the issuance of a new license. Licensing visits should be conducted for all new applications and may be conducted for all renewal applications involving large programs or license programs that present significant or unique technical issues. Additional guidance is provided below.

4.9.1 Pre-licensing Site Visits

4.9.1.1 Purpose of Pre-licensing Site Visits

Generally, pre-licensing visits are conducted for new entities that do not have an existing Agreement State or NRC license or licensees changing ownership to an unknown entity.

Reviewers should follow the guidance in Section 4.2.3 and use the PLG available in the Material Security Toolbox at https://scp.nrc.gov/controls.html to determine if a pre-licensing visit is needed. The purpose of the pre-licensing visit is to evaluate the applicant to provide a basis for confidence that radioactive material will be used for the purposes authorized under the license. By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis of confidence that the applicant will use the radioactive materials as specified in its license application. Pre-licensing visits are completed prior to the issuance of a new license.

4.9.2 Licensing Visits

4.9.2.1 Purpose of Licensing Visits

Licensing site visits are conducted by the responsible reviewer or a designated inspection staff member in order to accomplish one or more of the following objectives:

1. Evaluate the applicant's ability to conduct safe operations and comply with requirements.

2. Evaluate safety and technical issues that are not easily understood through correspondence or telephone conversations.

3. Expedite resolution of issues and concerns through discussions with the applicant.

4. Verify statements and commitments in the license application.

5. Provide a first-hand review of the applicant's staff, site, and facilities.

In addition, a security inspection may be required in accordance with IMC 2800, prior to authorizing certain quantities of radioactive materials. (See Sections 4.2.3 and 4.4.4 of this NUREG.)

4.9.2.2 Licensing Visits for New License Applications

Licensing visits should be conducted for the following types of new license applications, even when the applicant is a known entity:

1. Type A licenses of broad scope

2. panoramic irradiators authorized to possess greater than 10,000 curies (Ci) of byproduct material in sealed sources

3. manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material (e.g., aggregated Category 2 quantities or greater)

4. radioactive waste brokers

5. radioactive waste incinerators

6. commercial nuclear laundries

7. any other application that, in the judgment of the regional staff, involves complex technical issues, complex safety questions, risk significant quantities of radioactive material, or unprecedented issues that warrant a site visit

4.9.2.3 Licensing Visits for Amendments

Licensing visits should be conducted for any license amendment requesting a new authorization for the types of operations listed in Section 4.9.2.2. Licensing visits should be considered for amendments involving significant modification to the types of operations listed in Section 4.9.2.2.

4.9.2.4 Licensing Visits for Renewals

Licensing visits should be considered for renewals involving the types of activities listed in Section 4.9.2.2; however, in many cases, resource limitations can make this difficult for the Regions to support. For each significant renewal, an evaluation of proposed licensee program changes and inspection history should be performed. If the regional management and staff conclude that there are not significant program changes or unresolved licensing issues, and that a licensing visit would not be cost-effective, then a licensing visit need not be performed. This assessment should be documented as part of the renewal evaluation on Checklist A.4, Part 2 "Renewal Checklist–Technical Review."

4.9.2.5 Records of Pre-licensing and Licensing Site Visits

The reviewer should include the following in the documentation of site visits:

1. areas visited, including the proposed storage location(s)

2. persons and management contacted

3. assessment and evaluation for whether the materials will be used as intended

4. whether the users are knowledgeable of and have the ability to implement health, safety, and security controls commensurate with the type and quantity of materials requested

5. assessment that the facilities are adequate to ensure that materials will be used without undue risk to the public health and safety and the environment

The record should be maintained as an OAR, non-publicly available, sensitive, internal, predecisional document.

4.10 Categorical Exclusions for Materials Licensing Actions

4.10.1 Introduction

10 CFR Part 51 contains NRC's regulations implementing the National Environmental Policy Act of 1969. Most materials licensing actions are covered by "categorical exclusions," specifically those outlined in 10 CFR 51.22(c)(10), (14), and (20), and therefore do not require environmental analyses. A categorical exclusion is defined in 10 CFR 51.14 as a "category of actions which do not individually or cumulatively have a significant effect on the human environment and which the Commission has found to have no such effect in accordance with

criteria set out in § 51.22, and for which, therefore, neither an environmental assessment nor an environmental impact statement is required."

The next two subsections provide guidance on determining when materials license actions qualify for categorical exclusion, in accordance with 10 CFR Part 51, and identify examples of licensing actions that are not covered by categorical exclusion.

4.10.2 Licensing Actions Eligible for Categorical Exclusion

License Actions That Qualify for Categorical Exclusion Under 10 CFR 51.22(c)(14)(i) Through (xvi) and 10 CFR 51.22(c)(20)

This section duplicates much of the guidance in NUREG–1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs." It is included in this NUREG because processing forms and issuing procedure letters are considered administrative functions of the regional licensing staff. For more specific guidance, the reviewer should refer to NUREG–1748 and NUREG–1757, Volume 1, "Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees."

4.10.2.1 License Actions That Clearly Qualify for Categorical Exclusion

Some licensing actions are clearly encompassed by a categorical exclusion under the provision of 10 CFR 51.22. For example, decommissioning of sites where licensed operations have been limited to the use of radioactive materials in sealed sources, provided there is no evidence of leakage of radioactive material from these sealed sources, clearly qualify for categorical exclusion under 10 CFR 51.22(c)(20)(ii). Such categorically excluded licensing actions under the provision of 10 CFR 51.22 are not required to have an EA and do not need to be coordinated with NMSS. The following sentence should be included in the response to the applicant or licensee or in a memo to the file, and no further documentation by the NRC license reviewer is necessary.

"An environmental assessment for this action is not required because this action is categorically excluded under 10 CFR 51.22(c) **[insert appropriate paragraph number]**."

4.10.2.2 License Actions That Qualify for Categorical Exclusion After the NRC Staff Has Completed Additional Technical and/or License-based Justifications

Categorically excluded licensing actions do not need an EA, but all categorical exclusions should be documented in some manner. This documentation provides the explicit evidence that the staff carried out the NEPA process and provides the rationale for applying the categorical exclusion. Unless otherwise stated below, the licensing staff is required to place a written justification in the license file to support the determination that an EA is not needed. Examples of license actions that need either documentation or a justification are discussed below.

<u>GROUP 1 AND CERTAIN GROUP 2 LICENSE TERMINATION ACTIONS</u>

Certain terminations of licensed activities clearly qualify for categorical exclusion under 10 CFR 51.22(c)(20). These are essentially Group 1 and certain Group 2 decommissioning categories, as described in NUREG–1757 [that meet the requirements of 10 CFR 51.22(c)(20)].

When licensed activities clearly qualify for categorical exclusion, the close-out survey or leak test results, along with the submitted NRC Form 314, or equivalent, certifying the proper disposition of the licensee's radioactive materials, are sufficient documentation from the licensee.

FIELD STUDIES IN WHICH LICENSED MATERIAL ORIGINATING ON-SITE IS RELEASED INTO THE ENVIRONMENT

If a research and development or academic institution application or amendment request proposes to release to the environment radioactive materials that originated on-site (e.g., within the controlled property of the licensee), an EA is normally not needed because the activity is covered under categorical exclusion 10 CFR 51.22(c)(14)(v), provided:

- All releases originating on-site to the environment, such as air and liquid effluents and direct radiation from deposition of radioactive materials from the release (e.g., groundshine), comply with the "as low as reasonably achievable" (ALARA) principle and 10 CFR Part 20 requirements.

  ***Note**:* To assist in demonstrating compliance with the requirements of 10 CFR Part 20, the licensee should set ALARA goals for air effluents at a modest fraction of the values shown in Appendix B, Table 2, Columns 1 and 2, of 10 CFR 20.1001-20.2401. Experience indicates that values of about 10 millirems (mrem) per year from all of the licensee's radioactive air effluents should be practicable for almost all materials facility licensees (see Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities"). Therefore, as a first step toward demonstrating compliance with ALARA for radioactive air effluents, the licensee demonstrates that the nearest member of the general public receives no more than 10 mrem per year from all of the licensee's radioactive air effluents [e.g., licensee demonstrates it meets the requirements of 10 CFR 20.1101(d)].

- All releases on-site comply with all applicable decommissioning requirements [e.g., decommissioning recordkeeping requirements pursuant to 10 CFR 30.35(g)] and current decommissioning policies.

The licensee should provide documentation with its application addressing the above criteria to support why an EA is not needed.

For license actions that cannot meet the above criteria, the Regions should coordinate with NMSS to determine whether an EA is needed. For example, an EA would be required for discrete sources released to the environment, which originated on-site and are not recovered at the conclusion of the study or decommissioning. Examples of field studies that might require an EA include those that are not similar to normal routine research, development, and educational activities; those that deliberately release discrete sources to the environment; those that release sources that may not be recovered; or those that affect endangered species or historical/cultural resources.

4.10.2.3 Generic Application of Previous License Actions That Qualified Under Categorical Exclusion

If a previous technical and/or license-based analysis had been performed by NMSS that bounded the environmental radiological hazards or impacts to the public for the specific generic

issue under consideration, and the Region believes its specific license action is within the safety envelope of the previous generic analysis, then the Region need only cite the previous generic analysis. The Region should document its rationale for making this assessment and file copies of the previous analysis and its rationale in the license file. No coordination with NMSS is necessary. If the previous analysis referenced categorical exclusion 10 CFR 51.22(c)(14)(xvi), the documentation should include the original memorandum from the Director, NMSS, or his delegate.

4.10.3 Licensing Actions Not Eligible for Categorical Exclusion

Licensing actions for the following activities are not covered by categorical exclusions:

1. Use of radioactive tracers in field flood studies involving secondary and tertiary oil and gas recovery.

2. Performance of field studies in which licensed material is deliberately released directly into the environment for purposes of the study. [However, the use of tracers in well logging is specifically covered by the categorical exclusion in 10 CFR 51.22 (c)(14)(xi).]

3. Processing of source material for extraction of rare earth and other metals (currently licensed in HQ only).

4. Waste brokers who are authorized to store waste more than 180 days or to possess more than 50 Ci of radioactive material.

5. Any commercial waste disposal (currently licensed in HQ only).

6. Decommissioning actions that are Group 3 and above and certain Group 2 actions, as described in NUREG–1757, that do not qualify for the categorical exclusion under 10 CFR 51.22(c)(20). For certain Group 2 and Group 3 actions, the EA can be a "simple" EA in accordance with NUREG–1748 and does not have to be coordinated with NMSS.

Any application not covered by a categorical exclusion or that is beyond a "simple" EA as described in NUREG–1748 should be coordinated with NMSS as soon as possible so that specific guidance can be provided to develop an EA in accordance with 10 CFR 51.21. This coordination is necessary for tracking purposes and NMSS support. If the EA demonstrates that the proposed activity will not have an adverse impact on the environment, then the NRC staff will document this determination through a FONSI. If the EA indicates that the proposed licensing action may have an adverse impact on the environment, then the regional staff, in coordination with NMSS, will prepare an environmental impact statement in accordance with 10 CFR 51.20.

4.11 Guidance for Agency Action on Applications or Amendments—Materials Licenses

Three avenues of agency action are available to the NRC staff in reviewing a license application or amendment. The agency may administratively close, deny, or approve the license application or amendment. Denial and approval are considered final agency actions because they constitute an agency decision on the license application or amendment. Administrative

closure occurs upon a withdrawal request from the applicant or licensee or upon the licensee's or applicant's abandonment of their application/amendment, as described in this section. Administrative closure is an action taken without prejudice to the applicant or licensee such that it does not preclude the applicant/licensee from resubmitting the request at a future time.

It is important for license reviewers to keep the lines of communication open between the applicant or licensee and themselves by performing follow-up on oral and written communications in a timely manner. Requests for additional information (RAIs) should be provided to applicants or licensees as early in the review process as possible to ensure adequate time for the applicant or licensee to develop a response and for the license reviewer to evaluate the response. In special situations where the applicant or licensee requests an extension beyond the 30-day turnaround time to respond to a RAI, or other time as may be specified, the NRC staff should consider granting the extension.

1. License reviewers should address any deficiencies in an application or license amendment in a RAI (e.g., deficiency letter, e-mail). The correspondence should contain a statement that specifies the assumption that the applicant or licensee does not wish to pursue its application or license amendment if the NRC does not receive an adequate reply within 30 calendar days from the date of the request, or within such other time as may be specified.

2. If the applicant or licensee does not respond within 30 days of the request, or within such other time as may be specified, the license reviewer should contact the applicant or licensee to discuss the option of withdrawing the application or license amendment. If the license reviewer continues to receive no response, the license reviewer should consider whether the request should be denied or whether it should be administratively closed due to the licensee's or applicant's abandonment of the request, as appropriate.

4.11.1 Guidance for Administrative Closure of a New Application or License Amendment

Applications for materials licenses (new or amendment) may be administrative closed through (1) withdrawal of the request by the applicant or licensee or (2) the applicant's or licensee's abandonment of the request as described in further detail in Section 4.11.1.2.

New applications and license amendments that are dispositioned using this process are administratively closed without prejudice to the resubmission of the application.

Once the technical review of a new application has begun, no fees will be refunded. Application fees will be charged regardless of the NRC's disposition of a new application or the withdrawal of a requested action; however, if the requested action is resubmitted within 12 months from the date of the original application, no additional application fee is required. Direct all questions about the NRC's fees to the OCFO at NRC HQ in Rockville, MD, 301-415-7554. Information about fees may also be obtained by calling NRC's toll-free number, 800-368-5642, extension 415-7554. The e-mail address is Fees.Resource@nrc.gov.

4.11.1.1 Withdrawal

Withdrawing the application or license amendment means that the applicant or licensee has decided that they do not want the requested action processed; withdrawal, however, does not

preclude the applicant or licensee from resubmitting the application or amendment at a later date. The following items should be followed for withdrawing a licensing action:

- A decision to formally withdraw an application or amendment should be made by the applicant or licensee.

- There should be no case where a withdrawal is processed by a license reviewer without first discussing it with the applicant or licensee and receiving the applicant's or licensee's request to withdraw the application or amendment request.

- The applicant's or licensee's request to withdraw the application or amendment may be obtained via telephone (with the conversation documented in a telephone conversation record; see NRC Form 699 in Appendix B, Sample Letter B.2.2 of this NUREG) or written communication.

- Following the request to withdraw the application or amendment, the license reviewer should prepare a withdrawal confirmation letter stating the reason that the applicant is withdrawing the application or amendment and including the following statement, "This action is taken without prejudice to the resubmission of your request." The withdrawal confirmation letter should be prepared for the appropriate signature. An example of a withdrawal confirmation letter may be found in Appendix B, Sample Letters B.4 of this NUREG.

- If the applicant or licensee does not request withdrawal of an application or amendment and is actively working on addressing the concerns raised by the license reviewer, the license reviewer should determine whether the procedures specified in Section 4.12 are applicable.

- If the applicant or licensee does not request withdrawal of an application or amendment and does not take any action to address the license reviewer's concerns, the license reviewer should follow the guidance in Section 4.11.1.2 if the criteria for administratively closing an application or amendment due to abandonment are met or Section 4.11.2 if the criteria for denying the licensing action are met.

License reviewers may offer the applicant or licensee the opportunity to withdraw their application or amendment. The following circumstances are examples of when this may be appropriate:

1. The applicant or licensee requires an extended period of time (greater than 60 days) to gather the requested additional information.

2. The applicant or licensee has determined that the requested action on the application or amendment is no longer required (e.g., the requested AU is no longer employed by the licensee, the use is not needed).

3. Upon review of the application or amendment, the license reviewer determines that the current license authorizes the requested activity.

Withdrawal could be appropriate in other situations and would need to be evaluated on a case-by-case basis.

4.11.1.2 Abandonment

If the applicant or licensee does not request withdrawal of the application or amendment and does not take any action to address the license reviewer's concerns, the license reviewer should consider administrative closure of the application or amendment due to abandonment.

Procedurally, an applicant or licensee is assumed to have abandoned the application or amendment request if the applicant or licensee (1) fails to respond to an RAI within 30 days, or within such other time as may be specified (subsequent deficiency letters or contacts with the licensee via telephone or e-mail should be considered), or (2) fails to provide adequate information necessary for the license reviewer to determine whether the application meets the regulatory requirements within 30 days, or within such other time as may be specified. As noted in Section 4.11, correspondence requesting additional information includes a statement that specifies the assumption that the applicant or licensee does not wish to pursue its application or license amendment if the NRC does not receive an adequate reply within 30 calendar days from the date of the request or within such other time as may be specified.

Administratively closing an application for a materials license (new or amendment) due to abandonment requires coordination between the license reviewer and their management. If a new application or license amendment is administratively closed due to abandonment, the license reviewer should inform the applicant or licensee, in writing, of the nature of any deficiencies and the reason for the closure. An administrative closure letter should be prepared for either the license reviewer's or Branch Chief's signature, as determined by the license reviewer's management. A sample letter informing applicants or licensees of the reason for the closure is provided in Appendix B, Sample Letters B.4 of this NUREG. Additionally, if an existing licensee abandons a new application or license amendment, the license reviewer should discuss with their management whether there is a need for inspection of the licensee to determine why the licensee abandoned the submittal, especially if the license reviewer was unable to correspond with the licensee.

New applications and license amendments that are dispositioned using this process are administratively closed without prejudice to resubmission of the application.

If a response to a RAI or additional information regarding the licensing action is received after a new application or license amendment has been administratively closed, and the response or information is received not more than one year from the date of the closure, the licensing action should receive a new control number, and the review should proceed. Typically, no additional fee is required. Direct all questions about the NRC's fees to the OCFO at NRC HQ in Rockville, MD, 301-415-7554. Information about fees may also be obtained by calling NRC's toll-free number, 800-368-5642, extension 415-7554. The e-mail address is Fees.Resource@nrc.gov.

4.11.2 Guidance for Denying a New Application, License Amendment, or License Renewal

NRC management recognizes that some licensing requests do not satisfy NRC safety regulations and, therefore, warrant a denial. Denial of an application for a materials license (new, amendment, or renewal) requires coordination by the license reviewer, regional

management, NMSS, and Regional Counsel or OGC. As early in the review process as possible, the license reviewer should identify and coordinate with NMSS any application that:

1. results in questions by the license reviewer about the applicant's suitability; integrity (e.g., submission of incomplete, inaccurate, or misleading information); or ability or commitment to comply with the NRC regulations (e.g., financial instability or past inspection and enforcement history)

2. raises unique legal or technical issues

3. requests the use of radioactive materials for frivolous purposes

License reviewers should prioritize early identification and coordination with HQ management and staff on these issues to ensure that the license reviewer promptly prepares a letter of denial, if appropriate, or that regional and HQ management and staff agree on an appropriate strategy for handling the application.

Applications for materials licenses (new, amendment, or renewal) may be denied if the NRC staff determines that the application does not meet the general requirements specified in 10 CFR 2.108, 30.33, 40.32, 70.23, or any other applicable regulatory requirements. In these cases, the NRC staff informs the applicant or licensee in writing of the following:

1. the nature of any deficiencies and the reason for the denial

2. the right of the applicant to demand a hearing within 20 days from the date of the notice or such longer period as may be specified in the notice or required by the applicable regulations

For NRC HQ licensing actions, the denial letter should be prepared for the signature of the Director of the applicable division responsible for the licensing action. For NRC regional licensing actions, the denial letter should be prepared for the regional designee with signature authority for denial letters. Prior to signature of the denial letter, the letter should be reviewed and approved by the appropriate Branch Chief from NRC HQ or the Region and legal counsel (OGC for HQ denial letters and Regional Counsel for regional denial letters). The appropriate regional director should also review and approve the denial letter if the letter will be signed out by the Regional Administrator (RA). Sample denial letters informing applicants of the reason for the denial and their right to request a hearing are provided in Appendix B, Sample Letters B.4 of this NUREG.

Following receipt of concurrence from the appropriate Branch Chief on the denial letter, the Branch Chief and license reviewer should brief regional management regarding the intent to deny the licensing action. If the RA will sign the letter, they should also be briefed. If the individual who will sign the letter agrees with the denial, the license reviewer and/or Branch Chief will contact the applicant or licensee to inform them that the NRC plans to deny the licensing action. The license reviewer and/or Branch Chief will offer the applicant or licensee an opportunity to withdraw the licensing action. The license reviewer and/or Branch Chief should make it clear that if the applicant or licensee does not withdraw the licensing action, the NRC staff will issue the denial.

After a denial letter is signed and issued, the denial should be noticed on the NRC's Web site under "Material Licensing and Other Related Actions Received on a Monthly Basis," available at https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing-license-applications.html#material.

For denials involving license renewals, the NRC will inform the licensee that their license will expire when the term of the current license ends or that their license has already expired (i.e., timely renewal). The denial letter should specify the actions that the licensee should take regarding the radioactive material in their possession. If necessary, the cognizant NRC office will prepare an Order for divestiture of licensed material in the licensee's possession and decontamination of the licensee's facilities, if necessary. See the NRC's Enforcement Manual available at https://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html for more information on guidance for processing Orders and templates of Orders. All Orders will be reviewed and approved by OGC, OE, and signed by either the appropriate RA or the NMSS Director, or authorized designee. All regional Orders should be coordinated with NRC HQ management and cognizant technical staff. Also, cognizant inspection management and staff should be notified of the initiation of a denial letter.

4.12 Guidance for Suspending Review of a New Application, License Amendment, or License Renewal

The licensee or applicant may need more time to respond to RAIs or the license reviewer may need more time to complete the review of a licensing request due to the need for technical assistance from outside of their office, including information from a TAR response (see Section 4.16 of this NUREG). In such cases, the NRC may temporarily suspend review of a license application (new, amendment, or renewal) with respect to the missing or incomplete information. Suspension of the review of a licensing request is only a temporary internal administrative measure for ensuring efficient allocation of resources while the NRC is waiting for a response from the licensee or applicant or waiting for additional technical information. Suspension is not the final disposition of the licensing action and should not be confused with administrative closure or a denial of the application or amendment as described in Section 4.11.

Suspending review of an application for a materials license (new, amendment, or renewal) requires coordination between the license reviewer and their management. Review of applications for materials licenses may be suspended if the applicant or licensee is **actively communicating** with the reviewer but (1) is unable to respond to an RAI within 30 days, or within such other time as may be specified (subsequent deficiency letters or contacts with the licensee via telephone or e-mail should be considered), or (2) cannot provide adequate information necessary for the license reviewer to determine whether the application meets the regulatory requirements within 30 days, or within such other time as may be specified. For example, the NRC may consider temporarily suspending review of a license application if an applicant or licensee requests more time to respond to a RAI, and the RAI responses are essential for the NRC to continue reviewing the application. Review of an application for a materials license (new, amendment, or renewal) may also be suspended if the license reviewer is waiting for technical information from other offices at the NRC (e.g., information in a TAR response).

The NRC may inform the applicant or licensee, in writing, that a decision on the licensing request will be delayed as a result of the missing or incomplete information. This written communication should inform the applicant or licensee that, because of a delay in receiving

information from the applicant or licensee that is necessary for review of the licensing request, the NRC cannot project when it will make a determination on the licensing request. Further, the written communication should note that, once a complete response is received, the NRC will provide an updated date for the NRC to complete its review. The NRC should note in this communication that, if an adequate response is not received by a date specified in the communication, the NRC will administratively close or deny the request, as appropriate. The NRC may prepare this written communication via letter for either the license reviewer's or Branch Chief's signature, as determined by the license reviewer's management. A sample letter is provided in Appendix B, Sample Letter B.4.12 of this NUREG.

The NRC should also inform the applicant or licensee, in writing, that a decision on the licensing request will be delayed if the license reviewer requires additional time due to the need to obtain technical information from other offices at the NRC. This written communication should provide NRC contact information for the applicant or licensee to communicate with the NRC regarding the delay. The NRC may prepare this written communication via letter for either the license reviewer's or Branch Chief's signature, as determined by the license reviewer's management. A sample letter is provided in Appendix B, Sample Letter B.4.13 of this NUREG.

After one year from the date of suspension, if issues are not adequately resolved for a new application or license amendment, the license reviewer should attempt to contact the applicant or licensee again to determine if they will withdraw the licensing action. If the applicant or licensee will not withdraw the application or amendment, the license reviewer should discuss the licensing action with their management and begin the process of either initiating administrative closure (due to applicant/licensee abandonment) as discussed in Section 4.11.1.2 or initiating a denial of the licensing action as discussed in Section 4.11.2.

For license renewals, after one year from the date of suspension, the reviewer should discuss the suspended renewal application with their management and determine if the application should be denied as described in Section 4.11.2. A denial would require divestiture of all material in the licensee's possession upon expiration of the license (see Section 4.23 of this NUREG for additional information regarding license expiration). Cognizant inspection management and staff should be notified of the initiation of a denial letter.

For a suspended review of a materials license application (new, amendment, or renewal), if the applicant or licensee provides a response to a RAI or additional information related to the application within 12 months from the date of the original application, no additional application fee is required.

Note: **Suspension of review of an application for a licensing action does not imply or directly result in the suspension of the associated license.**

4.13 Significant Licensing Actions That May Warrant On-site Inspection

Significant licensing actions that warrant consideration for a special on-site inspection may include requests for the following:

1. an increase in the types, quantities (e.g., aggregated Category 2 quantities or greater), and uses of radioactive material [e.g., new modality, emergent technology, significant potential for increased radiation exposure to the public or occupational workers (e.g., radiotoxicity)]

2. a change in the use of unsealed or unregistered sources

3. a physical move of an existing facility or new use at a temporary jobsite

4. a new facility, since the previous inspection, including temporary jobsites, where radioactive materials will be used or stored

5. a new disposal method (e.g., incineration)

6. a significant increase or decrease in the number of AUs

7. a change of RSO

8. an amendment to an existing license to add a medical therapy modality under 10 CFR 35.1000

9. a Possession and Storage Only or Possession and Storage-in-Standby license

10. a cessation of licensed activities at an entire site or in any building or area

11. a change in Program Code(s) that affect the next inspection due date

In situations described above, the license reviewer may need to consider completing Checklist A.3, "Identification of Significant Licensing Action and/or Program Code Change." This checklist is used to alert management that a significant licensing action may have taken place and that an on-site inspection, prior to the next routine inspection, may be necessary to review the licensee's intended changes. The selection criteria above should not be considered all-inclusive, as there may be unique indicators that suggest that a licensed program has changed significantly.

All license reviewers should understand the elements of the checklist and complete it for potentially significant amendment or renewal licensing actions. The checklist should become an OAR.

4.14 Processing of Exemption Requests for Materials Licensees

This section provides guidance to the Regions for processing requests for exemptions. Materials licensees may be granted exemptions from NRC regulations pursuant to 10 CFR 30.11, 40.14, and 70.17. The license reviewer will review the exemption request to determine whether the proposed exemption is authorized by law; will not endanger life, property, or the common defense and security; and is otherwise in the public interest. Appendix D provides additional guidance on routine exemptions keyed to specific sections of the regulations. Some exemptions may be granted on a temporary basis, as explained below.

In addition, the DOE may contact the Regions to conduct activities at non-government-owned and controlled facilities. If the DOE's prime contractor or subcontractor manufacturers, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material under his prime contract or subcontract, then the Commission will determine whether the exemption under 10 CFR 30.12 is authorized by law and whether, under the terms of the contract or subcontract, there is adequate assurance that the work can be accomplished without undue risk to the public health and safety. See the "Memo to the Regions Regarding Issuance of

Desk Reference Guide for Standardization of Processes for Evaluating Certain Exemption Requests Under Title 10 of the *Code of Federal Regulations* 30.12, 40.11, and 70.11," available in the Material Security Toolbox at https://scp.nrc.gov/controls.html.

4.14.1 Routine Exemptions

Routine exemptions to specific regulations as contained in Appendix D of this NUREG may be granted by the Regions without HQ coordination. Appendix D describes the specific part(s) of a regulation that may be considered for exemption, outlines any other commitments or additional information that the licensee must submit prior to issuance of the exemption, and provides the license condition to be issued upon review and determination that the exemption can be granted.

The exemption request should be accompanied by:

- a description of the licensee-proposed exemption and the reason why it is needed
- a description of specific compensatory safety measures that will provide a level of protection equivalent to the regulation for which the licensee-proposed exemption is being requested
- a discussion of reasonable alternatives that have been considered by the licensee

4.14.2 Temporary Exemptions for Humanitarian, Emergency, or Other Non-Routine Conditions

Temporary exemptions may be appropriate in circumstances where a normal license amendment is not appropriate because of the nonrecurring, limited duration aspects of the exemption. If NMSS determines that conditions exist for granting temporary exemptions as described in this section, NMSS will notify any impacted Region(s) that they may grant temporary exemptions. The Regions may grant a temporary exemption to NRC regulations or license conditions, on a case-by-case basis, without referral to NMSS; however, the exemption request should be discussed with NMSS whenever possible.

Additionally, NMSS and Regional senior management should consider if a more comprehensive approach, in lieu of case-by-case temporary exemptions, may be needed for granting temporary regulatory relief during rare circumstances or events (e.g., pandemics) that impact a broad segment of materials licensees. OGC and OE should be involved in these discussions.

A temporary exemption should be granted only after a determination has been made that the circumstances surrounding the request are urgent and temporary; that an exemption will not endanger life, property, or the common defense and security; and that it is otherwise in the public interest. Temporary exemptions must be reviewed and approved by either OGC or Regional Counsel. Temporary humanitarian exemptions are generally found in the medical area and include requests for relief from 10 CFR 20.1301. Such exemptions should not be exercised repeatedly for the same set of circumstances for the same licensee.

All licensee requests for a temporary exemption of a regulation should be accompanied by the following:

- A discussion of the regulatory requirements for which an exemption is requested and the identification of the specific regulation(s) or license condition(s) involved in the exemption.

- A discussion of circumstances surrounding the situation requiring a temporary exemption to NRC regulations, including the need for prompt action by NRC licensing staff, and the probable consequences to the licensee if the request is not granted.

- A preliminary evaluation of the safety significance and potential consequence(s) of granting the proposed request.

- A discussion that justifies the duration of the exemption.

The licensee's request should be sent via facsimile or e-mail to the appropriate regional director, or designee, within the appropriate NRC Region. However, if circumstances do not permit time for the facsimile or e-mail, the licensee may make the request orally and read or describe the above information to the NRC staff. The oral request should be followed by written documentation within 24 hours. The follow-up written request should confirm the information submitted orally that the NRC specifically relied upon when granting the exemption.

This specific type of exemption may be granted orally by the appropriate regional director, or a designee. After granting the request, the appropriate regional director, or designee, should promptly send a letter to the licensee. This letter should follow the standard format provided in Appendix B, Sample Letter B.3.5 of this NUREG, which documents the circumstances surrounding the temporary exemption request, a statement as to whether the exemption was granted, and the duration of the exemption. The letter signed by the appropriate regional director, or designee, and the amended license, incorporating the temporary exemption and commitments made by the licensee, should normally be issued within 3 working days of granting the request. Concurrent with issuing the license exemption, an entry should be made into WBL.

A license amendment for a temporary exemption, as described above, does not change the overall nature and consequent environmental impact of the licensed activity. Accordingly, the license amendment for the temporary exemption should be evaluated to determine whether it meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(10) or any of the standard categorical exclusions for the respective licensing action.

If a categorical exclusion applies, the following sentence should be included in the response to the applicant/licensee or in a memo to the file:

- "An environmental assessment for this action is not required because this action is categorically excluded under 10 CFR 51.22(c)(*enter the appropriate paragraph)*."

4.14.3 Exemptions Requiring Coordination with NMSS

All requests for exemptions not described above should be forwarded, typically in a TAR, to the appropriate NMSS Division Director. The Regions should follow closely the guidance contained in Section 4.16 for TARs and submissions of exemption requests for consideration of NMSS approval. All exemption requests should be entered into WBL and ADAMS upon receipt. Examples of exemptions that require coordination with NMSS before being initiated by the Region are indicated below. Additionally, when an exemption is being considered by NMSS,

the Region should submit its evaluation of the merits of the exemption from a technical standpoint, as well as any generic implications, such as a need for rulemaking. Exemptions coordinated with NMSS must be reviewed and approved by OGC.

As part of the exemption request evaluation, the Region should draft an EA to determine whether the exemption would support a FONSI. The Region should follow the guidance in NUREG–1748 and Section 4.10 of this NUREG for drafting an EA.

Examples of Exemptions Requiring Coordination with NMSS

- Relief from any of the provisions of 10 CFR Part 20.

- Requests for relaxation of, or exemptions from, the training and experience requirements of 10 CFR Part 35 for physicians, teletherapy physicists, nuclear pharmacists, authorized nuclear pharmacists, and RSOs. These requests are coordinated with the NRC's Advisory Committee on the Medical Use of Isotopes.

4.14.4 Administrative Procedures for Issuing Exemptions

When granting an exemption or temporary exemption to a licensee, the reviewer should describe the specific exemption in the cover letter accompanying the amendment authorizing the exemption. This cover letter should include any special provisions or conditions associated with the exemption. Additionally, the reviewer should record the exemption on the license exemption tab of WBL and identify the specific section of the regulation to which the exemption was granted.

4.15 Expedited Reviews

4.15.1 NRC-Expedited Reviews on the Basis of National Security

The NRC will give an application high priority and expedite the review if the products or authorized activities are necessary to protect national security. The following five criteria should be met for a review to be expedited:

1. The U.S. military or a Federal agency (e.g., U.S. Customs and Border Protection, Federal law enforcement agencies) makes a request for expedited review directly to the NRC.

2. The appropriate agency official makes a request, in writing (e-mail is acceptable), to the appropriate Branch Chief or higher-level management.

3. The requesting agency should state that national security is at stake and briefly, and in general terms, describe the use of the products or authorized activities. A detailed description that could disclose sensitive information is not necessary. The NRC will expedite the review for security reasons, not for business reasons.

4. There are no alternative products or authorized activities, alternative products or authorized activities would be too costly, or the pursuit of alternative products or authorized activities would result in significant setbacks to plans or schedules.

5. The requesting agency commits to providing the necessary oversight of the applicant to ensure both of the following:

    a. The application is of sufficient quality and provides the necessary information to support an expedited review.

    b. The applicant is responsive to NRC RAIs.

In conducting the expedited review, NRC reviewers should be able to conclude, with reasonable assurance, that regulatory requirements are met. However, the rigor of the review should be commensurate with the risk that the products or authorized activities pose to public health and safety. The reviewer should exercise engineering judgment in determining that the products or authorized activities are safe and do not pose a risk to public health and safety.

4.15.2 NRC-Expedited Reviews for Reasons Other Than National Security

An application may be assigned a higher priority, upon request. Requests for higher priority should include adequate justification, as indicated. An individual who is duly authorized to act for and on behalf of the applicant or licensee should make the request, in writing, to the appropriate NRC manager and include the following information:

- If the justification for expedited review is the dire need for the products or authorized activities to protect public health and safety, the request should indicate that the products or authorized activities provide a currently unavailable benefit to society. The applicant should provide details of the need, including (i) who directly benefits from the use of the products or authorized activities, (ii) how they benefit, (iii) how existing products or authorized activities fail to provide that benefit, (iv) why the review must be accomplished in less than the normal review time, and (v) when the products or authorized activities are needed.

- If the justification for expedited review is commercial hardship, the request should describe the commercial hardship that the applicant is likely to experience if the evaluation process is delayed. The applicant should provide details of the hardship, including (i) who the hardship affects, (ii) how they are affected (e.g., bankruptcy, layoffs) and why completion of the action is the only way to avoid that effect, (iii) why the review should be accomplished in less than the normal review time, and (iv) when it is needed.

4.16 Technical Assistance Request—Materials Licensees

TARs are formal submittals from NRC Division Directors in one Division (regional or HQ) to an appropriate NMSS Division Director in another division to request technical or policy assistance. TARs involve nuclear materials issues within NMSS's scope of responsibilities (e.g., Sealed Source and Device registration evaluations; issues involving the storage, use, security, and disposal of radioactive material). TARs should only be submitted to support a licensing or inspection activity. Before a TAR is formally submitted to NMSS, the requesting Region should discuss the proposed TAR with NMSS during ad hoc conference calls/discussions between regional and HQ Branch Chiefs and technical staff.

***Note**:* Medical, MML, commercial, and academic TARs should be discussed at set monthly counterpart meetings.

The procedures for identifying, screening, preparing, and processing TARs are available in NMSS Policy and Procedures 7-05, "Procedures for Processing of Technical Assistance Requests." This includes the form for submitting to the appropriate NMSS Division. The latest revision of NMSS Policy and Procedures 7-05 should be used.

4.17 Processing Proprietary Information

Final NRC records and documents, including correspondence to and from the NRC regarding licensing actions, are available to the general public, except under certain circumstances, such as SUNSI[2], as specified in 10 CFR 2.390. A reviewer may receive information from an applicant or licensee that is marked as "proprietary," "confidential," "restricted," or "is the express property of Company X." The reviewer will need to determine whether the information is necessary to the licensing action. If the information is not necessary, it should be returned to the applicant.

In 10 CFR 2.390, NRC specifies the procedures and requirements for persons to submit sensitive information to NRC so that it may be properly protected from disclosure. This regulation is available electronically on the NRC Web site at https://www.nrc.gov/reading-rm/doc-collections/cfr. If the information is necessary, the reviewer should ensure that the applicant has submitted a formal request, in accordance with 10 CFR 2.390, for withholding the information. To ensure that the necessary information is submitted, applicants and licensees should also use Checklist A.7 in Appendix A of this NUREG, which identifies the documents and information needed to support a withholding determination.

The reviewer should evaluate the applicant's request for withholding against the requirements in 10 CFR 2.390 (see Appendix F of this NUREG for additional information).

The regulations list various forms of information that can be protected from public disclosure. These include the following:

- trade secrets and commercial or financial information
- interagency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with NRC
- certain records or information compiled for law enforcement purposes
- geological and geophysical information and data, including maps, or information concerning wells
- personnel, medical, or other information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy

The applicant or licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. License applications that contain sensitive information

[2]SUNSI will be replaced at the NRC by Controlled Unclassified Information (CUI) around the end of 2021. The CUI program will change how the NRC currently marks, handles, safeguards, and disseminates sensitive information.

should be marked as indicated below, in accordance with 10 CFR 2.390, before the information is submitted to the NRC. Key examples are as follows:

- Proprietary Information and Trade Secrets: If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Appendix A includes a checklist (Checklist A.7) for requests for withholding information from public disclosure.

- Personally Identifiable Information: Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII, and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice (IN) 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" and "Information Notices," respectively, at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

- Security-Related Information: Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive, unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities and associated security measures are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information, and the top of every page of a document that contains such information should be clearly marked: "Security-Related Information—Withhold Under 10 CFR 2.390." Pages having security-related sensitive information must be portion marked. Portion marking is accomplished by clearly indicating the portion(s) (e.g., subject, titles, paragraphs, bullets, or sub-bullets) that contain OUO-SRI by placing the abbreviation "OUO-SRI" in parentheses at the beginning of the applicable portion. For further information, see RIS 2005-31, Rev. 1, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 26, 2017, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Additional information on procedures and any updates regarding SUNSI are available on the NRC Internal Web site.

Except for personal privacy information, which is not subject to the affidavit requirement, if NRC determines that the application or affidavit is deficient (i.e., does not contain the required information as outlined in 10 CFR 2.390), the applicant will be notified that additional information is needed and that the review will continue when the required information is received.

If the request is denied, in whole or in part, the reviewer should give the applicant the option of withdrawing the information or application. If the applicant decides not to withdraw the information or application, the reviewer should notify the applicant, in writing, that the request for withholding information from the public has been denied and that the reviewer will disregard any references concerning the proprietary status of the information. Sample letters are provided in Appendix B, Sample Letters B.6 of this NUREG.

Any part of a license application or information a licensee or applicant provides that the NRC determines should be withheld from public disclosure will be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program," and the SUNSI information provided on the NRC Internal Web site. The licensee or applicant will be notified, in writing, whether NRC plans to honor the request. Management Directive 12.6 is available electronically on the NRC Web site at https://www.nrc.gov/reading-rm/doc-collections/management-directives/.

Anyone submitting a request to withhold information from public disclosure should thoroughly review 10 CFR 2.390 and be familiar with its requirements and limitations.

Withholding from public inspection will not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, NRC may send copies of this information to NRC consultants working in that area. NRC will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future, such that the information could then be made available for public inspection, the licensee or applicant should promptly notify the NRC. The licensee or applicant also should understand that NRC may have cause to review this determination in the future; for example, if the scope of a Freedom of Information Act request includes the information in question. In all review situations, if NRC makes a determination adverse to the above, the licensee or applicant will be notified in advance of any public disclosure. Anyone submitting commercial or financial information they believe to be privileged, confidential, or a trade secret must remember that the NRC's policy is to achieve an effective balance between legitimate concerns for the protection of competitive positions and the right of the public to be fully apprised of the basis for, and the effects of, licensing or rulemaking actions. It is within NRC's discretion to withhold such information from public disclosure.

4.18 Possession and Storage Only and Possession and Storage in Standby Licenses

When a licensee is unable to divest itself of radioactive material and the licensee is able to safely maintain control over the material, a request for regulatory relief (i.e., possession and storage only or possession and storage in standby) may be appropriate. The purpose of this section is to outline the procedure for converting an existing license that authorizes one or more activities to a possession and storage only or possession and storage in standby license. The principle difference between a possession and storage only license and a possession and storage in standby license is that the storage in standby license is used in situations where it has not been determined that operations have permanently ceased at the facility. This does not apply to requests for new licenses for the sole purpose of material storage. Any request for a new storage license will be handled on a case-by-case basis in coordination with NMSS. In addition, any request to place only some materials in storage while other operations continue

will be handled on a case-by-case basis. This information may be used as a guide, and program codes for possession and storage only or possession and storage in standby licenses should be used if such requests are granted.

The regulations offer licensees with a process for the Commission to grant alternate schedules for decommissioning. Consistent with 10 CFR 30.36(f), 10 CFR 40.42(f), or 10 CFR 70.38(f) and as further clarified in RIS 2015-19, Rev. 1, "Decommissioning Timeliness Rule Implementation and Associated Regulatory Relief" (dated September 27, 2016), licensees must submit a request to delay initiation of decommissioning to the NRC staff no later than 30 days prior to the 10 CFR 30.36(d), 10 CFR 40.42(d), or 10 CFR 70.38(d) notification deadline.[3]

Possession-Only Licenses for Active Military Sites

The rule, "Timeliness in Decommissioning of Materials Facilities" (known hereafter as the Decommissioning Timeliness Rule), amended 10 CFR Parts 2, 30, 40, 70, and 72, and established definitive criteria for timely decommissioning of unused portions of operating sites and of entire sites upon termination of operations (59 FR 36026; July 15, 1994). The Decommissioning Timeliness Rule establishes requirements for notifying the NRC of cessation of principal activities, establishes requirements for when licensees must submit decommissioning plans, and establishes timeliness requirements for initiating and completing decommissioning activities. The regulations also allow licensees to request, and the NRC to grant relief from, the timing requirements, if certain criteria are met. The NRC may issue a possession-only license for a term longer than two years[4] at a military site where the military no longer uses AEA material, but initiating decommissioning would interfere with ongoing military use of that site (e.g., a firing range where AEA licensable material was used but characterization and cleanup activities could be dangerous due to unexploded ordinance or would interfere with ongoing military use of the firing range). The military department (e.g., the Departments of Defense, the Army, the Navy, or the Air Force) needs to demonstrate that delaying decommissioning would not be detrimental to the public health and safety and is otherwise in the public interest. The criteria that these licensees must satisfy to obtain approval to delay initiation of decommissioning are in 10 CFR 30.36(f), 10 CFR 40.42(f), or 10 CFR 70.38(f). These criteria are also substantially similar to the criteria that licensees must satisfy to obtain a specific exemption pursuant to 10 CFR 30.11(a), 10 CFR 40.14(a), or 10 CFR 70.17(a).

In other words, in order to support issuance of a possession-only license for a term longer than two years to a military department for an active military site, the NRC would make the same findings that it must make to support approval of a 10 CFR 30.36(f), 10 CFR 40.42(f), or 10 CFR 70.38(f) request to delay initiation of decommissioning. The NRC staff would consider imposing license conditions similar to the requirements of the Decommissioning Timeliness Rule that are specifically tailored to account for the continued military use of the site.

[3]10 CFR 30.36(f), 10 CFR 40.42(f), or 10 CFR 70.38(f) is an appropriate mechanism to use to delay the initiation of the decommissioning process. This includes delaying the need to provide notification to NRC for decommissioning, which in turn, would delay the need to initiate decommissioning or submit a decommissioning plan.

[4]In turn, an MML may issue a possession-only permit for a term longer than two years, subject to these same criteria.

A licensee may satisfy the criteria that delaying decommissioning is otherwise in the public interest by demonstrating that initiation of decommissioning would interfere with ongoing military use of that site.

Depending upon the nature of the licensed materials and activities, the NRC may consider commitments to continue existing licensing conditions as a basis to ensure the continued protection of public health and safety.

Regulatory Considerations

In responding to requests for a possession and storage only or possession and storage in standby license, reviewers should consider the following:

1. The steps the licensee took to divest itself of licensed material. To verify a licensee's claim of inability to divest itself of the material, the license reviewer should request the licensee to submit, in writing, the following information to substantiate the claim:

    a. Is a disposal site authorized to receive the material available?

    b. Has the manufacturer or material supplier been requested to take back the material? Is the manufacturer or material supplier out of business?

    c. Has the licensee made attempts to find another licensee, authorized to possess the material, to whom the material may be transferred?

    d. Has the licensee considered alternate disposal methods such as recycle/reuse programs?

    e. Is the licensee financially able to explore an available disposal option?

    f. Are there any other conditions that could directly affect the licensee's ability to safely store the material or would cause the license reviewer to question the licensee's ability to safely store the material? For example, (1) an Order has been issued for nonpayment of fees, (2) the licensee is uncooperative or unresponsive to information requests or demands, (3) the licensee is in willful violation of NRC requirements or licensee officials have engaged in deliberate wrongdoing.

2. The ability of the licensee to safely possess and store the material for an extended period of time (e.g., until a disposal option is available). Where the licensee has the ability to safely store the material in the near-term, but the licensee's ability to continue to safely store the material for an extended period is suspect (e.g., licensee is experiencing financial difficulties and is expected to file or has already filed for bankruptcy, but is able to continue operations), the license should be designated for increased NRC contact by telephone to supplement routine inspections. See NUREG–1556, Volume 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses."

3. Whether there is a need to relieve the licensee of the radioactive material in its possession due to the high degree of probability that the licensee will not be able to

safely maintain control of the material. Refer to IMC 1303, "Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)," for additional guidance.

Reviewers should coordinate with inspection staff and request a special inspection to assess the licensee's situation, unless an inspection has been performed within the last 12 months. The decision to issue a possession-only or storage in standby license is based on the reviewer's evaluation of the licensee's particular situation and the licensee's demonstration that other options have been considered. In all cases, reviewers should make every effort to take appropriate actions before the license expires.

Reviewing Requests for Possession and Storage Only or Possession and Storage in Standby Licenses

If a licensee requests that its license be converted to possession and storage only or possession and storage in standby status, use Checklist A.8 to determine the proper classification of the license.

1. Determine whether the licensee has permanently ceased operations. If the licensee **has** decided to permanently cease principal activities or permanently ceased operations for the periods specified in 10 CFR 30.36(d), 40.42(d), and 70.38(d), the licensee is required to begin decommissioning upon permanent cessation of operations. Determine whether the licensee is able to proceed with decommissioning.

    a. If the licensee **can** proceed with decommissioning, then instruct the licensee that they should proceed with decommissioning and license termination. Do not amend the license to authorize possession and storage only. If the expiration date has not passed, the license should be amended to limit activities to decommissioning only. (Expired licenses do not need to be amended because, by rule, decommissioning is the only activity authorized.) If decommissioning is the only activity authorized, then change the program code to DECOMMISSIONING (see program codes 03900, 11900, 21135, 21215, 21325, and 22200).

    Note: Reviewers should coordinate with NRC inspection and decommissioning staff concerning site reviews and inspection activities before the program code is changed.

    b. If the licensee **cannot** proceed with decommissioning (e.g., demonstrates that all reasonable options for disposal have been exhausted), then review the licensee's application using Checklist A.8. When each item on the checklist has been adequately addressed, issue a possession and storage only license and change the program code to POSSESSION-ONLY–PERMANENT SHUTDOWN (see program codes 03800, 04430, 04431, 11800, and 23300). Change the authorized use condition in the license to read, "Possession and storage only with intent to dispose." The license should have a 2-year expiration date (see note below) that may be renewed if the licensee continues to demonstrate that it cannot divest itself of the radioactive material, in spite of the fact that it has taken all reasonable actions within its ability to dispose of the material.

    Note: When storage is authorized as a result of a licensee's inability to transfer or dispose of the material, storage is not considered to be a "principal activity" as defined in

10 CFR Parts 30.36, 40.42, and 70.38. However, the requirements in these regulations, to notify NRC and undertake decommissioning, are not applicable because NRC does not consider there to be any principal activity for the licensee to cease. For these licensees, any decommissioning issues will be addressed by NRC when the license comes up for renewal. Renewals will occur at least every 2 years. See Revision 1 to Administrative Letter 96-05, "Compliance with the Rule 'Timeliness in Decommissioning of Materials Facilities,'" and RIS 2015-19, Rev. 1, "Decommissioning Timeliness Rule Implementation and Associated Regulatory Relief." Administrative Letters and RISs can be found on the NRC's Generic Communications Web page under "Administrative Letters" and "Regulatory Issue Summaries" at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

2. If the licensee **has not** permanently ceased operations, inform the licensee that its license cannot be converted to possession-only status. Without permanent cessation of operations, the license can only be converted to storage in standby status. The intent of this designation is to clearly identify licensees that intend to restart operations. A possession and storage in standby license may grant some relief from operational requirements. If the licensee requests a possession and storage in standby license, review the licensee's application using Checklist A.8. When each item on the checklist has been adequately addressed, issue a possession and storage in standby license, and change the program code to STANDBY–NO OPERATIONS (see program codes 03810, 04432, 04433, 11810, and 23310). Change the authorized use condition in the license to read, "Possession and storage in standby. This license must be amended prior to any use." License conditions applicable to suspended operations may be maintained in the license for convenience while the license is in standby status.

   Note: The timeliness criteria in 10 CFR 30.36, 40.42, and 70.38 limit periods of inactivity to 24 months, unless the NRC has granted a request to extend this time period. Any license converted to possession and storage in standby status should have an expiration date no greater than 24 months from the date that operations ceased or the issue date (whichever is earlier), unless an extended period of inactivity has been authorized. Requests for extended periods of inactivity may be granted under 10 CFR 30.36(f), 40.42(f), and 70.38(f), if they are not detrimental to the public health and safety and are otherwise in the public interest. When decommissioning is delayed for long periods of time after operations have ceased, there is a risk that safety practices will become lax as key personnel relocate and licensee management interest wanes. In addition, waste disposal costs tend to increase significantly over time, and delaying decommissioning will result in higher costs to the public if the government eventually assumes responsibility for the decommissioning. Thus, requests for extended periods of inactivity should explain how postponing decommissioning would be in the public's interest.

4.19 Decommissioning Service Providers

4.19.1 Licensing Decommissioning Service Providers

The purpose of this section is to provide guidance for authorizing decommissioning service providers to perform site remediation work under their own license at temporary jobsite locations. This guidance applies to temporary jobsites owned or operated by other NRC licensees, as well as non-licensees. This guidance does not apply to the installation and maintenance of devices.

Activities needed to decommission a site depend on the type of operations conducted by the licensee and the residual radioactivity. The various site conditions for decommissioning have been divided into seven decommissioning groups, which are described in NUREG–1757, Volume 1, "Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees."

4.19.2 Decommissioning Activities

NRC licensees who meet the description for a Group 1 or Group 2 decommissioning category may contract with other licensees or decommissioning service providers who are licensed to perform certain decommissioning activities, in lieu of performing the activities themselves. These activities can include radiological surveys and other cleanup activities authorized by the license. Under these circumstances, the NRC licensee should ensure that documentation associated with decommissioning meets NRC regulatory requirements and guidance provided in NUREG–1757. Because Group 1 and Group 2 categories do not require any remediation, there does not need to be any coordination between the NRC and the contracted decommissioning service provider licensee.

NRC licensees who meet the description for a Group 3 or Group 4 decommissioning category that could require remediation of buildings or the site may contract with a licensed decommissioning service provider to perform the necessary radiological surveys or decommissioning activities. The licensees that meet a Group 3 or Group 4 decommissioning category generally do not have radiation safety programs or decommissioning procedures in place to safely perform these activities themselves. In this instance, the decommissioning service provider is implementing its NRC-approved procedures to carry out decommissioning of the site, separate buildings, or outdoor areas, such that there is no increase in potential health and safety impacts to workers or the public, as described in 10 CFR 30.36(g), 10 CFR 40.42(g), or 10 CFR 70.38(g). It is important to recognize that the decommissioning service provider does not take possession of the licensed material originating from the site, except to the extent that they may package and transport it to an authorized recipient.

In other instances, the NRC licensee may have sufficient procedures for a radiation safety program but not have adequate procedures for remediation activities. Therefore, it may be appropriate for the NRC licensee to contract with a decommissioning service provider to perform the necessary remediation activities, as stated above; yet the decommissioning service provider may continue to work under the NRC licensee's radiation safety program.

In either example described above for the Group 3 or Group 4 decommissioning category, it is important that a written agreement between the NRC licensee and the decommissioning service provider be initiated. The written agreement should specify which licensed activities will be performed under the decommissioning service provider's license and supervision, and which licensed activities will be performed under the site-owner's NRC license and supervision. Further, as part of the decommissioning service provider's license conditions, the NRC is to be notified of the scope of work at the temporary jobsite. This allows the NRC to review and approve the scope of work or specific procedures for decommissioning the proposed building(s) or site, without issuing a new license or amending an existing license. The NRC review of the scope of work and written agreement ensures that there is adequate oversight; adequate radiation protection measures; and sufficient control and handling procedures. This NRC review also ensures that the final site-specific derived concentration guidelines level (DCGL) meets the published screening criteria values. The NRC will issue a safety evaluation report (SER) for Group 3 and above decommissioning categories.

If there are site-specific DCGLs or other release criteria under the Group 4 decommissioning category, then specific approvals are required by the NRC for either the decommissioning service contractor's or site owner's NRC license. The NRC will subsequently generate the appropriate notifications, as required by NRC Policy and NUREG–1757, Volume 1. See Section 4.10.3 of this NUREG. The NRC will also issue an EA, as appropriate.

Finally, the NRC licensee may be required to submit a decommissioning plan (DP), in accordance with 10 CFR 30.36(g), 10 CFR 40.42(g), or 10 CFR 70.38(g), if the procedures and activities necessary to carry out decommissioning of the site, separate buildings, or outdoor areas have not been approved by the NRC.

NRC licensees who meet the description for decommissioning categories Groups 5-7 typically complete these higher group decommissioning activities under the authority of their own NRC license rather than under a decommissioning service provider's license. Primarily, these decommissioning categories involve possible groundwater contamination or restricted release criteria for the site, which involves remediation activities that are not typically authorized under a service provider's license. The remediation activities are approved by the NRC and authorized under the NRC licensee's DP. In the majority of cases, the NRC licensee contracts with a company to implement the DP and perform the remediation activities; however, the NRC licensee remains responsible for the eventual release of the site.

4.19.3 NRC Policy for Licensing Decommissioning Service Providers

Site owners or operators might not have radiation safety programs in place that are adequate to ensure the safety of activities to be performed by a decommissioning service contractor. Therefore, it is appropriate for contractors to operate under their own license at temporary jobsites when they are providing the radiation safety programs under which the decommissioning activities are being performed. This ensures that site owners or operators do not supervise activities for which they have no experience. It also allows the NRC to authorize work without issuing a new license or amending an existing license, and it allows enforcement actions directly against contractors when violations are associated with their radiation safety programs. However, the site owner or operator remains responsible for decommissioning financial assurance as the license holder, regardless of who the owner hires to perform specific activities.

General Guidance

In general, applications for decommissioning service providers should be made in accordance with the regulations and guidance applicable to the authorized use requested. For example, an application for broad authorization to handle a wide variety of radioactive materials during site remediation should be in accordance with 10 CFR Part 33 and NUREG–1556, Volume 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope." In addition to the existing regulations and guidance, the following specific provisions should be addressed.

Specific Provisions

1. The NRC licensee who owns or operates the site that requires remediation may be required to submit a DP pursuant to 10 CFR 30.36(g), 10 CFR 40.42(g), or 10 CFR 70.38(g). If the NRC licensee uses site-specific DCGLs or other release criteria under the Group 4 decommissioning category, then specific approvals are required by

the NRC. The NRC will subsequently generate appropriate notifications, as required by NRC Policy and NUREG–1757, Volume 1, and generate an EA, if applicable.

2. The NRC licensee may contract with a decommissioning service provider, as described in the "Decommissioning Activities" above. Depending on the written agreement between the NRC licensee and the decommissioning service provider, a notification containing the information described in Item #3 below should be submitted to the NRC by either the NRC licensee or the decommissioning service provider. This notification allows the NRC to make a decision on the adequacy of the program and procedures used to conduct the decommissioning activities described in the remediation work plan for the types of radionuclides at the buildings or site.

3. The decommissioning service provider is usually required by license condition to notify the appropriate regional office (referenced in Appendix D of 10 CFR Part 20), at least 14 days before initiating decommissioning activities at a temporary jobsite location, to provide the NRC with an opportunity for inspection of these activities. This notification includes:

   a. the characterization survey report, including source terms and concentration profiles with physical/chemical forms of the radionuclides at the temporary jobsite

   b. the specific site location

   c. a description of the remediation work plan, including waste management and disposition

   d. the estimated start date and completion date for the job

   e. the name and title of a point of contact for the job, including information on how to contact the individual

4. A decommissioning service provider license may authorize the use of licensed material only at temporary jobsite locations in the United States where NRC maintains jurisdiction, including areas of exclusive Federal jurisdiction within Agreement States. See FSME-14-039, "Clarification on the Determination of Regulatory Jurisdiction of Non-Federal Entities Conducting Cleanup Activities on Federal Property in Agreement States" (ADAMS Accession No. ML14086A466), to provide additional guidance to that in SA-500, "Jurisdiction Determinations" (ADAMS Accession No. ML110600350). Possession or use of materials at the service contractor's facilities should be authorized under a separate license. In addition, possession should be authorized only to the extent that licensed material originating from the site should be transferred to an authorized recipient or left at the site. Possession (at the temporary jobsite location) of calibration sources, reference standards, and contaminated equipment owned by the licensee may be authorized under the decommissioning service provider license.

5. The decommissioning service provider is usually required by license condition to establish a written agreement that specifies which licensed activities will be performed under the site owner's NRC license and supervision, and which licensed activities will be performed under the decommissioning service provider's license and supervision. This agreement facilitates NRC's assessment of responsibility of licensed activities during the decommissioning process. The agreement usually includes commitments by both

licensees to ensure safety, and it specifies whether there are any commitments by the decommissioning service provider to help the customer clean up the temporary jobsite if there is an accident.

6. The decommissioning service provider is usually required by license condition to maintain records of information important to decommissioning a temporary jobsite at the site, pursuant to 10 CFR 30.35(g), 40.36(f), and 70.25(g). The site owner should have access to the decommissioning records throughout the decommissioning process. The decommissioning service provider should transfer these records to the site owner when activities at the temporary jobsite are complete.

7. For waste collectors and waste processors, 10 CFR 30.35(c)(5) requires the collectors and processors, as defined in 10 CFR Part 20, Appendix G, to submit a decommissioning funding plan that includes a cost estimate as described in 10 CFR 30.35(e). Waste collectors and waste processors must submit the decommissioning funding plan to the appropriate regional office at the time the license is renewed and at intervals not to exceed 3 years pursuant to 10 CFR 30.35(e)(2).

8. An application for a decommissioning service provider license is not required to contain an emergency plan, even if the application requests authorization to use licensed material in quantities exceeding the threshold for an emergency plan. Service licensees are not in a position to establish all of the site-specific response measures necessary to execute an effective emergency plan for a temporary jobsite. However, in accordance with 10 CFR 30.34(f) and 10 CFR 30.32(i), it may be necessary for service providers to have an emergency plan or evaluation. Therefore, a license condition should be included for a decommissioning service provider license to specify that prior to handling licensed material at any one site in quantities requiring an emergency plan under 10 CFR 30.32(i), the decommissioning service provider must either obtain NRC approval of an evaluation demonstrating that an emergency plan is not required or submit written confirmation that licensee personnel have been trained and will follow an existing emergency plan for the temporary jobsite.

9. It is in the public interest to have decommissioning service provider licensees who can provide immediate services in the event of a release or other incident involving uncontrolled radioactive material. Even though decommissioning service providers are required by license condition to establish written agreements and provide advance notification to the appropriate regional office before providing services, they may have to take other actions in an emergency. Therefore, decommissioning service providers may be authorized by license condition to take reasonable actions in an emergency that depart from conditions in the license when the actions are immediately needed to protect public health and safety and there are no immediately apparent actions within the authorized procedures and license conditions that can provide adequate or equivalent protection. It is NRC's practice to require by license condition that these emergent actions be approved by the individual authorized under the license, typically the RSO, prior to taking any action. If practicable, the decommissioning service provider licensee should notify the NRC before, and in any case, immediately after taking such emergency action using the reporting procedure specified in 10 CFR 30.50(c).

10. The decommissioning service provider is usually required by license condition to notify the appropriate regional office within 30 days of completing activities at each temporary

jobsite location. The notification should include the status of the temporary jobsite and the disposition of the material used by the decommissioning service provider.

11. Decommissioning service provider licenses are not temporary licenses that are only in effect while work at a temporary jobsite is in progress. The decommissioning service provider applicant should make a clear commitment to maintain all radiation safety programs in an active status even between jobs. Decommissioning service provider licensees should not suspend radiation programs and then attempt to re-establish them when another customer is found. This commitment should provide reasonable assurance that the licensee will remain competent to use licensed material and undertake authorized activities. This commitment in the application should include the following:

    a. maintaining qualified personnel in key positions (e.g., RSO)

    b. holding required safety committee meetings

    c. performing regular maintenance and calibration of safety equipment and radiation protection instrumentation

    d. completing required training (including periodic retraining)

4.20 Licensing Actions Under 10 CFR 20.2002

If a licensee submits an application to dispose of licensee-generated material(s) by a method not already authorized in the regulations, then the Region should submit a TAR to NMSS in accordance with Section 4.16 of this NUREG. The TAR package should include (i) an initial technical assessment to justify why the licensing action meets 10 CFR 20.2002 and (ii) the dose assessment for the disposal of the subject material. NMSS will review the TAR package and determine whether the requested action meets 10 CFR 20.2002. If so, NMSS will provide a memorandum to the Region, documenting the results that need to be included in the official license file.

4.21 Reviewing Efforts to Dispose of Licensed Materials and Requesting DOE Assistance

Historically, licensees have been able to either dispose of their material as low-level radioactive waste or transfer the material to other licensees licensed to possess the material. For a number of reasons, including, but not limited to, regulatory and financial uncertainties and lack of access to a waste compact, licensees may be finding it increasingly difficult to divest themselves of the material in their possession.

The reviewer may make the licensee aware of the Conference of Radiation Control Program Directors (CRCPD) and that CRCPD has a program available that can assist licensees to explore options for divesture of unwanted radioactive material. The CRCPD offers information and assistance directly to licensees for finding affordable, legal disposition for radioactive material. The CRCPD maintains a list of vendors and brokers the licensee can contact to assist with the disposal or transfer of certain types of radioactive material.

Also, the CRCPD and DOE/National Nuclear Security Administration have created a program entitled 'Source Collection and Threat Reduction' (SCATR) to encourage the disposal of unwanted sources being stored and not used. The SCATR program is limited to sealed sources and sealed vials [small volumes (tens of milliliters)]. Examples of sources that would be eligible for the SCATR program include medical brachytherapy sources (Cesium-137 and Radium-226), eye applicators, low-activity sources that exceed the NRC's 120-day half-life limit for decay in storage, long half-life industrial sources, and calibration sources. Licensees who wish to participate in SCATR should register their sources at https://osrp.lanl.gov. However, be informed that registering the sources does not guarantee that they will be disposed of by this program. Additional information on the SCATR program may be found at https://www.crcpd.org/page/SCATR. The reviewer may provide this information to a licensee as a means to assist in the disposition of radioactive material. The licensee should be directed to contact CRCPD directly. The reviewer may contact NMSS or the Regional Agreement States Officer to obtain current CRCPD contact information. The reviewer may also contact CRCPD directly to obtain information for current programs available for divesture of radioactive materials, in order to provide the information to a licensee.

Under circumstances where a licensee is unable to divest itself of radioactive material and the licensee is unable to safely maintain control over the material, requests for assistance from DOE may be appropriate. NRC IMC 1303, "Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy" (ADAMS Accession No. ML041270561), establishes procedures for regional and HQ staff to request emergency assistance from DOE in retrieving and storing certain inadequately-controlled radioactive materials.

***Note**:* 10 CFR Part 62 provides procedures for licensees to petition the NRC for emergency access to low-level waste disposal facilities, as a last resort. Reviewers should discourage licensees from petitioning the NRC for emergency access under 10 CFR Part 62 until all other options have been exhausted. Reviewers should consult with NMSS management if they believe that 10 CFR Part 62 is a reasonable option.

4.22 Sensitive Unclassified Non-Safeguards Information[5]

The reviewer should use the latest SUNSI guidance available on the NRC Office of Information Services Web site (on the NRC internal Web site) for handling, marking, and protecting documents. The NRC issued RIS 2005-31, Rev. 1, in December 2017, which also provides information on what constitutes SUNSI. Following are the ADAMS sensitive value codes and the SUNSI categories to be used in the profile for the respective document in ADAMS.

ADAMS Sensitive Value Codes

1. Federal, State, Foreign Government, and International Agency Controlled
2. Internal–no review required (attorney work product and client predecisional enforcement)
3. Internal–periodic review required (all other sensitive internal info)
4. Privacy Act (includes PII)
5. Proprietary

[5]SUNSI will be replaced at the NRC by Controlled Unclassified Information (CUI) around the end of 2021. The CUI program will change how the NRC currently marks, handles, safeguards, and disseminates sensitive information.

6. Protected subject to adjudicatory Order. No periodic review required.
7. Security-Related-Periodic review required

SUNSI Categories

1. Allegation Information
2. Investigation Information
3. Security-Related Information
4. Proprietary Information
5. Privacy Act/PII
6. Federal-, State-, Foreign Government- and International Agency-Controlled Information
7. Sensitive Internal Information

NRC-generated documents (e.g., licenses) that contain SUNSI should be marked appropriately in the header and footer of the document. Prior to faxing a sensitive document to a licensee, the reviewer will verify that someone is physically present at the fax machine to receive it. Otherwise, the NRC staff may redact the sensitive information and fax the document and, then, mark the original as sensitive and mail it to the licensee. SUNSI may be e-mailed within the NRC firewall (HQ and Regions), except investigation information. E-mailing SUNSI outside of NRC HQ and Regions should only be done when it is essential for the official conduct of NRC business and must be protected in transmission outside of the NRC, as required by the Cybersecurity Act of 2015, and NRC Management Directive 12.5, "NRC Cybersecurity Program." The NRC-generated document should be entered into ADAMS as non-publicly available, sensitive, and with the appropriate document sensitivity value.

The NRC staff should review incoming documents (e.g., license application, amendment request) for sensitive information. If SUNSI information is identified, such as PII or "Security-Related Information," and the document is not appropriately marked, the NRC office responsible for the information must designate and mark it. The unredacted document should be profiled in ADAMS as non-publicly available, sensitive, and with the appropriate document sensitivity value. Once redacted, for example in response to a public request, the ADAMS profile would be changed.

RIS 2005-31, Rev. 1 contains screening criteria to identify security-related sensitive information. The threshold radionuclide activity is the IAEA Category 3 radionuclide quantities of concern. Table 4-1 provides these criteria.

Table 4-1. Category 3 Sensitive Unclassified Non-Safeguards Information (SUNSI) Marking Criteria

Radionuclide	Quantity of Concern[1] [terabecquerel (TBq)]	Quantity of Concern[2] (Curie)
Am-241	0.06	1.6
Am-241/Be	0.06	1.6
Cf-252	0.02	0.54
Cm-244	0.05	1.4
Co-60	0.03	0.81
Cs-137	0.1	2.7
Gd-153	1	27
Ir-192	0.08	2.2
Pm-147	40	1100
Pu-238	0.06	1.6
Pu-239/Be	0.06	1.6
Se-75	0.2	5.4
Sr-90 (Y-90)	1	27
Tm-170	20	540
Yb-169	0.3	8.1
Combinations of radioactive materials listed above[3]	See Footnote Below[4]	

[1]The aggregate activity of multiple, collocated sources should be included when the total activity exceeds the quantity of concern.

[2]TBq values are the regulatory standard and the curie values are rounded to two significant figures.

[3]Radioactive materials are to be considered collocated or "aggregated" if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material. See the definition of "aggregated" in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37 and related guidance in NUREG–2155, "Implementation Guidance for 10 CFR Part 37, 'Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,'" Revision 1, January 2015.

[4] For calculations concerning multiple sources or multiple radionuclides, see information following this table.

The licensee should use the "sum-of-fractions" methodology to evaluate combinations of multiple sources or multiple radionuclides when determining if a location meets or exceeds the threshold and is thus subject to the guidance in RIS 2005-31, Rev. 1.

- If multiple sources of the same radionuclide or multiple radionuclides are aggregated at a location, the licensee should determine the sum of the ratios of the total activity of each of the radionuclides to verify whether the activity at the location is less than the values in Table 4-1. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, the applicable requirements of this RIS 2005-31, Rev. 1, apply.

- First, determine the total activity for each radionuclide from Table 4-1. This determination is done by adding the activity of each individual source, the material in any device, and any loose or bulk material that contains the radionuclide. Then, use Eq. (4-1) to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 4-1 in the numerator of the equation and the corresponding threshold activity from Table 4-1 in the denominator of the equation. The licensee

should perform the calculations in metric values [i.e., terabecquerel (TBq)]; the numerator and denominator values must be in the same units.

$$\sum_{1}^{n} \frac{\mathrm{R_n}}{\mathrm{AR_n}} \geq 1 \rightarrow \left[\frac{\mathrm{R_1}}{\mathrm{AR_1}} + \frac{\mathrm{R_2}}{\mathrm{AR_2}} + \cdots + \frac{\mathrm{R_n}}{\mathrm{AR_n}}\right] \geq 1. \quad (4\text{-}1)$$

where:

R_1 = total activity for radionuclide 1
R_2 = total activity for radionuclide 2
R_n = total activity for radionuclide n
AR_1 = activity threshold for radionuclide 1
AR_2 = activity threshold for radionuclide 2
AR_n = activity threshold for radionuclide n

Additional clarification and examples for the specific screening criteria are provided in Table 4-2 as an aid to the reviewer. Any additional clarifications should be coordinated with the branch associated with source management and protection in NMSS.

Table 4-2. Sensitive Unclassified Non-Safeguards Information (SUNSI) Examples	
Addresses	All individual mailing addresses may be made public, even if they specify a room or suite number, or a building number, as long as the room or suite numbers are not associated with a radioactive device or material or with a type of use: Example 1 (mailing address): ABC State University 123 Maple Street, Suite 789 Collegetown, New Jersey 01234 Example 2 (mailing address): XYZ Radiography, Inc. 456 Main Street Anytown, Idaho 75678 For Material BELOW the thresholds, building numbers are publicly available, but room and suite numbers are non-publicly available since they are considered to be security-related information. Room and suite numbers may be made publicly available if they are in a mailing address and are not associated with a radioactive device or material or with a type of use, as noted above. Additional locations of use, as specified in License Condition X, may be made publicly available if the address does not specify a room or suite number. Example 3 (location of use) (Non-publicly available because the address contains a suite number): 123 Main Street, Suite C Anytown, Idaho 12345 Example 4 (location of use) (Publicly available because it is a building number): 123 Main Street Anytown, Michigan 12345 Example 5 (location of use) (Publicly available because it is a building or general location on a campus or a hospital, for example): East Campus Research facility or Main Campus
Possession Threshold	Documents related to licensees that fall BELOW the Category 3 possession thresholds can be released as not containing Security-Related SUNSI; EXCEPT that addresses containing information on exact locations (e.g., specific room number or suite number) of radioactive material would not be released to the public unless it is a mailing address. Exact location information about radioactive material should be redacted as Security-Related SUNSI before release to the public.

Table 4-2. Sensitive Unclassified Non-Safeguards Information (SUNSI) Examples	
Possession Threshold	Documents related to licensees that are ABOVE the Category 3 possession thresholds should be redacted to remove Security-Related SUNSI before release to the public.
Licenses with Activity ABOVE Threshold	If a document specifies an iridium (Ir)-192 camera, containing 60 curies (Ci) of material, this information can be released as long as it does not include a specific location or manufacturer model number in combination with the radionuclide and quantity. (Even when the quantity of material is greater than the International Atomic Energy Agency Category 3 thresholds.) • Withhold information that identifies specific buildings, rooms, or suites where radioactive material is located. • Withhold authorized quantities. • Withhold manufacturers and model numbers of sealed sources and devices. If the inspection report documents a SPEC Model 150 camera containing Ir-192, whether or not the location is provided, then it will have to be withheld. • Withhold information on actual inventory (therefore, if the camera is the only one in the inventory, then it will have to be withheld). • Release authorized radionuclides and form. • Release individual mailing addresses and street addresses where material is located. • Release radionuclide, mailing address, and street address (without building number or room number). • Release manufacturer and model numbers of sealed sources and devices, as long the document does not specify the specific location of use (i.e., room number or suite number). • Release serial numbers of devices, as long as the document does not specify the specific location of use (i.e., room number or suite number). • For example, leak tests results can be made publicly available for devices above the threshold, as long as the specific location of use is not identified.
Licenses with Activity BELOW Threshold	Release manufacturer and model numbers of sealed sources and devices, as long as the document does not specify the specific location of use (i.e., room number or suite number). Release serial numbers of devices, as long as the document does not specify the specific location of use (i.e., room number or suite number). For example, leak test results for devices below the threshold can be made publicly available, as long as the specific location of use is not identified.

4.23 License Termination, Expiration, Revocation, and Retirement

The termination process begins when a licensee requests or the NRC orders that the license be terminated prior to the expiration date or when the license has expired and the licensee has decided not to submit a new license application. For licenses that enter the termination process, WBL should be updated to reflect the change in status. When licensed activities are concluded, appropriate documentation is received (e.g., surveys, leak tests, waste disposal and/or transfer records, NRC Form 314), and reviewed by the NRC, a termination cover letter and an amended license is issued stating that the license is terminated. Upon issuing the amended license, the WBL status should be changed to Retired.

Checklist A.9, "Materials License Termination Form," should be used as a guide to process termination licensing actions. See Appendix A of this NUREG. After verifying the disposition of licensed material, the reviewer should prepare a transmittal cover letter and an amended license informing the licensee that the license has been terminated after the following:

- ensuring that a satisfactory closeout inspection and confirmatory survey were performed, if required, and

- obtaining decommissioning records as described in 10 CFR 30.35, 10 CFR 40.36, or 10 CFR 70.25, if required.

A sample termination transmittal cover letter is available in Appendix B, Sample Letter B.3.4 of this NUREG.

If a financial assurance instrument was maintained, then return the financial assurance instrument under appropriate cover to the licensee, using overnight mail or equivalent.

Each license has a definite expiration date, and the license expires at the expiration date if the licensee fails to apply for timely renewal before the expiration date. If a licensee does not choose to submit a new license application, the license will expire at the expiration date and the termination process should begin, as described above. Expired exempt distribution licenses do not need to go through the termination process, and the status in WBL should be changed to Retired. If a license has expired, the WBL status should be changed to Expired (except for exempt distribution licenses which should be changed to Retired once the license has expired). Also see Section 3.2.5 of this NUREG for additional information regarding expired licenses.

Based on nonpayment of fees to the NRC or certain enforcement actions, an Order would be issued to revoke a license. (See the NRC's Enforcement Manual available at https://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html for more information on revocation Orders.) The Order would direct the licensee with regard to disposition of the license. Upon issuance of the Order, the status of the license in WBL should be changed to Revoked. If further action for the licensee is required by the Order (e.g., termination), WBL should be changed to reflect this status.

Prior to issuing an amended license stating that the license is terminated, the reviewer should complete the following applicable checklists to ensure that databases are updated to reflect that the license has been terminated:

- A.9–Materials License Termination Form
- A.1–License Status Change (For Termination and Expiration)
- A.2–NSTS Update
- A.3–Identification of Significant Licensing Action and/or Program Code Change

When the checklist, transmittal cover letter, and amended license stating that the license is terminated are finalized, the documents should be maintained as OARs with the appropriate sensitivity value.

5 FEES

5.1 Introduction

Effective August 9, 1991, significant changes occurred to Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended," and 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC." These regulations govern the licensing, inspection, and annual fees charged to applicants, licensees, and holders of certificates of compliance, registrations of sealed sources and devices, approvals of quality assurance programs, and other approvals. The revised regulations implemented the requirements of the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508, which mandated that the U.S. Nuclear Regulatory Commission (NRC) recover approximately 90 percent of its budget. NRC's current fee schedule is found in 10 CFR Parts 170 and 171.

For the majority of small materials license applications, there are flat application fees. These fees must accompany the application per 10 CFR 170.31. NRC no longer charges amendment, renewal, or inspection fees under 10 CFR Part 170; however, as provided in 10 CFR 170.31, application fees are charged for amendment and renewal applications that would increase the scope of the existing license to a higher fee category or add a new fee category. NRC charges fees for amendments, renewals, or inspections for the "full cost" categories specified in 10 CFR Part 170. Fees for "full cost" categories are calculated using the applicable professional staff-hour rates identified in 10 CFR 170.20 for licensing and inspection and are billed on a quarterly basis for accumulated costs.

The majority of small materials licensees pay an annual fee. The basis for these charges is discussed in 10 CFR 171.16(b). Annual fees for new licenses are prorated based on the issue date of the license; however, when a request for possession-only, termination, downgrade, or decommissioning is filed, the annual fees are prorated based on the date the request is filed and the date the licensee permanently ceased the licensed activities.

The annual fees for most materials licenses are billed on the anniversary date of the license (licensees whose annual fees are $100,000 or more are assessed quarterly). The annual fee assessed will be the fee in effect on the license anniversary date. The anniversary date of the materials license is considered to be the first day of the month in which the original materials license was issued. For example, if the original materials license was issued on June 17, then for annual fee purposes, the anniversary date of the materials license is June 1, and the licensee will continue to be billed in June of each year for the annual fee in effect on June 1.

Procedures for processing fees have been developed in order to make the appropriate decisions regarding the licensees' liabilities for the fees and to assure that licensees receive the invoices for annual fees before the due date.

5.1.1 Procedures for Processing Fees

General Guidelines

1. In the interest of providing accurate, uniform, and legally correct information relating to fee policy, procedures, and requirements, and in order to minimize confusion, requests

for specific annual, license, or reciprocity fee information should be directed to the Office of the Chief Financial Officer (OCFO).

2. When applications are received with or without payment, the Licensing Assistant (LA) should enter the action into the Web-based Licensing (WBL) system. The LA should forward the payment to OCFO for processing, if applicable.

3. Applications received directly by OCFO will be promptly forwarded to the appropriate licensing staff.

4. To have the most up-to-date data on which to base the annual fee billings, the licensing staff should take necessary steps to complete termination, possession-only, and downgrade requests as soon as possible.

Undeliverable Mail

1. OCFO staff will make every effort to obtain valid addresses for invoices returned as undeliverable. In those instances where the file searches and telephone directory assistance are unsuccessful, OCFO will forward a copy of the invoices to the appropriate licensing staff for follow-up. The licensing staff should promptly advise OCFO of the correct address or other pertinent information (e.g., licensee out of business, license to be terminated).

2. OCFO staff members will notify the licensing staff of any requests for address changes submitted as a result of the annual fee invoices and of addresses obtained through other means for undelivered invoices. It is hoped that, through these measures, documents returned as undeliverable mail will be minimized in future Office of Nuclear Material Safety and Safeguards (NMSS) and OCFO mailings.

"Misclassification" of Licenses

To the extent possible, assertions by licensees and licensing staff that licenses are misclassified in fee category will be handled by OCFO; however, there will be instances where verification or clarification from the licensing staff is required. In such cases, OCFO will send a copy of the correspondence or provide an Agencywide Document Access and Management System (ADAMS) accession number to the appropriate licensing staff with an e-mail requesting assistance. Because the clarification or verification will be essential in determining the appropriate annual fee, the licensing staff should make every effort to respond by the due date given in the e-mail. OCFO will prepare the responses to the licensees and will assure that appropriate concurrences are obtained.

Processing Licensing Actions Prior to Fees Approval

It is current NRC policy not to delay the initial technical review process of a materials license application, up to the point of issuance, pending the receipt of a fee. A license will only be issued with the full payment of the fee.

Processing Reciprocity Applications (NRC Form 241)

See Section 3.2.10 for information regarding fees for Agreement State licensees requesting authorization to work in NRC jurisdiction.

5.2 Follow-Up Actions for Orders Revoking Licenses for Nonpayment

The purpose of this section is to provide guidance concerning procedures for coordinating with OCFO on Orders revoking licenses for nonpayment of fees. See the NRC's Enforcement Manual available at https://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html for more information on guidance for processing Orders and templates of Orders. The precise wording may vary depending on the circumstances of individual cases. This procedure applies to quality assurance approvals and Sealed Source and Device registrations, but actions for these authorizations may deviate from these procedures. Separate Orders for quality assurance approvals, Sealed Source and Device registrations, and exempt distribution licenses are available to the licensing staff in the NRC's Enforcement Manual available at https://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html. Also see Section 4.23 of this NUREG to ensure proper license status change when a license is revoked.

Guidance

1. When a licensee has failed to respond to notices of payment due, OCFO will prepare the Order and send it electronically to the Office of General Counsel (OGC) and to the responsible Division Director, or designee, for concurrence. The Region will attempt to locate the licensee by telephone or other means to determine if it has received the notices of payment. For licenses issued by Headquarters, these and other communications will go to NMSS. The Division Director, or designee, for Headquarters (HQ) or the Region will respond in 2 weeks with any comments and/or concurrence. OCFO will, after receiving concurrence, issue the Order, sending it via certified mail to the licensee, and the ADAMS accession number of the signed copies of the Order will be sent electronically to the appropriate regional manager or the appropriate branch within NMSS. Copies of draft and final Orders will be sent by OCFO to the responsible Branch Chief and LA in the Region or HQ electronically. OCFO will provide copies or ADAMS accession numbers of any additional material upon request.

2. Upon issuance of the Order, OCFO will enter the "refusal to pay" flag in WBL for this specific materials licensee to preclude any licensing actions being taken without first consulting with and getting approval from OCFO. OCFO staff will enter a "Status 6" in WBL, indicating that the license will be suspended within 30 days (unless the licensee pays all debts due to the NRC).

   Under the terms of the Order for Revoking Licenses for Nonpayment of Fees

   a. From the date of revocation until notified by the NRC, in writing, that the license has been terminated, the licensee must:

      (i) Restrict activity involving licensed material to only decommissioning and safe, secure storage or transfer of material.

      (ii) Continue to control entry into restricted areas until the licensee has determined and NRC has confirmed that such areas are suitable for release in accordance with NRC requirements.

b. If the licensee does not pay the debts due to the NRC within 30 days of the date of the Order, the license is revoked and the following applies:

(i) No later than the date of revocation, any licensee who is a manufacturer, distributor, or provider of services to other licensees must notify each customer or client, in writing, that authorization to provide any support has been revoked and that customers and clients may need to amend their licenses to be in compliance with NRC requirements.

(ii) No later than the date of revocation, the licensee must submit a written report to the Regional Division Director or affected HQ Division Director on the status of materials.

(iii) The licensee must arrange for disposal of any licensed material, either by return to the manufacturer or transfer to an authorized recipient. Such disposal must take place within 60 days of the date of revocation. The licensee must notify the Regional Division Director or affected HQ Division Director, in writing, within 5 days of such disposal.

(iv) Unless the licensee is required to submit a decommissioning plan (DP), within 60 days from the date of revocation, the licensee must begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, so that the building or outdoor area is suitable for release in accordance with NRC requirements. If the licensee is required to submit a DP, it should consult 10 CFR 30.36, 10 CFR 40.42, or 10 CFR 70.38, for specific requirements applicable to the submittal and implementation of such a plan.

Upon the Regional Administrator's (RA's) determination that the steps above have been satisfactorily completed, as necessary, the license will be terminated at a date specified by the RA. If the licensee still owes fees, OCFO will continue to take action.

Under the terms of the Order, any request for relaxation will be directed to the Chief Financial Officer. The Chief Financial Officer will coordinate action on the requests with the RA or HQ Division Director and make a determination on any such request with the concurrence of the RA or HQ Division Director.

3. Thirty days after issuance of the Order, OCFO will send a "Final Action" memorandum stating whether the license was revoked for nonpayment of fees or whether the licensee paid the invoice in full within the 30-day period, and, therefore, the Order is rescinded; the licensee submitted "good cause" for an extension of time or for relaxation or rescission; the licensee requested a hearing; or there is another basis that would stay the effectiveness of the Order, such as the Order not being delivered.

4. If the Final Action is the revocation of the license, OCFO will update WBL by entering a "Status 5," indicating that the license is revoked. OCFO is working on a tracking system to identify delinquent debtors that have been previously written off as bad debt so that incoming applications can be matched to these debtors.

5. The Region or HQ should contact the licensee 6 to 10 days after issuance of the Order to determine the status of the licensee's program, receipt of the Order, and its intentions

relative to the Order. Depending on the licensee's response, the Region or HQ may need to schedule inspections and confirmatory surveys, as appropriate.

6. Upon receipt of the Final Action memorandum from OCFO indicating the debt has not been paid and the license is revoked for nonpayment of the fees, the Region should contact the licensee by telephone promptly to determine the licensee's status and intentions with respect to compliance. If the licensee does not respond in writing within 7 days of the phone call, the Region should arrange to conduct an inspection of the facility within 30 days.

7. Licensees whose licenses have been revoked and who subsequently pay the debt owed after the 30-day period provided in the Order and who want to resume operation, should be advised that they must apply for a new license and pay the appropriate application fee. Unless these licensees apply for and are granted relaxation or rescission of the Order for good cause, such as evidence that there is some error of fact or law in the Order, the licensee must apply for a new license and pay any other outstanding debts to the NRC. Licensees who choose not to decommission must pay delinquent debt and apply for a new license promptly to avoid enforcement action. The revoked license will be terminated simultaneously with the issuance of the new license.

APPENDIX A

CHECKLISTS

Checklists

CHECKLIST A.1

A.1 License Status Change (For Termination and Expiration)

Purpose: To ensure proper transfer/disposal of radioactive materials and archiving of records.

Licensee Name: _____

License No.: _____ Docket No.: _____ Control No.: _____

Expiration Date: _____ Date of Contact: _____

Licensee Contact/Title: _____ Telephone Number: _____

Basis for Termination or Expiration: _____

Verification:	**YES, NO, N/A**
(1) Was an NRC Form 314 or equivalent completed?	
(2) The licensee under License No._____ has received material, including any generally licensed sources/devices and naturally-occurring and accelerator-produced radioactive material, and is authorized for it; document verification method (letter or telephone): See "Conversation Record" (NRC Form 699) in Appendix B, Sample Letter B.2.2 of this NUREG) • Documentation to support:	
(3) Close-out survey by licensee (NUREG–1757) Agencywide Document Access and Management System (ADAMS) Accession #:	
(4) Close-out survey by NRC (NUREG–1757) ADAMS Accession #:	
(5) Licensee submitted records Title 10 of the *Code of Federal Regulations* (10 CFR) 30.36(k); 40.42(k); 70.38(k)] ADAMS Accession #:	
NRC action(s) to be taken:	**YES, NO, N/A**
(1) Terminate license.	
(2) Change to Retired status in Web-based Licensing (WBL).	
(3) Were the Financial Assurance documents returned?	
(4) Was the National Source Tracking System (NSTS) database updated?	
(5) Was the Nuclear Materials Management and Safeguards Systems (NMMSS) database updated?	

License Reviewer: _____ Date: _____

Supervisor Approval: _____ Date: _____

CHECKLIST A.2

A.2 National Source Tracking System (NSTS) Update

Purpose: Ensure NSTS is updated with current and correct information.

Licensee Name:		
License No.:	Docket No.:	Control No.:

Nationally Tracked Source is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E, "Nationally Tracked Source Thresholds," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20. (See 10 CFR 20.2207 for reporting requirements.)

Answer the questions in the following table: If "Yes" is checked for any of the following, then provide the required information:

If:	**YES**	Then:
New license authorizing NSTS materials		Provide all NSTS information in the table below and inform licensee that they must meet the Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2207 requirements.
Existing license not authorized for NSTS sources but submitting an amendment to authorize NSTS materials		Provide all NSTS information in the table below and inform the licensee that they must meet the 10 CFR 20.2207 requirements.
Existing license amended to add a location for NSTS materials		List all location address(es) to be added in the table below.
Existing license amended to remove a location for NSTS materials		List all location address(es) to be removed in the table below.
Existing license change of NSTS-required administrative information		Provide the new/changed information in the table below.
Existing license amended to remove all NSTS materials		Delete license from NSTS PRIOR to issuing license, or contact NSTS Help Desk to have it removed
Existing license terminated		Verify that there are no sources in NSTS inventory, then delete license from NSTS.

The following administrative information is required to be in NSTS for licensees possessing NSTS materials. This information will be entered into NSTS by the designated NRC staff only. Licensees may have multiple contact persons and multiple locations of use.

NSTS data field	New/changed information
NSTS contact person name and title	
NSTS contact person telephone number	
NSTS contact person facsimile number	
NSTS contact person e-mail address	
Licensee Name	
Licensee Mailing Address	
ADD Location(s) of Use: Street/city/state/zip code or state “temporary jobsite”	
DELETE Location(s) of Use	

Signature and Date:

Reviewer:_____ Date: _____

NSTS Regional Representative: _____ Date: _____

CHECKLIST A.3

A.3 Identification of Significant Licensing Action and/or Program Code Change

Licensee Name: _____

License No.: _____ Docket No.:_____ Control No.: _____

Reviewer: _____Date: _____

Licensing Branch Chief:_____Date: _____

Purpose: To determine if a change in on-site inspection frequency is warranted.

An on-site inspection of the licensee identified above should be considered due to a recent significant licensing action involving one or more of the criteria described below. (Refer to Inspection Manual Chapter 2800.) In addition, a change or addition of program codes may change the next inspection date and should be evaluated here.

Examples of significant licensing actions:	**YES or NO**
Increased types, quantities (e.g., aggregated Category 2 or greater), and uses of radioactive material [e.g., new modality, emergent technology, significant potential for increased radiation exposure to the public or occupational workers (e.g., radiotoxicity)]	
A change in the use of unsealed or unregistered sources	
Physical move of a facility or new use at a temporary jobsite Address:	
A new facility since the previous inspection, including temporary jobsites, where materials will be used or stored	
A new disposal method (e.g., incineration) Describe:	
Significant increase or decrease in the number of authorized users Describe:	
Change of Radiation Safety Officer (RSO)	
An amendment to an existing license to add a medical therapy modality under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000	
Possession and Storage Only or Possession and Storage in Standby license issued	
Cessation of licensed activities at entire site or in any building or area [Refer to 10 CFR 30.36(d), (h), and (j)]–(Ensure Checklist A.9 is completed if Termination. The latest version of Checklist A.9 is available in the Materials Toolbox at https://www.nrc.gov/materials/miau/mat-toolkits.html.)	
Change in program code(s) that affect the next inspection due date Enter new program code(s) here: _____ (Make sure it matches program code(s) listed on Web-based Licensing (WBL) printout.)	

****

For Use By Inspection Branch

An on-site inspection of the licensee identified above should be considered because of a recent significant licensing action involving one or more of the criteria described above. (Refer to Inspection Manual Chapter 2800.)

The inspection branch may document their assessment, as deemed appropriate by the Region.

Change Date of Next Inspection?

☐ Yes – Next Inspection Date: _____ ☐ No

Comments:

_____

_____

_____

_____

Supervisor or Designee: _____ Date: _____

CHECKLIST A.4

A.4 Renewal Checklist

Licensee Name:		
License No.:	Docket No.:	Control No.:

Part 1—PERFORMANCE INDICATORS

Review records for the 5 years preceding this renewal application and interview appropriate NRC staff, if needed, with respect to the following indicators:

Performance Indicator	Conclusion	If YES, explain:
Escalated enforcement, or Office of Investigations investigation occurred or is ongoing	Yes ❒ No ❒	
Lost control of licensed material presumed in public domain that is reportable or resulted in a violation	Yes ❒ No ❒	
Unauthorized disposal or release of material that is reportable or resulted in a violation	Yes ❒ No ❒	
An overexposure that resulted in a violation	Yes ❒ No ❒	

A.4 Renewal Checklist

Part 2—TECHNICAL REVIEW

The following areas should be reviewed as part of the technical review of a license renewal application concurrent with guidance from the appropriate NUREG–1556 volume(s), as applicable. Indicate Yes, No, or NA (not applicable), as applicable.

Standard Review	Yes, No, or NA
Administrative Items, including name, place of use (a physical address), and signature, were provided.	
Financial assurance or decommissioning funding plan, if required, was submitted and is adequate.	
Emergency Plan, if required, was received and is adequate	
Program Management was reviewed, and the following were determined to be adequate: 1. Organizational structure 2. Changes in key staff members (Radiation Safety Officer (RSO), authorized users, etc.) who are directly responsible for the radiation safety program 3. Qualifications of key personnel, including the RSO	
Equipment and Facilities are commensurate with materials authorized.	
Environmental Assessment All uses qualify for a categorical exclusion in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 51.	
Sealed Sources and Devices reviewed against the current Sealed Source and Device Registry and verified to be correct.	
Major program changes conform to the applicable regulations.	
New and/or High Risk Technologies conform to applicable regulations.	
Changes of Control conform to the regulations, and the new entity is known or had a pre-licensing site visit, as required.	
Unsealed transuranic radioactive materials used by licensee.	
Major Areas reviewed against regulations and determined to be adequate.	
Licensing visit was performed? (Refer to Section 4.9.2 of this NUREG)	

Part 3—RISK-SIGNIFICANT RADIOACTIVE MATERIAL (RSRM)

Complete “RSRM” checklist in the Material Security Toolbox, available at https://scp.nrc.gov/controls.html, to document whether the licensee is (1) already subject to the 10 CFR Part 37 requirements; (2) plans to obtain aggregated Category 1 or Category 2 quantities of radioactive material, as defined in 10 CFR 37.5; or (3) is reducing possession limits below RSRM. Completed: Yes ❒ No ❒_____

Print / Sign License Reviewer Date

CHECKLIST A.5

A.5 Limited Review Checklist

Licensee Name:		
License No.:	Docket No.:	Control No.:

Part 1—PERFORMANCE INDICATORS

Review records for the 5 years preceding this renewal application and interview appropriate NRC staff, if needed, with respect to the following indicators:

Performance Indicator	Conclusion	If YES, explain:
Escalated enforcement, or Office of Investigations investigation occurred or is ongoing	Yes ❒ No ❒	
Lost control of licensed material presumed in public domain that is reportable or resulted in a violation	Yes ❒ No ❒	
Unauthorized disposal or release of material that is reportable or resulted in a violation	Yes ❒ No ❒	
An overexposure that resulted in a violation	Yes ❒ No ❒	

A.5 Limited Review Checklist

Part 2—TECHNICAL REVIEW

The following areas should be reviewed as part of the limited technical review of a license renewal application concurrent with guidance from the appropriate NUREG–1556 volume(s), as applicable. Indicate Yes, No, or NA (not applicable), as applicable. For limited technical reviews of a license renewal application, if the staff concisely documents why its prior reasoning remains applicable to the renewal period, a detailed review of unchanged design features or of programs that were previously reviewed and approved, would typically not be needed.

Limited Review	Yes, No, or NA
Administrative Items, including name, place of use (a physical address), and signature, were provided.	
Possession limits checked	
Financial assurance or decommissioning funding plan, if required, was submitted and is adequate.	
Program Management was reviewed, and the following were determined to be adequate: 1. Organizational structure 2. Qualifications of key staff members (Radiation Safety Officer (RSO), authorized users, etc.) who are directly responsible for the radiation safety program 3. Radiation safety audit program	
Equipment and Facilities are commensurate with materials authorized.	
Environmental Assessment All uses qualify for a categorical exclusion in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 51.	
Unreviewed requests. Review any new authorizations and any major program elements that require change as a result of a new requested authorization structure. Review any changes in the licensee's scope of operations.	
Major program changes conform to the applicable regulations (e.g., new broad scope authority, major facility additions or changes, additional research and development activities, or additional medical therapy modalities).	
New and/or High Risk Technologies conform to applicable regulations.	

Limited Review	Yes, No, or NA
Changes of Control conform to the regulations, and the new entity is known or had a pre-licensing site visit, as required.	
Changes in key staff members. Have there been any changes to key staff members directly responsible for the radiation safety program	
*Major Areas reviewed against regulations and determined to be adequate.	
Licensing visit was performed? (Refer to Section 4.9.2 of this NUREG)	

* If an obvious failure or a deficiency is identified in a significant area, a more thorough review of that area should be performed. If during the review, a finding that more than one area is not addressed in the renewal application or if the application contains a significant deficiency, a comprehensive technical review of the application should be considered. If a comprehensive technical review is performed, the reason for changing the limited review to a comprehensive review should be documented.

Area(s) of Focused Thorough Review:

Part 3—RISK-SIGNIFICANT RADIOACTIVE MATERIAL (RSRM)

Complete "RSRM" checklist in the Material Security Toolbox, available at https://scp.nrc.gov/controls.html, to document whether the licensee is (1) already subject to the 10 CFR Part 37 requirements; (2) plans to obtain aggregated Category 1 or Category 2 quantities of radioactive material, as defined in 10 CFR 37.5; or (3) is reducing possession limits below RSRM. Completed: Yes ❒ No ❒_____

PRINT / SIGN LICENSE REVIEWER **DATE**

CHECKLIST A.6

A.6 New and Renewal and Possession-Only—License Term of Less than 15 Years

Licensee Name:		
License No.:	Docket No.:	Control No.:
Assign License Term: _____ years		

The application and license records were reviewed against the following criteria to determine if a reduced license term is appropriate.

Criteria Examples	YES	NO
New Technology: The license authorizes a new high-risk technology that the industry, the particular licensee, or NRC has not had extensive experience in using or regulating.		
Enforcement History: The licensee, in the last inspection (or 5 years, whichever is longer), had a Severity Level I, II, or III violation.		
Possession and Storage: Possession and Storage Only and Possession and Storage in Standby licenses should be renewed every 2 years, and decommissioning issues should be addressed at that time.		
Early Termination: In the case that early termination is expected after renewal.		
Other, specify:		

If any of the above items are checked "YES," describe the Basis for Decision:

_____ Print / Sign License Reviewer	_____ Date
_____ Print / Sign Branch Chief (if less than 15 years)	_____ Date

CHECKLIST A.7

A.7 Checklist for Requests to Withhold Proprietary Information From Public Disclosure (Under 10 CFR 2.390)

In order to request that the U.S. Nuclear Regulatory Commission (NRC) withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:	
☐	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
☐	A nonproprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the nonproprietary portions intact. This copy should **not** be marked as proprietary.
☐	An affidavit that:
☐	Is signed under oath and affirmation (notarization may suffice)
☐	Clearly identifies (such as by name or title and date) the document to be withheld
☐	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information the organization is seeking to withhold and is authorized to apply for withholding on behalf of the organization.
☐	States that the organization submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
☐	Provides a rational basis for holding the information in confidence.
☐	Fully addresses the following issues:
☐	Is the information submitted to, and received by, the NRC in confidence? Provide details.
☐	To the best of the applicant's knowledge, is the information currently available from public sources?
☐	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
☐	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your organization, the amount of effort or money expended in developing the information, and the ease or difficulty for others to acquire the information.

CHECKLIST A.8

A.8 Checklist for Evaluating Requests for Possession-Only Permanent and Standby Licenses

Licensee Name:		
License No.:	Docket No.:	Control No.:

Note: Applicants must comply with all relevant requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 40, and 70. The following is a list of general requirements only. License reviewers must ensure that additional requirements associated with site-specific conditions are also addressed. When each statement is verified, check the box.

[ ] 1. All licensed material to be placed in storage is identified. For each sealed source or device containing a sealed source, the licensee has identified (if possible) the source and device by manufacturer, model number, serial number, isotope, activity, date of assay, and date of last leak test.

[ ] 2. If the licensee has permanently ceased operations, the application includes a detailed description of all efforts made to dispose of the licensed material, including telephone calls, letters, facsimiles, e-mails, personal contacts, etc. The disposal options that must be addressed are contained in Section 8.11 of the relevant NUREG–1556 volumes.

[ ] 3. The application includes a clear commitment not to use the licensed material for any purpose, pending disposal or authorization to restart (as applicable).

[ ] 4. The application includes a physical description of the facilities where the material will be stored if it is different from storage facilities already approved in the license. Any planned facility changes have been identified, and provisions to maintain exposures as low as reasonably achievable are adequate.

[ ] 5. If applicable, the application adequately addresses financial assurance for decommissioning in accordance with 10 CFR 30.35, 40.36, or 70.25, as appropriate. Uncertainties with regard to future disposal and decommissioning costs may exist with requests for possession-only licenses where no other options are available. However, these uncertainties do not exempt the licensee from providing decommissioning funding assurance, using the best information available at the time of application. The license reviewer should determine if the proposed financial assurance is appropriate for the licensee's specific situation.

[ ] 6. The application identifies the individual who will be responsible for maintaining control of the licensed material while it is in storage. The individual's training and experience, as described in the individual's resume, are adequate. The necessary qualifications will vary depending on the material being stored. In general, the responsible individual should have a working knowledge of basic radiation safety practices and the regulatory requirements associated with the material being stored.

A.8 Checklist for Evaluating Requests for Possession-Only Permanent and Standby Licenses

[ ] 7. The application includes an acceptable accountability program for assuring that the licensed material, especially risk-significant radioactive material (RSRM), remains in secure storage and is not used (inventoried at least annually). The program provides reasonable assurance that the licensee will maintain security.

[ ] 8. The application includes all planned changes to limit/decrease the licensee's radiation safety program, as a result of placing the licensed material in storage. These changes may include, but are not limited to, the following:

a. Dosimetry services
b. Worker training programs
c. Instrument calibration services
d. Inventories
e. Internal audits
f. Maintenance and visual inspection of equipment and facilities
g. Maintenance of records

[ ] 9. If applicable, the application includes a commitment to leak test sealed sources and devices containing sealed sources at least once every 10 years and within 6 months before use or transfer to an authorized recipient.

[ ] 10. The application has been coordinated with inspection and decommissioning staff concerning changes to inspection activities.

[ ] 11. If the licensee's ability to safely store the material for an extended period is suspect, designate the license for increased NRC contact by telephone to supplement routine inspections. Contact every 12 months is recommended.

[ ] 12. For possession-only licenses, include a condition that states, "The licensee will continue to take all actions within its ability to dispose of its material and notify NRC within 30 days if disposal is achieved."

CHECKLIST A.9

A.9 Materials License Termination Form

For acceptable methods of demonstrating the suitability of a site for unrestricted use, refer to NUREG–1757, *Consolidated NMSS Decommissioning Guidance*, Volume 1. The latest version of Checklist A.9 is available on the NRC's public Web site at: https://www.nrc.gov/materials/miau/mat-toolkits.html.

[Licensee Name] was determined to be Decommissioning Group **[Enter Group Number]**

Group 1 Licensees (Refer to Section 8.1 of NUREG–1757)

(Enter Yes or No)

_____ Licensee possessed and used only sealed sources, and their most recent leak tests are current and demonstrate that the sealed sources did not leak while in their possession. In addition, the NRC has determined that the facility meets the radiological criteria for unrestricted use in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1402 without further remediation or analysis.

Comments:

_____ Licensee possessed and used relatively short-lived radioactive material (i.e., $T_{1/2}$ less than or equal to 120 days) in an unsealed form, and the maximum activity authorized under the license has decayed to less than the quantity specified in 10 CFR Part 20, Appendix C. Also, the licensee's survey performed in accordance with 10 CFR 30.36 did not identify any residual levels of radiological contamination greater than decommissioning screening criteria. Therefore, the facility meets the radiological criteria for unrestricted use in 10 CFR 20.1402 without further remediation or analysis.

Comments:

Group 2 Licensees (Group 2—Refer to Section 9.1 of NUREG–1757)

(Enter Yes or No)

_____ Licensee possessed and used loose radioactive material in an unsealed form, which they routinely cleaned up. The licensee's survey performed in accordance with 10 CFR 30.36 did not identify any residual levels of radiological contamination greater than the decommissioning screening criteria. Therefore, the facility meets the radiological criteria for unrestricted use in 10 CFR 20.1402 without further remediation or analysis.

Comments:

Note: If the licensee meets any of the above, then a decommissioning plan (DP) or environmental assessment (EA) is not required. The basis for the categorical exclusion

(CatX) is one of the paragraphs under 10 CFR 51.22(c)(20). The selected CatX should be documented in the license termination letter to the licensee.

(If a Licensee is designated as one of the above, then end the Checklist here)

A.9 Materials License Termination Form

Group 3 Licensees (Refer to Section 10.1 of NUREG–1757)

(Enter Yes or No)

_____ Licensee demonstrated compliance with 10 CFR 20.1402 (Radiological criteria for unrestricted use) using the screening methodology.

_____ Licensee possessed and used sealed sources and cannot demonstrate current leak tight integrity.

_____ Licensee possessed and used small quantities of unsealed materials, such as carbon (C)-14 or tritium (H)-3, and required a DP, because they have not incorporated the necessary activities and procedures into their license prior to ceasing operations.

_____ Licensee needs an amendment to modify or add procedures to remediate buildings or sites.

_____ Complete an EA.

_____ Confirmatory survey or side-by-side survey completed. This depends on the licensee's survey and radioactive material use at the facility.

_____ Issue letter to the licensee documenting decommissioning plan (DP) review.

_____ Issue a *Federal Register* Notice to announce (1) receipt of the DP and NRC's intended actions and (2) announce a finding of no significant impact (FONSI).

Note: Group 3 decommissioning licensees may submit a simplified DP.

(If a Licensee is designated as Group 3, then end the Checklist here)

A.9 Materials License Termination Form

Group 4 Licensees (Refer to Section 11.1 of NUREG–1757)

(Enter Yes or No)

_____ Facilities decommissioned under Group 4 used licensed material in a manner that resulted in a release into the environment, activated adjacent materials, or resulted in persistent contamination of work areas but did not result in contamination of groundwater.

_____ These licensees cannot meet, or choose not to use, screening criteria so they must demonstrate that any residual radioactive material remaining at the site is within the levels specified in NRC's criteria for unrestricted use, by applying a comprehensive dose analysis.

_____ Complete an EA and issue a safety evaluation report (SER) to document the DP review.

_____ Perform and document confirmatory survey or side-by-side survey completed.

_____ Issue a *Federal Register* Notice to announce (1) receipt of the DP and NRC's intended actions and (2) announce a FONSI.

Note: Group 4 decommissioning licensees are required to submit a DP.

Group 5 Licensees (Refer to Section 12.1 of NUREG–1757)

(Enter Yes or No)

_____ Facilities that decommission under Group 5 have used licensed material in a manner that resulted in its release into the environment, activated adjacent materials, or resulted in persistent contamination of work areas, and resulted in contamination of ground water.

_____ Group 5 decommissioning includes licensees that intend to decommission their facilities in accordance with NRC criteria for unrestricted use, as described in 10 CFR 20.1402.

Note: Group 5 decommissioning licensees are required to submit a DP.

(If a Licensee is designated as Group 4 or 5, then end the Checklist here.)

A.9 Materials License Termination Form

Group 6 Licensees (Refer to Section 13.1 of NUREG–1757)

(Enter Yes or No)

_____ Facilities that decommission under Group 6 have used licensed material in a manner that resulted in releases to the environment, activated adjacent materials, or resulted in persistent contamination of work areas or ground water.

_____ Group 6 decommissioning includes licensees that intend to decommission the facility in accordance with NRC criteria for restricted use, as described in 10 CFR 20.1403.

***Note*:** Group 6 decommissioning licensees are required to submit a DP.

Group 7 Licensees (Refer to Section 14.1 of NUREG–1757)

(Enter Yes or No)

_____ Facilities that have residual radiological contamination present in building surfaces, soils, and possibly groundwater.

_____ These licensees intend to decommission their facilities such that residual radioactive material remains at the site in excess of the levels specified in NRC's criteria for unrestricted use.

_____ These licensees will apply site-specific criteria in a comprehensive dose analysis, in accordance with alternate criteria for license termination (10 CFR 20.1404).

_____ A site DP that identifies the land use, exposure pathways, institutional controls, and critical group for the dose analysis is required.

Note: These sites require extensive NRC review and are handled on a case-by-case basis with license termination specifically approved by a vote of the NRC Commissioners.

APPENDIX B

SAMPLE LETTERS

Sample Letters

B.1 Administrative Correspondence

B.1.1 Expiration Letter Sample

[INSERT DATE]
[INSERT NAME]
[INSERT ADDRESS]

Re: License No. **[INSERT LICENSE NUMBER]**

SUBJECT: **[NOTICE OF LICENSE EXPIRATION]**

[INSERT SALUTATION]:

Your U.S. Nuclear Regulatory Commission (NRC) license will expire within the next 2 months. If you wish to continue your licensed program, you should prepare and submit a renewal application on NRC Form 313 (Enclosure 1), following regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) and licensing guidance in NUREG–1556, "Consolidated Guidance About Materials Licenses."

You must submit an application for the renewal of your license at least **[INSERT SPECIFIED TIMEFRAME (e.g., 30 CALENDAR DAYS)]** before the expiration date on the license.

If you do not wish to renew your license, you must dispose of or transfer all licensed radioactive material in your possession in accordance with 10 CFR Parts 30, 40, and 70. After that, complete the enclosed NRC Form 314, "A Certificate of Disposition of Materials" (Enclosure 2), and return it before the expiration date of your license, with a request that your license be terminated. If you have already applied for timely renewal of your materials license, please disregard this letter.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Enclosures:
1. Form NRC 313
2. Form NRC 314

B.1.2 Acknowledgement–Receipt of Correspondence (NRC FORM 532)

Please use the most current version of this form, which may be found at ADAMS Accession No. ML18200A140

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee	Date
	License Number(s)
	Mail Control Number(s)
	Licensing and/or Technical Reviewer or Branch

This is to acknowledge receipt of your: ☐ Letter and/or ☐ Application Dated:

The initial processing, which included an administrative review, has been performed.

☐ Amendment ☐ Termination ☐ New License ☐ Renewal

☐ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Select a location (Use keyboard arrows to select). . .

NRC FORM 532 (05-2016)

B.1.3 Acknowledgment Letter for NRC Form 244 and 483 Requests

[INSERT DATE]

[INSERT NAME]
[INSERT ADDRESS]

SUBJECT: NRC FORM **[244 or 483]** REQUEST

[INSERT SALUTATION]:
[USE THE FOLLOWING FOR NEW FORMS:]

Enclosed is your validated NRC Form **[244, "Registration Certificate: Use of Depleted Uranium Under General License," or 483, "Registration Certificate: In Vitro Testing With Byproduct Material Under General License,"]** dated **[INSERT DATE]**. You have been issued registration no. **[INSERT NUMBER]**.

[USE THE FOLLOWING FOR REVISED FORMS:]

Enclosed is your validated NRC Form **[244, "Registration Certificate: Use of Depleted Uranium Under General License," or 483, "Registration Certificate: In Vitro Testing With Byproduct Material Under General License,"]** dated **[INSERT DATE]**, reflecting the requested change **[brief description of change]**. You have retained registration no. **[INSERT NUMBER]**.

Please be advised that a general license is valid indefinitely; therefore, there is no renewal process. However, the regulations under Title 10 of the *Code of Federal Regulations* (10 CFR) 31.11 or 40.25 require that any change in the information provided by a registrant on the initial registration certificate be reported to the Director, Office of Nuclear Material Safety and Safeguards, within 30 days after the effective date of such change. I have enclosed a blank form for your use in reporting any future changes. Please reference your registration number when you report changes.

[USE THE FOLLOWING PARAGRAPH ONLY IF THE LETTER IS DETERMINED TO BE PUBLICLY AVAILABLE AFTER THE SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION (SUNSI) REVIEW.] In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Please contact me at **[INSERT TELEPHONE NUMBER]** if I can be of any further assistance.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Enclosures:
1. Certificate **[INSERT NUMBER]**
2. Blank Form **[INSERT 244 or 483]**

B.1.4 Letter for Follow-Up On Returned Mail

[INSERT DATE]

[INSERT NAME]
[INSERT ADDRESS]

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[INSERT SALUTATION]:

This letter concerns your byproduct materials license issued by the U.S. Nuclear Regulatory Commission (NRC), identified below. Correspondence sent to the address on your license has been returned to us unopened. We have found through telephone contacts or other sources that you can be reached at the above address.

Please be advised that you must notify us of changes in your mailing address and/or location of licensed radioactive material. We would appreciate it if you would review your current license and confirm whether it correctly reflects your mailing address and locations of radioactive material. If there are changes, you should immediately submit an amendment request to: **[INSERT APPROPRIATE NRC OFFICE ADDRESS]**.

If we do not hear from you within **[INSERT SPECIFIED TIMEFRAME (e.g., 30 CALENDAR DAYS)]**, we plan to turn your files over to our Inspection Branch for appropriate review.

[USE THE FOLLOWING PARAGRAPH ONLY IF THE LETTER IS DETERMINED TO BE PUBLICLY AVAILABLE AFTER THE SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION (SUNSI) REVIEW.] In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Please contact me at **[INSERT TELEPHONE NUMBER]** if I can be of any further assistance.

Thank you for your cooperation.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT NUMBER]**
License No.: **[INSERT NUMBER]**

B.1.5 Acceptance Review Discontinuation Letter

[INSERT DATE]

[INSERT NAME]
[INSERT ADDRESS]

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[**INSERT SALUTATION**]:

This letter is to acknowledge receipt of your **[APPLICATION/LICENSING AMENDMENT]** dated **[INSERT DATE]**, requesting **[INSERT BRIEF DESCRIPTION]**. An initial processing of your request, which included an acceptance review, has been performed, and we found that the **[APPLICATION/LICENSING AMENDMENT]** is lacking in significant amounts of required information. The information your **[APPLICATION/LICENSING AMENDMENT]** did not provide is listed in the Enclosure.

The NRC staff has reviewed your **[APPLICATION/LICENSING AMENDMENT]** and concluded that it did not provide technical information in sufficient detail to enable the staff to complete its detailed review and make an independent assessment regarding the acceptability of the proposed **[APPLICATION/LICENSING AMENDMENT]** in terms of regulatory requirements and the protection of public health, safety, and the environment. With incomplete documents and the unavailability of adequate information, the NRC staff is unable to begin its detailed safety evaluation of the **[APPLICATION/LICENSING AMENDMENT]** in its entirety. This determination to not accept your **[APPLICATION/LICENSING AMENDMENT]** for review is made without prejudice; you may supplement your **[APPLICATION/LICENSING AMENDMENT]** and resubmit if you desire. If you decide to resubmit your **[APPLICATION/LICENSING AMENDMENT]**, please ensure that you have included the entire **[APPLICATION/LICENSING AMENDMENT]** with the missing information needed, as noted in the Enclosure, to allow the NRC staff to evaluate your **[APPLICATION/LICENSING AMENDMENT]**.

If you have any questions, please contact **[INSERT NAME]** of my staff at **[INSERT TELEPHONE NUMBER AND E-MAIL]**.

[USE THE FOLLOWING PARAGRAPH ONLY IF THE LETTER IS DETERMINED TO BE PUBLICLY AVAILABLE AFTER THE SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION (SUNSI) REVIEW.] In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT NUMBER]**
License No.: **[INSERT NUMBER]**

Enclosure: As stated

B.2 Deficiency Correspondence

B.2.1 Sample Deficiency Letter

[INSERT DATE]

[INSERT NAME]
[INSERT ADDRESS]

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[INSERT SALUTATION]:

We have reviewed your letter dated **[INSERT DATE OF SUBMITTAL]** **(ADAMS ACCESSION NUMBER)**. Before we can take further action, we will need the following additional information.

1. **[DESCRIBE THE DEFICIENCY AND INCLUDE A CLEAR STATEMENT SPECIFYING THE INFORMATION NEEDED]**

[USE THE FOLLOWING PARAGRAPH ONLY IF THE LETTER IS DETERMINED TO BE PUBLICLY AVAILABLE AFTER THE SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION (SUNSI) REVIEW.] In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

To continue review of your application, we request that you submit your response to this letter within **[INSERT TIME FRAME]** calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. We will assume that you do not wish to further pursue this licensing action if we do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, we encourage you to contact us at **[INSERT TELEPHONE NUMBER AND/OR E-MAIL ADDRESS]**.

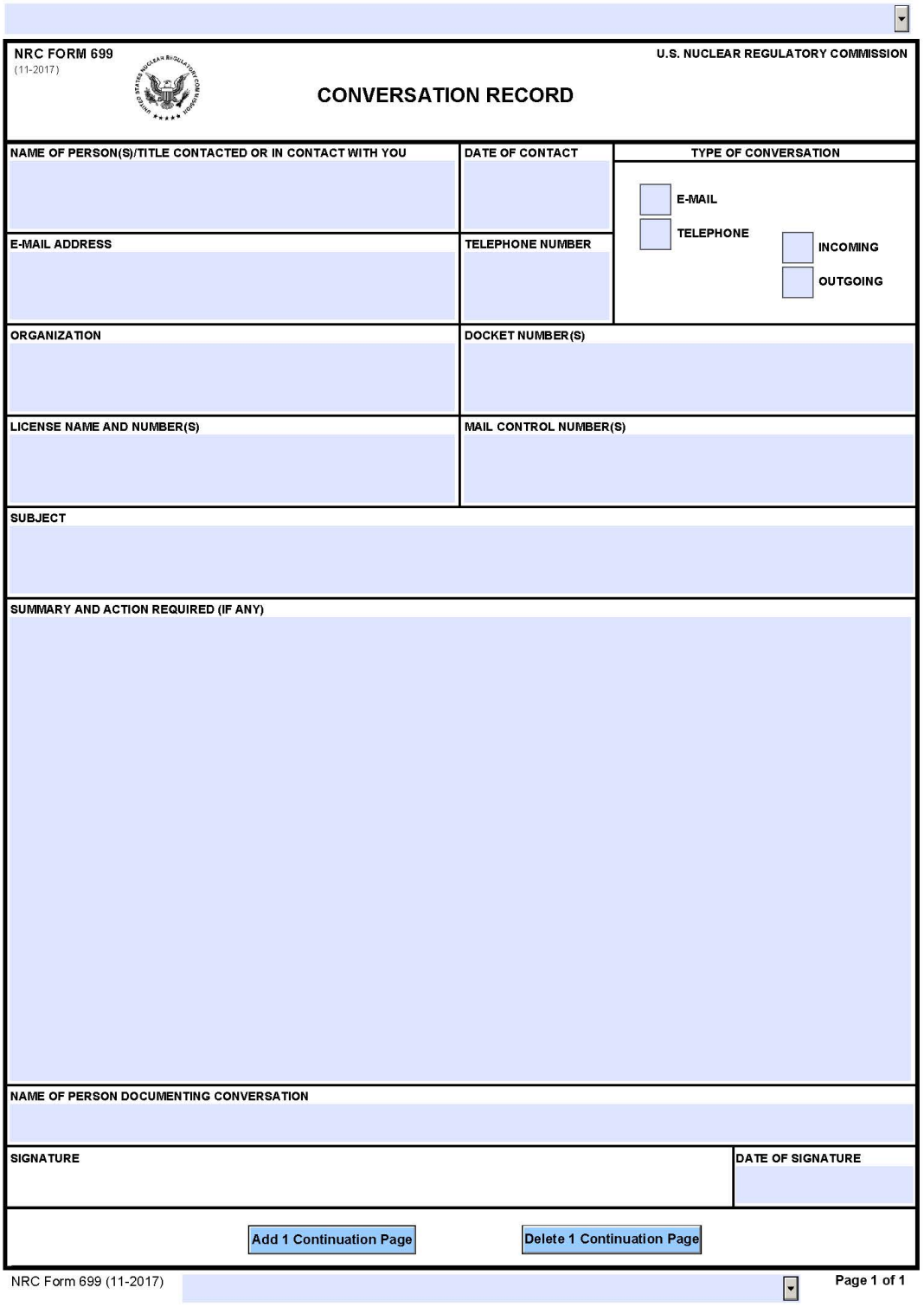
Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT NUMBER]**
License No.: **[INSERT NUMBER]**
Control No.: **[INSERT NUMBER]**

B.2.2 Conversation Record (NRC FORM 699)

Please use the most current version of this form, which may be found at ADAMS Accession No. ML18200A139



NRC FORM 699
(11-2017)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
		☐ E-MAIL ☐ TELEPHONE ☐ INCOMING ☐ OUTGOING
E-MAIL ADDRESS	TELEPHONE NUMBER	
ORGANIZATION	DOCKET NUMBER(S)	
LICENSE NAME AND NUMBER(S)	MAIL CONTROL NUMBER(S)	
SUBJECT		
SUMMARY AND ACTION REQUIRED (IF ANY)		
NAME OF PERSON DOCUMENTING CONVERSATION		
SIGNATURE	DATE OF SIGNATURE	

Add 1 Continuation Page Delete 1 Continuation Page

NRC Form 699 (11-2017) Page 1 of 1

B.3 Final Action Correspondence

B.3.1 Materials License Cover Letter for New Licenses

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: NEW LICENSE FOR **[INSERT LICENSEE NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

Enclosed is your U.S. Nuclear Regulatory Commission (NRC) Materials License No. **[INSERT LICENSE NUMBER]**, in accordance with your new license application, dated **[INSERT DATE]**. Your application is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. NRC **[INSERT OFFICE]** at **[INSERT TELEPHONE NUMBER]** so that we may provide appropriate corrections and answers.

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (10 CFR) 51.22(c).

Please be advised that your license expires at the end of the day, in the month and year stated in the license. Unless your license has been terminated, you must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations including 10 CFR Part 19, “Notices, Instructions and Reports to Workers: Inspection and Investigations;” 10 CFR Part 20, “Standards for Protection against Radiation;” and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

    a. When an authorized user (AU) or Radiation Safety Officer (RSO) permanently discontinues performance of duties under the license or has a name change; or
    b. When the mailing address listed on the license changes.

3. In accordance with 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

    a. When you decide to terminate all activities involving materials authorized under the license;
    b. If you decide not to acquire or possess and use authorized material; or
    c. When no principal activities under the license have been conducted for a period of 24 months.

4. Request and obtain a license amendment before you:

    a. Change Radiation Safety Officers;
    b. Possess radioactive material in excess of the amount, radionuclide, or form authorized on the license;
    c. Add or change the areas of use or address(es) of use identified in the license application or on the license; or
    d. Change the name or ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 60 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

[IF LICENSE IS A MEDICAL LICENSE, INCLUDE ITEM 6, BELOW, WITH SUBITEMS AS APPLICABLE.]

6. In accordance with 10 CFR 35.14, notify the NRC no later than 30 days after:

    a. The date that the licensee permits an individual to work as an AU, an authorized nuclear pharmacist, or an authorized medical physicist under 10 CFR 35.13(b)(1) through (b)(4);
    b. The date that an AU, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues duties under the license or has a name change;
    c. The date that the licensee's mailing address changes;
    d. The date that the licensee's name changes, where that name change does not constitute a transfer of control of the license, as described in 10 CFR 30.34(b); or
    e. The date that the licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 10 CFR 35.100 or 35.200.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation; or imposition of a civil penalty; or an Order suspending, modifying, or revoking your license, as specified in the NRC Enforcement Policy. Since serious consequences to employees and the public can result from failure to comply with NRC

requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance that NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

[IF LETTER AND LICENSE ARE BOTH PUBLIC (NON-SUNSI), INSERT THE PARAGRAPH BELOW]

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

[IF LETTER IS PUBLIC BUT THE LICENSE CONTAINS NON-PUBLIC INFORMATION (SUNSI), INSERT THE PARAGRAPHS BELOW]

NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through NRC's ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/, and the link for frequently asked questions regarding protection of security-related sensitive information may be located at https://www.nrc.gov/reading-rm/sensitive-info/faq.html.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

Enclosures:
1. License No. **[INSERT LICENSE NUMBER]**
2. New License Package

B.3.2 Materials License Cover Letter for License Amendments

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: AMENDMENT NO. **[INSERT AMENDMENT NUMBER]** TO RADIOACTIVE MATERIALS LICENSE FOR **[INSERT LICENSEE NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

Enclosed is Amendment No. **[INSERT AMENDMENT NUMBER]** to your U.S. Nuclear Regulatory Commission (NRC) Materials License No. **[INSERT LICENSE NUMBER]** in accordance with your **[INSERT DATE]** request. **[Add explanation of what was amended]** Your request is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

Please review the enclosed document carefully, and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. NRC **[INSERT OFFICE]** at **[INSERT TELEPHONE NUMBER]** so that we may provide appropriate corrections and answers.

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (10 CFR) 51.22(c).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation; or imposition of a civil penalty; or an Order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance that NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

[IF LETTER AND LICENSE ARE BOTH PUBLIC (NON-SUNSI), USE PARAGRAPH BELOW]

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

[IF LETTER IS PUBLIC BUT THE LICENSE CONTAINS NON-PUBLIC INFORMATION (SUNSI), USE PARAGRAPHS BELOW]

NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through NRC's ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/, and the link for frequently asked questions regarding protection of security-related sensitive information may be located at https://www.nrc.gov/reading-rm/sensitive-info/faq.html.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

Enclosure: Amendment No. **[INSERT AMENDMENT NUMBER]** to NRC License No. **[INSERT LICENSE NUMBER]**

B.3.3 Materials License Cover Letter for License Renewals

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: RENEWAL OF RADIOACTIVE MATERIALS LICENSE FOR **[INSERT LICENSEE NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

Enclosed is Amendment No. **[INSERT AMENDMENT NUMBER]** renewing your U.S. Nuclear Regulatory Commission (NRC) Materials License No. **[INSERT LICENSE NUMBER]**, in accordance with your **[INSERT DATE]** renewal application. Your application is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

Please review the enclosed document carefully, and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. NRC **[INSERT OFFICE]** at **[INSERT TELEPHONE NUMBER]** so that we may provide appropriate corrections and answers.

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (10 CFR) 51.22(c).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation; or imposition of a civil penalty; or an Order suspending, modifying, or revoking your license, as specified in the NRC Enforcement Policy. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance that NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

[IF LETTER AND LICENSE ARE BOTH PUBLIC (NON-SUNSI), USE PARAGRAPH BELOW]

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

[IF LETTER IS PUBLIC BUT THE LICENSE CONTAINS NON-PUBLIC INFORMATION (SUNSI), USE PARAGRAPHS BELOW]

NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through NRC's ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/ and the link for frequently asked questions regarding protection of security-related sensitive information may be located at https://www.nrc.gov/reading-rm/sensitive-info/faq.html.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

Enclosure: Amendment No. **[INSERT AMENDMENT NUMBER]** to NRC License No. **[INSERT LICENSE NUMBER]**

B.3.4 Materials License Cover Letter for Terminations

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: TERMINATION OF RADIOACTIVE MATERIALS LICENSE FOR **[INSERT LICENSEE NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

In letter dated **[INSERT DATE]**, **[INSERT NAME AND TITLE AS APPLICABLE]** notified the U.S. Nuclear Regulatory Commission (NRC) of a request to terminate NRC Materials License No. **[INSERT LICENSE NUMBER]**. Your letter is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (10 CFR) 51.22(c).

[FOR TERMINATION BASED ON FINAL STATUS SURVEYS, INSERT THE PARAGRAPHS BELOW]

The NRC staff has reviewed your final status surveys. Based on its review, the NRC staff has concluded that all licensable radioactive material has been removed from the facility **[OR INSERT DESCRIPTION OF FACILITIES]** and residual radioactive material attributable to licensed activities does not exceed current NRC criteria.

Based on these conclusions, no further remediation or actions are required with respect to NRC-regulated material. Your facilities are suitable for unrestricted use, and NRC Materials License No. **[INSERT LICENSE NUMBER]** is hereby terminated. (See Enclosure for the amended license stating that the license is terminated.)

[FOR TERMINATION BASED ON TRANSFER TO OTHER NRC LICENSE, INSERT THE PARAGRAPH BELOW]

In your letter dated **[INSERT DATE]**, you submitted information sufficient to permit the transfer of facilities at **[INSERT ADDRESS OR ADDRESSES]**, to another NRC licensee—**[INSERT LICENSEE NAME]**, NRC License No. **[INSERT LICENSE NUMBER]**. Based on its review, the NRC staff has concluded that all licensable radioactive material at **[INSERT ADDRESS]** has been transferred from **[INSERT LICENSEE NAME]**, NRC License No. **[INSERT LICENSE NUMBER]**, to **[INSERT LICENSEE NAME]**, NRC License No. **[INSERT LICENSE NUMBER]**. Based on this conclusion, no further remediation or actions with respect to NRC-regulated material are required on the part of **[INSERT LICENSEE NAME]**. The NRC understands that all records concerning the safe and effective decommissioning of the

[INSERT ADDRESS] facility have been transferred to and will be maintained by **[INSERT LICENSEE NAME]**, NRC License No. **[INSERT LICENSE NUMBER]**.

Accordingly, NRC License No. **[INSERT LICENSE NUMBER]** is hereby terminated. A copy of the amended license—Amendment No. **[INSERT AMENDMENT NUMBER]—**is enclosed.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NO.]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

Enclosure: Amendment No. **[INSERT AMENDMENT NUMBER]** to NRC License No. **[INSERT LICENSE NUMBER]** Stating that the License is Terminated

B.3.5 Temporary Exemption from NRC Regulation or License Condition

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: TEMPORARY EXEMPTION TO U.S. NUCLEAR REGULATORY COMMISSION (NRC) **[REGULATION OR LIST THE SPECIFIC LICENSE CONDITION(S)]**

[INSERT SALUTATION]:

Pursuant to the written request dated **[INSERT DATE]** for temporary exemption(s) from the requirements of **[INSERT NRC REGULATION OR LICENSE CONDITION]** by **[INSERT Name and Position of Requestor Representing The Licensee]**, the following temporary exemption(s) is (are) granted for the specified period of time:

[Each temporary exemption granted should be listed separately, with documentation of the circumstances surrounding the request and the duration of time for which the exemption is granted.]

[USE THIS PARAGRAPH ONLY FOR THE ISSUANCE OF AMENDMENTS THAT DID NOT REQUIRE AN ENVIRONMENTAL ASSESSMENT.]

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (10 CFR) 51.22(c).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If your understanding of the above temporary exemption differs from that set forth above, you are to notify **[INSERT CONTACT]** immediately, at **[INSERT TELEPHONE NUMBER]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: [**INSERT NUMBER]**
License No.: **[INSERT NUMBER]**
Control No.: **[INSERT NUMBER]**

B.4 SUMMARY OF SAMPLE DENIAL LETTERS

SAMPLE DENIAL	REQUESTED AUTHORIZATION	REASON FOR DENIAL(PERTINENT REGULATIONS)
B.4.1	License pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210 and 10 CFR 36.21 for registration of a sealed source	Radioactive material not as nondispersible, as practicable (10 CFR 36.21)
B.4.2	License pursuant to 10 CFR 32.51 to distribute device to persons generally licensed pursuant to 10 CFR 31.5	Accident doses exceed criteria in 10 CFR 32.51(a)(2)
B.4.3	Exemption from conducting sealed source inventories	Failure to provide adequate information (10 CFR 35.57, 35.400, and 35.500)
B.4.4	Amendment pursuant to 10 CFR 32.22 to distribute thumbstuds containing tritium to persons exempt from the licensing requirements	Determined that the end use of the thumbstuds was not reasonably foreseen [10 CFR 32.22(b)]
B.4.5	Addition of an authorized medical physicist	Inadequate training and experience [10 CFR 35.51(b)(1)], as demonstrated by a lack of training in medical physics or full time work experience
B.4.6	New location of use	Inadequate shielding evaluation to ensure dose limits to individuals of the public (10 CFR 20.1301)
B.4.7	Letter Denying Application for Renewal	Failure to provide requested information needed to complete the renewal application (10 CFR 2.108)

SUMMARY OF SAMPLE ADMINISTRATIVE CLOSURE LETTERS

SAMPLE WITHDRAWAL CONFIRMATION LETTER	REQUESTED AUTHORIZATION	REASON FOR WITHDRAWAL
B.4.8	Licensee determined that amendment request was no longer needed	Requested action no longer needed
B.4.9	Amendment request unnecessary because license authorizes requested activity	Requested action currently covered by existing license
B.4.10	Add an authorized user (AU)	AU needed additional time to obtain information

SAMPLE ADMINISTRATIVE CLOSURE LETTER DUE TO ABANDONMENT	REQUESTED AUTHORIZATION	REASON FOR SUSPENSION
B.4.11	New application	Request was lacking significant amounts of information and applicant was non-responsive to requests for additional information

SUMMARY OF SAMPLE SUSPENSION LETTERS

SAMPLE SUSPENSION LETTER	REQUESTED AUTHORIZATION	REASON FOR SUSPENSION
B.4.12	New application	Request was lacking significant amounts of information
B.4.13	License amendment request	NRC needs additional time to evaluate certain information in the request (e.g., waiting for a TAR response)

B.4.1 New Evaluation Request Denial Letter for Sealed Source and Device Registration

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT APPLICANT NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: DENIAL OF NEW EVALUATION REQUEST DATED **[INSERT DATE]** FOR **[INSERT APPLICANT NAME]**.

[INSERT SALUTATION]:

This letter is in response to your application dated **[INSERT DATE]**, and your letter dated **[INSERT DATE]** to the U.S. Nuclear Regulatory Commission (NRC) requesting registration of the Model **[INSERT MODEL NAME OR NUMBER]** sealed source. Your request is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.103, we are denying your request for registration of the Model **[INSERT MODEL NAME OR NUMBER]** sealed source.

[DESCRIBE THE REGULATORY REQUIREMENT/POLICY/GUIDANCE AND THE DEFICIENCIES; see the following example]:

We have determined that your Model **[INSERT MODEL NAME OR NUMBER]** source design is not acceptable for registration and licensing under 10 CFR 32.210 and 10 CFR 36.21. The provisions of 10 CFR 36.21 require that radioactive material in irradiators be as nondispersible as practical. Your application does not adequately justify your choice of cesium-137 chloride powder, a dispersible material. See Enclosure 1 for a detailed statement of the basis for the denial of the application, which includes the issue of dispersibility.

Pursuant to 10 CFR 2.103, you may request a hearing with respect to this denial within 20 days (or such longer period as may be specified in this letter) of the date of this letter. A request for hearing must be filed in accordance with the NRC requirements specified in 10 CFR Part 2, Subpart C. This request should reference this letter and Sealed Source and Device Evaluation Case No. **[INSERT CASE NUMBER]**.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosures will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Sealed Source and Device Case No.: **[INSERT CASE NUMBER]**

Enclosures:
1. Basis for Denial of Application for Registration of the Model XYZ Sealed Source
2. Deficiencies in the Application for Registration of the Model ABC Irradiator

B.4.2 Denial Letter for Distribution to General Licensees

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: DENIAL OF LICENSE REQUEST DATED **[INSERT DATE]** FOR **[INSERT APPLICANT NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

This letter is in response to your **[INSERT DATE]**, application to the U.S. Nuclear Regulatory Commission (NRC) requesting authorization to distribute the **[INSERT NAME OF DEVICE]** to persons generally licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) 31.5. After consideration of the application and supplemental information, we have concluded that the **[INSERT NAME OF DEVICE]** should not be authorized for distribution to generally licensed persons and have denied your application.

Accordingly, pursuant to Section 2.108, your application dated **[INSERT DATE]** is hereby denied for the reason(s) below.

[DESCRIBE THE REGULATORY REQUIREMENT/POLICY/GUIDANCE AND THE DEFICIENCIES; see the following example]:

10 CFR 32.51(a)(2) states that an applicant must provide reasonable assurance that a generally licensed device can be safely operated by persons not having been trained in radiological protection, and that under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of doses specified in Column IV of the table in 10 CFR 32.24 (15 rems to the whole body, 200 rems to the skin or extremities, and 50 rems to other organs). NRC finds that the accident dose criteria given in 10 CFR 32.51(a)(2) have not been met by your device, as explained below.

Portable moisture density gauges are frequently damaged in accidents and frequently lost or stolen, due to their common use in a construction environment. Your application analyzes a single accident scenario, where the gauge is crushed, and the sources remain in the shielded position. For this scenario, the projected doses you calculated meet the criteria specified in 10 CFR 32.51. Although you state that more severe accidents are unlikely, NRC had determined that a more severe accident scenario, where the gauge is severely damaged and the sources become unshielded, must be considered when evaluating whether the device

meets the 10 CFR 32.51(a)(2)(iii) criteria. Since unshielded sources from portable moisture density gauges have been found in the public domain, NRC believes that this is a reasonable scenario to consider.

For example, a portable moisture density gauge was struck by a truck, with the sources in the retracted position. The gauge was torn apart, and the cesium (Cs)-137 was separated from the gauge shielding. If an untrained person picked up an unshielded Cs-137 source and put it in his/her pocket, bringing the sources into contact with the body, the dose criteria specified in 10 CFR 32.51 would be exceeded in less than 1 hour.

In addition, NRC disagrees with your position that generally licensed gauges are no more likely to be stolen than specially licensed gauges. NRC recognizes that all gauge owners will take normal precautions to prevent theft; however, the NRC believes that the required security measures for specific licensees reduce the risk of theft and loss. Specific licensees are required to provide gauge users with radiological training, to provide security measures to prevent unauthorized access, theft, loss, and accidents involving the gauges, and to have emergency procedures that mitigate the consequences of accidents. General licensees are subject to less rigorous requirements.

NRC has concluded that, if the XYZ gauge were generally licensed, the associated reduction in applicable safety requirements would significantly increase the probability of serious accidents, including accidents due to mishandling following loss or theft. The probability for accidents exceeding the dose criteria specified in 10 CFR 32.51(a)(2)(iii) and 32.24 would be increased beyond a probability considered unlikely; therefore. NRC has determined that the XYZ gauge fails to meet the requirements for generally licensed devices with respect to accident conditions.

Pursuant to 10 CFR 2.103, you may request a hearing with respect to this denial within 20 days (or such longer period as may be specified in this letter) of the date of this letter. A request for hearing must be filed in accordance with the NRC requirements specified in 10 CFR Part 2, Subpart C. This request should reference this letter, Sealed Source and Device Case No., and Docket No. **[INSERT DOCKET NUMBER]**.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**

Sealed Source and Device Case No.: **[INSERT CASE NUMBER]**

B.4.3 Failure to Provide Sufficient Justification—License Amendment Request Denial Letter for R&D Licensee (Request for Exemption from Performing Inventory)

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: DENIAL OF AMENDMENT REQUEST DATED **[INSERT DATE]** FOR **[INSERT LICENSEE NAME]**, LICENSE NO. **[INSERT LICENSE NUMBER]**.

[INSERT SALUTATION]:

This letter concerns the subject request to amend your U.S. Nuclear Regulatory Commission (NRC) License No. **[INSERT LICENSE NUMBER]**. You have requested an exemption from conducting inventories of sealed sources if the source contains activities less than Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30 Schedule B quantities. Your request is available electronically from the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

In accordance with 10 CFR 2.103, your request to amend License No. **[INSERT LICENSE NUMBER]** is hereby denied for the reason(s) below:

[DESCRIBE THE REGULATORY REQUIREMENT/POLICY/GUIDANCE AND THE DEFICIENCIES; see the following example]:

NRC License No. **[INSERT LICENSE NUMBER]**, Condition No. **[INSERT CONDITION NUMBER]** states that inventories will be performed in accordance with NUREG–1556, Volume 7, Revision 1 guidance.

As noted in NUREG–1556, Volume 7, Revision 1, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers," academic, research and development, and other licensees of limited scope who use or possess sealed sources are required by license condition to perform inventories of sealed sources every 6 months. In your request dated **[INSERT DATE]**, you have not provided justification for NRC to make an exception to the requirement to perform inventories every 6 months. Note that if you submit a new request at a later date, you may refer to Control No. **[INSERT CONTROL NUMBER]** for the documentation you have already submitted.

Pursuant to 10 CFR 2.103, you may request a hearing with respect to this denial within 20 days (or such longer period as may be specified in this letter) of the date of this letter. A request for hearing must be filed in accordance with the NRC requirements specified in 10 CFR Part 2, Subpart C. This request should reference this letter, NRC License No. **[INSERT LICENSE NUMBER]** and Docket No. **[INSERT DOCKET NUMBER]**.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

B.4.4 Denial Letter for Distribution to Exempt Licensees—License Amendment Request

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: DENIAL OF AMENDMENT REQUEST DATED **[INSERT DATE]** FOR **[INSERT LICENSEE NAME]**, LICENSE NO. **[INSERT LICENSE NUMBER]**.

[INSERT SALUTATION]:

This letter is in response to your application, dated **[INSERT DATE]**, requesting the amendment of NRC License No. **[INSERT LICENSE NUMBER]**, to allow the distribution of thumbstuds containing tritium, under Title 10 of the *Code of Federal Regulations* (10 CFR), Section 32.22, to persons exempt from the licensing requirements, pursuant to 10 CFR 30.19. In accordance with 10 CFR 32.22(b), we have determined that the end-use of the thumbstuds cannot be reasonably foreseen. Therefore, pursuant to 10 CFR 2.103, your request to amend License No. **[INSERT LICENSE NUMBER]** is hereby denied. Please find attached a detailed statement of the basis for the denial of the application.

Pursuant to 10 CFR 2.103, you may request a hearing with respect to this denial within 20 days (or such longer period as may be specified in this letter) of the date of this letter. A request for hearing must be filed in accordance with the NRC requirements specified in 10 CFR Part 2, Subpart C. This request should reference this letter, NRC License No. **[INSERT LICENSE NUMBER]** and Docket No. **[INSERT DOCKET NUMBER]**.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Sealed Source and Device Case No.: **[INSERT CASE NUMBER]**

Enclosure:
Basis for Denial of Application

B.4.5 Inadequate Training and Experience—License Amendment Denial Letter for Medical Licensee

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: DENIAL OF AMENDMENT REQUEST DATED **[INSERT DATE]** FOR **[INSERT LICENSEE NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

This letter concerns the subject request to amend your U.S. Nuclear Regulatory Commission (NRC) License No. **[INSERT LICENSE NUMBER]**. You have requested to add **[INSERT NAME]** as **[an authorized user/an authorized medical physicist/the Radiation Safety Officer]** on the above license. Your amendment request is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.103, your request to amend License No. **[INSERT LICENSE NUMBER]** is hereby denied for the reason(s) below.

[DESCRIBE THE REGULATORY REQUIREMENT/POLICY/GUIDANCE AND THE DEFICIENCIES; SEE THE FOLLOWING EXAMPLE]

Per 10 CFR 35.51(b)(1), an authorized medical physicist must have 1 year of full-time training in medical physics and 1 year of full-time work experience under the supervision of an authorized medical physicist. The training and experience must occur in a clinical radiation facility that provides high-energy, external beam therapy and brachytherapy services. We were not able to confirm that **[INSERT NAME]** has the equivalent of two years of full-time training and experience as described above. Note that if you submit a new request at a later date, you may refer to Control No. **[INSERT CONTROL NUMBER]** for the documentation you have already submitted.

Pursuant to 10 CFR 2.103, you may request a hearing with respect to this denial within 20 days (or such longer period as may be specified in this letter) of the date of this letter. A request for hearing must be filed in accordance with the NRC requirements specified in 10 CFR Part 2, Subpart C. This request should reference this letter, NRC License No. **[INSERT LICENSE NUMBER]** and Docket No. **[INSERT DOCKET NUMBER]**.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

B.4.6 Inadequate Facility—License Amendment Denial Letter for Medical Licensee

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: DENIAL OF AMENDMENT REQUEST DATED **[INSERT DATE]** FOR **[INSERT LICENSEE NAME]**, LICENSE NO. **[INSERT LICENSE NUMBER]**.

[INSERT SALUTATION]:

This letter concerns the subject request to amend your U.S. Nuclear Regulatory Commission (NRC) License No. **[INSERT LICENSE NUMBER]**. You have requested to add a new location of use at **[INSERT ADDRESS]**. Your amendment request is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

In accordance with Title 10 *Code of Federal Regulations* (10 CFR) 2.103, your request to amend License No. **[INSERT LICENSE NUMBER]** is hereby denied for the reason(s) below:

[DESCRIBE THE REGULATORY REQUIREMENT/POLICY/GUIDANCE AND THE DEFICIENCIES; see the following example]:

10 CFR 20.1301, "Dose Limits for Individual members of the public," specifies that the licensee must conduct operations so that the total effective dose equivalent to individual members of the public from licensed operation does not exceed 100 millirem in a year. Based on review of your shielding evaluation submitted in your letter dated **[INSERT DATE]**, we were unable to confirm that your facility meets the required criterion. Note that if you submit a new request at a later date, you may refer to Control No. **[INSERT CONTROL NUMBER]** for the documentation you have already submitted.

Pursuant to 10 CFR 2.103, you may request a hearing with respect to this denial within 20 days (or such longer period as may be specified in this letter) of the date of this letter. A request for hearing must be filed in accordance with the NRC requirements specified 10 CFR Part 2, Subpart C. This request should reference this letter, NRC License No. **[INSERT LICENSE NUMBER]** and Docket No. **[INSERT DOCKET NUMBER]**.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

B.4.7 Sample Letter Denying Application for Renewal

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: DENIAL OF RENEWAL APPLICATION DATED **[INSERT DATE]** FOR **[INSERT LICENSEE NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

We have reviewed your **[INSERT DATE]** application for renewal of U.S. Nuclear Regulatory Commission (NRC) License No. **[INSERT LICENSE NUMBER]**. Your application is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**. Based on the review, our office determined that additional information was needed from you to complete the renewal. Accordingly, we prepared and sent you a written request for additional information via letter dated **[INSERT DATE]**. We have attempted to contact you via telephone on **[INSERT DATE]** and electronic mail on **[INSERT DATE]**, but have been unable to reach you. We have not received a reply from you.

Accordingly, pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 2.108, the NRC intends to deny your application for renewal of License No. **[INSERT LICENSE NUMBER]** for failure to supply information. Once your license has expired, you must divest yourself of licensed material presently possessed, meet the requirements in 10 CFR 30.36(d) and (e), and comply with any associated Orders from the NRC, if applicable.

You may request a hearing to contest this denial of your license renewal request. A request for hearing must be filed in accordance with the NRC requirements specified in 10 CFR Part 2, Subpart C. This request should reference this letter, NRC License No. **[INSERT LICENSE NUMBER]** and Docket No. **[INSERT DOCKET NUMBER]**.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

The NRC guidance for decontamination of your facility and equipment may be found in NUREG–1757, "Consolidated Decommissioning Guidance," Volumes 1, 2, and 3. Upon completion of your facility decontamination survey and transfer of materials, NRC may conduct inspections and independent surveys of your facility to verify compliance with 10 CFR 30.36(d) and (e).

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

B.4.8 License Amendment Withdrawal Confirmation Letter—Request No Longer Needed

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: WITHDRAWAL OF AMENDMENT REQUEST DATED **[INSERT DATE]** FOR **[INSERT LICENSEE NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

This letter concerns the subject request to amend your U.S. Nuclear Regulatory Commission (NRC) License No. **[INSERT LICENSE NUMBER]**. You have requested to **[INSERT SPECIFIC REQUEST]**. Your amendment request is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

Based on the **[TELEPHONE CONVERSATION, LETTER, FACSIMILE, OR E-MAIL, AS APPROPRIATE]** on **[INSERT DATE]**, you informed us that you no longer need the requested action and you are withdrawing the amendment request. Therefore, we have administratively closed your license amendment request. Note that if you submit a new request at a later date, you may refer to Control No. **[INSERT CONTROL NUMBER]** for the documentation you have already submitted.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

B.4.9 License Amendment Withdrawal Confirmation Letter—Requested Action Covered by Current License

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: WITHDRAWAL OF AMENDMENT REQUEST DATED **[INSERT DATE]** FOR **[INSERT LICENSEE NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

This letter concerns the subject request to amend your U.S. Nuclear Regulatory Commission (NRC) license No. [**INSERT LICENSE NUMBER]**. You have requested to **[INSERT DESCRIPTION OF REQUESTED AMENDMENT]**. Your request is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

Based on the **[TELEPHONE CONVERSATION, E-MAIL, LETTER, OR FACSIMILE, AS APPROPRIATE]** on **[INSERT DATE]**, we have determined that your license currently authorizes the requested activity such that an amendment to the license to authorize the activity is unnecessary. In accordance with our communication, we have noted that you have confirmed that the license amendment request should be withdrawn. Therefore, the referenced request has been administratively closed.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NO.]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

B.4.10 License Amendment Withdrawal Confirmation Letter—Additional Time Required to Obtain Preceptor Attestation Forms

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: WITHDRAWAL OF AMENDMENT REQUEST DATED **[INSERT DATE]** FOR **[INSERT LICENSEE NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

This letter concerns the subject request to amend your U.S. Nuclear Regulatory Commission (NRC) License No. **[INSERT LICENSE NUMBER]**. You have requested to add **[INSERT NAME OF PHYSICIAN/PHARMACIST/PHYSICIST, etc.]** as an authorized user under Title 10 of the *Code of Federal Regulations* (10 CFR) **[INSERT APPLICABLE REGULATIONS SUCH AS SECTION 35.300 OR INSERT THE SPECIFIC REQUEST]**. Your request is available electronically from the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

During a discussion on **[INSERT DATE]**, you informed us that you will require additional time to obtain preceptor attestation(s) to support your request. Based on the **[TELEPHONE CONVERSATION, LETTER, FACSIMILE, OR E-MAIL, AS APPROPRIATE]**, you have confirmed that you are withdrawing your request at this time. Accordingly, the referenced request has been administratively closed. Note that if you submit a new request at a later date, you may refer to Control No. **[INSERT CONTROL NUMBER]** for the documentation you have already submitted.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

B.4.11 New License Application Administrative Closure Letter Due to Abandonment—Request was Lacking Significant Amounts of Required Information and Applicant was Non-Responsive to Requests for Additional Information

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT APPLICANT NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: ADMINISTRATIVE CLOSURE DUE TO ABANDONMENT OF NEW LICENSE APPLICATION DATED **[INSERT DATE]** FOR **[INSERT APPLICANT NAME]**

[INSERT SALUTATION]:

We have reviewed your new license application dated **[INSERT DATE]** for a U.S. Nuclear Regulatory Commission (NRC) license. You have requested to **[INSERT BRIEF DESCRIPTION OF REQUESTED AUTHORIZATION]**. Your application is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

Based on the review, our office determined that additional information was needed from you to continue review of your new license application. Accordingly, we prepared and sent you a written request for additional information via letter dated **[INSERT DATE]**. The application was lacking significant amounts of information, as noted in the request for additional information letter described above. To date, that information has not been provided to our office. Therefore, we have administratively closed your application due to your lack of response to our request for additional information.

Note that if you submit a new request at a later date, you may refer to Control No. **[INSERT CONTROL NO.]** for the documentation you have already submitted. If you resubmit the application within 12 months from the date of your original new license application, any fees paid to date will be credited toward the application fee.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NO.]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

B.4.12 Suspension of Review Letter for New License Application—Request was Lacking Significant Amounts of Required Information

[INSERT DATE]

INSERT NAME]
[INSERT TITLE]
[INSERT APPLICANT NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: SUSPENSION OF REVIEW OF NEW LICENSE APPLICATION DATED **[INSERT DATE]** FOR **[INSERT APPLICANT NAME]**

[INSERT SALUTATION]:

We have reviewed your new license application dated **[INSERT DATE]** for a U.S. Nuclear Regulatory Commission (NRC) license. You have requested to **[INSERT BRIEF DESCRIPTION OF REQUESTED AUTHORIZATION]**. Your application is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

Based on the review, our office determined that additional information was needed from you to continue review of your new license application. Accordingly, we prepared and sent you a written request for additional information via letter dated **[INSERT DATE]**. As discussed subsequently via **[TELEPHONE CONVERSATION, E-MAIL, LETTER, OR FACSIMILE, AS APPROPRIATE]** dated **[INSERT DATE]**, the application is lacking significant amounts of information. To date, that information has not been provided to our office. In our conversation, you indicated that you needed additional time to gather, prepare, and submit the requested information. Accordingly, as discussed, we have suspended review of your application pending receipt of the additional requested information. Due to the delay in receiving the additional requested information that is necessary for review of your application, the NRC cannot project when it will make a determination on the application request. Once a complete response is received, the NRC will provide an updated date for the NRC to complete its review. If an adequate response is not received by **[INSERT DATE]**, the NRC will administratively close or deny the request, as appropriate.

Note that if your request is administratively closed, you may submit a new request at a later date and refer to Control No. **[INSERT CONTROL NO.]** for the documentation you have already submitted. If you resubmit the application within 12 months from the date of your original new license application, any fees paid to date will be credited toward the application fee.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NO.]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

B.4.13 Suspension of Review Letter for License Amendment—NRC Needs Additional Time to Evaluate Certain Information Provided in the Request

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: SUSPENSION OF REVIEW OF AMENDMENT REQUEST DATED **[INSERT DATE]** FOR **[INSERT LICENSEE NAME]**, NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

[INSERT SALUTATION]:

We have reviewed your request to amend your U.S. Nuclear Regulatory Commission (NRC) License No. **[INSERT LICENSE NUMBER]**. You have requested to **[INSERT BRIEF DESCRIPTION OF REQUESTED AUTHORIZATION]**. Your amendment request is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

Based on the review, our office determined we need additional time to evaluate certain information to continue the review of your amendment request. We will notify you if we need any additional information from you during our evaluation.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE NO.]** or **[INSERT E-MAIL ADDRESS]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT DOCKET NUMBER]**
License No.: **[INSERT LICENSE NUMBER]**
Control No.: **[INSERT CONTROL NUMBER]**

B.5 Reciprocity Correspondence

B.5.1 Reciprocity Procedures Letter

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: NRC RECIPROCITY FOR CALENDAR YEAR **[INSERT YEAR]**

[INSERT SALUTATION]:

This letter is a reminder that each Agreement State licensee (licensee) seeking to conduct activities under reciprocity in areas of Exclusive Federal jurisdiction, non-Agreement States, or in offshore waters (reciprocity activities) under the general license established in Title 10 of the *Code of Federal Regulations* (10 CFR), 150.20, for the first time in a calendar year must submit a request containing certain information to the U.S. Nuclear Regulatory Commission (NRC). This general license authorizes persons holding a specific license from an Agreement State to conduct the same activity in areas of Exclusive Federal jurisdiction, non-Agreement States, or in offshore waters, if the specific license issued by the Agreement State does not limit the authorized activity to specific locations or facilities.

An area of Exclusive Federal jurisdiction is an area over which the Federal Government exercises legal control without interference from the jurisdiction and administration of State law. If you are proposing to perform licensed activities on Federal property in an Agreement State, you must first determine the jurisdictional status of the area where you plan to work. If you are unsure about jurisdictional status of the work location on Federal land, you should contact the Federal agency that controls the facility where the work is to be performed. A written statement concerning the jurisdictional status is not required to file for reciprocity; however, you should obtain such a statement for reference and inspection purposes.

The authorization that you received in calendar year **[Insert Year]** to work under reciprocity in NRC jurisdiction will expire on **[INSERT DATE]**.

If you request reciprocity under this general license, you must submit (1) a completed and signed NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal jurisdiction, or Offshore Waters;" (2) a copy of your Agreement State specific license; and (3) the fee specified in 10 CFR 170.31, Item No. 16, as required by 10 CFR 150.20(b)(l). **The current fee is $ [INSERT FEE]**, though this is subject to change. You can either fax this information to **[Insert Fax Number]** or scan and e-mail it to **[Regional Reciprocity E-mail]**. The NRC must receive this filing a minimum of 3 days before the licensee engages in reciprocity activities. For your information and use in filing for reciprocity, an electronic version of NRC Form 241 can be found on the NRC's Web site at https://www.nrc.gov/reading-rm/doc-collections/forms/. Guidance on required information and how to file NRC Form 241 may be found in NUREG–1556, Volume 19, Sections 5 and 7,

accessible from the NRC Web site at:
https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v19/.

If you have submitted an NRC Form 241 to the NRC, you do not have to obtain positive authorization from the NRC before performing the activities requested on the form. If the NRC determines that the form contains omissions or errors, the NRC staff will contact you in an attempt to obtain the correct information. If the discrepancies cannot be resolved and you do not qualify for the general license, the NRC will inform you of this determination and indicate that you have not complied with the requirements of 10 CFR 150.20. In this case, you are not authorized to perform reciprocity activities and must cease any activities that have begun in NRC jurisdiction until the NRC resolves the discrepancies.

Under the general license, a general licensee conducting reciprocity activities is limited to a total of 180 days in any calendar year. Reciprocity activities conducted in offshore waters are not subject to the 180-day limit. The NRC tracks reciprocity usage on the basis of approved usage days. The NRC will not approve any activity under the general license that would exceed the 180-day limit. It is important that you track the days of use and submit changes to dates of work, when applicable. Storage of material in NRC jurisdiction is considered a reciprocity activity; days when material is stored and not used count toward the 180-day limit.

Licensees who perform activities using separate Agreement State licenses must submit separate reciprocity requests. For example, if a licensee has separate radiography and service licenses, and performs reciprocity work under both, the licensee must submit a separate NRC Form 241 and a separate payment for the initial filing for each license. The activities under reciprocity will be limited to 180 days separately for each license.

The NRC expects that you will review the information provided on NRC Form 241, as well as the regulations cited in 10 CFR 150.20(b), to ensure that your radiation safety program is in compliance with NRC regulations before conducting reciprocity activities.

If you perform reciprocity activities in NRC jurisdiction, you must conduct these activities in accordance with the conditions specified in your Agreement State license; representations made in NRC Form 241; and other rules, regulations, and Orders of the NRC, now or hereafter in effect. Failure to file NRC Form 241 before performing under reciprocity or failure to comply with these regulations or to conduct your radiation safety program in compliance with NRC regulations while operating under reciprocity may result in NRC enforcement action. Such actions could include the issuance of a notice of violation, imposition of a civil penalty, or an Order to take certain actions as described in the NRC Enforcement Policy, which is available on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

Your reciprocity activities in NRC jurisdiction are subject to inspection by NRC personnel. As an Agreement State licensee operating under reciprocity, you must be aware of NRC requirements concerning your activities. Your lack of awareness of NRC requirements and applicable provisions will not prevent the NRC from taking appropriate enforcement action.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at:
https://www.nrc.gov/reading-rm/adams.html.

If you have any questions about the regulations or the application process, please feel free to contact **[INSERT NAME, APPROPRIATE REGION]**, reciprocity lead, at **[INSERT TELEPHONE NUMBER]** or by e-mail at [**INSERT RECIPROCITY E-MAIL**].

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: [**INSERT NUMBER]**
State of: **[INSERT AGREEMENT STATE NUMBER]**
License No.: **[INSERT NUMBER]**

B.5.2 Acknowledgment Letter for Form 241 Submittals

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: INITIAL NRC FORM 241 FOR CALENDAR YEAR **[INSERT YEAR**]

[INSERT SALUTATION]:

You have been approved to perform licensed activities in NRC jurisdiction under reciprocity, as described on the attached NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters."

This letter acknowledges receipt of your initial NRC Form 241 dated **[INSERT DATE]**, and the **[INSERT AMOUNT]** application fee, submitted to the NRC Region **[REGIONAL NUMBER]** office to request authority to conduct licensed activities in NRC jurisdiction under the authority of a general license pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 150.20. Your Agreement State license is recognized as valid for the proposed use of licensed materials in NRC jurisdiction. The total days of usage and storage through this reciprocity request is **[INSERT NUMBER]** days. Your general license under 10 CFR Part 150.20, shall expire on December 31, **[INSERT YEAR]**, and must be renewed at that time if you want to continue the proposed activities after that date.

Using the NRC Form 241 at: www.nrc.gov/reading-rm/doc-collections/forms/nrc241.pdf, please submit an amended NRC Form 241 before you (1) change or add work locations, dates of work, or work site contacts or clients; (2) change radioactive material being used; or (3) perform work activities different from the information submitted on the initial NRC Form 241. If you choose to manipulate and save changes to the NRC Form 241 directly from the NRC Web site, you will need the full Adobe Acrobat Reader software. All changes to the information submitted on the NRC Form 241 must include, as a minimum, the following information: (1) client name; (2) client telephone number; (3) complete or descriptive address of work location, including GPS coordinates if known; (4) work location telephone number; (5) dates of work; (6) list of radioactive material which will be possessed, used, installed, serviced or tested; (7) Agreement State license number; (8) expiration date of Agreement State license; (9) name of your contact at the work location; and (10) signature of the Radiation Safety Officer (RSO) or management representative.

Working under reciprocity in NRC jurisdiction requires you to comply with the NRC's regulations, as described in 10 CFR Part 150.20. This general license authorizes you to conduct the same activity, as authorized on your **[INSERT AGREEMENT STATE]** license, in areas of exclusive Federal jurisdiction, non-Agreement States, or in offshore waters. Reciprocity activities are limited to a total of 180 days in any calendar year, though reciprocity activities conducted in offshore waters are not subject to this limit. The NRC tracks reciprocity usage on the basis of approved usage days. It is important that you track the days of use and submit changes to

dates of work, when applicable. Storage of material in NRC jurisdiction is considered to be included in reciprocity activities; days when material is stored and not used count toward the 180-day limit.

If you are proposing to perform licensed activities on Federal property in an Agreement State, you must first determine the jurisdictional status of the area where you plan to work. If you are unsure about jurisdictional status of the work location on Federal land, you should contact the Federal agency that controls the facility where the work is to be performed. A written statement concerning the jurisdictional status is not required to file for reciprocity; however, you should obtain such a statement for reference and inspection purposes.

You must conduct licensed activities in NRC jurisdiction under reciprocity, in accordance with the conditions specified in your Agreement State license; representations made in NRC Form 241; and other rules, regulations, and Orders of the NRC, now or hereafter in effect. Failure to comply with these regulations or to conduct your radiation safety program in compliance with NRC regulations while operating under reciprocity may result in NRC enforcement action as described in the NRC Enforcement Policy, which is available on the NRC Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

Your reciprocity activities in NRC jurisdiction are subject to inspection by NRC personnel. As an Agreement State licensee operating under reciprocity, you are responsible for compliance with NRC requirements concerning your activities. Your lack of awareness of NRC requirements and applicable provisions will not prevent NRC from taking appropriate enforcement action.

The regulations require you to notify this office 3 days prior to beginning generally licensed activity in the calendar year. A range of proposed dates not to exceed one month may be provided, when accompanied by a list of scheduled work dates and locations for that period.

Enclosed is an approved copy of your initial NRC Form 241. This document and any future NRC Form 241 changes will not be made publicly available through the Agencywide Documents Access and Management System (ADAMS), the NRC's electronic document system.

If there are any questions regarding this determination or if you have questions concerning this letter or other aspects of working in NRC jurisdiction under reciprocity, please contact me at **[INSERT TELEPHONE NUMBER]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

License No. **[INSERT NUMBER]**

Enclosure:

NRC Approved Copy of Initial NRC Form 241

INFORMATION NEEDED BY NRC FROM CALLER

CONCERNING INCIDENT INVOLVING RADIATION SOURCES

The following information will be helpful to enable the U.S. Nuclear Regulatory Commission (NRC), Region X, Division X to determine emergency actions that should be taken. Obtain as much of this information as possible at the time of the first contact by the caller.

Make necessary notifications to local authorities as well as to NRC as required. (Even if it is not required, you may report any incident to NRC by calling NRC's Emergency Operations Center, which is staffed 24 hours a day and accepts collect calls.) NRC notification is required when licensed material is lost or stolen, when devices are damaged or involved in accidents that result in doses in excess of 10 CFR 20.2203 limits or may cause or threaten to cause an exposure in excess of 10 CFR 20.2203 limits. Additionally, a report is required when it becomes apparent that attempts to recover a source stuck below the surface will be unsuccessful.

Reports to NRC must be made within the reporting time frames specified in the regulations.

Notification and reporting requirements are found in 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 30.50, 10 CFR 40.60, 10 CFR 70.50, or other NRC or Department of Transportation reporting requirements, as applicable.

NRC Emergency Operations Center: 301-816-5100

1. Caller's Identification:

   Location/Affiliation:

   Telephone Number: ( )

2. Location and description of incident:

3. Has the incident been isolated? Barricaded? Roped off? Otherwise restricted to prevent public entry?

4. Name of the person, trucking company, manufacturing plant, doctor's office, etc., associated with or cause of incident?

5. What type of radiation source (radioactive material, device type) is involved?

6. Any indication of the quantity of radioactive material involved? (Amount spilled on the ground, size of package in the vehicle, quantity identified on paperwork?)

7. What type of package is the radioactive material contained within?

8. Any readings from radiation detection instruments? Who took the measurements? (Type of instrument, scale of measurement, name, agency, and telephone number at responder's location.)

Fee Transmittal Sheet–Reciprocity

[INSERT DATE]

MEMORANDUM TO: ARB, DOC, OCFO

FROM: MIB, DNMS, Region III

SUBJECT: Transmittal of Reciprocity Fees – Initial NRC Form 241

Control Number: _____
(2-digit calendar year)-(2-letter state code)-(State License No.)

Licensee Name: _____

Fee Category: _____

Type of Fee _____

Amount of Payment: _____

Check: Check Number: _____ Date of Check: _____

Credit card: Type: _____ Last 4 digits: _____
(Visa, MC, AmEx, Disc, etc.)

Verification of payment made directly to U.S. Bank (Yes or No) _____

ADAMS Acc. No.: _____
(If not yet available, scan and attach NRC Form 241)

State License No.: _____

Date received: _____

Date submitted: _____

Submitted by: _____

Date Completed _____

Completed By _____

Scan this form with any attachments and e-mail to **[Regional Fee E-Mail Address]** (if available) with “Fee Sheet” in the subject line within 5 business days of receipt.

B.6 Withholding Correspondence

B.6.1 Agreement with Request to Withhold Information from Pubic Disclosure

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED ON **[INSERT APPLICATION, LETTER, FORM]** FROM PUBLIC DISCLOSURE

[INSERT SALUTATION]:

By **[INSERT APPLICATION, LETTER, FORM]** from **[INSERT LICENSEE'S NAME]** dated **[INSERT DATE]**, and affidavit dated **[INSERT DATE]**, you submitted **[INSERT PROPRIETARY, CONFIDENTIAL]** material consisting of **[BRIEF DESCRIPTION, EXAMPLE, PERSONAL, OR CLIENT INFORMATION]** and requested that it be withheld from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390. This letter is our response to your request.

You stated that the submitted information should be considered exempt from public disclosure for the following reasons:

1. **[INSERT REASON PROVIDED IN REQUEST]**

2. **[INSERT REASON PROVIDED IN REQUEST]**

We have reviewed your application, affidavit, and **[INSERT PROPRIETARY, CONFIDENTIAL]** material, in accordance with the requirements of 10 CFR 2.390, and on the basis of your statements have determined that the submitted information sought to be withheld does contain **[INSERT PROPRIETARY, CONFIDENTIAL]** information. Therefore, the **[INSERT BRIEF DESCRIPTION OF INFORMATION TO BE WITHHELD]** contained in **[INSERT APPLICATION, LETTER, FORM]**, marked as **[INSERT PROPRIETARY, CONFIDENTIAL]** will be withheld from public disclosure, pursuant to 10 CFR 2.390(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended. Your request for withholding will be maintained by **[INSERT APPROPRIATE ORGANIZATION]** indefinitely.

Withholding documents from public inspection will not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future, such that the information could then be made available for public inspection, you should promptly notify the U.S. Nuclear Regulatory Commission (NRC). You should understand that NRC may have cause to review this determination in the future (e.g., if the scope of a Freedom of Information Act request includes your information). In all review situations, if NRC makes a determination adverse to the decision above, you will be notified in advance of any public disclosure.

If you have any questions concerning this action, please feel free to contact me at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT NUMBER]**
License No.: **[INSERT NUMBER]**
Control No.: **[INSERT NUMBER]**

B.6.2 Disagreement with Request to Withhold Information from Public Disclosure

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED ON **[APPLICATION, LETTER, OR FORM]** FROM PUBLIC DISCLOSURE

[INSERT SALUTATION]:

By **[INSERT APPLICATION, LETTER, FORM]** from **[INSERT LICENSEE'S NAME]** dated **[INSERT DATE]**, and affidavit dated **[INSERT DATE]**, you submitted **[INSERT PROPRIETARY, CONFIDENTIAL]** material consisting of **[INSERT BRIEF DESCRIPTION, EXAMPLE, PERSONAL OR CLIENT INFORMATION]** and requested that it be withheld from public disclosure, pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390. This is our response to your request.

We have reviewed your **[INSERT APPLICATION, LETTER, FORM]** and the material in accordance with the requirements of 10 CFR 2.390 and, for the following reasons, have determined that the submitted information, in whole or in part, sought to be withheld, does not contain proprietary information.

1. **[INSERT REASON PROVIDED IN REQUEST]**

2. **[INSERT REASON PROVIDED IN REQUEST]**

Therefore, we have determined that the material, specifically **[brief description]**, should be released for public disclosure. In accordance with 10 CFR 2.390(c), this information is being forwarded to you as notice that the information will be made available to the public within 30 days of the date of this letter. If within that time you request withdrawal of these documents in accordance with 10 CFR 2.390(c) or provide additional reasons for the withholding of information, your request will be considered in light of applicable statutes and regulations and a determination made as to whether the documents should be withheld from public disclosure or returned to you.

Withholding documents from public inspection will not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public disclosure should change in the future, such that the information could then be made available for public inspection, you should promptly notify the U.S. Nuclear Regulatory Commission (NRC). You should understand that NRC may have cause to review this determination in the future (e.g., if the scope of a Freedom of Information Act request includes your withheld information). In all review situations, if NRC makes a determination adverse to the above, you will be notified in advance of any public disclosure.

If you have any questions concerning this action, please feel free to contact me at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT NUMBER]**
License No.: **[INSERT NUMBER]**
Control No.: **[INSERT NUMBER]**

B.6.3 Partial Agreement with Request to Withhold Information from Public Disclosure

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED ON **[INSERT APPLICATION, LETTER, FORM]** FROM PUBLIC DISCLOSURE

[INSERT SALUTATION]:

By **[INSERT APPLICATION, LETTER, FORM]** from **[INSERT LICENSEE'S NAME]** dated **[INSERT DATE]**, and affidavit dated **[INSERT DATE]**, you submitted **[INSERT PROPRIETARY, CONFIDENTIAL]** material consisting of **[INSERT BRIEF DESCRIPTION, EXAMPLE, PERSONAL OR CLIENT INFORMATION]** and requested that it be withheld from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390. This is our response to your request.

We have reviewed your application and the material in accordance with the requirements of 10 CFR 2.390 and, on the basis of your statements, have determined that only certain information contained in **[INSERT APPLICATION, LETTER, FORM]** is **[INSERT PROPRIETARY, CONFIDENTIAL]**.

The **[INSERT BRIEF DESCRIPTION]** information contained in **[INSERT APPLICATION, LETTER, FORM]**, marked as **[INSERT PROPRIETARY, CONFIDENTIAL]** does contain **[INSERT PROPRIETARY, CONFIDENTIAL]** information and will, therefore, be withheld from public disclosure pursuant to 10 CFR 2.390(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended. Your request for withholding will be maintained by Region **[INSERT NUMBER]** indefinitely.

We have also determined that, for the following reason(s), the information contained in **[INSERT APPLICATION, LETTER, FORM]** does not contain proprietary information.

1. **[INSERT REASON PROVIDED IN REQUEST]**

2. **[INSERT REASON PROVIDED IN REQUEST]**

Therefore, the **[INSERT BRIEF DESCRIPTION]** contained in **[INSERT APPLICATION, LETTER, FORM]** should be released for public disclosure. In accordance with 10 CFR 2.390(c), this information is being forwarded to you as notice that the information will be made available to the public 30 days from the date of this letter. If within that time you request withdrawal of these documents, in accordance with 10 CFR 2.390(c), or provide additional

reasons for the withholding of information, your request will be considered in light of applicable statutes and regulations and a determination made as to whether the documents should be withheld from public disclosure or returned to you.

Withholding documents from public inspection will not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public disclosure should change in the future, such that the information could then be made available for public inspection, you should promptly notify the U.S. Nuclear Regulatory Commission (NRC). You should understand that NRC may have cause to review this determination in the future (e.g., if the scope of a Freedom of Information Act request includes your withheld information). In all review situations, if NRC makes a determination adverse to the above, you will be notified in advance of any public disclosure.

If you have any questions concerning this action, please feel free to contact me at **[INSERT TELEPHONE NUMBER]** or **[INSERT E-MAIL]**.

Sincerely,

[INSERT NAME]
[INSERT TITLE]
[INSERT ORGANIZATION]

Docket No.: **[INSERT NUMBER]**
License No.: **[INSERT NUMBER]**
Control No.: **[INSERT NUMBER]**

APPENDIX C

STANDARD LICENSE CONDITIONS

Standard License Conditions

GENERAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) license reviewers should use standard license conditions to the maximum extent possible to maintain consistency between the regional offices. Proposed revisions to standard license conditions or proposed new standard license conditions should be coordinated with the regional office or Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of the General Counsel (OGC) or a Regional Counsel before use. **Standard license conditions should not restate requirements in the regulations. The standard license conditions in the Web-Based Licensing (WBL) system should be used by the license reviewer to specify the applicable license conditions for a license since WBL contains the most current standard license conditions.** Standard license conditions are also available for review at the NRC's public Web site: https://www.nrc.gov/materials/miau/mat-toolkits.html.

When issuing an amendment or renewal to an existing license, the license reviewer should review the standard license conditions on the license to ensure that the language matches the most current standard license conditions in WBL. For any standard license conditions that don't match the language in WBL, those conditions should be updated on the license. For any license conditions that don't exist in WBL, those conditions should be discussed with the license reviewer's branch chief and NMSS and should be removed from the license unless required as a nonstandard condition on the license. Any changes to license conditions on a license should be noted in the cover letter for the license amendment or renewal.

For a license amendment, the review of the standard license conditions on a license only needs to be performed on the first amendment issued after issuance of this NUREG revision. The license reviewer should document the review of the standard license conditions in WBL.

In addition, before issuing a license or license amendment with nonstandard conditions (see Section 4.6.2 of this NUREG), reviewers should coordinate with the inspection staff and the applicant or licensee to ensure that all parties have the same understanding of all license conditions, especially any conditions unique to a particular license. The cover letter accompanying the licensing package should identify and bring to the licensee's attention any unique conditions on the license.

New standard license conditions involving recordkeeping requirements must receive clearance from the Office of Management and Budget (OMB) prior to use. Licensing staff should not use the recordkeeping portion of any condition until notified that OMB clearance has been obtained.

The regulations specified in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," impose physical security requirements for the possession and use of the most risk-significant radioactive materials. NRC licensees were required to fully implement the new regulation by March 19, 2014. Upon implementation of 10 CFR Part 37, the NRC rescinded the security Orders. Therefore, the license conditions associated with the interim security measures should be removed from licenses upon the next amendment or renewal of each license.

On January 27, 2010, NMSS recommended that license reviewers place maximum possession limits for radionuclides on some of the specific licenses. The maximum possession limits are not applicable to licensees authorized 10 CFR 35.100 and 35.200 uses, and certain service providers. If multiple sources are used, then the activity per source should be indicated along with the total maximum possession limit for the sources. The maximum possession limit should no longer indicate, “No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State” without stating a maximum possession limit. The license reviewer should use, for example, “370 megabecquerels (MBq) (10 millicuries) and no single source to exceed the maximum activity specified in the certification of registration issued by the NRC or an Agreement State” as an acceptable entry for Subitem 8 of the license.

APPENDIX D

ROUTINE EXEMPTIONS

Routine Exemptions

D.1 10 CFR Part 30

D.1.1 10 CFR 30.35(a)(1)

Regions may grant exemptions to Title 10 of the *Code of Federal Regulations* (10 CFR) 30.35(a)(1), which states that, "Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix B to Part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved, if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix B to Part 30."
Regions may issue exemptions from the 10 CFR 30.35 decommissioning funding plan requirements to a licensee or applicant under 10 CFR 35.200 (medical facility) or 10 CFR 32.72 (nuclear pharmacy) who applies for possession of germanium (Ge)-68/gallium (Ga)-68 medical use generators, if the licensee submits and maintains for U.S. Nuclear Regulatory Commission (NRC) inspection, a legally binding agreement that ensures the device will be returned to the manufacturer or distributor at the end of use. The legally binding agreement between the licensee and generator manufacturer or distributor must highlight licensee commitments to return expired generators back to the manufacturer or distributor and also must include a manufacturer or distributor commitment to take expired generators back. The Regions should consult with regional counsel or the Office of the General Counsel (OGC) to confirm that a legally binding agreement is in place prior to issuing the exemption.
The following license condition should be used: "Notwithstanding the requirements of 10 CFR 30.35(a)(1), the licensee is exempt from the requirement to have a decommissioning funding plan needed for the possession and use of Ge-68/Ga-68 medical use generators (make/model # of generators), based on the commitments between the licensee and manufacturer (name of manufacturer/distributor), described in the letter/application dated **[insert date]**."

D.2 10 CFR PART 35

D.2.1 10 CFR 35.655(a)

Regions may grant exemptions to the provision of Title 10 of the *Code of Federal Regulations* (10 CFR) 35.655(a) relating to teletherapy units, which states in relevant part, that, "a licensee shall have each teletherapy . . . unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first . . ."
The Region may grant the licensee an exemption to extend the time for servicing and inspection of a teletherapy unit if the licensee provides information relevant to the items described below, and this information has been determined sufficient by staff: • a description of the exemption needed and the reason why it is needed • a description of compensatory safety measures that will provide a level of protection equivalent to the regulation for which the exemption is being requested • a discussion of how reasonable alternatives have been considered
The following license condition should be used. In general, the maximum interval from one inspection and servicing to the next that the license reviewer will allow under this exemption is 6 years. "Notwithstanding the requirements of 10 CFR 35.655 (a), the licensee is authorized to extend until **[insert date]** the time interval for inspection and servicing of its teletherapy unit."

D.3 10 CFR PART 36

Although many provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 36 apply to converted teletherapy units, compliance with certain applicable provisions of the rule may be impractical, and exemptions will be granted from specific sections of 10 CFR Part 36, provided that the licensee requests and technically justifies the exemption. Technical justifications and commitments acceptable for exemptions from specific sections of 10 CFR Part 36 are described in an appendix of NUREG–1556, Volume 6, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses."

APPENDIX E

NON-ROUTINE EXEMPTIONS

Non-Routine Exemptions

Title 10 of the *Code of Federal Regulations* (10 CFR) 30.12, 10 CFR 40.11, and 10 CFR 70.11

Regions may grant exemptions to U.S. Department of Energy (DOE) prime contractors or subcontractors that use byproduct, source, and special nuclear materials, in accordance with 10 CFR 30.12, 10 CFR 40.11, and 10 CFR 70.11, respectively, when the prime contractor or subcontractor is performing work under their contract with DOE at a location that is not owned or controlled by the U.S. government.

The U.S. Nuclear Regulatory Commission (NRC) regulations in 10 CFR Parts 30, 40, and 70 describe exemptions from specified regulatory requirements for prime contractors under certain DOE contracts. For example, 10 CFR 30.12, which applies to persons using byproduct material, grants exemptions from licensing under Part 30 to certain DOE prime contractors or subcontractors to the extent that the contractor—under the prime contract—manufactures, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material at a government-owned or controlled site for activities identified in the regulation. The phrase "government-controlled site" means a site leased or otherwise made available to the government under terms that afford to the NRC rights of access and control substantially equal to those that the NRC would possess if it were the holder of the fee as agent of and on behalf of the government[1].

In addition to the above exemption, DOE contractors who manufacture, produce, transfer, receive, acquire, own, possess or use byproduct material under the terms of their contract, but not on a government-controlled site may apply to the NRC for an exemption under a separate provision of 10 CFR 30.12 that provides for such an exemption under 10 CFR 30.12, 10 CFR 40.11, and 10 CFR 70.11 to be issued when the Commission determines (i) that the activity is undertaken pursuant to the prime contract; (ii) that the prime contractor or subcontractor's proposed activity is authorized by law; and (iii) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

In situations where the nongovernment-owned or controlled site is located in an Agreement State, the exemption process is set forth in a Commission Policy Statement[2]. The NRC may issue case-by-case exemptions upon a joint determination with the Agreement State that the necessary findings have been made that the proposed activity is undertaken pursuant to the prime contract, that there is adequate assurance that the work specified in the contract or subcontract can be accomplished without undue risk to public health and safety and that the exemption of such contractor or subcontractor is authorized by law. Most Agreement State regulations require that the determination to grant a specific exemption be made jointly with the NRC. The ultimate decision is with the NRC, and the Agreement State concurs.

The following step-by-step procedure applies a consistent process for determining and executing exemptions for DOE prime contractors and subcontractors set forth in 10 CFR Parts 30, 40, and 70. This procedure refers to 10 CFR 30.12, but the process would be the same for the other parts as well.

[1] 29 FR 14401 (1964)

[2] 46 FR 7540 (1981)

Below are the step-by-step guidance details to evaluate requests under 10 CFR 30.12, 10 CFR 40.11, and 10 CFR 70.11.

1. At least 90 days before the initiation of work activities, the DOE prime contractor or subcontractor should provide the necessary information for an exemption to the NRC. The exemption requester should also notify the Agreement State Director (if the facility is in Agreement State jurisdiction). The NRC reviewer should, in coordination with the Regional State Agreement Officer (RSAO), forward the package to the Agreement State Director if it was not already sent. The appropriate NRC regional office reviews the exemption request for work activities to be conducted at a non-government-owned or controlled site. If information is missing or the request is incomplete, the qualified regional license reviewer (hereafter to be referred to as license reviewer) should provide a request for additional information to the exemption requester and identify the areas that are deficient.

2. The license reviewer should inform the following individuals of the pending request with as much specific information as possible, as soon as possible:

   - The applicable regional management staff (licensing branch chief and appropriate division director)
   - The applicable branch in Office of Nuclear Material Safety and Safeguards/Division of Materials Safety, Security, State, and Tribal Programs (NMSS/MSST)
   - For a facility in Agreement State jurisdiction, the chief of the branch associated with Agreement State issues
   - The applicable RSAO if the activity will occur in an Agreement State
   - For a facility in NRC jurisdiction, the chief of the branch with licensing responsibilities
   - The applicable Regional State Liaison Officer if the activity will occur in NRC jurisdiction

3. For a facility in an Agreement State, the license reviewer, in coordination with the RSAO, should contact the respective Agreement State as soon as possible to discuss the logistics for the joint review and the determination of the exemption. The license reviewer will send information provided by the DOE prime contractor or subcontractor to the respective Agreement State point of contact as soon as possible. For a facility in NRC jurisdiction, no Agreement State coordination is needed.

4. The license reviewer should forward the copy of the contract between the DOE and the prime contractor or subcontractor and the site access agreements to the Office of the General Counsel (OGC) mailbox at RidsOgcMailCenter.Resource@nrc.gov as soon as possible and ask that the contract be reviewed to determine whether the requested exemption is for activities under the prime contract and authorized by law. NMSS/MSST/branch associated with Agreement State issues or NMSS/MSST/branch with licensing responsibilities point of contact (POC) and appropriate regional staff should be copied on the e-mail.

5. For a facility in an Agreement State jurisdiction, the branch associated with Agreement State issues will

   - provide a POC from NMSS/MSST
   - inform NRC's Office of Nuclear Security and Incident Response (NSIR) and any other office, as necessary
   - provide assistance to the Region and Agreement State, if needed

   For a facility in an NRC jurisdiction, the branch with licensing responsibilities will

   - provide a POC from NMSS/MSST
   - inform NSIR and any other office, as necessary
   - provide assistance to the Region, if needed

6. The license reviewer will review the procedures in accordance with applicable guidance provided in the "Memo to the Regions Regarding Issuance of Desk Reference Guide (DRG) for Standardization of Processes for Evaluating Certain Exemption Requests Under Title 10 of the *Code of Federal Regulations* 30.12, 40.11, and 70.11," available in the Material Security Toolbox at https://scp.nrc.gov/controls.html. The reviewer should complete the License Reviewer Checklist in Attachment 2 of the DRG, and, as necessary, review the relevant sections (e.g., operating and emergency procedures, leak testing, and applicable security of radioactive material) of the appropriate NUREG–1556 series (e.g., Volume 7) licensing guidance. The reviewer should also ensure that the contractor has provided executed site-access agreements for each proposed activity location. Based on the review, the license reviewer will make a determination whether the work thereunder provides reasonable assurance that the public health and safety will be adequately maintained during the conduct of the activity.

7. The license reviewer will draft a DOE Exemption Evaluation and acceptance letter, if appropriate. The DOE Exemption Evaluation will serve to document whether there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety, and whether the exemption can be extended for the requested work activity.

8. For a facility in Agreement State jurisdiction, once the license reviewer has their branch chief's approval on the draft DOE Exemption Evaluation, the license reviewer will send the draft DOE Exemption Evaluation to the Agreement State with a copy to the RSAOs. Typically, the Agreement State is provided 7 to 14 days to review the request and will either request additional information from the DOE contractor or subcontractor POC or inform the NRC that they have no objection to proceeding forward. If additional information is needed, the Agreement State should request the information through the RSAO and the NRC license reviewer will work with the DOE contractor to obtain the additional information. Within 14 days, OGC should provide their decision regarding whether the activity is authorized by law to the license reviewer. OGC's determination should be placed in ADAMS and profiled as Non-Public; Official Use Only–Sensitive Internal Information (Management Directive 3.4, Section A.7).

9. For a facility in an Agreement State jurisdiction, once the Agreement State Director has no objection to the path forward and OGC has acknowledged that the activity was authorized by law, then the DOE Exemption Evaluation and acceptance letter should be reviewed by the appropriate regional branch chief or by a qualified license reviewer. The appropriate regional division director will grant the approval, concur on the DOE Exemption Evaluation, and sign the acceptance letter consistent with the delegation of authority.

For a facility in NRC jurisdiction, the DOE Exemption Evaluation and acceptance letter should be reviewed by the appropriate regional branch chief or by a qualified license reviewer. The appropriate regional division director will grant the approval, concur on the DOE Exemption Evaluation, and sign the acceptance letter consistent with the delegation of authority.

APPENDIX F

PROCEDURES FOR NRC PERSONNEL REGARDING REQUESTS TO WITHHOLD INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)

Procedures for NRC Personnel Regarding Requests to Withhold Information From Public Disclosure (Under 10 CFR 2.390)

In Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public inspections, exemptions, requests for withholding," the U.S. Nuclear Regulatory Commission (NRC) permits individuals submitting documents to the NRC to request that trade secrets or privileged or confidential commercial or financial information in those documents be withheld from public disclosure. [Refer to 10 CFR 2.390(a)(4)]. Trade secrets and commercial or financial information deemed privileged or confidential by the submitter are commonly known in the aggregate as "proprietary information," although the regulation does not use that term.

The regulation at 10 CFR 2.390 requires a person who proposes that a document be withheld from public disclosure on the grounds that it contains proprietary information to submit an application for withholding accompanied by an affidavit that provides the reasons for the proposed withholding. [Refer to 10 CFR 2.390(b)(1)(iii)].

Information relating to requests for withholding information from public disclosure on other grounds, such as personal privacy reasons, can be found at 10 CFR 2.390(a).

The Commission has directed that internal procedures be created to ensure that the NRC staff expeditiously determines whether a request for nondisclosure of proprietary information will be granted. Only those portions of a document containing proprietary information may be withheld from public disclosure under these procedures; nonproprietary portions should not be withheld from public disclosure unless a separate basis for withholding applies. The NRC staff also should ascertain promptly whether the submitter would like a document returned, if possible, in those cases where the agency denies the request to withhold proprietary information from public disclosure.

Upon receipt of a document requested to be withheld from public disclosure as containing proprietary information or proprietary in whole, the NRC staff will promptly determine, in consultation with the regional counsel, whether the justification provided by the submitter in its affidavit supports a finding that the information sought to be withheld is proprietary and thus should be withheld from public disclosure. If an affidavit has not been provided with the document, an affidavit from the owner must be submitted pursuant to10 CFR 2.390(b)(1) before a determination is made on whether to withhold the information. Again, it is important, when reviewing the request and supporting affidavit, to bear in mind that the presence of proprietary information in a document does not justify withholding the entire document if nonproprietary information can be reasonably segregated from proprietary information. If the NRC staff determines that some information or the entire document submitted to the NRC is proprietary, the NRC staff should prepare a written response to the person who has requested nondisclosure stating that the proprietary information or document, as appropriate, will be withheld from public disclosure on the grounds that the withheld information or document constitutes trade secrets or commercial or financial information deemed privileged or confidential. [Refer to 10 CFR 2.390(a)(4)].

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This technical report provides guidance to U.S. Nuclear Regulatory Commission (NRC) management and staff regarding administrative licensing procedures and agency policies for reviewing NRC materials licensing requests. The report is specifically intended for NRC staff; however, Agreement States may find the information useful in implementing their radiation protection programs.

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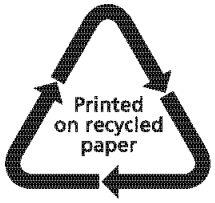

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