

Consolidated Guidance About Materials Licenses

Guidance About Administrative Licensing Procedures

Draft Report for Comment

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Draft Report for Comment

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Any interested party may submit comments on this report for consideration by the U.S. Nuclear Regulatory Commission (NRC) staff. Comments may be accompanied by additional relevant information or supporting data. Please specify the report number NUREG–1556, Volume 20, Revision 1, in your comments, and send them by the end of the comment period specified in the *Federal Register* notice announcing the availability of this report.

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1

ABSTRACT

2 This technical report contains information intended to document the materials licensing process
3 and provide licensing guidance for the U.S. Nuclear Regulatory Commission staff. This report
4 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 NRC staff. This revision provides a general update to the previous information contained in NUREG–1556, Volume 20, issued December 2000.

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

6 Daniel S. Collins, Director
7 Division of Materials Safety, Security, State, and Tribal Programs
8 Office of Nuclear Material Safety and Safeguards

CONTENTS

2	ABSTRACT	iii
3	FOREWORD.....	v
4	FIGURES	xi
5	TABLES.....	xi
6	ACKNOWLEDGMENTS.....	xiii
7	ABBREVIATIONS	xv
8	1 PURPOSE OF REPORT.....	1-1
9	2 AGREEMENT STATES.....	2-1
10	2.1 Jurisdiction Determination	2-1
11	2.2 Reciprocal Recognition of Specific Licenses.....	2-3
12	3 LICENSING ASSISTANT GUIDANCE	3-1
13	3.1 Web-Based Licensing (WBL) System	3-1
14	3.1.1 WBL Guidance.....	3-1
15	3.1.2 Notice of License Expiration	3-1
16	3.2 Administrative Procedures	3-1
17	3.2.1 Acceptance of Documents by the NRC	3-1
18	3.2.2 Initial Processing of Incoming Licensing Actions	3-2
19	3.2.3 Processing Misdirected Materials Licensing Applications	3-4
20	3.2.4 Follow-Up on Mail Returned From Licensees.....	3-5
21	3.2.5 Follow-Up on Expired Materials Licenses.....	3-6
22	3.2.6 Preparation and Distribution of Completed Licensing Documents	3-7
23	3.2.7 Availability, Security, and Integrity of Materials License Files	3-8
24	3.2.8 Coordinators for Certain Federal Organizations	3-10
25	3.2.9 Processing General License Registration Certificates.....	3-10
26	3.2.10 Processing Reciprocity Applications (Form 241).....	3-13
27	4 LICENSE REVIEWER GUIDANCE	4-1
28	4.1 Introduction.....	4-1
29	4.1.1 NUREG-1556 Series.....	4-1
30	4.1.2 Enhanced Security and Control Through Licensed Activities	4-2
31	4.2 Processing New License Applications.....	4-2
32	4.2.1 Application Package	4-2
33	4.2.2 Deficiencies	4-3
34	4.2.3 Prelicensing Checklist and Risk Significant Radioactive	
35	Material Checklist	4-4
36	4.2.4 National Source Tracking System	4-4
37	4.2.5 Processing a New Master Materials License (MML) Application.....	4-5
38	4.3 Processing Amendments	4-5
39	4.4 Processing Renewals	4-6
40	4.4.1 Performance Indicator Review.....	4-6
41	4.4.2 Technical Review.....	4-7
42	4.4.3 Risk Significant Radioactive Material Review	4-11
43	4.4.4 Expiration Date Review	4-11
44	4.5 Deficiency Letters, Calls, Facsimiles, and E-Mails	4-11
45	4.5.1 Application for License Renewal.....	4-12
46	4.6 Creating the License	4-13

1	4.6.1	Standard Licenses and Standard License Conditions	4-13
2	4.6.2	Nonstandard License Conditions	4-14
3	4.6.3	Establishing License Expiration Dates	4-14
4	4.6.4	Issuance of Final Licensing Action	4-15
5	4.7	Guidance for Multi-Site Licenses	4-16
6	4.7.1	Description of Multi-Site License	4-16
7	4.7.2	Program Management	4-17
8	4.7.2.1	General Information	4-17
9	4.7.2.2	Corporate Management	4-17
10	4.7.2.3	Radiation Safety Officer	4-18
11	4.7.2.4	Radiation Safety Support Staff	4-18
12	4.7.2.5	Radiation Safety Committee	4-19
13	4.7.3	Communication	4-19
14	4.7.4	Additional Program Areas for Review	4-20
15	4.7.5	Master Materials License	4-20
16	4.8	Opportunity for an Informal Hearing—Materials Licensing	4-20
17	4.9	Licensing Site Visits	4-21
18	4.9.1	Prelicensing Site Visits	4-22
19	4.9.1.1	Purpose of Prelicensing Site Visits	4-22
20	4.9.2	Licensing Visits	4-22
21	4.9.2.1	Purpose of Licensing Visits	4-22
22	4.9.2.2	Licensing Visits for New License Applications	4-22
23	4.9.2.3	Licensing Visits for Amendments	4-23
24	4.9.2.4	Licensing Visits for Renewals	4-23
25	4.9.2.5	Records of Prelicensing and Licensing Site Visits	4-23
26	4.10	Categorical Exclusions for Materials Licensing Actions	4-24
27	4.10.1	Introduction	4-24
28	4.10.2	Licensing Actions Eligible for Categorical Exclusion	4-24
29	4.10.2.1	License Actions That Clearly Qualify for Categorical	
30		Exclusion	4-24
31	4.10.2.2	License Actions That Qualify for Categorical	
32		Exclusion After the NRC Staff Has Completed	
33		Additional Technical and/or License-based	
34		Justifications	4-24
35	4.10.2.3	Generic Application of Previous License Actions That	
36		Qualified Under Categorical Exclusion	4-25
37	4.10.3	Licensing Actions Not Eligible for Categorical Exclusion	4-26
38	4.11	Guidance for Withdrawing, Suspending, or Denying Applications or	
39		Amendments—Materials Licenses	4-26
40	4.11.1	Guidance for Withdrawing an Application or License Amendment	4-27
41	4.11.2	Guidance for Suspending an Application	4-28
42	4.11.3	Guidance for Denying an Application	4-29
43	4.12	Significant Licensing Actions That May Warrant On-site Inspection	4-30
44	4.13	Processing of Exemption Requests for Materials Licensees	4-31
45	4.13.1	Routine Exemptions	4-31
46	4.13.2	Temporary Exemptions for Humanitarian or Emergency Reasons	4-32
47	4.13.3	Exemptions Requiring Coordination with NMSS	4-33
48	4.13.4	Administrative Procedures for Issuing Exemptions	4-34
49	4.14	Expedited Reviews	4-34
50	4.14.1	NRC-Expedited Reviews on the Basis of National Security	4-34

1	4.14.2	NRC-Expedited Reviews for Reasons Other Than National	
2		Security	4-35
3	4.15	Technical Assistance Request—Materials Licensees	4-35
4	4.16	Processing Proprietary Information	4-35
5	4.17	Possession and Storage Only and Possession and Storage in Standby	
6		Licenses	4-38
7	4.18	Decommissioning Service Providers	4-41
8		4.18.1 Licensing Decommissioning Service Providers	4-41
9		4.18.2 Decommissioning Activities	4-41
10		4.18.3 NRC Policy for Licensing Decommissioning Service Providers	4-43
11	4.19	Licensing Actions Under 10 CFR 20.2002	4-46
12	4.20	Reviewing Efforts to Dispose of Licensed Materials and Requesting	
13		DOE Assistance	4-46
14	4.21	Sensitive Unclassified Nonsafeguards Information	4-47
15	4.22	License Termination	4-49
16	5	FEES	5-1
17	5.1	Introduction	5-1
18		5.1.1 Procedures for Processing Fees	5-1
19	5.2	Follow-Up Actions for Orders Revoking Licenses for Nonpayment	5-3
20	6	SAFETY CULTURE	6-1
21	APPENDICES		
22	APPENDIX A	CHECKLISTS	A-1
23	APPENDIX B	SAMPLE LETTERS	B-1
24	APPENDIX C	STANDARD LICENSE CONDITIONS	C-1
25	APPENDIX D	ROUTINE EXEMPTIONS	D-1
26	APPENDIX E	NON-ROUTINE EXEMPTIONS	E-1
27	APPENDIX F	PROCEDURES FOR NRC PERSONNEL REGARDING	
28		REQUESTS TO WITHHOLD INFORMATION FROM PUBLIC	
29		DISCLOSURE (UNDER 10 CFR 2.390)	F-1
30	APPENDIX G	SAFETY CULTURE POLICY STATEMENT	G-1

1	FIGURES	
2	Figure	Page
3	2-1 U.S. Map: Locations of NRC Offices and Agreement States	2-1

4	TABLES	
5	Table	Page
6	2-1 Who Regulates the Activity?	2-2
7	4-1 Category 3 SUNSI Marking Criteria	4-50
8	4-2 SUNSI Examples	4-51
9	6-1 Traits of a Positive Safety Culture	6-2

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ABBREVIATIONS

ACMUI	NRC Advisory Committee on the Medical Uses of Isotopes
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
ALARA	as low as reasonably achievable
AU	authorized user
CFR	Title of the <i>Code of Federal Regulations</i>
CRCPD	Conference of Radiation Control Program Directors
DCGL	derived concentration guidelines level
DNMS	Division of Nuclear Materials Safety
DOE	U.S. Department of Energy
DP	decommissioning plan
EA	Environmental Assessment
EPACT	Energy Policy Act
FCSE	Division of Fuel Cycle Safety, Safeguards, and Environmental Review
FONSI	Finding of No Significant Impact
GLTS	General License Tracking System
HQ	Headquarters
IAEA	International Atomic Energy Agency
ID	identification
IMC	Inspection Manual Chapter
IN	Information Notice
LA	Licensing Assistant
LVS	License Verification System
MSLB	Materials Safety Licensing Branch
MSST	Division of Materials Safety, Security, State, and Tribal Programs
MD	Management Directive
MML	Master Materials License
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
NUDOCS	Nuclear Documents 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
PDF	Portable Document Format
PII	personally identifiable information
PM	Project Manager
RA	Regional Administrator
RAI	request for additional information
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
UF6	Uranium Hexafluoride
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 NRC staff; however, Agreement States may find the information useful in implementing their radiation protection programs. This document contains information on inspection frequencies, 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:

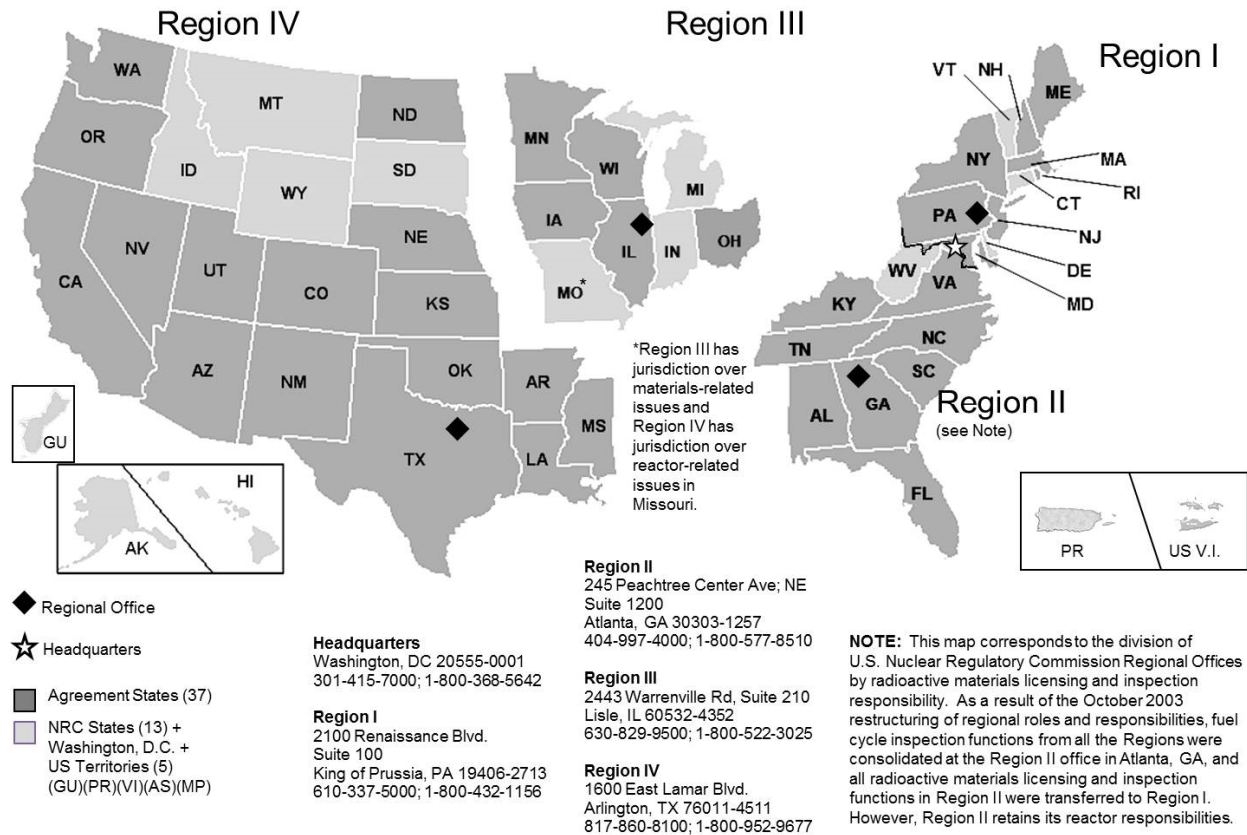
- Appendix A contains checklists that are helpful for documenting the acceptance review of certain categories of licensing actions.
- Appendix B contains standard letters that may be edited to meet case-by-case requirements, including sample withdrawal, suspension, and denial letters.
- Appendix C contains a link to and a list of standard license conditions.
- Appendix D contains generic exemptions that the Regions may authorize without approval from NRC Headquarters (HQ).
- Appendix E contains nonroutine 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.
- Appendix G contains the NRC's Safety Culture Policy Statement.

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.

¹Locations of NRC Offices and Agreement States



¹Current regional office addresses can be verified at <http://www.nrc.gov/about-nrc/locations.html>

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

1 In the special situation of work at federally controlled sites in Agreement States, it is necessary
2 to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement
3 State has regulatory authority. These areas can also include Tribal lands of federally
4 recognized Indian Tribes.² The NRC has regulatory authority over land determined to be
5 “exclusive Federal jurisdiction,” while the Agreement State may have jurisdiction over
6 nonexclusive Federal jurisdiction land. Applicants are responsible for determining, in advance,
7 the jurisdictional status of the specific areas where they plan to conduct licensed operations.
8 Additional guidance on determining jurisdictional status is found in the Office of Nuclear Material
9 Safety and Safeguards (NMSS) procedures in the State Agreement (SA) series, SA-500,
10 “Jurisdiction Determination,” which is available at <https://scp.nrc.gov/>. Once on the Web site,
11 use the link for “NMSS Procedures” in the left-hand column under “Resources & Tools.”

12 Table 2-1 provides a quick way to evaluate whether the NRC or an Agreement State has
13 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 <i>Code of Federal Regulations</i> (10 CFR) 30.12, “Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts;” also, see 10 CFR 40.11, and/or 10 CFR 70.11, if applicable)	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 ³
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State	Agreement State

²For 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.

³The 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 who 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 ⁴
Non-Federal entity in Agreement State at federally controlled site not subject to exclusive Federal jurisdiction	Agreement State ⁴
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 ⁴

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) is available 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.

⁴Section 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.

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

7 Additionally, guidance for the NRC staff regarding processing of reciprocity applications
8 (NRC Form 241) is contained in Section 3.2.11 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 will normally be printed for each licensing action request for use by the LA or license reviewer. WBL identifies and tracks the various operations authorized under a license by 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. Every other month, the HQ LA should generate a standard form letter using WBL. A sample letter is provided in Appendix B. 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 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. Paper applications 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 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, and a public version of the transmittal letter should be added to ADAMS. Documents are made available to the public in accordance with current procedures (typically after the review is complete). 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 nonpublicly available (see Section 4.16 of this NUREG). Documents containing information that meets one of the Sensitive Unclassified Non-Safeguards Information (SUNSI) criteria (see Section 4.21 of this NUREG) should be entered into ADAMS in their entirety, but the file should be profiled in ADAMS as nonpublicly 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.

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 technical reviewer's use in completing the licensing action. Technical reviewers can obtain WBL worksheets electronically from the Reports section of WBL.

To process the large number of requests for licensing actions effectively and efficiently, each licensing action should receive an initial acceptance review using NRC Form 532, "Acknowledgement—Receipt of Correspondence" (available at 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. The LA can routinely perform the administrative acceptance review. For complex licensing actions, the LA may wish to confer with a member of the technical staff. This initial administrative processing does not in any way replace 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 review. 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.

Technical Acceptance Review Procedure

1. Within 30 days of the receipt of a request for any licensing action, the NRC regional office or HQ should perform an acceptance review of the licensing request and take the following actions:
 - a. Confirm that all necessary information needed for the application form, normally NRC Form 313 (available at <https://www.nrc.gov/reading-rm/doc-collections/>) or licensing action request letter, are complete and the form or letter has been

signed and dated by the applicant's certifying official. In general, a license reviewer performs this step.

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

c. 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).

d. For license renewals, identify if the licensee requests any amendments or new authorizations that may need to be expedited by a license amendment rather than being delayed for review of the renewal application.

e. Identify if the licensee requests any exemptions from the regulations. (This should be only specific licensee requests. This administrative review need not identify if a specific procedure submitted would require an exemption.)

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 a Headquarters 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 check 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 forms (see Section 3.2.10) 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 assure 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 license file, WBL should be corrected. An administrative corrected copy of the license should be sent to the licensee to reflect the correction in WBL.
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 reviewed, and (if possible) the inspection staff should conduct a site visit. This is

1 especially important for licenses that involve large quantities of radioactive materials.
2 The regional licensing staff should inform the licensee to submit a change of address
3 request, along with any amendment requests associated with the change of address.

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

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

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

16 **3.2.5 Follow-Up on Expired Materials Licenses**

17 The identification and review of expired licenses is an important part of the material licensing
18 and inspection program, as shown in Checklist A.1. The following procedure for expired
19 licenses should be followed:

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

23 2. A license is considered expired if a renewal application has not been received or
24 postmarked on or before 30 days prior to the expiration date. WBL automatically
25 distinguishes between licenses that are considered under timely renewal and licenses
26 that are expired, provided the regional offices and HQ have correctly classified the
27 Action Type as Renewal and the status as Pending Renewal. Licensing staff should
28 note that an expired license cannot be renewed; however, it can be superseded by a
29 new license.

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

38 4. The regional licensing staff should coordinate with the inspection staff and take
39 appropriate follow-up action on expired licenses. If the license includes large quantities
40 of radioactive materials, then follow-up action should be prompt. This follow-up action
41 may include a visit to the facility to ensure that radioactive materials are not possessed
42 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 Records and FOIA/Privacy Services Branch, Office of Information Services.

3.2.6 Preparation and Distribution of Completed Licensing Documents

Completed licensing documents will be prepared and distributed per ADAMS Document Submission Guidelines (ADAMS Accession No. ML010390031). 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 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. Use NRC Form 580 to add a new or modify an existing program code. 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 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>.

4. 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.
5. 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 (ADAMS Accession No. ML010390031) for the distribution instructions.
6. Completed material 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.
7. 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" and MD 12.7, "NRC Safeguards Information Security Program." 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 nonpublicly available (see Section 4.16 of this NUREG). Documents containing information that meets one of the SUNSI criteria (see Section 4.21 of this NUREG) should be entered into ADAMS in their entirety, but the file should be profiled in ADAMS as nonpublicly available and with the corresponding sensitive value code.
8. All correspondence addressed to, or that involves activities of, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) must be marked Official Use Only. These documents will be profiled in ADAMS as nonpublicly available.
9. 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 (NUDOCS), the Public Document Room's Bibliographic Retrieval System, and the Regulatory Information Distribution System.

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

1 Most of NRC's Official Agency Records (OARs) and other nonrecord reference materials will be
2 maintained in ADAMS. ADAMS will store OARs, including programmatic and administrative
3 records that were kept in paper recordkeeping systems, with the exception of unclassified
4 safeguards information and other sensitive records determined to be inappropriate for electronic
5 maintenance. The NRC staff will add records to ADAMS using the guidance provided in the
6 appropriate final ADAMS Document Templates located in the ADAMS Document Manager.

7 The term OAR has the same meaning and definition for Federal Record as defined in 44 U.S.C.
8 3301. In 44 U.S.C. 3301, the term Federal Record includes the following:

9 All books, papers, maps, photographs, machine-readable materials, or other documentary
10 materials, regardless of physical form or characteristics, made or received by an agency of the
11 United States Government under Federal law or in connection with the transaction of public
12 business and preserved or appropriate for preservation by that agency or its legitimate
13 successor as evidence of the organization, functions, policies, decisions, procedures,
14 operations, or other activities of the Government or because of the information value of the data
15 in them.

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

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

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

29 Management Directive 3.1, "Freedom of Information Act"

30 Management Directive 3.4, "Release of Information Act"

31 Management Directive 3.5, "Document Management"

32 Management Directive 12.2, "NRC Classified Information Security Program"

33 Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program"

34 Management Directive 12.7, "NRC Safeguards Information Security Program"

35 10 CFR 2.390 "Public Inspections, Exemptions, Requests for Withholding"

36 NRC SUNSI Web site at: <https://www.internal.nrc.gov/ois/divisions/irsd/sunsi/index.html>

3.2.8 Coordinators for Certain Federal Organizations

Certain Federal organizations coordinate licensing actions through a central office. These coordinators may support a single, multisite license, master materials license, 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, 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/Materials Safety Licensing Branch (MSLB) 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 31.11 and 10 CFR 40.25, 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 Form 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 a 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

MSLB 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, 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. Mail the signed, original form with an acknowledgment letter back to the applicant. A sample acknowledgment letter is provided in Appendix B.

Note: All new NRC Form 244 and 483 requests will be maintained in ADAMS. The historical hard copy requests are maintained by MSLB. 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 by 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.

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 jobsite 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.

Note: This section duplicates much of the guidance in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20." It was included in this NUREG because processing forms and issuing procedure letters are considered administrative functions of the regional licensing staff.

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 proprietary 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."

1 Definitions—Categories of Legislative Jurisdiction

- 2 1. Exclusive Federal Jurisdiction—This term is applied in those instances where
3 only Federal laws are applicable, pursuant to the U.S. Constitution or through
4 cession by a State.
- 5 2. Concurrent Legislative Jurisdiction—This term is applied in those instances
6 where the State concerned has reserved the right to exercise, concurrently with
7 the Federal Government, all of the same authority.
- 8 3. Partial Legislative Jurisdiction—This term is applied in those instances where the
9 State concerned has granted the Federal Government certain portions of the
10 State's authority but has reserved the right to exercise, by itself or concurrently
11 with the Federal Government, other authority (e.g., the right to tax private
12 property).¹
- 13 4. Proprietary Interest—This term is applied to those instances wherein the
14 Federal Government has acquired some right of title to an area in a State but has
15 not obtained any measure of the State's authority over the area.

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

- 18 1. American Indian owned companies operating on federally recognized Tribal lands or
- 19 2. Private (non-American Indian owned) companies operating on federally recognized
20 Tribal lands.

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

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

32 Persons intending to use byproduct, source, or special nuclear material in Antarctica should
33 contact the National Science Foundation, which has management responsibility for the
34 United States Antarctic Program.

35 NRC cannot effectively maintain accurate information regarding jurisdictional status of Federal
36 lands or facilities throughout the country because of the large number of sites and the fact that

¹When 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).

1 their status frequently changes. It is the responsibility of the licensee to ask a representative
2 (e.g., contract officer, base environmental health officer, district office staff, Judge Advocate
3 General) of the respective Federal agency whose responsibility it is to exercise Federal control
4 over the site to help determine the jurisdictional status of the land. A written statement
5 concerning the jurisdictional status is not required for the licensee to file reciprocity. If there is
6 any question, then the regional staff should make their own determination by contacting the
7 Federal or state agency with control over the site.

8 The Regions may consider maintaining a list or database of jurisdictional determinations;
9 however, it is recognized that the list may change, especially with military base realignments
10 and closures.

11 **Responsibilities and Authorities**

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

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

18 **Regional Offices**

- 19 1. Before January 1 of each year, issue a procedures letter (see sample in Appendix B) to
20 all reciprocity licensees who filed during the previous year.
- 21 2. Provide a procedures letter or equivalent to new applicants requesting reciprocity.
- 22 3. Review each submitted NRC Form 241 to ensure that the requested activity of the
23 Agreement State licensee is in accordance with 10 CFR 150.20 and is authorized under
24 the Agreement State license at a temporary jobsite. If the activity requested is not in
25 accordance with the provisions of 10 CFR 150.20, then contact the Agreement State
26 licensee regarding the lack of conformance with the NRC general license requirements.
- 27 4. Enter the licensee information from the NRC Form 241 into WBL.
- 28 5. Profile all reciprocity documents as nonpublicly available in ADAMS.
- 29 6. Distribute the signed NRC Form 241, and provide notification to the appropriate
30 authorities, including the NRC regional office having jurisdiction in the area(s) where the
31 Agreement State licensee intends to operate under reciprocity. Signature authority for
32 the reviewing officials of the reciprocity activities requested on NRC Form 241 should be
33 designated according to regional policy.

34 **NRC Form 241 Requirements**

- 35 1. Agreement State licensees requesting reciprocity for activities conducted in areas of
36 NRC jurisdiction are subject to the provisions of 10 CFR 150.20. Under 10 CFR 150.20,
37 the first time within a calendar year that an Agreement State licensee conducts
38 reciprocity activities, it must file a completed NRC Form 241, provide one copy of its

1 Agreement State license, and the appropriate fee, as specified in fee category 16 of
2 10 CFR 170.31, unless one or more of the exemptions in 10 CFR 170.11(a)(4) are
3 applicable. See 10 CFR 150.20(b)(1) for further details; the licensee must submit the
4 required documentation at least 3 days before performing any work activities.

5 2. All questions concerning reciprocity fees should be referred to OCFO.

6 3. In completing NRC Form 241, the Agreement State licensee should provide sufficient
7 information to enable NRC to conduct unannounced inspections at the location provided.

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

10 5. In general, applicants prefer to file for reciprocity by using facsimile transmissions or
11 e-mail. Either of these electronic methods is acceptable and avoids any possible delays
12 because of the mail system.

13 6. The initial NRC Form 241 must be received by NRC at least 3 days before the licensee
14 engages in each proposed activity. A copy of the Agreement State license and the
15 check or credit card application on NRC Form 629 should accompany NRC Form 241.
16 A copy of the check serves as a promissory note from the applicant to NRC. It is the
17 responsibility of the applicant to ensure that the NRC regional office receives the
18 documentation within the specified 3-day time frame.

19 7. If the electronic method for filing the required NRC Form 241 information is not
20 available to the licensee as a result of an emergency or for other unforeseen reasons,
21 then the RA (or the RA's designee) can waive the time requirements specified in
22 10 CFR 150.20(b)(1) for the initial and subsequent filing of NRC Form 241, provided the
23 Agreement State licensee requesting reciprocity performs the following actions:

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

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

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

32 **Processing Initial NRC Form 241 (Refer to NUREG-1556, Volume 19)**

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

38 **Note:** The initial NRC Form 241 may be submitted with the location and dates of work
39 still to be determined. This is acceptable; however, the general licensee will have to

1 submit a *change* to the NRC Form 241 with the specific location, dates of work when
2 activities are to commence. *Changes* include identifying previously unidentified work
3 locations, changing the radioactive material authorization, adding or deleting dates of
4 work activities, or specifying work activities different from the activities identified on the
5 initial NRC Form 241. See "Processing Changes to NRC Form 241."

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

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

- 17 3. Verify that the NRC Form 241 package contains a check or credit card payment using
18 NRC Form 629, for the required fee payment specified in 10 CFR 170.31; one
19 complete copy of a valid, active Agreement State license; and the initial NRC Form 241,
20 properly signed.

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

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

36 **Note:** An Agreement State licensee cannot qualify for a general license under the
37 provisions of 10 CFR 150.20 if the license the Agreement State issued limits the activity
38 authorized by the license to specific installations or locations. The license must
39 authorize temporary jobsite locations for the general license to be applicable under
40 10 CFR 150.20.

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

- 1 6. When it is determined that the applicant has provided the required information and the
2 correct fee payment, an authorized staff member will sign and date NRC Form 241 as
3 the reviewing official.
- 4 **Note:** Signature authority for the reviewing official for reciprocity activities requested by
5 NRC Form 241 should be designated according to regional policy.
- 6 7. For an initial NRC Form 241, enter the Agreement State licensee information, work
7 location, and dates of work activity into WBL. The entire calendar year may be entered
8 for each offshore location because there is not a 180-day time limit for the work activity.
- 9 **Note:** For offshore waters, the description must include: (i) oil field, (ii) block number,
10 (iii) platform or laybarge, and (iv) the name of the laybarge, as applicable.
- 11 8. A unique WBL number is generated for each location entered into the system. For
12 offshore waters, a unique number is assigned to the entire Gulf or Ocean in lieu of a
13 specific location of work. This unique number should be entered on NRC Form 241
14 under the Location Reference Number, for use by the licensee on subsequent changes
15 to the NRC Form 241. Additionally, the WBL number is updated to ADAMS as the
16 "Case/Reference Number" by Document Process Center.
- 17 9. Generate an Acknowledgment Letter (refer to the sample in Appendix B). Additionally,
18 print a copy of the "Information Notice (IN): Information Needed by the NRC from Caller
19 Concerning Incident Involving Radiation Sources" (refer to the sample in Appendix B).
- 20 10. The approved copy of NRC Form 241, Acknowledgment Letter, and the Information
21 Notice may be transmitted via facsimile, e-mail, or other available and efficient method of
22 transmission to the licensee. The original should be placed in the mail to the licensee.
- 23 11. Licensing staff should promptly notify, via facsimile or e-mail, the appropriate regional
24 office that has the responsibility for inspecting the reciprocity activities for those activities
25 that are priority 1, 2, or 3, as defined in IMC-2800. The licensing staff should annotate
26 "copy to Region _____," indicating the appropriate Region for distribution.
- 27 12. A copy of the completed reciprocity package should be scanned into ADAMS as
28 nonpublicly available and sensitive (Item Code A.3) and declared as an OAR.
- 29 13. A copy of the approved NRC Form 241 and Acknowledgment Letter should be provided
30 to the appropriate Agreement State.
- 31 14. Generate a Fee Transmittal sheet to OCFO (refer to Appendix B). Make one copy of the
32 check or NRC Form 629 and attach it to the Fee Transmittal sheet and send it to OCFO
33 at NRC HQ in Rockville, Maryland, 301-415-7554. For additional information about fees,
34 call NRC's toll-free number, 800-368-5642, extension 415-7554. The e-mail address is:
35 Fee.Resource@nrc.gov.
- 36 The regional office should not upload the fee sheet to ADAMS. The regional office may choose
37 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 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 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/about-nrc/regulatory/enforcement/current.html>. 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.

4. Verify that the applicant has filed the initial NRC Form 241 and is currently authorized 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 number. Record the WBL 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 must 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 for those activities that are priority 1, 2, or 3 (see IMC 2800). 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 nonpublicly available and sensitive (Item Code A.3) and declared as an OAR.
11. On a routine basis, 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 NRC Form 241 request. 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.

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

6 **Potentially Exceeding 180-day Limit**

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

13 **Apparent Noncompliance with 10 CFR 150.20**

- 14 1. If the NRC Form 241 describes activities that appear to be in noncompliance with
15 the Agreement State specific license or other regulatory requirements, take the
16 following actions:
- 17 a. Where the Agreement State license limits use to a specific address or location,
18 advise the licensee, by telephone or in writing, within 3 days of receipt of the
19 initial NRC Form 241 request, that reciprocity cannot be granted under the
20 current license. Suggest that the applicant apply to the Agreement State
21 licensing authority for a license amendment permitting temporary jobsite
22 locations on its Agreement State License, or in the alternative, apply to the
23 appropriate NRC regional office for a specific NRC license authorizing the
24 activity requested.
- 25 b. In cases where general license activities are considered potential violations
26 of 10 CFR 150.20 (e.g., activities were started prior to when the initial
27 NRC Form 241 was submitted, the Agreement State license has expired, the
28 Agreement State license limits locations of use, the 180-day land-based limit in a
29 calendar year is exceeded, or failure to comply with NRC regulations while
30 conducting activities in exclusive Federal jurisdiction) that may result in NRC
31 enforcement action(s) against the licensee, these violations should be treated in
32 accordance with the NRC Enforcement Policy, which is available at
33 <https://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

34 **NRC Form 241—Equivalence or Misdirection**

- 35 1. Equivalence—There may be cases where the Agreement State licensee submits a letter
36 in lieu of NRC Form 241. This process is acceptable, provided the letter contains all of
37 the information required by NRC Form 241, including one complete copy of a valid
38 Agreement State license and the required fee payment. Changes to the NRC Form 241
39 may be provided on company letterhead with the revised information provided and
40 signed by the RSO or management representative.

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

5 **Retention and Disposal of Reciprocity Licensing Documents**

6 All reciprocity licensing documents, including the initial NRC Form 241, authorized revisions,
7 supporting documentation, and 10 CFR 2.390 requests, must be retained and/or destroyed in
8 accordance with the approved records disposition schedules contained in NUREG-0910,
9 "NRC Comprehensive Records Disposition Schedule." NRC Schedule 2-24.4.d in
10 NUREG-0910 requires that license files be retained for 20 years after license termination.
11 Documents associated with an NRC Form 241 should be retained for 20 years following the
12 year the Form 241 was in effect. ADAMS is the official agency record; therefore, hardcopy
13 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. This guidance assumes that applications will be filed and reviewed in accordance with the guidance set forth in the NUREG–1556 series. If the licensee does not use the NUREG–1556 series, the review of the applicant's submittal may take longer to complete.

To standardize and simplify the review processes, reviewers should use, as a minimum, all available NUREG–1556 tools, including processes, criteria, and checklists, when reviewing license applications. An applicant may request authorization to use licensed materials in more than one program type. In this case, the reviewer would need to 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. A number 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 NRC Inspection Manual Chapter (IMC) 2800 to identify the program code with the highest inspection priority. 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 series does not request information thought to be critical to 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 4.15 for specific guidance about TARs.

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 (EPAAct), 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 EPAAct, most NORM continues to be regulated by the States. The NRC will only license NORM if it is a discrete source.

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 preclicensing guidance to require on-site visits of unknown applicants prior to issuing a license authorizing possession of any radioactive material (see SECY-07-0147) (Agencywide Document Access and Management System (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, or 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 a License Verification System (LVS). The LVS is intended to provide an automated capability for external stakeholders (licensees and other government users) to verify the legitimacy of a license and 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) and cannot be 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 material 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 health and minimize danger to life and property. If the licensing action does not contain sufficient information, issue an Acceptance Review Discontinuation letter. Otherwise, start the normal review of the application. An example of the Acceptance Review Discontinuation letter is contained in B.1.5. Each Acceptance Review Discontinuation letter should be entered into ADAMS.

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

1 consist of a comparison of all material the applicant submitted against the requirements in the
2 regulations, guidance provided in the appropriate NUREG–1556 volume, and any specific
3 policy guides.

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

10 If the applicant is required to implement Title 10 of the *Code of Federal Regulations* (10 CFR)
11 Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Materials”
12 prior to the issuance of their license, review the implementation of 10 CFR Part 37 during the
13 on-site security review [referenced in the risk significant radioactive material (RSRM) checklist].
14 The conduct of the on-site security review prior to the issuance of their license would allow the
15 applicant to take possession of an aggregated Category 1 or Category 2 quantity of radioactive
16 material upon issuance of their license. The RSRM checklist is available in the Material
17 Security Toolbox at <https://scp.nrc.gov/controls.html>. Under 10 CFR Part 37, security plans are
18 not submitted to the NRC during licensing, but may be subject to review and inspection.

19 **4.2.2 Deficiencies**

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

31 All deficiencies should be clearly documented and communicated to the applicant. Depending
32 on the type and complexity of the information needed, the reviewer may obtain the information
33 by sending a formal written request to the applicant, or for simple answers and clarifications, by
34 notifying the applicant of the need for information via telephone or e-mail. Submittal of an
35 inadequate or deficient application may delay the issuance of the license. If the applicant does
36 not provide a response within the specified timeframe or the response is inadequate, the license
37 reviewer should contact the applicant and discuss the option of withdrawing the application. A
38 withdrawal of the application means that the applicant has given up pursuit of the requested
39 action. However, it does not preclude the applicant from resubmitting their application at a
40 later date.

41 Normally, the NRC expects the applicant to respond within 30 days of the date of the request for
42 additional information (RAI). Applicants may request an extension of time in order to respond to
43 any correspondence or RAI about its application, provided the NRC determines that there is
44 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 Prelicensing Checklist and Risk Significant Radioactive Material Checklist

Prelicensing checklist guidance was developed to provide a basis for confidence that radioactive material will be used for the purposes authorized under the license and to identify license applications that will require additional security measures. This checklist and guidance apply 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 checklist and guidance were developed to establish a basis for confidence that the radioactive material requested in the licensing action will be used as specified in the license application. The prelicensing checklist is available in the Material Security Toolbox at <https://scp.nrc.gov/controls.html>.

The RSRM checklist and guidance contains information about the on-site security review. An on-site security review (a review of on-site security measures) is conducted during the licensing process for applicants who have not yet received their license and are seeking authority to possess aggregated Category 1 or Category 2 quantities of radioactive material. The purpose of the on-site security review is to verify that applicants and licensees requesting aggregated Category 1 or Category 2 quantities of radioactive material have implemented the applicable 10 CFR Part 37 security requirements prior to taking possession of these radioactive materials. The RSRM checklist is 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, it is the responsibility of the reviewer to maintain the licensee information and use locations as accurately 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/ismfp/nsts/credentialing.html>.

The reviewer should initiate Checklist A.2, "National Source Tracking System (NSTS) Update," in 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 Radiation Safety Officer (RSO)]
2. NSTS Contact Telephone Number
3. NSTS Contact Facsimile Number

1 4. NSTS Contact E-mail Address

2 5. Licensee Name

3 6. Licensee Mailing Address

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

5 For those licenses that authorize temporary jobsites, NSTS should reflect “temporary jobsite” as
6 the location of use.

7 The NRC has established a Help Desk to assist users by answering questions and resolving
8 issues related to credentialing, login procedures, system use, transaction reporting, and any
9 problems encountered in using the NSTS. Reviewers can e-mail NSTSHelp@nrc.gov or call
10 1-877-671-6787 to contact the NSTS Help Desk.

11 **4.2.5 Processing a New Master Materials License (MML) Application**

12 Upon receiving an application for an MML license, perform the following within 15 days:

- 13 • Appoint a regional MML project manager (PM).
- 14 • Establish an MML application review team, which consists of HQ and regional staff.

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

- 17 • Process and track all actions, including licensing, inspections, incidents or events,
18 allegations, investigations, and enforcement.
- 19 • Identify MML licensees with a history of health and safety issues or
20 programmatic concerns.
- 21 • Transfer or archive NRC license docket folders for terminated MML facility licenses.

22 **4.3 Processing Amendments**

23 The licensee is obligated to keep the license current. If any of the information provided in the
24 original application changes in a way that requires an amendment to the license, as required by
25 the regulations, or in any way affects specific items concerning NRC jurisdiction, then the
26 licensee must submit an application for a license amendment to reflect the change, prior to the
27 change taking place. The licensee should identify the specific changes in the amendment
28 request and discuss the basis for the changes. The reviewer should focus their evaluation on
29 only those areas that the licensee indicates need revision. If the licensee completely resubmits
30 the entire application, the reviewer should request that the licensee specifically identify the
31 requested changes. The licensee may opt to resubmit the request and only discuss the specific
32 changes, or the licensee may identify the changes by marking or highlighting the modified text.

33 If the licensing action does not contain sufficient information, issue an Acceptance Review
34 Discontinuation letter. Otherwise, start the normal review of the application. An example of the

Acceptance Review Discontinuation letter is contained in B.1.5. Each Acceptance Review Discontinuation letter should be entered into ADAMS.

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 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 Section 4.4.2.
3. Evaluate the RSRM checklist available in the Material Security Toolbox at <https://scp.nrc.gov/controls.html>, if the applicant or licensee is requesting aggregated Category 1 or Category 2 quantities of radioactive material.
4. Determine whether conditions exist to necessitate an expiration date of less than 15 years.

4.4.1 Performance Indicator Review

The reviewer should review records, including the following: docket file, 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 nonescalated 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 4.11.3. 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 has been cited with a violation for the loss of control of licensed material that is 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 previous 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.

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, or equivalent, 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.

If an applicant 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)].

1 3. Emergency Plan

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

6 4. Program Management

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

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

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

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

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

21 5. Equipment and Facilities

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

24 6. Environmental Assessments

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

29 7. Sealed Sources and Devices

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

33 8. Major Program Changes

34 Determine whether the requested major program change(s) conform to the applicable
35 regulations and NUREG-1556 guidance. Examples may include a new broad-scope
36 authority; introduction of iodination with millicurie quantities of iodine-131 or iodine-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 Perfexion gamma stereotactic radiosurgery unit.

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 prelicensing visit, as required. Also, the reviewer should determine whether the new entity is consistently implementing the program, as submitted with the change of control. The reviewer should also verify whether any financial assurance documents are affected by the change of control.

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 the U.S. National Institute of Standards and Technology (NIST) event (ADAMS Accession No. ML093080053). This 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.

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 brief overview of the remainder of the application to verify that the major areas discussed in the appropriate NUREG–1556 volume are present. If the reviewer detects an obvious failure or a deficiency in a significant area, then a more focused review of that area should be performed. 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.

Note: Regional license reviewers should determine from the review of the licensee's docket file 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 a focused review on those areas that depart from the NUREG–1556 guidance.

4.4.3 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 should be used as part of every 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 is 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.

4.4.4 Expiration Date Review

The use of license authorizations shorter than 15 years may be used only on a case-specific basis and only when approved by NRC management. Justification to reduce the expiration date from 15 years should be documented in Checklist A.5. The following are 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.
- Early Termination: In the case that early termination is expected after renewal.
- 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.

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 licensees, document any information requests, and elicit the appropriate applicant response. The reviewer should communicate with the applicant 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 *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 also focus efforts on improving, reducing, and eliminating requests for additional information. 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.

Application for a New License or for an Amendment

A. 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, e-mail, facsimile, or deficiency letter to the applicant or licensee. Telephone deficiencies should be limited to simpler requests and should be documented on NRC Form 699, "Conversation Record" (see Appendix B 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. 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 consider working with the applicant or licensee to obtain the necessary information during the review period. If the applicant or licensee does not provide adequate information after such an exchange, the reviewer may complete a partial 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. 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 will not withdraw the application, the reviewer should discuss with their management regarding whether the application should be suspended or denied (see Section 4.11 of this NUREG).
4. If a response to the deficiency letter is received after an application has been suspended 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).

4.5.1 Application for License Renewal

A. Deficiencies

1. Any simple, significant, or complex deficiencies in an application for license renewal should be described in a deficiency letter, by telephone, facsimile, or e-mail to the licensee. 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. 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 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 should be considered. The reviewer should work with the licensee to obtain the necessary information during the review period. 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 4.11.3. A denial would require divestiture of all material in the licensee's possession upon expiration of the license.

B. Extensions

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 licensees' continued requests for extensions.

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 Appendix C of this NUREG and WBL when creating a license for an applicant. **WBL contains the most current standard license conditions.** Some instances may exist where the reviewer may need to authorize customized 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, production of byproduct material by an accelerator), 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 nonroutine and not included in the sample license. The reviewer should refer to the approved list of standard license conditions in WBL and Appendix C. The standard conditions are organized in categories of authorization. Use of standard license conditions should not substitute for obtaining information from applicants and licensees. Reviewers should first try to obtain commitments that will be captured by the license condition that references the documents that contain the commitments (tie-down condition) rather than creating new license conditions.

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).

The reviewer should also refer to IMC 2800 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 4.21 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 simple issues that the licensee did not address, even after being asked to provide the information in a deficiency request, then the reviewer may use custom license conditions to achieve closure rather than protracted negotiations with the applicant. Simple issues are the requests for information identified in the NUREG–1556 series. The reviewer should use standard license conditions whenever possible; however, custom conditions may be used when necessary. The license reviewer should write the custom license condition to state the requirement clearly and simply. Custom license conditions may need to be approved by the appropriate branch chief and documented. This strategy is intended to streamline the licensing process to be more responsive to licensees and provide more flexibility to 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 special 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. NRC management must approve all license authorizations, which are shorter than 15 years. The

following are some examples of conditions that may exist for licenses issued for shorter than 15 years. See memorandum dated August 18, 2017, "Procedure for Implementing the 15 Year Materials Licenses Term" (ADAMS Accession No. ML17200D110) for additional expiration date information.

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.

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

Possession and Storage-Only and Possession and Storage-in-Standby licenses may be renewed every 2 years, and decommissioning issues will be addressed at that time. Further information is provided in Section 4.17 of this NUREG.

Use Checklist A.5 in Appendix A entitled, "New and Renewal and Possession-Only Amendments—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.

Note: The reviewer may consider reviewing the new license with a first-time applicant to thoroughly review each license condition with the new applicant.

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 4.21 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. A sample cover letter is provided in Appendix B.
4. 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.
5. 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.

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

7. Appendix B 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 specific 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.

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 address 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 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.

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

- 1 h. assurance that senior management has an active role in sharing program
- 2 responsibilities with the RSO when an RSC is not established
- 3 i. review of and involvement with program audits and evaluations, through membership
- 4 on the RSC or otherwise

5 2. Site Management

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

8 **4.7.2.3 Radiation Safety Officer**

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

- 15 1. frequency of reporting to, and meetings with, executive and site management
- 16 2. regular site visits, monitoring (e.g., facility/site surveys and review of reports and records
- 17 for each site), and feedback to site personnel, as well as support staff, to ensure that
- 18 daily operations at each site include radiation safety activities, approved procedures,
- 19 safe practices, and compliance with regulations and license conditions
- 20 3. periodic, interactive (i.e., with feedback) program audits at each site, indicating audit
- 21 frequency and reporting commensurate with site operations
- 22 4. mechanisms for being alerted and responding to unsafe practices and urgent situations
- 23 that may occur at any site
- 24 5. authority to make decisions and terminate unsafe practices and activities jeopardizing
- 25 the safety of workers, the public, or environment

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

28 **4.7.2.4 Radiation Safety Support Staff**

29 The RSO may be supported by staff who assist in the maintenance and control of the radiation
30 safety program at each site or a number of sites. The RSO may delegate radiation safety tasks
31 to these individuals; however, the authority and responsibility remains with the RSO. Support
32 staff duties, including provisions for reporting to the RSO, should be clearly specified, in writing,
33 with sufficient time allotted for completion. Provisions for regular interaction and feedback from
34 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

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
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.” 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, and that material licensing actions may be conducted under the procedures of Subpart L of 10 CFR Part 2.

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 EA (see Section 4.10 of this NUREG). After NRC's technical review, any draft or final finding of no significant impact 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 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 Regulatory Issue Summary (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/>.

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 the Office of the General Counsel (OGC) before proceeding with any additional activities or notifications.

4.9 Licensing Site Visits

There are two types of site visits: (i) prelicensing site visits and (ii) licensing site visits. These site visits are not considered inspections. A prelicensing 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 or renewal byproduct material applications involving large programs or license

programs that present significant or unique technical issues. Additional guidance is provided below.

4.9.1 Prelicensing Site Visits

4.9.1.1 Purpose of Prelicensing Site Visits

Generally, prelicensing 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 prelicensing checklist available in the Material Security Toolbox at <https://scp.nrc.gov/controls.html> to determine if a prelicensing visit is needed. The purpose of the prelicensing 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. Prelicensing 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.

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 veracity of the applicant is a known entity:

1. Type A licenses of broad scope
2. panoramic irradiators authorized to possess greater than 10,000 curies of byproduct material in sealed sources
3. manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material
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, or unprecedented issues that warrant a site visit

In addition, a security inspection may be required in accordance with IMC 2800, prior to authorizing certain quantities of radioactive materials.

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 above. Licensing visits should be considered for amendments involving significant modification to the types of operations listed above.

4.9.2.4 Licensing Visits for Renewals

Licensing visits should be considered for renewals involving the types of activities listed above; 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 staff concludes 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 Prelicensing 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 and safety 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 Guidelines of the Council on Environmental Quality requiring the preparation of environmental impact statements pursuant to the National Environmental Policy Act of 1969. The basic policy on EAs, environmental statements, and findings of no significant impact for most materials licensing actions are covered by "categorical exclusions," 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 EA 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. 10 CFR 51.22(c)(10) is not discussed below, because this subsection of the regulations covers amendments that are administrative in nature.

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, "Consolidated Decommissioning Guidance."

4.10.2.1 License Actions That Clearly Qualify for Categorical Exclusion

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/Division of Fuel Cycle Safety, Safeguards, and Environmental Review (FCSE). However, 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 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

Such categorically excluded licensing actions do not need an EA. 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.

GROUP 1 LICENSE TERMINATION ACTIONS

Certain terminations of licensed activities clearly qualify for categorical exclusion under 10 CFR 51.22(c)(20). These are essentially Group 1 decommissioning categories, as described in NUREG-1757. 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.

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 and 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, 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.
- 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 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). 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 millirems 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.

Documentation that supports the licensee's application as meeting the above criteria is sufficient to support why an EA is not needed.

For license actions that cannot meet the above criteria, the Regions should coordinate with NMSS/FCSE 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 which are not recovered at the conclusion of the study or decommissioning, or where a field study may 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/FCSE 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. [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 curies of radioactive material.
5. Any commercial waste disposal (currently licensed in HQ only).
6. Decommissioning actions that are Group 2 and above, as described in NUREG–1757, and do not qualify for the categorical exclusion under 10 CFR 51.22(c)(20). For Groups 2 and 3, the EA can be a “simple” EA in accordance with NUREG–1748 and does not have to be coordinated with NMSS/FCSE.

Any application not covered by a categorical exclusion or that is beyond a “simple” EA described above should be coordinated with NMSS/FCSE 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 finding of no significant impact (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/FCSE, will prepare an environmental impact statement in accordance with 10 CFR 51.20.

4.11 Guidance for Withdrawing, Suspending, or Denying Applications or Amendments—Materials Licenses

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 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 an 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 an 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.

4.11.1 Guidance for Withdrawing an Application or License Amendment

Withdrawing the application or license amendment means that the applicant or licensee has decided they don't want the requested action processed; withdrawal 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 the license reviewer withdraws the application or amendment 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 on this NUREG) or written communication.
- Following the request to withdraw the application or amendment, the license reviewer should prepare a withdrawal letter stating the reason the applicant is withdrawing the application or amendment and the statement, "This action is taken without prejudice to the resubmission of your request." The withdrawal letter should be prepared for the appropriate signature. An example of a withdrawal letter may be found in Appendix B.
- If the applicant or licensee does not agree to withdraw an application or amendment and is actively working on addressing the concerns raised by the license reviewer, the license reviewer should follow the guidance in Section 4.11.2 if the criteria for suspending an application or amendment are met.
- If the applicant or licensee does not agree to withdraw 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 4.11.3 if the criteria for denying an application or amendment 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.

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 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 Office of the Chief Financial Officer 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 Suspending an Application

Suspension of a licensing action is only a temporary administrative measure and should not be the final disposition of the licensing action. Suspension is not intended to be a legal denial of the application or amendment but rather an internal business practice that allows the licensing action to remain legally open without counting against the timeliness metrics for the NRC's licensing program.

Suspending an application for a materials license (new or amendment) requires coordination between the license reviewer and their management. Applications for materials licenses (new or amendment) may be suspended if the applicant or licensee is actively communicating with the reviewer but (1) fails to respond to an RAI within 30 days, or within such other time as may be specified (subsequent deficiency letters 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. In these cases, inform the applicant or licensee, in writing, of the nature of any deficiencies and the reason for the suspension. The suspension 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 suspension letter informing applicants or licensees of the reason for the suspension is provided in Appendix B.

Prior to issuing the suspension letter, the license reviewer or reviewer's Branch Chief should contact the applicant or licensee to inform them that the NRC plans to suspend the licensing action. The license reviewer or Branch Chief will offer the applicant or licensee an opportunity to withdraw the licensing action for further discussion of the issues. The license reviewer or Branch Chief should make it clear that if the applicant or licensee does not withdraw the licensing action, the NRC staff will suspend the licensing action.

After one year from the issuance of the suspension letter, if issues are not adequately resolved, 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 initiating a denial of the licensing action as discussed in Section 4.11.3. For a licensing action that is suspended, if the applicant or licensee provides a response to an 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 a licensing action doesn't imply or directly result in the suspension of the associated license.

4.11.3 Guidance for Denying an Application

Denial of an application for a materials license (new, amendment, or renewal) is an infrequent event that requires coordination by the license reviewer, regional management, and NMSS. However, NRC management recognizes that some licensing requests don't satisfy NRC safety regulations and, therefore, warrant a denial. As early in the review process as possible, 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 (1) the NRC staff determines that the application does not meet the general requirements specified in 10 CFR 30.33, 40.32, 70.23, or other applicable regulatory requirements or (2) the applicant or licensee fails to respond to an RAI within 30 days from the date of the request, or within such other time as may be specified, as required by 10 CFR 2.108, or (3) the applicant or licensee fails to provide an adequate response within 30 days, or within such other time as may be specified, necessary for the license reviewer to determine whether the application meets the regulatory requirements. In these cases, inform the applicant or licensee in writing of the following:

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

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

1 licensing actions, the denial letter should be prepared for the regional designee with signature
2 authority for denial letters. Prior to signature of the denial letter, the letter should be reviewed
3 and approved by the appropriate Branch Chief from NRC HQ or the Region and legal counsel
4 (OGC for HQ denial letters and Regional Counsel for regional denial letters). The Director,
5 Division of Nuclear Materials Safety (DNMS) should also review and approve the denial letter if
6 the letter will be signed out by the Regional Administrator (RA). Sample denial letters informing
7 applicants of the reason for the denial and their right to request a hearing are provided in
8 Appendix B of this NUREG.

9 Following receipt of concurrence from the appropriate Branch Chief on the denial letter, the
10 Branch Chief and license reviewer should brief the DNMS Director regarding the intent to deny
11 the licensing action. If the RA will sign the letter, they should also be briefed. If the individual
12 who will sign the letter agrees with the denial, the license reviewer and/or Branch Chief will
13 contact the applicant or licensee to inform them that the NRC plans to deny the licensing action.
14 The license reviewer and/or Branch Chief will offer the applicant or licensee an opportunity to
15 withdraw the licensing action for further discussion of the issues. The license reviewer and/or
16 Branch Chief should make it clear that if the applicant or licensee does not withdraw the
17 licensing action, the NRC staff will issue the denial.

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

22 For denials involving license renewals, the NRC will inform the licensee that their license will
23 expire when the term of the current license ends or that their license has already expired
24 (i.e., timely renewal). The denial letter should specify the actions that the licensee should take
25 regarding the radioactive material in their possession. If necessary, the cognizant NRC office
26 will prepare an Order for divestiture of licensed material in the licensee's possession and
27 decontamination of the licensee's facilities, if necessary. All Orders will be reviewed and
28 approved by OGC, OE, and signed by either the appropriate RA or the NMSS Director. All
29 regional orders should be coordinated with NRC HQ management and cognizant technical staff.

30 **4.12 Significant Licensing Actions That May Warrant On-site Inspection**

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

- 33 1. an increase in the types, quantities, and uses of radioactive material [e.g., new modality,
34 emergent technology, significant potential for increased radiation exposure to the public
35 or occupational workers (e.g., radiotoxicity)]
- 36 2. a change in the use of unsealed or unregistered sources
- 37 3. a physical move of an existing facility or new use at a temporary jobsite
- 38 4. a new facility, since the previous inspection, including temporary jobsites, where
39 radioactive materials will be used or stored
- 40 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 significant amendment or renewal licensing actions. The checklist should become an OAR.

4.13 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 regulation. Some exemptions may be granted on a temporary basis, as explained below.

In addition, the DOE may contact the Regions to conduct activities at nongovernment 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 (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." (ADAMS Accession No. ML16123A138).

4.13.1 Routine Exemptions

Exemptions to specific regulations contained in Appendix D 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

4.13.2 Temporary Exemptions for Humanitarian or Emergency Reasons

The Regions may grant a temporary exemption to NRC regulations or license conditions, on a case-by-case basis, without referral to NMSS in certain circumstances; however, the exemption request should be discussed with NMSS whenever possible. Temporary exemptions may be appropriate in circumstances where

- A normal license amendment is not appropriate because of the nonrecurring, short duration (normally 7 days or less) nature of the exemption.
- The noncompliance would normally result in a Severity Level IV violation, as described in the Enforcement Policy.

A temporary exemption should be granted only after a determination has been made that the circumstances surrounding the request are urgent and temporary and that an exemption will not endanger life, property, or the common defense and security, and that it is otherwise in the public interest. Temporary humanitarian exemptions are generally found in the medical area and include requests for relief from 10 CFR 20.1302. 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 DNMS Director, 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 Director, DNMS. After granting the request, the Director, DNMS, should promptly send a letter to the licensee. This letter should follow the standard format provided in Appendix B, 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 Director, DNMS, 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, an entry should be made into WBL.

A license amendment for a temporary exemption, as described above, is not considered a permanent licensing action and does not change the 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. Pursuant to 10 CFR 51.22(b), no EA need be prepared in connection with the issuance of a license amendment for a temporary exemption.

If an exemption 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, since this action is categorically excluded under 10 CFR 51.22(c)(*enter the appropriate paragraph*).”

4.13.3 Exemptions Requiring Coordination with NMSS

All requests for exemptions not described above should be forwarded, in a TAR, to the appropriate NMSS Division Director. The Regions should follow closely the guidance contained in Section 4.15 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.

As part of the exemption request evaluation, the Region should draft an EA to determine whether the exemption would constitute 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 (ACMUI).

- Request for relief from 10 CFR 35.400(d) and (g) for authorization of gold-198 and iodine-125 seeds for intracavitary and topical applications.

4.13.4 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 this 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.

4.14 Expedited Reviews

4.14.1 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.

4.14.2 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.

4.15 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 requesting 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, 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," dated December 9, 2016 (ADAMS Accession No. ML13095A163). This includes the form for submitting to the appropriate NMSS Division.

4.16 Processing Proprietary Information

Final NRC records and documents, including correspondence to and from NRC regarding licensing actions, are available to the general public, except under certain circumstances, such as SUNSI, 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.

1 In 10 CFR 2.390, NRC specifies the procedures and requirements for persons to submit
2 sensitive information to NRC so that it may be properly protected from disclosure. This
3 regulation is available electronically on the NRC Web site at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr)
4 [rm/doc-collections/cfr](https://www.nrc.gov/reading-rm/doc-collections/cfr). If the information is necessary, the reviewer should ensure that the
5 applicant has submitted a formal request, in accordance with 10 CFR 2.390, for withholding the
6 information. To ensure that the necessary information is submitted, applicants and licensees
7 should also use Checklist A.6 in Appendix A of this NUREG, which identifies the documents and
8 information needed to support a withholding determination.

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

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

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

21 The applicant or licensee should identify, mark, and protect sensitive information against
22 unauthorized disclosure to the public. License applications that contain sensitive information
23 should be marked as indicated below, in accordance with 10 CFR 2.390, before the information
24 is submitted to the NRC. Key examples are as follows:

- 25 • **Proprietary Information and Trade Secrets:** If it is necessary to submit proprietary
26 information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow
27 this procedure could result in disclosure of the proprietary information to the public or
28 substantial delays in processing the application. Appendix A includes a checklist
29 (Checklist A.6) for requests for withholding information from public disclosure.
- 30 • **Personally Identifiable Information:** Personally identifiable information (PII) about
31 employees or other individuals should not be submitted unless specifically requested by
32 the NRC. Examples of PII are social security number, home address, home telephone
33 number, date of birth, and radiation dose information. If PII is submitted, a cover letter
34 should clearly state that the attached documents contain PII, and the top of every page
35 of a document that contains PII should be clearly marked as follows: "Privacy Act
36 Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory
37 Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the
38 U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice (IN)
39 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information,"
40 dated November 15, 2013, which can be found on the NRC's Generic Communications

1 Web page under “Regulatory Issue Summaries” and “Information Notices,” respectively,
2 at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.

- 3 • Security-Related Information: Following the events of September 11, 2001, the NRC
4 changed its procedures to avoid the release of information that terrorists could use to
5 plan or execute an attack against facilities or citizens in the U.S. As a result, certain
6 types of information are no longer routinely released and are treated as sensitive,
7 unclassified information. For example, certain information about the quantities and
8 locations of radioactive material at licensed facilities and associated security measures
9 are no longer released to the public. Therefore, a cover letter should clearly state that
10 the attached documents contain sensitive security-related information, and the top of
11 every page of a document that contains such information should be clearly marked:
12 “Security-Related Information—Withhold Under 10 CFR 2.390.” For the pages having
13 security-related sensitive information, an additional marking should be included (e.g., an
14 editorial note box) adjacent to that material. For further information, see RIS 2005-31,
15 Rev. 1, “Control of Security-Related Sensitive Unclassified Non-Safeguards Information
16 Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of
17 Source, Byproduct, and Special Nuclear Material,” dated December 26, 2017, which can
18 be found on the NRC’s Generic Communications Web page under “Regulatory Issue
19 Summaries” at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>. Additional
20 information on procedures and any updates is available at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/sensitive-info.html)
21 [rm/sensitive-info.html](https://www.nrc.gov/reading-rm/sensitive-info.html).

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

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

32 Any part of a license application or information a licensee or applicant provides that the NRC
33 determines should be withheld from public disclosure will be handled in accordance with
34 Management Directive 12.6, “NRC Sensitive Unclassified Information Security Program,” and
35 the licensee or applicant will be notified, in writing, that NRC plans to honor the request.
36 Management Directive 12.6 is available electronically on the NRC Web site at
37 <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.

4.17 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 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 as secondary codes if such requests are granted.

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 following information from the licensee, in writing, 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. The 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 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.7 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. 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 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.7. 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, 40, and 70. However, the requirements 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.'" (All generic communications are available on the external NRC Web site.)

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 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.7. 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. Such requests should explain how postponing decommissioning would be in the public's interest.

4.18 Decommissioning Service Providers

4.18.1 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."

4.18.2 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

1 license. Under these circumstances, the NRC licensee should ensure that documentation
2 associated with decommissioning meets the regulatory requirements and guidance provided in
3 NUREG–1757. Since Group 1 and Group 2 categories do not require any remediation by
4 definition, there does not need to be any coordination between the NRC and the contracted
5 decommissioning service provider licensee.

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

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

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

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

41 Finally, the NRC licensee may be required to submit a decommissioning plan (DP), in
42 accordance with 10 CFR 30.36(g), if the procedures and activities necessary to carry out
43 decommissioning of the site, separate buildings, or outdoor areas have not been approved by
44 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.

4.18.3 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), and 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 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.

- 1 3. The decommissioning service provider is usually required by license condition to notify
2 the appropriate regional office (referenced in Appendix D of 10 CFR Part 20), at least
3 14 days before initiating decommissioning activities at a temporary jobsite location,
4 to provide the NRC with an opportunity for inspection of these activities. This
5 notification includes:
- 6 a. the characterization survey report, including source terms and concentration
7 profiles, including physical/chemical forms of the radionuclides at the
8 temporary jobsite
- 9 b. the specific site location
- 10 c. a description of the remediation work plan, including waste management
11 and disposition
- 12 d. the estimated start date and completion date for the job
- 13 e. the name and title of a point of contact for the job, including information on how
14 to contact the individual
- 15 4. A decommissioning service provider license may authorize the use of licensed material
16 only at temporary jobsite locations in the United States where NRC maintains
17 jurisdiction, including areas of exclusive Federal jurisdiction within Agreement States.
18 Possession or use of materials at the service contractor's facilities should be authorized
19 under a separate license. In addition, possession should be authorized only to the
20 extent that licensed material originating from the site should be transferred to an
21 authorized recipient or left at the site. Possession (at the temporary jobsite location) of
22 calibration sources, reference standards, and contaminated equipment owned by the
23 licensee may be authorized under the decommissioning service provider license.
- 24 5. The decommissioning service provider is usually required by license condition to
25 establish a written agreement that specifies which licensed activities will be performed
26 under the site owner's NRC license and supervision, and which licensed activities will be
27 performed under the decommissioning service provider's license and supervision. This
28 agreement facilitates NRC's assessment of responsibility of licensed activities during the
29 decommissioning process. The agreement usually includes commitments by both
30 licensees to ensure safety, and it specifies whether there are any commitments by the
31 decommissioning service provider to help the customer clean up the temporary jobsite if
32 there is an accident.
- 33 6. The decommissioning service provider is usually required by license condition to
34 maintain records of information important to decommissioning a temporary jobsite at the
35 site, pursuant to 10 CFR 30.35(g), 40.36(f), and 70.25(g). The site owner should have
36 access to the decommissioning records throughout the decommissioning process. The
37 decommissioning service provider should transfer these records to the site owner when
38 activities at the temporary jobsite are complete.
- 39 7. 10 CFR 30.35(c)(5) requires waste collectors and waste processors, as defined in 10
40 CFR Part 20, Appendix G, to submit a decommissioning funding plan that includes a
41 cost estimate as described in 10 CFR 30.35(e). Waste collectors and waste processors
42 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 30.34(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 30.34(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 job site 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)

4.19 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 4.15 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.

4.20 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 divestiture 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 be contacted 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 collect sources being stored and not used, which could—as an aggregate—be used for malicious intent. The SCATR program is limited to sources that do not meet the International Atomic Energy Agency's definition of Category 1 and Category 2 sources. Examples of sources that would be eligible for the SCATR program include medical brachytherapy sources (Cs-137), 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 <http://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 <http://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 divestiture 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 Materials 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.

4.21 Sensitive Unclassified Nonsafeguards Information

The reviewer should use the latest SUNSI guidance available on the NRC Office of Information Services Web site at <https://www.internal.nrc.gov/sunsi/> 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 PI)
5. Proprietary
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. Then, mark the original as sensitive and mail it to the licensee. SUNSI may be e-mailed within the NRC firewall (HQs and Regions), except investigation information. E-mailing SUNSI outside of NRC HQs 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 nonpublicly 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,” the document does not need to be marked; however, the document should be profiled in ADAMS as nonpublicly available, sensitive, and with the appropriate document sensitivity value.

Incoming documents marked as containing Security-Related SUNSI will generally be accepted without further review.

RIS 2005-31, Rev. 1 contains screening criteria to identify security-related sensitive information. The threshold radionuclide activity is the IAEA Category 3 radionuclides of concern. The following table provides this criteria.

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.

$$\sum_1^n \left[\frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \frac{R_n}{AR_n} \right] \geq 1. \quad (4-1)$$

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 below as an aide to the reviewer. Any additional clarifications should be coordinated with the Source Management and Protection Branch in NMSS.

4.22 License Termination

NUREG-1757 is a three-volume report that contains the regulatory guidance pertaining to the decommissioning of facilities, final status survey, and financial assurance. The reviewer should refer to the appropriate guidance when reviewing requests for termination of a license.

Checklist A.8, "Materials License Termination/Expiration Form" should be used as a guide to process these types of licensing actions. After verifying the disposition of licensed material, ensuring that a satisfactory closeout inspection and confirmatory survey were performed, and obtaining decommissioning records required by 10 CFR 30.36, 40.61, and 70.51, if required, the reviewer should prepare a letter and license informing the licensee that the license has been terminated. A sample transmittal letter is available in Appendix B.

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

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

- A.8—Materials License Termination/Expiration Form
- A.2—NSTS Update
- A.3—Identification of Significant Licensing Action and/or Program Code Change

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

Table 4-1. Category 3 SUNSI Marking Criteria		
Radionuclide	Quantity of Concern¹ (TBq)	Quantity of Concern² (Ci)
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	

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

²TBq values are the regulatory standard and the Curie values are rounded to two significant figures.

³Radioactive 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 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.

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

Table 4-2. SUNSI Examples	
Addresses	<p>All individual <u>mailing addresses</u> 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:</p> <p>Example 1 (mailing address): ABC State University 123 Maple Street, Suite 789 Collegetown, New Jersey 01234</p> <p>Example 2 (mailing address): XYZ Radiography Inc. 456 Main Street Anytown, Idaho 75678</p> <p>For Material BELOW the thresholds, <u>building</u> numbers are publicly available, but <u>room</u> and <u>suite</u> numbers are non-publicly available. <u>Room</u> and <u>suite</u> 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.</p> <p>Additional locations of use, as specified in License Condition 10, may be made publicly available if the address does not specify a room or suite number.</p> <p>Example 3 (location of use) (Non-publicly available, because of the suite number): 123 Main Street, Suite C Anytown, Idaho 12345</p> <p>Example 4 (location of use) (Publicly available, because it is a building number) 123 Main Street Anytown, Michigan 12345</p> <p>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</p>
Possession Threshold	<p>Documents related to licensees that fall BELOW the Category 3 possession thresholds can be released as not containing Security-Related SUNSI; EXCEPT that information on <u>exact</u> 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.</p> <p>Documents related to licensees that are ABOVE the Category 3 possession thresholds must be withheld as Security-Related SUNSI.</p>

Table 4-2.	SUNSI Examples
Licenses with Activity <u>ABOVE</u> Threshold	<p>If a document specifies an Ir-192 camera, containing 60 curies of material, this information can be released as long as it does not include a specific location <u>or</u> manufacturer model number in combination with the radionuclide and quantity. (Even when the quantity of material is greater than the IAEA category 3 thresholds.)</p> <p>However, if this is the <u>only</u> camera in the company's <u>inventory</u>, then it can not be released and the information is considered SUNSI.</p> <ul style="list-style-type: none"> • Release authorized radionuclides and form. • Withhold authorized quantities. • Withhold manufacturers and model numbers of sealed sources and devices. If the inspection report documents a SPEC Model 150 camera containing Iridium-192, whether or not the location is provided, then it will have to be withheld. • Withhold information that identifies specific buildings, rooms, or suites where radioactive material is located. • Release individual mailing addresses and street address where material is located. • Withhold information on actual inventory (therefore, if the camera is the only one in the inventory, then it will have to be withheld.) <p>Release radionuclide, mailing address, street address (without building number or room number).</p> <p>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).</p> <p>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).</p> <p>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.</p>
Licenses with Activity <u>BELOW</u> Threshold	<p>Release manufacturer and model numbers of sealed source and devices, as long as the document does not specify the specific location of use (i.e., room number or suite number)</p> <p>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).</p> <p>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.</p>

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 checks or bank drafts, the Licensing Assistant (LA) should enter the action into the Web-based Licensing (WBL) system. The LA should make two copies of the check. Next, the LA will send the check to OCFO for processing.
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 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 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 3.2.11 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. An example of the Order, entitled "ORDER REVOKING LICENSE WITHIN 30 DAYS BASED ON NONPAYMENT OF LICENSE FEES" is provided in Appendix B. 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.

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 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 (HQ), these and other communications will go to NMSS. The Division Director for 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 Director of the Division of Nuclear Materials Safety (DNMS) (for the Region) 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 HQs 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) 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

- 1 licensee must notify the Regional Division Director or affected HQs
2 Division Director, in writing, within 5 days of such disposal.
- 3 (ii) No later than the date of revocation, any licensee who is a manufacturer,
4 distributor, or provider of services to other licensees must notify each
5 customer or client, in writing, that authorization to provide any support has
6 been revoked and that customers and clients may need to amend their
7 licenses to be in compliance with NRC requirements.
- 8 (iii) Unless the licensee is required to submit a DP, within 60 days from the
9 date of revocation, the licensee must begin decommissioning its site, or
10 any separate building or outdoor area that contains residual radioactivity,
11 so that the building or outdoor area is suitable for release in accordance
12 with NRC requirements. If the licensee is required to submit a DP, it
13 should consult 10 CFR 30.36, 10 CFR 40.42, or 10 CFR 70.38, for
14 specific requirements applicable to the submittal and implementation of
15 such a plan.
- 16 (iv) No later than the date of revocation, the licensee must submit a written
17 report to the Regional Division Director or affected HQs Division Director
18 on the status of materials.
- 19 Upon the Regional Administrator's (RA's) determination that the steps above have been
20 satisfactorily completed, as necessary, the license will be terminated at a date specified by the
21 RA. If the licensee still owes fees, OCFO will continue to take action.
- 22 Under the terms of the Order, any request for relaxation will be directed to the Chief Financial
23 Officer (CFO). The CFO will coordinate action on the requests with the RA or HQs Division
24 Director and make a determination on any such request with the concurrence of the RA or HQs
25 Division Director.
- 26 3. Thirty days after issuance of the Order, OCFO will send a "Final Action" memorandum
27 stating whether the license was revoked for nonpayment of fees or whether the licensee
28 paid the invoice in full within the 30-day period, and, therefore, the Order is rescinded;
29 the licensee submitted "good cause" for an extension of time or for relaxation or
30 rescission; the licensee requested a hearing; or other basis that would stay the
31 effectiveness of the Order, such as the Order not being delivered.
- 32 4. If the Final Action is the revocation of the license, OCFO will update WBL by entering a
33 "Status 5," indicating that the license is revoked. OCFO is working on a tracking system
34 to identify delinquent debtors that have been previously written off as bad debt so that
35 incoming applications can be matched to these debtors.
- 36 5. The Region or HQ should contact the licensee 6 to 10 days after issuance of the Order
37 to determine the status of the licensee's program, receipt of the Order, and its intentions
38 relative to the Order. Depending on the licensee's response, the Region or HQ may
39 need to schedule inspections and confirmatory surveys, as appropriate.
- 40 6. Upon receipt of the Final Action memorandum from OCFO indicating the debt has not
41 been paid and the license is revoked for nonpayment of the fee, the Region should
42 contact the licensee by phone promptly to determine the licensee's status and intentions

1 with respect to compliance. If the licensee does not respond in writing within 7 days of
2 the phone call, the Region should arrange to conduct an inspection of the facility within
3 30 days.

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

6 SAFETY CULTURE

Individuals and organizations performing regulated activities are expected to establish and maintain a positive safety culture, commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to the U.S. Nuclear Regulatory Commission (NRC) authority.

“Nuclear safety culture” is defined in the NRC’s safety culture policy statement (76 FR 34773; June 14, 2011) as “the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.” Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal-conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). Refer to Table 6-1 for the traits of a positive safety culture from NRC’s safety culture policy statement.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, NRC’s safety culture policy statement and traits are not incorporated into the regulations. Safety culture traits may be inherent to an organization’s existing radiation safety practices and programs.

Refer to Appendix G of this NUREG for the NRC’s safety culture policy statement. More information on NRC activities relating to safety culture can be found at <https://www.nrc.gov/about-nrc/safety-culture.html>.

Table 6-1. Traits of a Positive Safety Culture		
Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected, commensurate with their significance.	All individuals take personal responsibility for safety.
Work Processes	Continuous Learning	Environment for Raising Concerns
The process of planning and controlling work activities is implemented so that safety is maintained.	Opportunities to learn about ways to ensure safety are sought out and implemented.	A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.
Effective Safety Communications	Respectful Work Environment	Questioning Attitude
Communications maintain a focus on safety.	Trust and respect permeate the organization.	Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

1

APPENDIX A

2

CHECKLISTS

Checklists

CHECKLIST A.1

A.1 License Status Change Control (For Terminated, Expired, and Retired Licenses)

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 Contract: _____

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) 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) <ul style="list-style-type: none">• Documentation to support:	
(3) Close-out survey by licensee (NUREG-1757) ADAMS Accession ML#:	
(4) Close-out survey by NRC (NUREG-1757) ADAMS Accession ML#:	
(5) Licensee submitted records [10 CFR 30.36(k)(4); 40.61; 70.51]	
NRC action(s) to be taken:	YES, NO, N/A
(1) Retire/terminate license.	
(2) Change to retired status in WBL.	
(3) Remove from the Materials Docket room after _____ months (usually 6 months).	
(4) License No. _____ replaces/supersedes License No. _____	
(5) Were the Financial Assurance documents returned?	
(6) Was the National Source Tracking System (NSTS) database updated?	
(7) Was the Nuclear Materials Management and Safeguards Systems (NMMSS) database updated?	

License Reviewer: _____ Date: _____

Supervisor Approval: _____ Date: _____

Expired License Number: _____

New License Number: _____

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 (10 CFR 20.2207)—that which is listed in Category 1 and Category 2 of Appendix E to 10 CFR Part 20, “Nationally Tracked Source Thresholds” and is required to be entered into the NSTS.

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 10 CFR 20.2207 requirements.
Existing license not authorized for NSTS sources 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 <u>add</u> a location for NSTS materials		List all location address(es) to be added in the table below.
Existing license, amended to <u>remove</u> 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 <u>remove all NSTS materials</u>		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 (Note: <i>Temporary jobsite is a location of use</i>)	
DELETE Location(s) of Use	

Signature and Date:

- 1 Reviewer: _____ Date: _____
- 2 NSTS Regional Representative: _____ Date: _____

CHECKLIST A.3

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

2 Licensee Name: _____

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

4 Reviewer: _____ Date: _____

5 Licensing Branch Chief: _____ Date: _____

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

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

Examples of significant licensing actions:	YES or NO
Increased types, quantities, 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 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 [Ref: 10 CFR 30.36(d), (h), & (j)]—(Ensure Checklist A.8 is completed if Termination)	
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 WBL printout.)	

1 **For Use By Inspection Branch**

2 An on-site inspection of the licensee identified above should be considered because of a recent
3 significant licensing action involving one or more of the criteria described above.

4 *Ref.: IMC2800.*

5 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: _____

1

CHECKLIST A.42 **A.4 Renewal Checklist**

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

3 **Part 1—PERFORMANCE INDICATORS**

4 Review records for the 5 years preceding this renewal application and/or interview appropriate
 5 staff with respect to the following indicators:

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

CHECKLIST A.4

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 to ensure the application conforms to the 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 determined to be adequate: 1. Organizational structure conforms with regulations and guidance 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 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 and NUREG–1556 guidance.	
New and/or High Risk Technologies conform to applicable regulations, NUREG–1556 guidance, or NRC Web site guidance for 10 CFR 35.1000.	
Changes of Control conform to the regulations, NUREG–1556 guidance, and the new entity is known or had a precicensing site visit, as required.	
Unsealed transuranic radioactive materials used by licensee.	
Major Areas reviewed against NUREG–1556, as applicable and determined to be adequate.	
Licensing visit was performed? (Refer to Section 4.9.2 of this NUREG)	

1 **Part 3—RSRM**

2 Complete “RSRM” checklist in the Material Security Toolbox, available at
3 <https://scp.nrc.gov/controls.html>, to document whether the licensee is (1) already subject to the
4 10 CFR Part 37 requirements; (2) plans to obtain aggregated Category 1 or Category 2
5 quantities of radioactive material, as defined in 10 CFR 37.5; or (3) is reducing possession limits
6 below RSRM. Completed: Yes ☐ No ☐ _____

7 Print / Sign License Reviewer

Date

CHECKLIST A.5

A.5 New and Renewal and Possession-Only—License Termination 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	

1

CHECKLIST A.6

2

A.6 Checklist for Requests to Withhold Proprietary Information From Public Disclosure (Under 10 CFR 2.390)

3

<p>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 <i>Code of Federal Regulations</i> (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:</p>	
<input type="checkbox"/>	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
<input type="checkbox"/>	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.
<input type="checkbox"/>	An affidavit that:
<input type="checkbox"/>	Is signed under oath and affirmation (notarization may suffice)
<input type="checkbox"/>	Clearly identifies (such as by name or title and date) the document to be withheld
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.
<input type="checkbox"/>	Provides a rational basis for holding the information in confidence.
<input type="checkbox"/>	Fully addresses the following issues:
<input type="checkbox"/>	Is the information submitted to, and received by, the NRC in confidence? Provide details.
<input type="checkbox"/>	To the best of the applicant's knowledge, is the information currently available from public sources?
<input type="checkbox"/>	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
<input type="checkbox"/>	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.7

A.7 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 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.

- | | | |
|--------------------------|----|--|
| <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | 3. | The application includes a clear commitment not to use the licensed material for any purpose, pending disposal or authorization to restart (as applicable). |
| <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | 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. |

CHECKLIST A.7

A.7 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 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.8

A.8 Materials License Termination/Expiration Form

For acceptable methods of demonstrating the suitability of a site for unrestricted use, refer to NUREG-1757, *Consolidated NMSS Decommissioning Guidance*, Volume 1.

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

(Enter Yes or No)

_____ (Group 1—Refer to Section 8.1 of NUREG-1757) This 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 10 CFR 20.1402 without further remediation or analysis.

Comments:

_____ (Group 1—Refer to Section 8.1 of NUREG-1757) This 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—Refer to Section 9.1 of NUREG-1757) This 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)

CHECKLIST A.8

A.8 Materials License Termination/Expiration 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-14 (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 Environmental Assessment (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 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) Checklist A.8

A.8 Materials License Termination/Expiration 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.

- 1 _____ Complete an EA and issue a safety evaluation report (SER) to document the
2 DP review.
- 3 _____ Perform and document confirmatory survey or side-by-side survey completed.
- 4 _____ Issue a *Federal Register* Notice to announce (1) receipt of the DP and NRC's
5 intended actions and (2) announce a FONSI.
- 6 **Note:** Group 4 decommissioning licensees are required to submit a DP.
- 7 Group 5 Licensees (Refer to Section 12.1 of NUREG-1757)
- 8 (Enter Yes or No)
- 9 _____ Facilities that decommission under Group 5 have used licensed material in a
10 manner that resulted in its release into the environment, activated adjacent
11 materials, or resulted in persistent contamination of work areas, and resulted in
12 contamination of ground water.
- 13 _____ Group 5 decommissioning includes licensees that intend to decommission their
14 facilities in accordance with NRC criteria for unrestricted use, as described in
15 10 CFR 20.1402.
- 16 **Note:** Group 5 decommissioning licensees are required to submit a DP.
- 17 ***(If a Licensee is designated as Group 4 or 5, then end the Checklist here.)***

1 **CHECKLIST A.8**

2 **A.8 Materials License Termination/Expiration Form**

3 Group 6 Licensees (Refer to Section 13.1 of NUREG-1757)

4 (Enter Yes or No)

5 _____ Facilities that decommission under Group 6 have used licensed material in a
6 manner that resulted in releases to the environment, activated adjacent
7 materials, or resulted in persistent contamination of work areas or ground water.

8 _____ Group 6 decommissioning includes licensees that intend to decommission the
9 facility in accordance with NRC criteria for restricted use, as described in
10 10 CFR 20.1403.

11 **Note:** Group 6 decommissioning licensees are required to submit a DP.

12 Group 7 Licensees (Refer to Section 14.1 of NUREG-1757)

13 (Enter Yes or No)

14 _____ Facilities that have residual radiological contamination present in building
15 surfaces, soils, and possibly groundwater.

16 _____ These licensees intend to decommission their facilities such that residual
17 radioactive material remains at the site in excess of the levels specified in NRC's
18 criteria for unrestricted use.

19 _____ These licensees will apply site-specific criteria in a comprehensive dose analysis,
20 in accordance with alternate criteria for license termination (10 CFR 20.1404).

21 _____ A site DP that identifies the land use, exposure pathways, institutional controls,
22 and critical group for the dose analysis is required.

23 **Note:** These sites require extensive NRC review and are handled on a case-by-case basis with
24 license termination specifically approved by a vote of the NRC Commissioners.

1

APPENDIX B

2

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

1 **B.1.2 Acknowledgement–Receipt of Correspondence, NRC FORM 532**

2 Please use the most current version of this form, which may be found at
 3 ADAMS Accession No. ML18200A140“

NRC FORM 532 <small>(05-2016)</small>		ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE	U.S. NUCLEAR REGULATORY COMMISSION
Name and Address of Applicant and/or Licensee <div style="background-color: #e0e0ff; height: 100px; width: 100%;"></div>		Date <div style="background-color: #e0e0ff; height: 20px; width: 100%;"></div> License Number(s) <div style="background-color: #e0e0ff; height: 20px; width: 100%;"></div> Mail Control Number(s) <div style="background-color: #e0e0ff; height: 20px; width: 100%;"></div> Licensing and/or Technical Reviewer or Branch <div style="background-color: #e0e0ff; height: 20px; width: 100%;"></div>	
This is to acknowledge receipt of your: <input type="checkbox"/> Letter and/or <input type="checkbox"/> Application Dated: <div style="background-color: #e0e0ff; width: 100px; height: 15px;"></div>			
The initial processing, which included an administrative review, has been performed. <input type="checkbox"/> Amendment <input type="checkbox"/> Termination <input type="checkbox"/> New License <input type="checkbox"/> Renewal			
<input type="checkbox"/> There were no administrative omissions identified during our initial review.			
<input type="checkbox"/> 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.			
<input type="checkbox"/> 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.			
<input type="checkbox"/> The following administrative omissions have been identified: <div style="background-color: #e0e0ff; height: 50px; width: 100%;"></div>			
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: <div style="background-color: #e0e0ff; height: 80px; width: 100%; display: flex; align-items: center; justify-content: center;"> <div style="border: 1px solid #ccc; padding: 5px;"> Select a location (Use keyboard arrows to select). . . </div> <div style="width: 10px; height: 100%; background-color: #ccc; border-left: 1px solid #000; margin-left: 5px;"></div> </div>			

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 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 of Nuclear Material Safety and Safeguards within 30 days from 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 NONSAFEGUARDS 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 PHONE 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 of 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 PHONE 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]

Dear [INSERT SALUTATION]:

This letter is in response to your licensing request dated **[INSERT DATE]**, requesting **[INSERT BRIEF DESCRIPTION]**. In reviewing the application/licensing amendment/renewal, we find that it is lacking in significant amounts of required information. The information your **[APPLICATION/LICENSING AMENDMENT/RENEWAL]** did not provide is listed in the Enclosure.

With incomplete documents and the unavailability of adequate information, the NRC staff is unable to continue with the review of your **[APPLICATION/LICENSING AMENDMENT/RENEWAL]**. Therefore, we have discontinued the review of your **[APPLICATION/LICENSING AMENDMENT/RENEWAL]**. This is without prejudice to resubmission of your **[APPLICATION/LICENSING AMENDMENT/RENEWAL]**. When you decide to resubmit your **[APPLICATION/LICENSING AMENDMENT/RENEWAL]**, please ensure that you have included the entire **[APPLICATION/LICENSING AMENDMENT/RENEWAL]** with the missing information needed, as noted in the Enclosure, to allow the NRC staff to evaluate your **[APPLICATION/LICENSING AMENDMENT/RENEWAL]**.

If you have any questions, please contact **[INSERT NAME]** of my staff at **[INSERT PHONE 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 document 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. 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 PHONE 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]**

1 **B.2.2 Conversation Record (NRC FORM 699)**

2 **Please use the most current version of this form, which may be found at**
 3 **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	
		<input type="checkbox"/> E-MAIL <input type="checkbox"/> TELEPHONE <div style="display: inline-block; vertical-align: middle; margin-left: 20px;"> <input type="checkbox"/> INCOMING <input type="checkbox"/> OUTGOING </div>	
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]

Dear **[INSERT SALUTATION]**:

Enclosed is your U.S. Nuclear Regulatory Commission (NRC) Materials License No.
[INSERT LICENSE NUMBER], in accordance with your **[INSERT DATE]** new license
application. Your application is available electronically from the Agencywide Documents Access
and Management System (ADAMS) at Accession No. **[INSERT ACCESSION NUMBER]**.

The NRC needs your Taxpayer Identification Number in order to make payments
(refunds). Please complete and return NRC Form 531, "Request for Taxpayer Identification
Number," to the highlighted address in Item 5 on Form 531. NRC Form 531 can be found at:
<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>.

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 PHONE NUMBER] so that we may provide appropriate corrections and answers.

An environmental assessment for this action is not required, since 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 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 90 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 General Statement of Policy and Procedure

1 for NRC Enforcement Actions. Since serious consequences to employees and the public can result
2 from failure to comply with NRC requirements, prompt and vigorous enforcement action will be
3 taken when dealing with licensees who do not achieve the necessary meticulous attention to detail
4 and the high standard of compliance that NRC expects of its licensees.

5 The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy
6 statement and not a regulation, it sets forth the agency's *expectations* for individuals and
7 organizations to establish and maintain a positive safety culture. You can access the policy
8 statement and supporting material that may benefit your organization on NRC's safety culture
9 Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We
10 strongly encourage you to review this material and adapt it to your particular needs in order to
11 develop and maintain a positive safety culture as you engage in NRC-regulated activities.

12 **[IF LETTER AND LICENSE ARE BOTH PUBLIC (NON-SUNSI), INSERT THE PARAGRAPH**
13 **BELOW]**

14 In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this
15 letter and its enclosure will be available electronically for public inspection in the NRC Public
16 Document Room or from the NRC's ADAMS, accessible from the NRC Web site at
17 <http://www.nrc.gov/reading-rm/adams.html>.

18 **[IF LETTER IS PUBLIC BUT LICENSE IS NON-PUBLIC (SUNSI), INSERT THE**
19 **PARAGRAPHS BELOW]**

20 NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security-
21 related sensitive information and guidance for handling and marking of such documents. This
22 ensures that potentially sensitive information is not made publicly available through NRC's
23 ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in
24 accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed
25 license document is exempt from public disclosure because its disclosure to unauthorized
26 individuals could present a security vulnerability. The RIS may be located on the NRC's
27 Generic Communications Web page under "Regulatory Issue Summaries" at
28 <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>, and the link for frequently asked
29 questions regarding protection of security-related sensitive information may be located at
30 <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

1 A copy of this letter will be available electronically for public inspection in the NRC Public
2 Document Room or from the NRC's ADAMS, accessible from the NRC Web site at
3 <http://www.nrc.gov/reading-rm/adams.html>.

4 Sincerely,

5 [INSERT NAME]
6 [INSERT TITLE]
7 [INSERT ORGANIZATION]

8 Docket No.: [INSERT DOCKET NUMBER]
9 License No.: [INSERT LICENSE NUMBER]
10 Control No.: [INSERT CONTROL NUMBER]

11 Enclosures: 1. License No. [INSERT LICENSE NUMBER]
12 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]

Dear **[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 PHONE NUMBER] so that we may provide appropriate corrections and answers.

An environmental assessment for this action is not required, since 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 General Statement of Policy and Procedure
for NRC Enforcement Actions. 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 <http://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 <http://www.nrc.gov/reading-rm/adams.html>.

[IF LETTER IS PUBLIC BUT LICENSE IS NON-PUBLIC (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 <http://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 <http://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 <http://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]**

Dear **[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 PHONE NUMBER]** so that we may provide appropriate corrections and answers.

An environmental assessment for this action is not required, since 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 General Statement of Policy and Procedure for NRC Enforcement Actions. 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 <http://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.

1 **[IF LETTER AND LICENSE ARE BOTH PUBLIC (NON-SUNSI), USE PARAGRAPH BELOW]**

2 In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of
3 this letter and its enclosure will be available electronically for public inspection in the NRC Public
4 Document Room or from the NRC's ADAMS, accessible from the NRC Web site at
5 <http://www.nrc.gov/reading-rm/adams.html>.

6 **[IF LETTER IS PUBLIC BUT LICENSE IS NON-PUBLIC (SUNSI), USE PARAGRAPHS**
7 **BELOW]**

8 NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security-
9 related sensitive information and guidance for handling and marking of such documents. This
10 ensures that potentially sensitive information is not made publicly available through NRC's
11 ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in
12 accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed
13 license document is exempt from public disclosure because its disclosure to unauthorized
14 individuals could present a security vulnerability. The RIS may be located on the NRC's
15 Generic Communications Web page under "Regulatory Issue Summaries" at
16 <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/> and the link for frequently asked
17 questions regarding protection of security-related sensitive information may be located at
18 <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

19
20 A copy of this letter will be available electronically for public inspection in the NRC Public
21 Document Room or from the NRC's ADAMS, accessible from the NRC Web site at
22 <http://www.nrc.gov/reading-rm/adams.html>.

23 Sincerely,

24 **[INSERT NAME]**
25 **[INSERT TITLE]**
26 **[INSERT ORGANIZATION]**

27 Docket No.: **[INSERT DOCKET NUMBER]**
28 License No.: **[INSERT LICENSE NUMBER]**
29 Control No.: **[INSERT CONTROL NUMBER]**

30 Enclosure: Amendment No. **[INSERT AMENDMENT NUMBER]** to NRC License No.
31 **[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]**

Dear **[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, since 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.

[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,

1 NRC License No. **[INSERT LICENSE NUMBER]** is hereby terminated. A copy of the
2 terminated license—Amendment No. **[INSERT AMENDMENT NUMBER]**—is enclosed.

3 In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of
4 this letter and its enclosure will be available electronically for public inspection in the NRC Public
5 Document Room or from the NRC's ADAMS, accessible from the NRC Web site at
6 <http://www.nrc.gov/reading-rm/adams.html>.

If you have questions, please contact **[INSERT NAME]** at **[INSERT PHONE NO.]** or
[INSERT E-MAIL ADDRESS].

7 Sincerely,

8 **[INSERT NAME]**
9 **[INSERT TITLE]**
10 **[INSERT ORGANIZATION]**

11 Docket No.: **[INSERT DOCKET NUMBER]**
12 License No.: **[INSERT LICENSE NUMBER]**
13 Control No.: **[INSERT CONTROL NUMBER]**

14 Enclosure: Amendment No. **[INSERT AMENDMENT NUMBER]** to NRC License No.
15 **[INSERT LICENSE NUMBER]**

**B.3.5 Materials License Cover Letter Consenting to Transfer of Control—
Transfer Not Yet Confirmed by the Licensee**

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: CONSENT TO [INSERT DIRECT OR INDIRECT, AS APPLICABLE] CHANGE OF
CONTROL FOR [INSERT LICENSEE NAME], NRC LICENSE NO.
[INSERT LICENSE NUMBER]

Dear [INSERT SALUTATION]:

By letter dated [INSERT DATE], [INSERT LICENSEE NAME] (you) submitted to the
U.S. Nuclear Regulatory Commission (NRC) a Request for Consent to [INSERT DIRECT OR
INDIRECT] Change of Control of 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].

Based on the information provided, we understand that as a result of a proposed
[INSERT MERGER, SALE, ETC., AS APPROPRIATE] between [INSERT COMPANY NAME]
and [INSERT COMPANY NAME], control of [INSERT COMPANY NAME], will
[INSERT INDIRECTLY OR DIRECTLY, AS APPROPRIATE] be transferred to
[INSERT COMPANY NAME]. We further understand that this transfer will not result in any
change to the [INSERT LICENSEE NAME, LICENSED MATERIALS, PERSONS USING THE
LICENSED MATERIAL, LOCATION OF USE OF LICENSED MATERIAL, OR PERSONS
RESPONSIBLE FOR THE LICENSEE'S RADIATION SAFETY PROGRAM, AS
APPLICABLE].

Based on the above understandings and as more fully detailed in the enclosed NRC staff's
Safety Evaluation Report (SER), which documents the NRC staff's review of the request, we
have no objection to the proposed transfer. Please note that you will need to notify us promptly,
in writing, after the transaction has been finalized, and include a signed copy of the
[INSERT MERGER, SALE, ETC., AS APPROPRIATE] agreement confirming completion of the
transaction. With this information, we can issue an administrative amendment to your NRC
license to reflect the transaction, if necessary. If this planned [INSERT MERGER, SALE, ETC.,
APPROPRIATE] has not been consummated within 30 days of the date of this letter, please
notify us in writing. Please contact [INSERT NAME] at [INSERT PHONE NUMBER], or by
e-mail at [INSERT E-MAIL ADDRESS] if you have any questions regarding this letter.

An environmental assessment for this action is not required, since this action is categorically
excluded under Title 10 of the *Code of Federal Regulations* (10 CFR) 51.22(c).

1 In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of
2 this letter and its enclosure will be available electronically for public inspection in the NRC Public
3 Document Room or from the NRC's ADAMS, accessible from the NRC Web site at
4 <http://www.nrc.gov/reading-rm/adams.html>.

5 If you have questions, please contact **[INSERT NAME]** at **[INSERT PHONE NUMBER]** or
6 **[INSERT E-MAIL ADDRESS]**.

7 Sincerely,

8 **[INSERT NAME]**
9 **[INSERT TITLE]**
10 **[INSERT ORGANIZATION]**

11 Docket No.: **[INSERT DOCKET NUMBER]**
12 License No.: **[INSERT LICENSE NUMBER]**
13 Control No.: **[INSERT CONTROL NUMBER]**

14 Enclosure: SAFETY EVALUATION REPORT FOR PROPOSED CHANGE OF CONTROL
15 FOR NRC LICENSE NO. **[INSERT LICENSE NUMBER]**

**B.3.6 Materials License Cover Letter for Transfer of Control—Transfer
Completed and Confirmed by Licensee**

[INSERT DATE]

[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE, ZIP CODE]

SUBJECT: CONSENT TO [INSERT DIRECT OR INDIRECT, AS APPLICABLE] CHANGE OF
CONTROL FOR [INSERT LICENSEE NAME] AND AMENDMENT, NRC LICENSE
NO. [INSERT LICENSE NUMBER]

Dear [INSERT SALUTATION]:

By letter dated [INSERT DATE], [INSERT LICENSEE NAME] (you) submitted to the
U.S. Nuclear Regulatory Commission (NRC) a Request for Consent to [INSERT DIRECT OR
INDIRECT] Change of Control of 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].

Based on the information provided, we understand that as a result of a [INSERT MERGER,
SALE, ETC., AS APPROPRIATE] between [INSERT COMPANY NAME] and
[INSERT COMPANY NAME], control of [INSERT COMPANY NAME], has been
[INSERT INDIRECTLY OR DIRECTLY, AS APPROPRIATE] transferred to [INSERT COMPANY
NAME]. We further understand that this transfer has not resulted in any change to the
[INSERT LICENSEE NAME, LICENSED MATERIALS, PERSONS USING THE LICENSED
MATERIAL, LOCATION OF USE OF LICENSED MATERIAL, OR PERSONS RESPONSIBLE
FOR THE LICENSEE'S RADIATION SAFETY PROGRAM, AS APPLICABLE].

Based on the above understandings and as more fully detailed in the enclosed NRC staff's
Safety Evaluation Report (SER), which documents the NRC staff's review of the request, we
have no objection to the proposed transfer.

Also enclosed is Amendment No. [INSERT AMENDMENT NUMBER] to your NRC Materials
License No. [INSERT LICENSE NUMBER], in accordance with your request.

Please review the enclosed documents carefully and be sure that you understand all conditions.
If there are any errors or questions regarding either document or this letter, please contact
[INSERT NAME] at [INSERT PHONE NO.], or by e-mail at [INSERT E-MAIL ADDRESS] so
that we may provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically
excluded under Title 10 of the *Code of Federal Regulations* (10 CFR) 51.22(c).

1 The transferee **[INSERT LICENSEE NAME]** should note its responsibilities as an NRC
2 licensee. Specifically, unless your license has been terminated, you must conduct your
3 program involving radioactive materials in accordance with the conditions of your NRC license,
4 representations made in your license application, and NRC regulations. In particular, you are
5 responsible for any NRC inspection and enforcement issues, investigations, facility
6 decontamination, and decommissioning funding resources. Finally, please be advised, under
7 10 CFR 30.34(b), a control of an NRC license cannot be directly or indirectly transferred without
8 prior written consent from the NRC.

9 You will be periodically inspected by the NRC. Failure to conduct your program in accordance with
10 NRC regulations, license conditions, and representations made in your license application and
11 supplemental correspondence with the NRC will result in enforcement action against you. This
12 could include issuance of a notice of violation, or imposition of a civil penalty, or an order
13 suspending, modifying or revoking your license as specified in the General Statement of Policy and
14 Procedure for NRC Enforcement Actions. Since serious consequences to employees and the
15 public can result from failure to comply with NRC requirements, prompt and vigorous enforcement
16 action will be taken when dealing with licensees who do not achieve the necessary meticulous
17 attention to detail and the high standard of compliance which NRC expects of its licensees.

18 The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy
19 statement and not a regulation, it sets forth the agency's *expectations* for individuals and
20 organizations to establish and maintain a positive safety culture. You can access the policy
21 statement and supporting material that may benefit your organization on NRC's safety culture Web
22 site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly
23 encourage you to review this material and adapt it to your particular needs in order to develop and
24 maintain a positive safety culture as you engage in NRC-regulated activities.

25 **[IF LETTER AND LICENSE ARE BOTH PUBLIC (NON-SUNSI), INSERT THE**
26 **PARAGRAPH BELOW]**

27 In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of
28 this letter and its enclosure will be available electronically for public inspection in the NRC Public
29 Document Room or from the NRC's ADAMS, accessible from the NRC Web site at
30 <http://www.nrc.gov/reading-rm/adams.html>.

31 **[IF LETTER IS PUBLIC BUT LICENSE IS NON-PUBLIC (SUNSI), INSERT THE**
32 **PARAGRAPH BELOW]**

33 NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security-
34 related sensitive information and guidance for handling and marking of such documents. This
35 ensures that potentially sensitive information is not made publicly available through NRC's
36 ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in
37 accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed
38 license document is exempt from public disclosure because its disclosure to unauthorized
39 individuals could present a security vulnerability. The RIS may be located on the NRC's Generic
40 Communications Web page under "Regulatory Issue Summaries" at [http://www.nrc.gov/reading-](http://www.nrc.gov/reading-rm/doc-collections/gen-comm/)
41 [rm/doc-collections/gen-comm/](http://www.nrc.gov/reading-rm/doc-collections/gen-comm/) and the link for frequently asked questions regarding protection
42 of security related sensitive information may be located at [http://www.nrc.gov/reading-](http://www.nrc.gov/reading-rm/sensitive-info/faq.html)
43 [rm/sensitive-info/faq.html](http://www.nrc.gov/reading-rm/sensitive-info/faq.html).

1 A copy of this letter will be available electronically for public inspection in the NRC Public
2 Document Room or from the NRC's ADAMS, accessible from the NRC Web site at
3 <http://www.nrc.gov/reading-rm/adams.html>.

4 Sincerely,

5 [INSERT NAME]
6 [INSERT TITLE]
7 [INSERT ORGANIZATION]

8 Docket No.: [INSERT DOCKET NUMBER]
9 License No.: [INSERT LICENSE NUMBER]
10 Control No.: [INSERT CONTROL NUMBER]

11 Enclosures: 1. Amendment No. [INSERT AMENDMENT NUMBER] to NRC License No.
12 [INSERT LICENSE NUMBER]

13 2. SAFETY EVALUATION REPORT FOR PROPOSED CHANGE OF CONTROL
14 FOR NRC LICENSE NO. [INSERT LICENSE NUMBER]

B.3.7 Temporary Exemption from NRC Regulation or License Condition

[INSERT DATE]

[INSERT NAME]

[INSERT ADDRESS]

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 NEW LICENSES, AMENDMENT, AND RENEWALS THAT DID NOT REQUIRE AN ENVIRONMENTAL ASSESSMENT.]

An environmental assessment for this action is not required, since 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]**

1 B.4 SUMMARY OF SAMPLE DENIAL LETTERS PURSUANT TO 10 CFR 2.103

SAMPLE DENIAL	REQUESTED AUTHORIZATION	REASON FOR DENIAL(PERTINENT REGULATIONS)
B.4.1	License pursuant to 10 CFR 32.210 and 10 CFR 36.21 for registration of a sealed source	Radioactive material not 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 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.

2 SUMMARY OF SAMPLE WITHDRAWAL LETTERS

SAMPLE WITHDRAWAL	REQUESTED AUTHORIZATION	REASON FOR WITHDRAWAL
B.4.8	Licensee determined that they would decommission the facility rather than renew the license	Requested action no longer needed
B.4.9	Production/use of zirconium-89	Requested action currently covered by existing license
B.4.10	Add an authorized user (AU)	AU needed additional time to obtain information

1

SUMMARY OF SAMPLE SUSPENSION LETTER

SAMPLE SUSPENSION	REQUESTED AUTHORIZATION	REASON FOR SUSPENSION
B.4.11		Request was lacking significant amounts of information

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].

Dear [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 Agency-wide 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 <http://www.nrc.gov/reading-rm/adams.html>.

1 If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE**
2 **NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

3 Sincerely,

4 **[INSERT NAME]**
5 **[INSERT TITLE]**
[INSERT ORGANIZATION]

6 Sealed Source and Device Case No.: **[INSERT CASE NUMBER]**

7 Enclosures:

- 8 1. Basis for Denial of Application for Registration
9 of the Model XYZ Sealed Source
10 2. Deficiencies in the Application for Registration
11 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 AND ZIP CODE]

SUBJECT: DENIAL OF LICENSE REQUEST DATED [INSERT DATE] FOR [INSERT APPLICANT NAME], NRC LICENSE NO. [INSERT LICENSE NUMBER]

Dear **[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-137 was separated from the gauge shielding. If an untrained person picked up an unshielded cesium-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 <http://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 to Perform 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]**.

Dear **[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.

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," requires academic, research and development, and other licensees of limited scope who use or possess sealed sources 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 our current licensing guidance 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.

1 Pursuant to 10 CFR 2.103, you may request a hearing with respect to this denial within 20 days
2 (or such longer period as may be specified in this letter) of the date of this letter. A request for
3 hearing must be filed in accordance with the NRC requirements specified in 10 CFR Part 2,
4 Subpart C. This request should reference this letter, NRC License No. **[INSERT LICENSE**
5 **NUMBER]** and Docket No. **[INSERT DOCKET NUMBER]**.

6 In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this
7 letter will be available electronically for public inspection in the NRC Public Document Room or
8 from ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

9 If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE**
10 **NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

11 Sincerely,

12 **[INSERT NAME]**
13 **[INSERT TITLE]**
[INSERT ORGANIZATION]

14 Docket No.: **[INSERT DOCKET NUMBER]**
15 License No.: **[INSERT LICENSE NUMBER]**
16 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].

Dear [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 <http://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 AND ZIP CODE]

SUBJECT: DENIAL OF AMENDMENT REQUEST DATED [INSERT DATE] FOR
[INSERT LICENSEE NAME], NRC LICENSE NO. [INSERT LICENSE NUMBER]

Dear [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].

1 In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this
2 letter and its enclosure will be available electronically for public inspection in the NRC Public
3 Document Room or from ADAMS, accessible from the NRC Web site at
4 <http://www.nrc.gov/reading-rm/adams.html>.

5 If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE**
6 **NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

7 Sincerely,

8 **[INSERT NAME]**
9 **[INSERT TITLE]**
10 **[INSERT ORGANIZATION]**

11 Docket No.: **[INSERT DOCKET NUMBER]**
12 License No.: **[INSERT LICENSE NUMBER]**
13 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].

Dear [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 Agency-wide 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 mrem 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 <http://www.nrc.gov/reading-rm/adams.html>.

1 If you have any questions, please contact **[INSERT NAME]** at **[INSERT TELEPHONE**
2 **NUMBER]** or **[INSERT E-MAIL ADDRESS]**.

3 Sincerely,

4 **[INSERT NAME]**
5 **[INSERT TITLE]**
6 **[INSERT ORGANIZATION]**

7 Docket No.: **[INSERT DOCKET NUMBER]**
8 License No.: **[INSERT LICENSE NUMBER]**
9 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]**

Dear **[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. A "Notice of Proposed Denial of Application" and an "Order Revoking License within 20 Days Based on Incomplete Renewal Application" is enclosed.

If you do not provide all requested information within 20 days of the enclosed order, or request a hearing within 20 days (or such longer period as may be specified in this letter) of the date of the enclosed order, your renewal application is denied and your license is revoked. In such event, you must divest yourself of licensed material presently possessed and follow the enclosed order, which requires you to comply with 10 CFR 30.36(d) and (e).

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 <http://www.nrc.gov/reading-rm/adams.html>.

1 The NRC guidance for decontamination of your facility and equipment may be found in
2 NUREG–1757, “Consolidated Decommissioning Guidance,” Volumes 1, 2, and 3. Upon
3 completion of your facility decontamination survey and transfer of materials, NRC may conduct
4 inspections and independent surveys of your facility to verify compliance with 10 CFR 30.36(d)
5 and (e).

6 If you have any questions, please contact **[INSERT NAME]** at **[INSERT PHONE NUMBER]** or
7 **[INSERT E-MAIL ADDRESS]**.

8 Sincerely,

9 **[INSERT NAME]**
10 **[INSERT TITLE]**
[INSERT ORGANIZATION]

11 Docket No.: **[INSERT DOCKET NUMBER]**
12 License No.: **[INSERT LICENSE NUMBER]**
13 Control No.: **[INSERT CONTROL NUMBER]**

14 Enclosure: Order Revoking **[INSERT LICENSEE NAME]**, U.S. NRC License No.
15 **[INSERT LICENSE NUMBER]**

B.4.8 License Amendment Withdrawal Letter—Request No Longer Needed

[INSERT DATE]

**[INSERT NAME]
[INSERT TITLE]
[INSERT LICENSEE NAME]
[INSERT STREET ADDRESS]
[INSERT CITY, STATE AND ZIP CODE]**

**SUBJECT: WITHDRAWAL OF AMENDMENT REQUEST DATED [INSERT DATE] FOR
[INSERT LICENSEE NAME], NRC LICENSE NO. [INSERT LICENSE NUMBER]**

Dear [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 email, as appropriate]** on **[INSERT DATE]**, in which you informed us that you no longer need the requested action, we have withdrawn your application. 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 <http://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 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]

Dear [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 [INSERT telephone conversation, e-mail, letter, or facsimile, as appropriate] on [INSERT DATE], we have determined that your license currently authorizes the requested activity. In accordance with our communication, we have noted that you have confirmed that the application should be withdrawn. Therefore, the referenced request has been closed without further action on our part.

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 <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions, please contact [INSERT NAME] at [INSERT PHONE 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 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]

Dear [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.] for authorization of uses 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 closed without further action on our part. 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 <http://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]

1 **B.4.11 New License Application Suspension Letter—Request was Lacking**
2 **Significant Amounts of Required Information**

3 [INSERT DATE]

4 **INSERT NAME]**
5 **[INSERT TITLE]**
6 **[INSERT LICENSEE NAME]**
7 **[INSERT STREET ADDRESS]**
8 **[INSERT CITY, STATE, ZIP CODE]**

9 SUBJECT: SUSPENSION OF NEW LICENSE APPLICATION DATED **[INSERT DATE]** FOR
10 **[INSERT APPLICANT NAME]**

11 Dear **[INSERT SALUTATION]**:

12 We have reviewed your new license application dated **[INSERT DATE]** for a U.S. Nuclear
13 Regulatory Commission (NRC) license. You have requested to **[INSERT BRIEF**
14 **DESCRIPTION OF REQUESTED AUTHORIZATION]**. Your application is available
15 electronically from the Agencywide Documents Access and Management System (ADAMS) at
16 Accession No. **[INSERT ACCESSION NUMBER]**.

17 Based on the review, our office determined that additional information was needed from you to
18 continue review of your new license application. Accordingly, we prepared and sent you a
19 written request for additional information via letter dated **[INSERT DATE]**. As discussed
20 subsequently via **[INSERT telephone conversation, e-mail, letter, or facsimile, as**
21 **appropriate]** dated **[INSERT DATE]**, the application is lacking significant amounts of
22 information. To date, that information has not been provided to our office. In our conversation,
23 you indicated that you needed additional time to gather, prepare, and submit the requested
24 information. Accordingly, as discussed, we have suspended your application pending receipt of
25 the additional requested information. Note that if you submit a new request at a later date, you
26 may refer to Control No. **[INSERT CONTROL NO.]** for the documentation you have already
27 submitted. If you resubmit the application within 12 months from the date of your original new
28 license application, any fees paid to date will be credited toward the application fee.

29 In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of NRC's "Rules
30 of Practice and Procedure," a copy of this letter and its enclosure will be available electronically
31 for public inspection in the NRC Public Document Room or from ADAMS, accessible from the
32 NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

1 If you have any questions, please contact **[INSERT NAME]** at **[INSERT PHONE NO.]** or
2 **[INSERT E-MAIL ADDRESS]**.

3 Sincerely,

4 **[INSERT NAME]**
5 **[INSERT TITLE]**
6 **[INSERT ORGANIZATION]**

7 Docket No.: **[INSERT DOCKET NUMBER]**
8 License No.: **[INSERT LICENSE NUMBER]**
9 Control No.: **[INSERT CONTROL NUMBER]**

B.5.1 Order Denying an Application for License Renewal

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of)
) Docket No. **[INSERT DOCKET NUMBER]**
[INSERT LICENSEE NAME]) License No. **[INSERT LICENSE NUMBER]**
[INSERT STREET ADDRESS])
[INSERT CITY, STATE, ZIP CODE])

ORDER REVOKING LICENSE WITHIN 20 DAYS BASED ON
FAILURE TO PROVIDE ADEQUATE RENEWAL APPLICATION

I.

[INSERT LICENSEE NAME] (Licensee) is the holder of Materials License No. **[INSERT LICENSE NUMBER]**, issued by the U.S. Nuclear Regulatory Commission (NRC) pursuant to the Atomic Energy Act of 1954, as amended, that authorizes the activities stated therein. The license expired on **[INSERT EXPIRATION DATE]**.

II.

Pursuant to 10 CFR **[INSERT 30.37, 40.43, or 70.33, as applicable]**, the Licensee is required to apply for a renewal application prior to the expiration listed on the license. The application must contain information outlined in 10 CFR **[INSERT 30.32, 40.31, or 70.22, as applicable]**. Although the Licensee submitted application dated **[INSERT DATE]**, information contained therein failed to contain all required information. Accordingly, NRC attempted to contact the Licensee requesting additional information via letter dated **[INSERT DATE]**. To date, no response has been received from the Licensee.

To date, the additional information has not been received, as required by 10 CFR Part **[INSERT 30, 40, or 70, as applicable]**. Pursuant to this Order, if the Licensee does not provide all information within 20 days from the date of this Order, the license will be revoked under the terms of this Order and the Licensee will, in the future, not be able to operate under NRC License **[INSERT LICENSE NUMBER]**. If the former Licensee wants to resume operations after revocation of the license, the former Licensee will have to apply for and be issued a new license. Applying for a new license requires payment of an application fee.

III.

I have concluded that the Licensee has violated NRC requirements concerning the submission of an application to renew the license, prior to the license's expiration date. Therefore, pursuant to Sections 81, 161b, 161c, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part **[INSERT 30, 40, or 70, as applicable]**, IT IS HEREBY ORDERED THAT:

- 1 A. License No. **[INSERT LICENSE NUMBER]** is revoked, effective 20 days from the date
2 of this Order unless, within this 20-day period, the Licensee provides all information
3 required under 10 CFR Part **[INSERT 30, 40, or 70, as applicable]** to renew the license.
- 4 B. After license revocation, the license remains in effect, pursuant to 10 CFR 30.36, with
5 respect to the possession, transfer, and storage of licensed nuclear material remaining
6 in the Licensee's possession, as contamination or in other forms, until the Commission
7 notifies the Licensee in writing that the license is terminated.
- 8 C. From the date of revocation until notified by the Commission, in writing, that the license
9 is terminated the Licensee shall:
- 10 a. restrict activity involving licensed nuclear material to decommissioning and safe,
11 secure storage or transfer of material;
- 12 b. continue to control entry into restricted areas until the Licensee has determined,
13 and the NRC has confirmed, that such areas are suitable for release in
14 accordance with NRC requirements;
- 15 c. continue to conduct all required inventories and required testing for
16 contamination and/or testing for sealed sources for leakage;
- 17 d. continue to comply with all National Source Tracking System reporting
18 requirements, as applicable; and continue to comply with any applicable NRC
19 rules, regulations, or orders, including applicable sections of 10 CFR 30.36.
- 20 D. Within 5 days of the date of revocation, the Licensee shall submit a written report to the
21 NRC that includes: (1) a listing of all materials still in the possession of the Licensee,
22 and (2) a description of the conditions of storage of retained material and actions being
23 taken to control access to the material.
- 24 E. If the Licensee provides services to other licensees:
- 25 a. Within 5 days of the date of revocation, the Licensee must notify, in writing, each
26 customer or client that authorization to provide services has been suspended.
27 Furthermore, the Licensee must notify its customers and clients that they may
28 need to amend their licenses to be in compliance with the NRC requirements if
29 their license specifically states reliance on the services of the Licensee.
- 30 b. Within 10 days of the date of revocation, the Licensee must provide the NRC:
- 31 a. evidence of the notification described in Item E.a above, and
32 b. a list of customers or clients notified.
- 33 F. Within 60 days of the date of revocation, the Licensee shall dispose of, or transfer to
34 another authorized recipient or recipients, all NRC-licensed material, including
35 residual radioactive material, possessed under the authority of the license
36 **[INSERT LICENSE NO.]**.

- 1 G. Within 5 days after each transfer or disposal, the Licensee shall notify the NRC, in
2 writing, of the disposition of the material, including in the written notice details as to how,
3 where, and when disposition of the material took place.
- 4 H. The license shall be terminated by the NRC, in writing, upon satisfaction of the
5 requirements of 10 CFR 30.36.
- 6 I. After the license is revoked, the former Licensee may not resume previously licensed
7 operations until:
- 8 a. the former Licensee has applied for and been issued a new license under
9 10 CFR Part 30; and
- 10 b. all debts to NRC, including the fee for the new license, have been paid in full.
- 11 J. All notifications and submissions to the NRC pursuant to this Order shall be made, in
12 writing, to the **[INSERT APPROPRIATE TITLE AND ADDRESS]**.

13 The **[INSERT APPROPRIATE TITLE]** may relax or rescind, in writing, any of the above
14 conditions upon a showing by the Licensee of good cause. A request for modification of the
15 above conditions shall be submitted to the Director, **[INSERT APPROPRIATE TITLE]**, in writing
16 and under oath or affirmation, and must be received within 20 days from the date of this Order.

17 IV.

18 In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected
19 by this Order may, submit an answer to this Order within 20 days of its issuance. The answer
20 shall be in writing and under oath or affirmation, and shall specifically admit or deny each
21 allegation or charge made in this Order. The answer shall set forth the matters of fact and law
22 on which the Licensee or other person adversely affected relies and the reasons as to why this
23 Order should not have been issued.

24 Any answer shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission,
25 ATTN: Chief, Rulemakings and Adjudications Staff, Washington, DC 20555-0001. Copies shall
26 also be sent to the **[INSERT APPROPRIATE OFFICE]**; the Assistant General Counsel for
27 Materials Litigation and Enforcement at the same address; the **[INSERT APPROPRIATE TITLE**
28 **AND OFFICE AND ADDRESS]**, and to the Licensee if the answer is by a person other than
29 the Licensee.

30 In addition, the Licensee and any other persons adversely affected by this Order may request a
31 hearing on this Order within 20 days of its issuance. Where good cause is shown, consideration
32 will be given to extending the time to request a hearing. A request for extension of time must be
33 made, in writing, to the **[INSERT APPROPRIATE TITLE AND OFFICE]**, and include a
34 statement of good cause for the extension. If a person other than the Licensee requests a
35 hearing, that person shall set forth with particularity the manner in which his or her
36 interest is adversely affected by this Order and shall address the criteria set forth in
37 10 CFR 2.309(d) and (f).

1 If the Licensee or a person whose interest is adversely affected requests a hearing, the
2 Commission will issue an Order designating the time and place of any hearing. If a hearing
3 is held, the issue to be considered at such hearing shall be whether this Order should
4 be sustained.

5 A request for hearing must be filed in accordance with the NRC E-Filing rule, which became
6 effective on October 15, 2007. The NRC E-Filing Final Rule was issued on August 28, 2007,
7 (72 Fed. Reg. 49,139) and codified in pertinent part at 10 CFR Part 2, Subpart C. The E-Filing
8 process requires participants in adjudicatory proceedings to submit and serve documents over
9 the internet or, in some cases, to mail copies on electronic optical storage media. Participants
10 may not submit paper copies of their filings, unless they seek an exemption in accordance with
11 the procedures described below.

12 To comply with the procedural requirements associated with E-Filing, at least 5 days prior to the
13 filing deadline, the requestor must contact the Office of the Secretary by e-mail at
14 hearingdocket@nrc.gov, or by calling (301) 415-1677, to request (1) a digital identification (ID)
15 certificate, which allows the participant (or its counsel or representative) to digitally sign
16 documents and access the E-Submittal server for any NRC proceeding in which it is
17 participating; and/or (2) creation of an electronic docket for the proceeding (even in instances
18 when the requestor (or its counsel or representative) already holds an NRC-issued digital ID
19 certificate). Based upon this information, the Secretary will establish an electronic docket for the
20 hearing in this proceeding if the Secretary has not already established an electronic docket.
21 Information about applying for a digital ID certificate also is available on NRC's public Web site
22 at <https://www.nrc.gov/site-help/e-submittals.html>.

23 Once a requestor has obtained a digital ID certificate and a docket has been created, the
24 requestor can then submit a request for a hearing through the Electronic Information Exchange.
25 Submissions should be in Portable Document Format (PDF), in accordance with NRC guidance
26 available on the NRC public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

27 A filing is considered complete at the time the filer submits its document through the Electronic
28 Information Exchange. To be timely, electronic filings must be submitted to the E-Filing system
29 no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-
30 Filing system time-stamps the document and sends the submitter an e-mail notice confirming
31 receipt of the document. The E-Filing system also distributes an e-mail notice that provides
32 access to the document to the NRC Office of the General Counsel and any others who have
33 advised the Office of the Secretary that they wish to participate in the proceeding, so that the
34 filer need not serve the document on those participants separately. Therefore, any others who
35 wish to participate in the proceeding (or their counsel or representative) must apply for and
36 receive a digital ID certificate before a hearing request is filed so that they can obtain access to
37 the document via the
38 E-Filing system.

39 A person filing electronically using the agency's adjudicatory E-Filing system may seek
40 assistance though the "Contact Us" link located on the NRC Web site at
41 <http://www.nrc.gov/sitehelp/e-submittals.html> or by calling the NRC Electronic Filing Help Desk,
42 which is available between 9:00 a.m. and 6:00 p.m., Eastern Time, Monday through Friday,
43 excluding government holidays. The toll-free help line number is (866) 672-7640. A person
44 filing electronically may also seek assistance by sending an e-mail to the NRC Electronic Filing
45 Help Desk at MSHD.Resource@nrc.gov.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by (1) first-class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, ATTN: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket, which is available to the public at <https://www.nrc.gov/about-nrc/regulatory/adjudicatory.html>, unless excluded pursuant to an Order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submissions.

V.

In the absence of a request for hearing, or written approval of an extension of time in which to request a hearing, License No. **[INSERT LICENSE NUMBER]** shall be revoked and all other provisions in Part III of this Order shall be final 20 days after the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions in Part III shall be final when the extension expires if a hearing request has not been received.

VI.

In lieu of filing an answer to the Order, the Licensee may submit all information requested by the NRC in Request for Additional Information letter from NRC dated **[INSERT DATE]**. This information must be received by the **[INSERT APPROPRIATE TITLE AND OFFICE]** within 20 days of the date of this Order. To confirm receipt, contact the Office of the **[INSERT APPROPRIATE TITLE AND OFFICE]**.

This Order is withdrawn if, within 20 days of the date of this Order, the **[INSERT APPROPRIATE TITLE AND OFFICE]** receives all information requested by the NRC in Request for Additional Information letter from NRC dated **[INSERT DATE]**.

1 Failure to meet the requirements of this Order may subject the Licensee and its agents to civil
2 penalties and criminal sanctions.

3 FOR THE NUCLEAR REGULATORY COMMISSION

4 */RA/*

5 **[INSERT NAME]**

6 **[INSERT TITLE]**

7 **[INSERT ADDRESS]**

8 This **[INSERT DAY OF ORDER]** of **[INSERT MONTH YEAR OF ORDER]**

9 CONTACT: **[INSERT NAME AND OFFICE]**

10 **[INSERT PHONE NUMBER]**

B.5.2 Order Revoking License for Nonpayment of Fees

[INSERT DATE]

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of)	
)	Docket No. [INSERT NUMBER]
[INSERT NAME])	License No. [INSERT NUMBER]
[INSERT ADDRESS])	

ORDER REVOKING LICENSE FOLLOWING
IMMEDIATELY EFFECTIVE 30-DAY SUSPENSION

I.

[INSERT LICENSEE NAME] [Licensee] is the holder of Materials License No. **[INSERT NUMBER]**, issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to the Atomic Energy Act of 1954, as amended, that authorizes the activities stated therein. The license has an expiration date of **[INSERT DATE]**.

II.

Pursuant to 10 CFR 171.16, the Licensee is required to pay an annual fee for this license. The Licensee's annual fee for License No. **[INSERT NUMBER]** for Fiscal Year **[INSERT YEAR]**, as set forth in fee category **[INSERT CATEGORY]** of 10 CFR 171.16(d), is \$ **[INSERT ANNUAL FEE]**. In accordance with 10 CFR Part 15, the Licensee was sent an original invoice dated **[INSERT DATE]**, a second notice dated **[INSERT DATE]**, and a final notice dated **[INSERT DATE]**, requesting payment. The final notice of payment due specifically informed the Licensee that nonpayment of the fee may result in the suspension or revocation of the license, in accordance with the enforcement provisions of the Commission's regulations, namely, 10 CFR 171.23. To date, the annual fees(s) have not been paid, as required by 10 CFR Part 171. This Order suspends License No. **[INSERT NUMBER]**, as explained below. If the fee and any other delinquent debts to NRC are paid within 30 days of the date of issuance of this Order, this Order will be withdrawn, and the Licensee will be permitted to resume operations under License No. **[INSERT NUMBER]**, if all other requirements are met. If the Licensee does not pay all debts within 30 days of the date of issuance of this Order, the license will be revoked by the terms of this Order, and the Licensee will, in the future, not be able to operate under License No. **[INSERT NUMBER]**. If the former Licensee wants to resume operations after revocation of the license, the former Licensee will have to pay all debts to NRC and apply for and be issued a new license.

III.

I have concluded that the Licensee has willfully violated NRC requirements. In addition, prior notice of the violation and an opportunity to achieve compliance was provided. Therefore,

pursuant to 10 CFR 2.202, I find that the violation requires that this Order be immediately effective. In view of the foregoing and pursuant to Sections **[INSERT 53, 63, OR 81]**, 161b, 161c, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 170.41, 171.23, and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

- A. License No. **[INSERT NUMBER]** is suspended for 30 days from the date of issuance of this Order, with respect to receipt and use of licensed nuclear materials. If, within this 30-day period, the Licensee does not pay all debts due to NRC, the license will automatically be revoked, effective 30 days from the date of issuance of this Order. During the time that the license is suspended, and after license revocation, the license remains in effect, pursuant to 10 CFR [30.36, 40.42, or 70.38], with respect to the possession, transfer, and storage of licensed nuclear material remaining in the Licensee's possession, as contamination or in other forms, until the Commission notifies the Licensee, in writing, that the license is terminated.
- B. Until notified by the Commission, in writing, that the license is terminated, the Licensee must
 - 1. Restrict activity involving licensed nuclear material to decommissioning and safe, secure storage or transfer of material.
 - 2. 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.
- C. Unless full payment is made, the Licensee must, within 30 days from the date of this Order, arrange for disposal or transfer to an authorized recipient of any licensed nuclear material acquired or possessed under the authority of License No. **[INSERT NUMBER]** and must take all actions required by 10 CFR [30.36, 40.42, or 70.38]. Such disposal must take place within 60 days of the date of this order.
- D. Within 5 days after disposal of the material, the Licensee must notify, in writing, the Director, Division of Nuclear Material Safety, for NRC Region **[INSERT NUMBER]**, at **[INSERT ADDRESS]**, of the disposition of all licensed nuclear material acquired or possessed under the authority of License No. **[INSERT NUMBER]**, including in the written notice details as to how, where, and when disposition of the material took place.
- E. Within 30 days from the date of this Order, if the Licensee manufactures, distributes, or provides services to other licensees, the Licensee must notify, in writing, each customer or client that authorization to provide any of these services has been suspended. Furthermore, the Licensee must notify its customers and clients that they may need to amend their licenses to be in compliance with NRC requirements, if their license specifically states reliance on the service of the Licensee. The Licensee must provide the Director, Division of Nuclear Material Safety, for NRC Region **[INSERT NUMBER]** at **[INSERT ADDRESS]** evidence of the notification and a list of customers or clients notified.
- F. Within 65 days of the date of this Order, the Licensee must conduct an adequate final radiation survey of the premises where the licensed activities were carried out, pursuant to 10 CFR 30.36(j), 40.42(j), or 70.38(j), and submit a written report of the results of this

survey to the Director, Division of Nuclear Material Safety, for NRC Region
[INSERT NUMBER], [INSERT ADDRESS].

G. Within 30 days of the date of this Order, the Licensee must submit a written report to the Director, Division of Nuclear Material Safety, for NRC Region [INSERT NUMBER] at [INSERT ADDRESS] that includes (1) a listing of all materials disposed of, transferred, or still in the possession of the Licensee; (2) a description of the conditions of storage of retained material and actions being taken to control access to the material; and (3) for any material not disposed of or transferred, a description of the actions taken to attempt to dispose of or transfer the material and why those actions were unsuccessful.

H. The License must be terminated upon satisfaction of the requirements of 10 CFR [30.36, 40.42, or 70.38].

I. After the license is revoked, the former Licensee may not resume previously licensed operations until

1. The former Licensee has applied for and been issued a new license under 10 CFR Parts [30, 40, and 70]

2. All debts to NRC, including the fee for the new license, have been paid in full.

The Chief Financial Officer may relax or rescind, in writing, any of the above conditions upon a showing by the Licensee of good cause. A request for modification of the above conditions must be submitted to the Chief Financial Officer, with a copy to the Director, Division of Nuclear Material Safety, NRC Region [INSERT NUMBER], in writing and under oath or affirmation, and must be received within 30 days from the date of issuance of this Order.

IV.

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order. This answer must be received by the Office of the Chief Financial Officer within 30 days of the date of this Order.

Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made, in writing, to the Chief Financial Officer, and include a statement of good cause for the extension.

The answer must be in writing and under oath or affirmation, and it must specifically admit or deny each allegation or charge made in this Order. The answer must set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why this Order should not have been issued. Any answer or request for hearing must be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Rulemakings and Adjudications Staff, Washington, DC, 20555. Copies must also be sent to the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC, 20555; the Assistant General Counsel for Hearings and Enforcement at the same address; the Regional Administrator, NRC Region [INSERT NUMBER], [INSERT ADDRESS]; and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person must set forth with particularity the manner in which his or her interest is adversely affected by this Order and must address the criteria set forth in 10 CFR 2.714(d).

1 If the Licensee or a person whose interest is adversely affected requests a hearing, the
2 Commission will issue an Order designating the time and place of any hearing. If a hearing is
3 held, the issue to be considered at such hearing will be whether this Order should be sustained.

4 Pursuant to 10 CFR 2.202(c)(2)(i), the Licensee, or any other person adversely affected by this
5 Order may, in addition to demanding a hearing, at the time the answer is filed or sooner, move
6 the presiding officer to set aside the immediate effectiveness of the Order on the ground that the
7 Order, including the need for immediate effectiveness, is not based on adequate evidence but
8 on mere suspicion, unfounded allegations, or error. The motion must state with particularity the
9 reasons why the order is not based on adequate evidence and must be accompanied by
10 affidavits or other evidence relied on.

11 V.

12 In the absence of any request for hearing, or written approval of an extension of time in which to
13 request a hearing, this Order will be final 30 days from the date of this Order, without further
14 order or proceedings. If an extension of time for requesting a hearing has been approved, the
15 provisions specified in Part III will be final when the extension expires, if a hearing request has
16 not been received. AN ANSWER OR REQUEST FOR HEARING MUST NOT STAY THE
17 IMMEDIATE EFFECTIVENESS OF THIS ORDER.

18 VI.

19 In lieu of filing an answer to the Order, the Licensee may pay the total amount specified below.
20 This amount must be received by the Office of the Chief Financial Officer within 30 days of the
21 date of this Order. This Order is withdrawn if, within 30 days of the date of this Order, the Office
22 of the Chief Financial Officer receives the total amount specified below:

Amounts Due
Calculated Through:

<u>Invoice Date</u>	<u>Invoice Number</u>	<u>Amount Billed</u>	<u>Late Charges Due</u>	<u>Amount Due</u>
1.				
2.				
3.				

Total Amount \$

1 The total amount listed above is a delinquent debt to the United States. Failure to pay the total
2 amount within 30 days of the date of this Order may, pursuant to 10 CFR Part 15, result in
3 referral of the delinquent debt to a collection agency, referral to the U.S. General Accounting
4 Office, or the U.S. Department of Justice for collection, or other action deemed appropriate.
5 Pursuant to 10 CFR 15.29, the Commission may not consider an application for a license from
6 the Licensee unless all previous delinquent debts of the Licensee to NRC, including the
7 delinquent debt(s) identified in this Order, have been paid in full. In addition, failure to meet the
8 requirements of this Order may subject the Licensee and its agents to civil penalties and
9 criminal sanctions.

10 FOR THE NUCLEAR REGULATORY COMMISSION

11 Chief Financial Officer

12 Dated at Rockville, Maryland

13 this **[INSERT DAY OF THE MONTH]** day of **[INSERT MONTH]**, 20**[INSERT YEAR]**

B.6 Reciprocity Correspondence

B.6.1 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]**

Dear **[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/>.

1 If you have submitted an NRC Form 241 to the NRC, you do not have to obtain positive
2 authorization from the NRC before performing the activities requested on the form. If the NRC
3 determines that the form contains omissions or errors, the NRC staff will contact you in an
4 attempt to obtain the correct information. If the discrepancies cannot be resolved and you do
5 not qualify for the general license, the NRC will inform you of this determination and indicate
6 that you have not complied with the requirements of 10 CFR 150.20. In this case, you are not
7 authorized to perform reciprocity activities and must cease any activities that have begun in
8 NRC jurisdiction until the NRC resolves the discrepancies.

9 Under the general license, a general licensee conducting reciprocity activities is limited to a total
10 of 180 days in any calendar year. Reciprocity activities conducted in offshore waters are not
11 subject to the 180-day limit. The NRC tracks reciprocity usage on the basis of approved usage
12 days. The NRC will not approve any activity under the general license that would exceed the
13 180-day limit. It is important that you track the days of use and submit changes to dates of
14 work, when applicable. Storage of material in NRC jurisdiction is considered a reciprocity
15 activity; days when material is stored and not used count toward the 180-day limit.

16 Licensees who perform activities using separate Agreement State licenses must submit
17 separate reciprocity requests. For example, if a licensee has separate radiography and service
18 licenses, and performs reciprocity work under both, the licensee must submit a separate
19 NRC Form 241 and a separate payment for the initial filing for each license. The activities
20 under reciprocity will be limited to 180 days separately for each license.

21 The NRC expects that you will review the information provided on NRC Form 241, as well as
22 the regulations cited in 10 CFR 150.20(b), to ensure that your radiation safety program is in
23 compliance with NRC regulations before conducting reciprocity activities.

24 If you perform reciprocity activities in NRC jurisdiction, you must conduct these activities in
25 accordance with the conditions specified in your Agreement State license; representations
26 made in NRC Form 241; and other rules, regulations, and Orders of the NRC, now or hereafter
27 in effect. Failure to file NRC Form 241 before performing under reciprocity or failure to comply
28 with these regulations or to conduct your radiation safety program in compliance with NRC
29 regulations while operating under reciprocity may result in NRC enforcement action. Such
30 actions could include the issuance of a notice of violation, imposition of a civil penalty, or an
31 Order to take certain actions as described in the NRC Enforcement Policy, which is available on
32 the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

33 Your reciprocity activities in NRC jurisdiction are subject to inspection by NRC personnel. As an
34 Agreement State licensee operating under reciprocity, you must be aware of NRC requirements
35 concerning your activities. Your lack of awareness of NRC requirements and applicable
36 provisions will not prevent the NRC from taking appropriate enforcement action.

1 -2-

2 If you have any questions about the regulations or the application process, please feel free to

3 contact **[INSERT NAME, APPROPRIATE REGION]**, reciprocity lead, at **[INSERT NUMBER]** or

4 by e-mail at **[INSERT RECIPROCITY E-MAIL]**.

5 Sincerely,

6 **[INSERT NAME]**

7 **[INSERT TITLE]**

[INSERT ORGANIZATION]

8 Docket No.: **[INSERT NUMBER]**

9 State of: **[INSERT AGREEMENT STATE NUMBER]**

10 License No.: **[INSERT NUMBER]**

B.6.2 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]

Dear [INSERT SALUTATION]

You have been approved to perform licensed activities in NRC jurisdiction under reciprocity, as described on the attached NRC Form 241.

Please submit an amended NRC Form 241 before you (1) change work locations, dates, or clients; (2) change radioactive material being used; or (3) perform work activities different from the information submitted on the initial NRC Form 241.

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 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>.

1 Your reciprocity activities in NRC jurisdiction are subject to inspection by NRC personnel. As an
2 Agreement State licensee operating under reciprocity, you are responsible for compliance with
3 NRC requirements concerning your activities. Your lack of awareness of NRC requirements
4 and applicable provisions will not prevent NRC from taking appropriate enforcement action.

5 If there are any questions regarding this determination or if you have questions concerning this
6 letter or other aspects of working in NRC jurisdiction under reciprocity, please contact me at
7 **[INSERT NUMBER]**.

8 Sincerely,

9 **[INSERT NAME]**
10 **[INSERT TITLE]**
11 **[INSERT ORGANIZATION]**

1 Fee Transmittal Sheet–Reciprocity

[INSERT DATE]

2 MEMORANDUM TO: ARB, DOC, OCFO
3 FROM: MIB, DNMS, Region III
4 SUBJECT: Transmittal of Reciprocity Fees – Initial NRC Form 241

5 Control Number: _____
6 (2-digit calendar year)-(2-letter state code)-(State License No.)

7 Licensee Name: _____

8 Fee Category: _____

9 Type of Fee _____

10 Amount of Payment: _____

11 Check: Check Number: _____ Date of Check: _____

12 Credit card: Type: _____ Last 4 digits: _____
13 (Visa, MC, AmEx, Disc, etc.)

14 Verification of payment made directly to U.S. Bank (Yes or No) _____

15 ADAMS Acc. No.: _____
16 (If not yet available, scan and attach NRC Form 241)

17 State License No.: _____

18 Date received: _____

19 Date submitted: _____

20 Submitted by: _____

21 Date Completed _____

22 Completed By _____

23 Scan this form with any attachments and e-mail to [Regional Fee E-Mail Address] (if available)
24 with “Fee Sheet” in the subject line within 5 business days of receipt

B.7 Withholding Correspondence

B.7.1 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

Dear **[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 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

1 promptly notify the U.S. Nuclear Regulatory Commission (NRC). You should understand that
2 NRC may have cause to review this determination in the future (e.g., if the scope of a Freedom
3 of Information Act request includes your information). In all review situations, if NRC makes a
4 determination adverse to the decision above, you will be notified in advance of any
5 public disclosure.

6 If you have any questions concerning this action, please feel free to contact me at
7 **[INSERT PHONE NUMBER]** or **[INSERT E-MAIL]**.

8 Sincerely,

9 **[INSERT NAME]**
10 **[INSERT TITLE]**
11 **[INSERT ORGANIZATION]**

12 Docket No.: **[INSERT NUMBER]**
13 License No.: **[INSERT NUMBER]**
14 Control No.: **[INSERT NUMBER]**

B.7.2 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**

Dear [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 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

1 promptly notify the U.S. Nuclear Regulatory Commission (NRC). You should understand that
2 NRC may have cause to review this determination in the future (e.g., if the scope of a Freedom
3 of Information Act request includes your withheld information). In all review situations, if NRC
4 makes a determination adverse to the above, you will be notified in advance of any
5 public disclosure.

6 If you have any questions concerning this action, please feel free to contact me at
7 **[INSERT PHONE NUMBER]** or **[INSERT E-MAIL]**.

8 Sincerely,

9 **[INSERT NAME]**
10 **[INSERT TITLE]**
11 **[INSERT ORGANIZATION]**

12 Docket No.: **[INSERT NUMBER]**
13 License No.: **[INSERT NUMBER]**
14 Control No.: **[INSERT NUMBER]**

B.7.3 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

Dear **[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 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

1 statutes and regulations and a determination made as to whether the documents should be
2 withheld from public disclosure or returned to you.

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

7 If the basis for withholding this information from public disclosure should change in the future,
8 such that the information could then be made available for public inspection, you should
9 promptly notify the U.S. Nuclear Regulatory Commission (NRC). You should understand that
10 NRC may have cause to review this determination in the future (e.g., if the scope of a Freedom
11 of Information Act request includes your withheld information). In all review situations, if
12 NRC makes a determination adverse to the above, you will be notified in advance of any
13 public disclosure.

14 If you have any questions concerning this action, please feel free to contact me at
15 **[INSERT PHONE NUMBER]** or **[INSERT E-MAIL]**.

16 Sincerely,

17 **[INSERT NAME]**
18 **[INSERT TITLE]**
19 **[INSERT ORGANIZATION]**

20 Docket No.: **[INSERT NUMBER]**
21 License No.: **[INSERT NUMBER]**
22 Control No.: **[INSERT NUMBER]**

1

APPENDIX C

2

STANDARD LICENSE CONDITIONS

Standard License Conditions

GENERAL INFORMATION

The recordkeeping requirements of certain license conditions 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 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 special conditions should be coordinated with the regional office or Office of Nuclear Material Safety and Safeguards (NMSS) before use. Items 6, 7, and 8 on the Materials License, including maximum possession limits, are provided as examples to encourage consistency between the regional offices. However, these items may be changed to reflect actual conditions under the license, without coordination with NMSS. This appendix lists the standard license conditions that existed when the current revision to NUREG-1556, Volume 20 was developed. **The Web-Based Licensing (WBL) system contains the most current standard license conditions.**

In addition, before issuing a license with nonstandard conditions, reviewers should coordinate with the inspection staff and licensees to ensure that all parties have the same understanding of all license conditions, especially any conditions unique to a particular licensee. The cover letter accompanying the licensing package should identify and bring to the licensee's attention any unique conditions on the license.

Following September 11, 2001, NRC issued security orders to require licensees to implement interim security measures. The interim security measures were also incorporated as conditions of the applicable licenses for public health and safety.

The regulations specified in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37 "Physical Protection of Byproduct 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. The requirements of 10 CFR Part 37 superseded the security orders, which will require removal of the interim security measures conditions, upon the next amendment or renewal of the license.

On January 27, 2010, NMSS recommended that license reviewers place maximum possession limits for radionuclides on some of the specific licenses (ADAMS Accession No. ML093510241). The maximum possession limits are not applicable for 10 CFR 35.100 and 35.200, 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 NRC or an Agreement State" without stating a maximum possession limit. The license reviewer should use, for example, "10 millicuries total 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.

License Condition Name in WBL	License Condition	Program Codes
Animals/Animal Products Not for Human Consumption	Experimental animals, or the products from experimental animals, that have been administered licensed material shall not be used for human consumption.	01100, 01110, 01120, 02110, 02400, 03610, 03611, 03612, 03613, 03620, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Authorized to Distribute, Specific Products	The licensee is authorized to distribute the following series of self-luminous [specify products (e.g., compasses and knives models, gunsights)] devices provided the amount of [hydrogen-3] does not exceed the amount specified in the following table: Device Model, Maximum Activity	03254
Cleaning, Maintenance, Repair of Gauges	Any cleaning, maintenance, or repair of the gauge(s) that requires detaching the source or source rod from the gauge shall be performed only by the manufacturer or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	03121
Contaminated Equipment	Except for calibration sources, reference standards, and radioactively contaminated equipment owned by the licensee, receipt, storage, and use incidental to any activity of licensed material at each temporary job site shall be limited to material originating from each site. This material must either be transferred to an authorized recipient or remain at the site after licensee activities are completed.	03219, 03234
Contamination in Tracer Studies Exempt	Pursuant to 10 CFR 32.11, and in accordance with the [application/letter] dated [insert date], the licensee is authorized to introduce byproduct material as contamination in tracer studies and to transfer ownership and possession of the product or material containing byproduct material to persons exempt from the requirements for a license provided in 10 CFR 30.14. The concentrations of byproduct material at the time of transfer shall not exceed the concentrations in 10 CFR 30.70 nor shall the product be likely to be incorporated in any food, beverage, cosmetic, or other commodity or product designed for ingestion or inhalation by, or application to, a human being. The concentrations at the boundary shall not exceed the limits in 10 CFR 20.1302. The licenses shall report such transfers in accordance with 10 CFR 32.12.	03250

License Condition Name in WBL	License Condition	Program Codes
Decay In-Storage (A)	Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.	01100, 01110, 01120, 02110, 02400, 02410, 02500, 02511, 02513, 02600, 03112, 03210, 03211, 03212, 03213, 03214, 03220, 03232, 03240, 03241, 03242, 03243, 03244, 03610, 03611, 03612, 03613, 03620, 03800, 03810, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Decay In-Storage (B)	A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.	01100, 01110, 01120, 02110, 02400, 02410, 02500, 02511, 02513, 02600, 03112, 03210, 03211, 03212, 03213, 03214, 03220, 03232, 03240, 03241, 03242, 03243, 03244, 03610, 03611, 03612, 03613, 03620, 03800, 03810, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623

License Condition Name in WBL	License Condition	Program Codes
Decay In-Storage (Header)	The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash provided:	01100, 01110, 01120, 02110, 02400, 02410, 02500, 02511, 02513, 02600, 03112, 03210, 03211, 03212, 03213, 03214, 03220, 03232, 03240, 03241, 03242, 03243, 03244, 03610, 03611, 03612, 03613, 03620, 03800, 03810, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Destructive Tests	The licensee shall not conduct destructive tests involving source material such that airborne radioactivity would be released to the unrestricted areas as defined in 10 CFR 20.1003.	11221
Device Components Not Related to Radiological Safety (A)	The licensee may maintain, repair, or replace device components that are not related to the radiological safety of the device containing licensed material and that do not result in the potential for any portion of the body to come into contact with the primary beam or result in increased radiation levels in accessible areas.	03120, 03130, 03214
Device Components Not Related to Radiological Safety (B)	The licensee may not maintain, repair, or replace any of the following device components: (i) the sealed source, (ii) the source holder, (iii) source drive mechanism, (iv) on-off mechanism (shutter), (v) shutter control, (vi) shielding, (viii) or any other component related to the radiological safety of the device, except as provided otherwise by specific condition of this license.	03120, 03130, 03214
Distribution 10 CFR 32.14	Pursuant to 10 CFR 32.14, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," the licensee is authorized to distribute byproduct material as contained in gas-filled display tubes to persons exempt from licensing pursuant to 10 CFR 30.15, or equivalent provisions of the regulations of any Agreement State.	03251

License Condition Name in WBL	License Condition	Program Codes
Distribution Device Info	Each device distributed pursuant to the conditions of this license shall be in accordance with the following table: Device model Number Isotope Source Model Number Maximum Activity Per Source	02513
Distribution Device Info	Each device distributed pursuant to the conditions of this license shall be in accordance with the following table: Device Model Number Isotope Source Model Number Maximum Activity Per Source	03240, 03241, 03242, 03243, 03244
Distribution Device Info, Not Exceeding Amounts Specified	The following products [if needed: manufactured in accordance with NRC Sealed Source and Device Registration No. (insert number)], may be distributed, provided the amount of [insert isotope] contained in the device does not exceed the amounts specified in the following table: Device/Series Model Maximum Activity per Device	03250, 03251, 03254, 03255
Distribution Location of Use	The licensee may distribute licensed material from its facilities located at <<!LicenseLocations!>>	03211, 03214, 03221, 03250, 03251, 03252, 03253, 03254, 03255, 03256, 03257, 11240
Distribution Locations	The licensee may distribute material from licensee's facilities located at <<!LicenseLocations!>>	02511, 02513, 03240, 03241, 03242, 03243, 03244, 03250, 03251, 03252, 03253, 03254, 03255, 03256, 03257, 11240
Distribution Product Info	Each product distributed under this license shall not contain, as of the assay date, more than the quantity of byproduct material listed in the following table: Byproduct Material Product Name Maximum Activity	02511, 03240, 03241, 03242, 03243, 03244
Distribution Source Info	Each sealed source distributed under this license shall not contain, as of the assay date, more than the quantity of byproduct material listed in the following table: Byproduct Material Model Number Chemical and/or Physical Form Maximum Activity	02513
Duties of the Teletherapy Physicist	Notwithstanding the requirements of 10 CFR 35.961, [insert name] may perform the duties of the teletherapy physicist for those full-calibration and spot-check measurements specified in 10 CFR Part 35.	02300, 02310

License Condition Name in WBL	License Condition	Program Codes
Emergency Action to Protect Public Health and Safety	If approved by a Radiation Safety Officer specifically identified in this license, the licensee may take reasonable action in an emergency that departs from conditions in this license when the action is immediately needed to protect public health and safety and no action consistent with all license conditions that can provide adequate or equivalent protection is immediately apparent. The licensee shall notify the U.S. Nuclear Regulatory Commission Headquarters Operations Center at 301-816-5100 and the U.S. Nuclear Regulatory Commission Regional contact before, if practicable, and in any case immediately after taking such emergency action using the reporting procedure specified in Appendix D of 10 CFR Part 20.	03219, 03234
Emergency Plan (A)	Obtain U.S. Nuclear Regulatory Commission approval of an evaluation demonstrating that an emergency plan is not required pursuant to 10 CFR [30.32(l), 40.31(j), and 70.22(l)], or	03219, 03234
Emergency Plan (B)	Submit written confirmation to the U.S. Nuclear Regulatory Commission, in accordance with Appendix D of 10 CFR part 20, that licensee personnel have been trained and will follow the provisions of an existing emergency plan approved by the U.S. Nuclear Regulatory Commission or an Agreement State for the temporary job site.	03219, 03234
Emergency Plan (Header)	Notwithstanding the requirements in 10 CFR [30.32(l), 40.31(j), and 70.22(l)], the licensee is not required to establish an emergency plan. Before taking possession of licensed material at a temporary job site in quantities requiring an emergency plan, the licensee shall either:	03219, 03234
Emergency Reasonable Action	If approved by a Radiation Safety Officer specifically identified in this license, the licensee may take reasonable action in an emergency that departs from conditions in this license when the action is immediately needed to protect public health and safety and no action consistent with all license conditions that can provide adequate or equivalent protection is immediately apparent. The licensee shall notify the U.S. Nuclear Regulatory Commission Headquarters Operations Center at 301-816-5100 and the U.S. Nuclear Regulatory Commission Regional contact before, if practicable, and in any case immediately after taking such emergency action using the reporting procedure specified in Appendix D of 10 CFR Part 20.	03234

License Condition Name in WBL	License Condition	Program Codes
Energy Compensation Source	The opening, repair, or modification of any Energy Compensation Source must be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	03111
Exempt from Independent Backup Access Control	Notwithstanding the requirements of 10 CFR 36.23(b), the licensee is exempt from having an independent backup access control to detect personnel entry while sources are exposed, based on the commitments described in the [letter/application] dated [insert date] .	03511, 03521
Exempt from Monitor Integrated with Personnel Access Door Locks	Notwithstanding the requirements of 10 CFR 36.23(c), the licensee is exempt from having the monitor integrated with personnel access door locks to prevent room access when radiation levels are high, based on the commitments described in the [letter/application] dated [insert date] .	03511, 03521
Exempt from Source Movement Control—10 CFR Part 36	Notwithstanding the requirements of 10 CFR 36.23(f), the licensee is exempt from having a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time, based on the commitments described in the [letter/application] dated [insert date] .	03511, 03521
Exempt from Visible and Audible Alarm—10 CFR Part 36	Notwithstanding the requirements of 10 CFR 36.23(d), the licensee is exempt from having a visible and audible alarm within the treatment area, based on the commitments described in the [letter/application] dated [insert date] .	03511, 03521
Exemption from Console Key Attached to Survey Meter—10 CFR Part 36	Notwithstanding the requirements of 10 CFR 36.31(a), the licensee is exempt from the requirement to have a console key attached to a portable survey meter by a chain or cable, and the door to the radiation room requires the same key, based on the commitments described in the [letter/application] dated [insert date] . The radiation room door key shall be attached to the portable survey meter.	03511, 03521
Exemption from Position Indicator Requirement for Source in Transit—10 CFR Part 36	Notwithstanding the requirements of 10 CFR 36.31(b), the licensee is exempt from the requirement to have a separate position indicator to indicate when the source is in transit, in accordance with the [letter/application] dated [insert date] .	03511

License Condition Name in WBL	License Condition	Program Codes
Exemption from Radiation Room Control Requirement— 10 CFR Part 36	Notwithstanding the requirements of 10 CFR 36.67(b)(2), the licensee is exempt from the requirement to have a control in the radiation room that must be activated prior to irradiation and that would not allow the source to be moved from the shielded position unless the door to the radiation room is locked within a preset time, based on the commitments described in the [letter/application] dated [insert date] .	03511, 03521
Exemptions from 10 CFR 36.27 (a) and (b)—10 CFR Part 36	Notwithstanding the requirements of 10 CFR 36.27(a) and (b), the licensee is exempt from [insert what is exempted], based on the commitments described in the [letter/application] dated [insert date] .	03511, 03521
Extended Time for Inspection/Servicing Teletherapy/Gamma Stereotactic Unit	Notwithstanding the requirements of 10 CFR 35.655, the licensee is authorized to extend until [insert date] the time interval for inspection and servicing of its [insert teletherapy unit or gamma stereotactic unit] .	02300, 02310
Field Station, Radiographic Installation, Temporary Job Sites (A)	Licensed material may be only at the licensee's facilities located at <<LicenseLocations!>> <<FieldStations!>> <<RadiographicInstallations!>>	03111, 03112, 03310, 03320, 03800, 03810
Field Station, Radiographic Installation, Temporary Job Sites (B)	Licensed material may be stored or used at the following: (i) Field Station(s): <<FieldStations!>>, (ii) Permanent radiographic installation(s): <<RadiographicInstallations!>>, (iii) Temporary job site(s): Anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.	03111, 03112, 03310, 03320, 03800, 03810
Financial Assurance Exempt for Sealed Source Exchanges	This licensee is exempt from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.	02300, 02310

License Condition Name in WBL	License Condition	Program Codes
Financial Assurance not required	[If needed] In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR [30.35(d) or 40.36(b) or 70.25(d)] for establishing decommissioning financial assurance.	01100, 01110, 01120, 02110, 03610, 03611, 03612, 03613, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Financial Assurance Required	In addition to the possession limits in Item 8, as specified in 10 CFR [30.35(d) or 40.36(b) or 70.25(d)], the licensee shall further restrict the possession of: (i) [unsealed byproduct material or unsealed special nuclear material] to quantities less than [10^4 or 10^5] of the applicable limits in Appendix B of 10 CFR Part 30, or (ii) readily dispersible source material to quantities less than or equal to 100 microcuries, or (iii) sealed byproduct material to quantities less than or equal to [10^{10} or 10^{12}] of the applicable limits in Appendix B of 10 CFR Part 30.	01100, 01110, 01120, 02110, 03610, 03611, 03612, 03613, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Gauge Mounting Requirements (A)	The gauge must be mounted in accordance with written instructions provided by the manufacturer.	03120, 03124, 03130, 03310
Gauge Mounting Requirements (B)	The gauge must be mounted in a location compatible with the Conditions of Normal Use and Limitations and/or Other Considerations of Use in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State.	03120, 03124, 03130, 03310
Gauge Mounting Requirements (C)	The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded.	03120, 03124, 03130, 03310
Gauge Mounting Requirements (D)	The gauge must be received in good conditions (e.g., the package was not damaged).	03120, 03124, 03130, 03310
Gauge Mounting Requirements (E)	The gauge must not require any modification to fit in the proposed location.	03120, 03124, 03130, 03310
Gauge Mounting Requirements (Footer)	Mounting does not include electrical connection, activation, or operation of the gauge. The source must remain fully shielded, and the gauge may not be used until it is installed and made operational by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such operations.	03120, 03124, 03130, 03310
Gauge Mounting Requirements (Header)	The licensee may initially mount a gauge, if permitted by the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State, and under the following conditions:	03120, 03124, 03130, 03310

License Condition Name in WBL	License Condition	Program Codes
Gauge Shutter Testing (A)	Each gauge shall be tested for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or at such longer intervals as specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or the equivalent regulations of an Agreement State.	03120, 03124, 03130, 03310
Gauge Shutter Testing (B)	Notwithstanding the periodic on-off mechanism (shutter) and indicator test, the requirement does not apply to gauges that are stored, not being used, and have the shutter lock mechanism in a locked position. The gauges exempted from this periodic test shall be tested before use. Records of test results shall be maintained for 3 years from the date of each test.	03120, 03124, 03130, 03310
Gemstones- Below the Exempt Concentrations	[If needed] The licensee shall evaluate any gemstones that the licensee has determined are below the exempt concentrations, and have subsequently been irradiated with an accelerator, using appropriate instrumentation and following appropriate procedures to ensure that any induced radionuclides do not exceed the concentration limits specified in 10 CFR 30.70, Schedule A, and the approved derived concentration limits for radionuclides not appearing in 10 CFR 30.70.	03250
Gemstones—Periodic Confirmatory Measurements	[If needed] The licensee shall not accept any material unless it is accompanied by documentation indicating that the material has been analyzed and found to contain less than exempt concentrations as specified in 10 CFR 30.14 and 30.70 and in accordance with NOTE 2 of 10 CFR 30.70. The licensee shall ensure that the measurement process was adequate to measure radioactivity below the exempt concentrations. The licensee shall perform periodic confirmatory measurements, as approved, of the material received to ensure the regulatory requirements are met.	03250
Gemstones—Requirements of 10 CFR 32.11	Notwithstanding the requirements of 10 CFR 32.11(c), the licensee may distribute processed (topaz and tourmaline, or other specific gemstones as covered by the application) for the purpose of being worn by human beings. These may contain radionuclides that do not appear in 10 CFR 30.70 at concentrations up to those specified in the application, applying NOTE 2 of 10 CFR 30.70.	03250

License Condition Name in WBL	License Condition	Program Codes
Incineration Disposal	Pursuant to 10 CFR 20.1302(c) and 10 CFR 20.2002, the licensee is authorized to dispose of licensed material by incineration [NOTE: add reference (i.e, as described in Attachment 11-1 to application dated Month, DD, YYYY)] , provided the gaseous effluent from incineration does not exceed the limits specified for air of Table II, in Appendix B of 10 CFR Part 20.	03235
Incinerator Ash/Disposal	Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1 through 83, except as identified below, as ordinary waste in a landfill, provided that the concentration of radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values of Table II, Column 2 in Appendix B of 10 CFR Part 20. For hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99, and thallium-204, the concentration can be no greater than one-tenth of the value of Table II, Column 2 in Appendix B of 10 CFR Part 20. If more than one radionuclide is present in the ash, the sum of fractions rule applies.	03235
Increased Controls	[NOTE: If needed, include] The licensee will comply with the requirements for “Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern” (IC) [Agencywide Documents Access and Management System (ADAMS) Accession No. ML053130364] as Attachment B to the “Order Imposing Increased Controls” (ADAMS Accession No. ML053130218) published in the Federal Register on December 1, 2005 (70 FR 72128); and with the “Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials” (Fingerprinting Order) (ADAMS Accession No. ML073230831) published in the Federal Register on December 13, 2007 (72 FR 70901). The licensee shall complete implementation of said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in “Table 1: Radionuclides of Concern” contained within the Fingerprinting Order. Notwithstanding any provisions of the Commission’s regulations to the contrary, all measures implemented or actions taken in response to these Orders shall be maintained until the Commission orders	03225, 03226

License Condition Name in WBL	License Condition	Program Codes
Increased Controls (Continued)	otherwise, or until the Commission explicitly modifies its regulations to reflect the increased controls and fingerprinting requirements, and states in modifying its regulations, that the revisions are to supersede these Orders. The licensee shall notify the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC, 20555, in writing, within 25 days after it has completed the requirements of this condition. In addition, licensee responses applicable to this license condition shall be marked as "Withhold from Public Disclosure under 10 CFR 2.390."	
Inspecting/Servicing Intravascular Brachytherapy Afterloader Device	The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed by the manufacturer or persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	02110, 02240
Irradiation and Distribution of Foods for Human Consumption	Irradiation and distribution of foods for human consumption shall be in accordance with the rules and regulations of the Food and Drug Administration and the U.S. Department of Agriculture.	03521
Irradiator Installation Survey	After installation of the irradiator and/or Cobalt-60 or Cesium-137 source(s) and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room.	03511, 03521
Irradiator Procedures	The procedures (contained in the manufacturer's instruction manual), for the irradiator authorized by this license, shall be followed, and a copy of the procedures shall be made available to each person using or having responsibility for the use of the device.	03510, 03511, 03520, 03521
Irradiator Requirements J.L. Shepherd Mark I/81-22 (A)	Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and	03510, 03520

License Condition Name in WBL	License Condition	Program Codes
Irradiator Requirements J.L. Shepherd Mark I/81-22 (B)	Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and	03510, 03520
Irradiator Requirements J.L. Shepherd Mark I/81-22 (C)	Have room monitors installed that will: (i) operate at all times when the irradiator is in use; and (ii) activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and (iii) detect an radiation leaking from the irradiator door; and (iv) be visible to the irradiator user when he is next to the irradiator; or	03510, 03520
Irradiator Requirements J.L. Shepherd Mark I/81-22 (D)	If a room monitor is not installed, have available a calibrated and operable survey meter that will be used to: (i) determine the radiation level at the irradiation door when the door is closed; and (ii) check for any increase in radiation levels each time the irradiator door is opened.	03510, 03520
Irradiator Requirements J.L. Shepherd Mark I/81-22 (E)	If abnormal radiation levels or any malfunctions of the irradiator are detected at any time, the licensee shall cease using the irradiator, restrict access to the area housing the irradiator, immediately notify the Radiation Safety Officer, and submit all reports required under 10 CFR Part 20, Part 21, or Part 30.	03510, 03520
Irradiator Requirements J.L. Shepherd Mark I/81-22 (F)	Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	03510, 03520
Irradiator Requirements J.L. Shepherd Mark I/81-22 (Header)	For each J.L. Shepherd and Associates, Mark I or Model 81-22, Cesium-137 irradiator installed and used, the licensee shall:	03510, 03520
Irradiator/Calibrator/HDR/etc. Installation Survey	After installation of the [irradiator/calibrator/HDR/etc.] and prior to the initiation of the [irradiator/calibration/medical program], a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the [irradiator/calibrator/HDR/etc.] room.	02110, 02120, 02230, 02240, 03221, 03222, 03225, 03226

License Condition Name in WBL	License Condition	Program Codes
Labeling	Except for maintaining labeling as required by 10 CFR Part 20, or Part 71, the licensee shall obtain authorization from the U.S. Nuclear Regulatory Commission before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective certificate of registration issued either by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or by an Agreement State.	02500, 03120, 03121, 03122, 03124, 03210, 03510, 03520
Labeling Requirements Tags (A)	Each sealed source containing licensed material to be used outside of a shielded exposure device shall have a durable, legible, and visible tag permanently attached by a durable ring. The tag shall be at least 1 inch square, shall bear a conventional radiation symbol prescribed in 10 CFR 20.1901(a), and a minimum of the following instructions: "DANGER-RADIOACTIVE MATERIAL," "DO NOT HANDLE" and "NOTIFY CIVIL AUTHORITIES IF FOUND."	03710
Labeling Source Holder/Tool	The licensee shall ensure that each source holder or tool containing radioactive material bears a durable and clearly visible label bearing the radiation symbol and the words "Caution, Radioactive Material." The label must be on the smallest component that contains the licensed material, which is transported as a separate piece of equipment.	03110, 03111
Leak Test Exemption (A)	Notwithstanding the periodic leak test required by 10 CFR 34.27(c)(1) and (e), the requirement does not apply to radiography sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before use or transfer to another person. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.	03310, 03320
Leak Test Exemption (B)	Sealed source authorized for use other than radiography shall be tested for leakage and shall be inventoried in accordance with 10 CFR 34.27 and 10 CFR 34.29.	03310, 03320
Leak Test Exemption (C)	This licensee is authorized to analyze leak test samples in accordance with the [application/letter] dated [insert date] .	03310, 03320

License Condition Name in WBL	License Condition	Program Codes
Licensee Shall Not Open/Remove Sources	[Insert: Sealed sources, Source rods, Foil sources, or Detector cells] containing licensed material shall not be opened [Insert: or sources removed from source holders or detached from source rods, or foil sources removed from detector cells] by the licensee, except as specifically authorized.	01100, 01110, 01120, 02110, 02120, 02230, 02231, 02240, 02400, 02500, 03120, 03121, 03122, 03124, 03130, 03210, 03211, 03219, 03220, 03221, 03222, 03225, 03234, 03310, 03320, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Location of Storage	Licensed material shall only be stored only at the licensee's facilities located at:	03111, 03112, 03310, 03320, 03800, 03810
Location of Use (used or stored only)	Licensed material may be used or stored only at the licensee's facilities located at: <<!LicenseLocations!>>	03120, 03122, 03124, 03210, 03211, 03510, 03511, 03520, 03521, 11200, 11210, 11220, 11221, 11230, 11300, 11900

License Condition Name in WBL	License Condition	Program Codes
Location of Use (used or stored)	Licensed material may be used or stored at the licensee's facilities located at:	01100, 01110, 01120, 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 02300, 02310, 02400, 02410, 02500, 02511, 02513, 02600, 02700, 02710, 03121, 03123, 03130, 03212, 03213, 03214, 03215, 03220, 03221, 03222, 03225, 03226, 03310, 03610, 03611, 03612, 03620, 03710, 03800, 03810, 04610, 04611, 04612, 04613, 04614, 04615, 04618, 04619, 04620, 04621, 04622, 04623, 11800, 11810, 22110, 22111, 22120, 22140, 22150, 22151, 22160, 22170, 22200, 23300, 23310
Location of Use and Temporary Job Sites	Licensed material may be used or stored only at the licensee's facilities located at <<LicenseLocations!>> and may be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate State regulatory agency.	03111, 03112, 03120, 03122, 03210, 03211, 03219, 03225, 03226, 03234, 03310, 03320, 03800, 03810, 11200, 11210, 11220, 11221, 11230, 11300, 11800, 11810, 11900

License Condition Name in WBL	License Condition	Program Codes
Location of Use and Users	Licensed material may be used at [insert MML: (i.e., United States Air Force)] facilities by: (1) [United States Air Force] personnel as authorized by permits issued by the [insert name of Radiation Safety Committee (i.e., National Radiation Safety Committee)] ; and (2) users who are not [insert MML: (i.e., United States Air Force)] personnel when such use is authorized by the [insert name of Radiation Safety Committee (i.e., National Radiation Safety Committee)] and is conducted in work spaces under the control of the [insert MML: (i.e., United States Air Force)] .	03614
Location of Use Off-Shore	Licensed Material may be used only at the licensee's facilities located at: [specify the Producer, Official Protraction Diagram Oil Field Name, Block Number, Gulf of Mexico (or Pacific Ocean), Platform OSC assigned number or latitude/longitude if the platform number has not been assigned or if the device is placed subsea.]	03110, 03111
Location of Use/Specific Address for Material	Licensed material listed in Subitem Nos. [insert subitem] through [insert subitem] may be used at the licensee's facilities located at <<LicenseLocations!>>.	01100, 01110, 01120, 02110, 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 02300, 02310, 02400, 02410, 02500, 02511, 02513, 02600, 02700, 02710, 03110, 03111, 03112, 03113, 03120, 03121, 03122, 03124, 03130, 03210, 03211, 03212, 03213, 03710, 04618, 04619, 04620, 04621, 04622, 04623, 11200, 11210, 11220, 11221, 11230, 11300, 11800, 11810, 11900

License Condition Name in WBL	License Condition	Program Codes
Location of Use/Specific Address for Material (2)	Licensed material listed in Subitem No. [insert subitem] may be used only at the licensee's facilities located at <<!LicenseLocations!>>.	01100, 01110, 01120, 02110, 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 02300, 02310, 02400, 02410, 02500, 02511, 02513, 02600, 02700, 02710, 03110, 03111, 03112, 03113, 03120, 03121, 03122, 03124, 03130, 03210, 03211, 03212, 03710, 04618, 04619, 04620, 04621, 04622, 04623, 11200, 11210, 11220, 11221, 11230, 11300, 11800, 11810, 11900
Locations of Use and Temporary Job Sites	Licensed material may be used or stored only at the licensee's facilities located at <<!LicenseLocations!>> and may be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.	03124
Loss of Contact with Nuclear-Powered Pacemaker Patient	The licensee shall report to the U.S. Nuclear Regulatory Commission, in accordance with Appendix D of 10 CFR Part 20, within 10 days after discovery of loss of contact with a nuclear-powered pacemaker patient.	22160

License Condition Name in WBL	License Condition	Program Codes
Maintenance, Repair, Cleaning, Replacement, and Disposal	Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	01120, 02110, 03123, 03124, 03211, 03610, 03611, 03612, 03620, 04610, 04611, 04612, 04613, 04614, 04615, 04622, 04623
Material Not for Use in Field Applications	The licensee shall not use licensed material in field applications where activity is released, except as provided otherwise by specific condition of this license.	01100, 01110, 01120, 02110, 03610, 03611, 03612, 03613, 03620, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Material Not for Use In/On Humans	The licensee shall not use the licensed material in or on humans. [NOTE: if needed, add the following: except as provided otherwise by specific condition of this license].	01100, 01110, 01120, 02400, 03240, 03241, 03242, 03243, 03244, 03610, 03611, 03612, 03613, 03620, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Maximum Radiation Levels	Pursuant to 10 CFR 20.1301(c) and in reliance on statements, procedures and representations made by the licensee in the [application/letter] dated [insert date] , the following maximum radiation levels are hereby authorized in the following unrestricted areas: Maximum Radiation Level Unrestricted Area	02120, 02230, 02240, 02300, 02310, 03120, 03210, 03310
Mobile Nuclear Medicine Activities	Licensed material incident to mobile nuclear medicine activities may be delivered to the licensee's mobile van located at temporary job sites when trained licensee personnel are present to receive the licensed material.	02220, 02231
Modifications to the Source Rack	The licensee is authorized to make modifications to the source rack, as requested in [application/letter] dated [insert date] . The licensee shall test the movement of the source rack for proper operation in accordance with 10 CFR 36.41(f) and (i) prior to source loading.	03521

License Condition Name in WBL	License Condition	Program Codes
No Distribution Authorized	This license does not authorize distribution to persons exempt from licensing.	02500
No Irradiator Repairs	The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.	03510, 03511, 03520, 03521
No Opening or Removal	Sealed sources or detector cells containing licensed material shall not be opened or the foil sources removed from the detector cell by the licensee.	03123
No Possession	This license does not authorize possession or use of licensed materials.	02511, 02513, 03240, 03241, 03242, 03243, 03244, 03250, 03251, 03252, 03253, 03254, 03255, 03256, 03257, 11240
No Possession at Customer Facility	The licensee does not take possession of the radioactive materials and/or sealed sources while at the customer' s facility [insert as needed—for example “except for analytical samples”] .	03219, 03226, 03234
No Temporary Job Sites Authorized	This license does not authorize the use of licensed material at temporary job sites for uses already specifically authorized by a customer's license. If a customer also holds a license issued by the U.S. Nuclear Regulatory Commission or an Agreement State, the licensee shall establish a written agreement between the licensee and the customer specifying which licensee activities shall be performed under the customer's license and supervision, and which licensee activities shall be performed under the licensee's supervision pursuant to this license. The agreement shall include a commitment by the licensee and the customer to ensure safety, and any commitments by the licensee to help the customer clean up the temporary job site if there is an accident. A copy of this agreement shall be included in the notification required by license condition [insert number] .	03219, 03234
Non-Commercial Distribution	This license does not authorize commercial distribution of licensed material.	03214, 03220, 03232, 03610, 03611, 04610, 04611, 04612, 04613

License Condition Name in WBL	License Condition	Program Codes
Non-Commercial Distribution 10 CFR Part 30	This license does not authorize commercial distribution to persons exempt from licensing pursuant to [insert applicable regulation, such as 10 CFR 30.19 or 10 CFR 30.14 through 30.21, inclusive] .	03214
Non-Commercial Distribution 10 CFR Part 31	This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or to persons exempt from licensing pursuant to [insert applicable regulation, such as 10 CFR 30.18] .	03214
Non-Commercial Distribution Pursuant to 10 CFR 31 and/or 32	This license does not authorize commercial distribution of licensed material pursuant to 10 CFR 32.72 or 10 CFR 32.74 to persons generally licensed pursuant to 10 CFR Part 31 or equivalent regulations of any Agreement State; or to persons exempt from licensing pursuant to 10 CFR 30.14 through 10 CFR 30.21 inclusive, or equivalent regulations of any Agreement State.	03210, 03214
Non-Routine Maintenance Allowed	The following services shall not be performed by the licensee: (i) installation, (ii) initial radiation surveys, (iii) relocation, (iv) removal from service, (v) dismantling, (vi) alignment, (vii) replacement, (viii) disposal of the sealed source, and (ix) nonroutine maintenance or repair of components related to the radiological safety of the gauge [i.e., the sealed source, the source holder, source drive mechanism, on-off mechanism (shutter), shutter control, shielding]. These services shall be performed only by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	03120, 03124, 03130, 03310
Non-Routine Maintenance Allowed (A)	[Insert the services authorized in this license, delete remaining: (i) Installation, (ii) initial radiation surveys, (iii) relocation, (iv) removal from service, (v) dismantling, (vi) alignment, (vii) replacement, (viii) disposal of the sealed source, and (ix) nonroutine maintenance or repair of components related to the radiological safety of the gauge] shall be performed only by [insert name(s)] , or other individuals who have completed the training specified in [insert application/letter] dated [insert date] , or by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	03120, 03124, 03130, 03310

License Condition Name in WBL	License Condition	Program Codes
Non-Routine Maintenance Allowed (B)	The following services shall not be performed by the licensee: [Insert which services are NOT authorized in this license, delete remaining:] Installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the sealed sources, and non-routine maintenance or repair of components related to the radiological safety of the gauge. These services shall be performed only by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	03120, 03124, 03130, 03310
Non-routine Maintenance of Gauges	The licensee may detach the source rod from the gauge(s) for the purpose of cleaning, maintenance, or repair of the gauge(s), in accordance with procedures outline in the [application/letter\dated] [insert date] .	03121
Not Authorized to Perform Source Changes	[THIS LICENSE CONDITION IS USED IF THE LICENSEE IS NOT AUTHORIZED TO PERFORM SOURCE CHANGES.] The licensee is not authorized to perform source changes in the exposure devices. These services shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such activities.	03310, 03320
Notification of Field Stations	[NOTE: Use this condition in a case-by-case basis, if applicable] The licensee shall notify the U.S. Nuclear Regulatory Commission, in accordance with Appendix D of 10 CFR Part 20, of any field stations established in non-Agreement States within 7 days of establishment.	03110, 03111, 03112, 03113
Notification of Transferring or Disposing of Depleted Uranium Shielding	The licensee shall inform the U.S. Nuclear Regulatory Commission, Regional Office, prior to transferring or disposing of depleted uranium shielding.	11200, 11210, 11220, 11221, 11230, 11300, 11800, 11810, 11900

License Condition Name in WBL	License Condition	Program Codes
Notification to NRC (A)	The licensee shall notify the U.S. Nuclear Regulatory Commission, in accordance with Appendix D of 10 CFR Part 20, in writing, at least 14 days before initiating activities under this license at a temporary job site, excluding routine packaging or repackaging for purposes of transporting and not requiring a job or site-specific work package, and characterization and/or final surveys where radioactive materials and/or radiation are not likely to be detected. This notification shall include: (1) The estimated type, quantity, and physical/chemical forms of licensed material to be used; (2) the specific site location; (3) a description of planned activities, including waste management and disposition; (4) the estimated start date and completion date for the job; and (5) the name and title of a point of contact for the job, including information on how to contact the individual.	03219, 03234
Notification to NRC (B)	Within 30 days of completing activities at each job site location, the licensee shall notify the U.S. Nuclear Regulatory Commission, in accordance with Appendix D of 10 CFR Part 20, in writing, of the temporary job site status and the disposition of any licensed material used.	03219, 03234
Nuclear-Powered Pacemakers	The physician(s) responsible for follow-up, explanation, and return of nuclear-powered pace makers to the manufacturer for proper disposal is/are <<AuthorizedUsersMDMO!>>:	22160
Operating Requirements	The licensee shall operate each device containing licensed material within the manufacturer's specified temperature and environmental limits, such that the shielding and shutter mechanism of the source holder are not compromised.	03120, 03124, 03130, 03310
Operating Temperature Control Mechanism (A)	[This LC is only applicable to Gas Chromatographs] Detector cells containing a titanium tritide foil or scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations from an Agreement State.	03123, 03610
Operating Temperature Control Mechanism (B)	[This LC is only applicable to Gas Chromatographs] When in use, detector cells containing a titanium tritide foil or scandium tritide foil shall be vented to the outside.	03123, 03610

License Condition Name in WBL	License Condition	Program Codes
Outdoor Target Area	The total amount of depleted uranium contained in spent munitions which may remain in the Outdoor Target Area under the authorization of this license shall not exceed [insert amount] kilograms. Records of inventory of material fired into and retrieved from the Outdoor Target Area shall be maintained.	11221
Ownership/Possession Written Approval	The licensee may not take ownership or possession of radioactive material(s) and/or source(s) originating from a client's site, without prior notification and written approval from the U.S. Nuclear Regulatory Commission.	03219, 03234
Packaging Waste	Prepackaged wastes containing licensed material may be possessed anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material; except prepackaged wastes containing special nuclear material, which may be picked up, received, and possessed anywhere in the United States.	03232
Patient Follow-Up Nuclear-Powered Pacemakers	The licensee shall continue patient follow-up and replacement procedures for the nuclear-powered pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear-powered pacemaker by return to the manufacturer shall be followed upon the death of the patient. If return of the explanted pacemaker by return to the manufacturer is not possible, explanted pacemakers may be disposed of in accordance with the commitments, representations, and procedures in the [letter/application] dated [insert date] .	22160
Periodic Reports	The licensee shall file periodic reports, as specified in 10 CFR 32.16 and 10 CFR 32.25(c).	03240, 03241, 03242, 03243, 03244, 03250, 03251, 03252, 03253, 03254, 03255, 03256, 03257, 11240

License Condition Name in WBL	License Condition	Program Codes
Pharmacist	Pharmacists, as defined in 10 CFR 35.2, designated in writing to work as authorized nuclear pharmacists by the licensee's Radiation Safety Committee, shall meet the requirements in 10 CFR 32.72(b)(2)(iii) or meet the training and experience criteria in 10 CFR 35.55 and 10 CFR 35.59, recentness of training. [Exceptions may be made on a case-by-case basis in accordance with procedures described in the letter(s) dated [insert date] . The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.	02500
Physical Inventory	The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 3 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.	01100, 01110, 01120, 02110, 02400, 02500, 02513, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03240, 03241, 03242, 03243, 03244, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623, 11200, 11210, 11220, 11221, 11230, 11300, 11800, 11810, 11900
Physical Inventory (A)	The licensee shall require permittees to conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under their respective permits.	03614
Physical Inventory (B)	The licensee shall require that permittees maintain records of physical inventories for 3 years from the date of each inventory. Records shall include the quantities and kinds of licensed material, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory.	03614

License Condition Name in WBL	License Condition	Program Codes
Portable Gauge Barriers	Each portable nuclear gauge shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The gauge or its container must be locked when in transport or storage, or when not under the direct surveillance of an authorized user.	03121
Possession for Broad Type B	If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, then the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.	01110, 03611, 04612, 04613, 04620, 04621
Possession for Broad Type C	If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, then the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.	01120, 03612, 04614, 04615, 04622, 04623
Possession Limit for Nuclear-Powered Pacemakers	The specified possession limit for nuclear-powered pacemakers includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.	22160
Program Changes to Procedures (A)	The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee, in accordance with established procedures prior to implementation.	01100, 02110, 03211, 03610, 04610, 04611, 04618, 04619
Program Changes to Procedures (B)	The revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.	01100, 02110, 03211, 03610, 04610, 04611, 04618, 04619
Program Changes to Procedures (C)	The licensee's staff is trained in the revised procedures prior to implementation.	01100, 02110, 03211, 03610, 04610, 04611, 04618, 04619
Program Changes to Procedures (D)	The licensee's audit program evaluates the effectiveness of the change and its implementation.	01100, 02110, 03211, 03610,

License Condition Name in WBL	License Condition	Program Codes
Program Changes to Procedures (D) (Continued)		04610, 04611, 04618, 04619
Program Changes to Procedures (Header)	Notwithstanding the requirements of License Condition [Insert Tie-Down Condition Number] , the licensee is authorized to make program changes and changes to procedures specifically identified in the [application/letter] dated [insert date] , which were previously approved by the U.S. Nuclear Regulatory Commission and incorporated into the license without prior Commission approval as long as:	01100, 02110, 03211, 03610, 04610, 04611, 04618, 04619
Proposed Changes in Packaging, Labeling, Shielding, Instructions	Any proposed changes in packaging, labeling, shielding, or instructions for use and storage shall be submitted for review to the U.S. Nuclear Regulatory Commission, in accordance with Appendix D of 10 CFR Part 20. The approval of the changes shall be received by the licensee prior to implementing any of the changes.	02511, 02513, 03240, 03241, 03242, 03243, 03244
Pulsed Neutron Generator Tool Not Energized	The pulsed neutron generator tool should not be energized before going down-hole to a depth of at least 200 feet or into a calibration tank.	03110, 03111
Pulsed Neutron Generator Tool Not Retracted	The pulsed neutron generator tool should not be retracted to the surface or from the calibration tank until sufficient time has allowed for activation products in the tool to decay in accordance with [application/letter] dated [insert date] .	03110, 03111
Radiation Safety Committee	Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the [Note: enter licensee's Radiation Safety Committee name] . The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.	01100, 03211, 03610, 03613, 04610, 04611, 04616, 04617, 04618, 04619
Radiation Safety Committee requests	[insert name of Radiation Safety Committee (i.e., National Radiation Safety Committee)] shall submit requests for approval to the U.S. Nuclear Regulatory Commission for exemptions from the Commission's regulations.	03614
Records for Decommissioning	The licensee shall maintain records of information important to decommissioning for each temporary job site, pursuant to 10 CFR 30.35(g), 40.36(f), and 70.25(g). The records shall be made available to the customer upon request. At the completion of activities at a temporary job site, the licensee shall transfer these records to the customer for retention.	03219, 03234

License Condition Name in WBL	License Condition	Program Codes
Redistribution of Alpha-, Beta-, or Photon-Emitting Radioactive Drugs	Notwithstanding the requirements of 10 CFR 32.72(c), the licensee may redistribute alpha-, beta-, or photon-emitting radioactive drugs, which have been initially distributed by another radiopharmaceutical supplier licensed pursuant to 10 CFR 32.72, without verifying the radioactivity of the dosage. The licensee must not manipulate the dosage, including the packaging and label.	02511
Registration Certificate Reference	The following device containing byproduct material designed and manufactured in accordance with NRC registration certificate Nos. [NR-xxxx-D-101-E and NR-xxxx-D- 101-E] , may be distributed according to this license, provided the amount of americium-241 contained in the device does not exceed the amount specified in the following table: Device Model, Maximum Quantity Per Device	03255
Registration Certificate Reference-Industrial Device	The following industrial device containing byproduct material designed and manufactured in accordance with NRC registration certificate No. [NR-xxxx-D-101-E] , for the purpose of [i.e., measuring qualitative or quantitative chemical composition], may be distributed according to this license provided the amount of [i.e., Nickel-63] contained in the device does not exceed the amount specified in the following table: Gas Chromatograph Model, Device Model, Maximum Quantity Per Device	03257
Registration Under 10 CFR 32.210	The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission, pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.	02110, 03211, 03610, 03611, 03612, 03620, 04610, 04611, 04612, 04613, 04614, 04615
Release of Field Stations	The licensee shall not vacate or release a field station or storage location for unrestricted use whose address is identified in Condition [insert condition number] , without prior U.S. Nuclear Regulatory Commission approval. Records as described in 10 CFR 30.36(j) shall be submitted to support the request for unrestricted use.	03110, 03111, 03112, 03113
Report of Nuclear-Powered Pacemaker Death or Issue	The licensee shall report to the U.S. Nuclear Regulatory Commission in accordance with Appendix D of 10 CFR Part 20, within 24 hours of occurrence, discovery of the death of any nuclear-powered pacemaker patient, and any adverse reaction and/or malfunction involving a pacemaker system, including the leads. A written report giving details of the adverse reaction and/or malfunction shall be submitted within 30 days.	22160

License Condition Name in WBL	License Condition	Program Codes
Requirements in 10 CFR 35.14 for MML (notifications)	Notwithstanding the requirements in 10 CFR 35.14 to notify the U.S. Nuclear Regulatory Commission, the [insert MML name: (i.e., United States Air Force, Department of Veterans, Navy)] medical use permittees are authorized to make the notification required in 10 CFR 35.14 to the [insert MML entity (i.e., Department of Veterans National Health Physics Program Director)] provided the appropriate requirements in 10 CFR 35.13 (b) and 35.14 are met].	03614
Requirements in 10 CFR 35.6 for MML (human research subjects)	[insert name of Radiation Safety Committee (i.e., National Radiation Safety Committee)] shall assure that all uses of byproduct material on human research subjects are authorized and performed in accordance with the requirements in 10 CFR 35.6.	03614
Restricted Possession for 10 CFR 30.72 for Emergency Plan	In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72, which require consideration of the need for an emergency plan for responding to a release of licensed material.	01100, 02110, 03211, 03212, 03213, 03214, 03219, 03232, 03234, 03610, 03611, 03613, 04610, 04611, 04612, 04613, 04616, 04617
Restriction of Irradiator Maintenance	The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	03510, 03511, 03520, 03521
Restriction of Irradiator Maintenance Exception	Except for the repair or maintenance operations described in [letter/application] dated [insert date] , the licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	03510, 03511, 03520, 03521
Retrieve, Receive and Dispose of Radioactive Waste	The licensee is authorized to retrieve, receive, and dispose of radioactive waste from its customers, limited to radiopharmacy-supplied syringes and vials and their contents.	02500

License Condition Name in WBL	License Condition	Program Codes
RSO	The Radiation Safety Officer (RSO) for this license is <<!RSOName!>>.	01100, 01110, 01120, 02110, 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 02300, 02310, 02400, 02410, 02500, 02511, 02513, 02600, 03110, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03212, 03213, 03214, 03215, 03219, 03220, 03221, 03222, 03225, 03226, 03232, 03235, 03236, 03240, 03241, 03242, 03243, 03244, 03310, 03320, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03620, 03710, 03800, 03810, 03900, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623, 11200, 11210, 11220, 11221, 11230, 11300, 11800, 11810, 11900, 22110, 22111, 22120, 22140, 22150, 22151, 22160, 22170, 22200, 23300, 23310

License Condition Name in WBL	License Condition	Program Codes
Sealed Source Leak Test (A)	Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.	01100, 01110, 01120, 02231, 02400, 02500, 02513, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03234, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03620, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Sealed Source Leak Test (B)	Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.	01100, 01110, 01120, 02231, 02400, 02500, 02513, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03234, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03620, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623

License Condition Name in WBL	License Condition	Program Codes
Sealed Source Leak Test (C)	Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.	01100, 01110, 01120, 02231, 02400, 02500, 02513, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03234, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03614, 03620, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Sealed Source Leak Test (D)	In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.	01100, 01110, 01120, 02231, 02400, 02500, 02513, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03234, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03614, 03620, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623

License Condition Name in WBL	License Condition	Program Codes
Sealed Source Leak Test (E)	Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.	01100, 01110, 01120, 02231, 02400, 02500, 02513, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03234, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03614, 03620, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Sealed Source Leak Test (F)	Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.	01100, 01110, 01120, 02231, 02400, 02500, 02513, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03234, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03614, 03620, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623

License Condition Name in WBL	License Condition	Program Codes
Sealed Source Leak Test (G)	The leak test shall be capable of detecting the presence of 185 becquerels [0.005 microcuries] of radioactive material on the test sample. If the test reveals the presence of 185 becquerels [0.005 microcuries] or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission, in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.	01100, 01110, 01120, 02231, 02400, 02500, 02513, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03234, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03614, 03620, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Sealed Source Leak Test (H) Authorized for Collection and Analysis	[THE LICENSE CONDITION IS USED IF THE LICENSEE IS AUTHORIZED TO COLLECT AND ANALYZE LEAK TEST SAMPLES] Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.	01100, 01110, 01120, 02231, 02400, 02500, 02513, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03234, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03614, 03620, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623

License Condition Name in WBL	License Condition	Program Codes
Sealed Source Leak Test (H) Not Authorized for Analysis	<p>[THIS LICENSE CONDITION IS USED IF THE LICENSEE IS NOT AUTHORIZED TO PERFORM LEAK TEST ANALYSIS.] Analysis of leak test samples and/or contamination shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is authorized to collect leak test samples but not perform the analysis.</p>	01100, 01110, 01120, 02231, 02400, 02500, 02513, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03234, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03614, 03620, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Sealed Source Leak Test (I)	Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.	01100, 01110, 01120, 02231, 02400, 02500, 02513, 03111, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03214, 03219, 03220, 03221, 03222, 03225, 03226, 03234, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03614, 03620, 03710, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623

License Condition Name in WBL	License Condition	Program Codes
Sealed Sources Inspection/Test Prior to Transfer	Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.	01100, 01110, 01120, 03210, 03212, 03213, 03214, 03610, 03611, 03612, 03613, 03620, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623
Sealed Sources Leak Test (A) for MML	The licensee shall require permittees to conduct leak tests of sealed sources and detector cells. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.	03614
Sealed Sources Leak Test (B) for MML	Notwithstanding Paragraph A of this Condition, sealed sources designated to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.	03614
Separate Keys for Personnel Lock and Barrier Entrance	Notwithstanding the requirements of 10 CFR 36.23(a), the licensee may use separate keys to operate the lock on the personnel entrance door or barrier and to move the sources in accordance with procedures described in the [letter/application] dated [insert date] .	03511, 03521
Shipment of Plutonium	Except for plutonium contained in a medical device designed for individual human application, no plutonium, regardless of form, shall be delivered to a carrier for shipment by air transport or transported in an aircraft by the licensee except in packages the design of which U.S. Nuclear Regulatory Commission has specifically approved for transport of plutonium by air.	22110, 22111, 22120, 22140, 22150, 22151, 22160, 22170, 22200, 23300, 23310

License Condition Name in WBL	License Condition	Program Codes
Shutter Locked	The licensee shall assure that the shutter mechanism of each device containing licensed material is locked in the closed position during periods when a portion of an individual's body may be subject to the direct radiation beam. The licensee shall review and modify, as appropriate, its "lock-out" procedures whenever a new device is obtained to incorporate the device manufacturer's recommendations.	03120, 03124, 03130, 03310
Source Retrieval	The licensee is authorized to conduct source retrieval activities, in accordance with [application/letter] dated [insert date] .	03310, 03320
Storage of Waste	Radioactive waste possessed under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the licensee's [application/letter] dated [insert date] .	01100, 01110, 02110, 03211, 03225, 03226, 03610, 03611, 03620, 04610, 04611, 04612, 04613, 04618, 04619, 04620, 04621
Supervision or Physical Presence of Individuals Designated by RSO	Licensed material shall only be used by, or under the supervision and in the physical presence of, individuals who have been designated in writing by the Radiation Safety Officer and have been trained (A) as specified in the [application/letter] dated [insert date] ; and (B) in accordance with the provisions of 10 CFR 34.43	03310, 03320
Supervision or Physical Presence of Name Listed	Licensed material shall only be used by, or under the supervision and in the physical presence of, [insert name(s)] .	03221, 03222, 03232, 03900, 22120
Supervision or Physical Presence of Trained Individuals	Licensed material shall only be used by, or under the supervision and in the physical presence of, individuals who have received the training described in the [application/letter] dated [insert date(s)] . The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.	03121, 22140
Survey After Installation	Prior to initial use and after installation, relocation, dismantling, alignment, or any other activity involving the source or removal of the shielding, the licensee shall assure that a radiological survey is performed to determine radiation levels in accessible areas around, above, and below the gauge with the shutter open. This survey shall be performed only by persons authorized to perform such services by the U.S. Nuclear Regulatory Commission or an Agreement State.	03120, 03124, 03130, 03310

License Condition Name in WBL	License Condition	Program Codes
Temporary Job Sites, Anywhere in the United States	Licensed material may be [used or stored] only at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.	03124, 03219, 03225, 03226, 03234
Temporary Job Sites, Specific Locations	Licensed material may be used or stored at the licensee's facilities located at: [insert address] Licensed material may be used at temporary job sites anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.	02220, 03120, 03121, 03123, 03211, 11200, 11210, 11220, 11221, 11230, 11300, 11800, 11810, 11900
Tiedown	Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.	01100, 01110, 01120, 02400, 02410, 02500, 02511, 02513, 02600, 02700, 02710, 03110, 03111, 03112, 03113, 03120, 03121, 03122, 03123, 03124, 03130, 03210, 03211, 03212, 03213, 03214, 03215, 03219, 03220, 03221, 03222, 03225, 03226, 03232, 03234, 03235, 03236, 03240,

License Condition Name in WBL	License Condition	Program Codes
Tiedown (Continued)		03241, 03242, 03243, 03244, 03250, 03251, 03252, 03253, 03254, 03255, 03256, 03257, 03310, 03320, 03510, 03511, 03520, 03521, 03610, 03611, 03612, 03613, 03620, 03710, 03800, 03810, 03900, 04610, 04611, 04612, 04613, 04614, 04615, 04616, 04617, 04618, 04619, 04620, 04621, 04622, 04623, 11200, 11210, 11220, 11221, 11230, 11240, 11300, 11800, 11810, 11900, 22110, 22111, 22120, 22140, 22150, 22151, 22160, 22170, 22200, 23300, 23310
Tiedown Allowing Licensee to Make Changes to Radiation Protection Program	Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted, in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program, as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.	02110, 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 02300, 02310

License Condition Name in WBL	License Condition	Program Codes
Tiedown Allowing Licensee to Make Changes to Radiation Protection Program MML	Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below [insert any disclaimers, if necessary (i.e., excluding VHA Directive 1105.1, VHA Handbook 1105.1, and the internal procedures listed in NHPP Internal Procedure No. 1, etc.)] . The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.	03614
Tiedown for 35.1000 Uses	[USE THIS TIE-DOWN LICENSE CONDITION IF THE LICENSEE IS APPROVED TO CHANGE/REVISE LICENSE COMMITMENTS FOR 35.1000 USE (IF NRC GUIDANCE IS UPDATED AT A LATER DATE)] Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted, in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program, as provided for in 10 CFR 35.26 and applicable guidance updates for 10 CFR 35.1000 uses. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.	02240
Transportation Public Roads	Except for vehicle maintenance, the licensee shall not move mobile nonintrusive inspection systems on public roads unless specific authorization is obtained from the U.S. Nuclear Regulatory Commission.	03130

License Condition Name in WBL	License Condition	Program Codes
Use by or Under Supervision of	Licensed material shall only be used by, or under the supervision of, [insert name(s)] .	02400, 02410, 02513, 03122, 03123, 03124, 03210, 03214, 03215, 03219, 03220, 03221, 03222, 03225, 03226, 03235, 03236, 03240, 03241, 03242, 03243, 03244, 03612, 03613, 03620, 03710, 03800, 03810, 03900, 04614, 04615, 04616, 04617, 11200, 11210, 11220, 11221, 11230, 11300, 11800, 11810, 11900, 22110, 22111, 22120, 22140, 22150, 22151, 22160, 22170, 22200, 23300, 23310
Use by or Under Supervision of—MML	Licensed material shall only be used by, or under the supervision of, {insert individuals designated by [insert name of Radiation Safety Committee (i.e., National Radiation Safety Committee)] }.	03614
Use by or Under Supervision of Trained Individuals	Licensed material shall only be used by, or under the supervision of, individuals who have received the training described in the [application/letter] dated [insert date] , and have been designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.	03120, 03122, 03130, 03220, 03225, 03226, 03234, 03710
Use by or Under Supervision of Trained Individuals and Physical Presence	Licensed material shall only be used by, or under the supervision and in the physical presence of, individuals who have received the training described in the [application/letter] dated [insert date] , and have been designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.	03510, 03511, 03520, 03521

License Condition Name in WBL	License Condition	Program Codes
Use of Licensed Material	[insert MML name (i.e., United States Air Force)] regulations, policies, and directives governing the use of licensed material must be consistent with the U.S. Nuclear Regulatory Commission's regulations.	03614
Use of Material	Licensed material shall only be used by, or under the supervision and in the physical presence of, individuals who have received the training described in the [application/letter] dated [insert date(s)] . The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.	03121
Use of Radioactive Markers for Subsurface Monitoring	Notwithstanding the requirement of 10 CFR 39.47, pursuant to 10 CFR 39.91, and in accordance with statements, representations, and procedures contained in [insert reference (i.e., the letters dated Month, DD, YYYY, Month, DD, YYYY, and Month, DD, YYYY)] , the licensee may use radioactive markers with activities of 100 microcuries or less of cobalt-60 and 50 microcuries or less of cesium-137 for subsurface monitoring in surface cased oil and/or gas wells, provided that a member of the public would not receive more than 100 millirems annually, in the event the sources ruptured.	03110, 03111
Use Under Supervision 10 CFR 32.72 (A)	A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4).	02500
Use Under Supervision 10 CFR 32.72 (B)	Authorized Nuclear Pharmacists: <<!NuclearPharmacists!>>	02500
Use Under Supervision 10 CFR 32.72 (C)	Authorized Users for Non-Medical Use: <<!NonMedicalUsers!>>	02500
Use Under Supervision 10 CFR 32.72 (header)	Licensed material shall only be used by, or under the supervision of:	02500
Use Under Supervision of RSO	Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.	01110, 03212, 03611, 04612, 04613, 04620, 04621
Use Under Supervision of RSO, Well Logging	Licensed material shall only be used by, or under the supervision and in the physical presence of the Radiation Safety Officer, or individuals who have been trained in accordance with the [application/letter] dated [insert date] . The licensee shall maintain records of individuals designated as logging supervisor(s) and logging assistant(s).	03110, 03111, 03112

License Condition Name in WBL	License Condition	Program Codes
Use Under Supervision Under 10 CFR 33.15(b)	Licensed material shall only be used by or under the supervision of individuals meeting the requirements stated in 10 CFR 33.15(b) for the materials and uses as indicated: <<!AuthorizedUsers!>>	03213, 03612, 04614, 04622, 04623
Use Under Supervision Under 10 CFR 33.15(b)	Licensed material shall only be used by or under the supervision of individuals meeting the requirements stated in 10 CFR 33.15(b) for the materials and uses as indicated: <<!AuthorizedUsers!>>	01120
Use Under Supervision Under 10 CFR 35.13 and 35.14 (A)	Individuals permitted to work as [insert either authorized users, authorized nuclear pharmacists, and/or authorized medical physicists, as appropriate] in accordance with 10 CFR 35.13 and 10 CFR 35.14.	02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 02300, 02310
Use Under Supervision Under 10 CFR 35.13 and 35.14 (B)	The following individuals are authorized users for the material and medical uses as indicated: <<!AuthorizedUsers!>> <<!AuthorizedUsersMDMO!>>	02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 02300, 02310
Use Under Supervision Under 10 CFR 35.13 and 35.14 (C)	The following individuals are authorized users for nonmedical uses as indicated: <<!AuthorizedUsers!>> <<!NonMedicalUsers!>>	02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 02300, 02310
Use Under Supervision Under 10 CFR 35.13 and 35.14 (D)	The following individuals are authorized medical physicists for the materials and uses as indicated: <<!AuthorizedUsers!>> <<!MedicalPhysicists!>>	02120, 02121, 02200, 02210, 02220, 02230, 02231, 02240, 02300, 02310
Use Under Supervision Under 10 CFR 35.13 and 35.14 (E)	[AS NEEDED] Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.	02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 02300, 02310
Use Under Supervision Under 10 CFR 35.13 and 35.14 (Header)	Licensed material shall only be used by, or under the supervision of:	02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 02300, 02310
Use Under Supervision Under 10 CFR 35.2 (A)	The use of licensed material in or on humans shall be by an authorized user, as defined in 10 CFR 35.2.	02110

License Condition Name in WBL	License Condition	Program Codes
Use Under Supervision Under 10 CFR 35.2 (B)	Individuals designated to work as [insert either authorized users, authorized nuclear pharmacists, or authorized medical physicists, as applicable] as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, and/or any U.S. Nuclear Regulatory Commission guidance established for 10 CFR 35.1000 uses, and shall be designated, in writing, by the licensee's Radiation Safety Committee.	02110
Use Under Supervision Under 10 CFR 35.2 (C)	Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.	02110
Use Under Supervision Under 10 CFR 35.2 (D)	[AS NEEDED] Licensed material [in item #] shall only be used by, or under the supervision of, individuals who have received the training described in the [application/letter] dated [insert date] , and have been designated in writing by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.	02110
Utilization Facility on Human Subjects	This license does not authorize the use of radiation from an NRC licensed utilization facility on human subjects.	03614
Watches Under 30.15 (A)	The timepieces, hands, and dials have been manufactured in accordance with the International Atomic Energy Agency, International Standards Organization, OECD Nuclear Energy Agency, American National Standards Institute or equivalent industry standard; and	03250
Watches Under 30.15 (B)	The amount of tritium on the timepieces, hands, and dials is not in excess of the maximum permissible amounts authorized in 10 CFR 30.15(a)(1).	03250
Watches Under 30.15 (Header)	Each lot of timepieces, hands, and dials received, containing tritium for distribution for use under 10 CFR 30.15, must be accompanied by a certificate which attests to the following:	03250
Well Logging Leak Test (A)	Notwithstanding the periodic leak test required by 10 CFR 39.35, the requirement does not apply to sources, except sources containing plutonium, that are stored and not being used. The sources exempted from this periodic test shall be tested for leakage before use or transfer to another person.	03110, 03111, 03112, 03113

License Condition Name in WBL	License Condition	Program Codes
Well Logging Leak Test (B)	Sealed sources authorized for use other than well logging shall be tested for leakage and shall be inventoried in accordance with 10 CFR 39.35 and 10 CFR 39.37.	03110, 03111, 03112, 03113
Well Logging Leak Test (C)	No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.	03110, 03111, 03112, 03113

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APPENDIX D

2

ROUTINE EXEMPTIONS

1 **Routine Exemptions**

2 **10 CFR 30.35(a)(1)**

Regions may grant exemptions to 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 Ge-68/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 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]**.”

1 **D.1 10 CFR PART 35**

2 **D.1.1 10 CFR 35.655(a)**

Regions may grant exemptions to the provision of 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 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.”

1 **D.2 10 CFR PART 36**

2 Although many provisions of 10 CFR Part 36 apply to converted teletherapy units, compliance with
3 certain applicable provisions of the rule may be impractical, and exemptions will be granted from
4 specific sections of 10 CFR Part 36, provided that the licensee requests and technically justifies the
5 exemption. The following are technical justifications and commitments acceptable for exemptions from
6 specific sections of 10 CFR Part 36.

7 **D.2.1 10 CFR 36.23(a)**

Regions may grant exemptions to 10 CFR 36.23(a), which states, in part, that, “The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources...”

Grant this exemption only when the licensee commits to have the operator present for the entire period of time that the key is in the control panel. For converted teletherapy units, the use of a single key or even several keys on a key-ring may be impractical. The key-switch on many control panels is a 3-position switch that controls electrical power to the teletherapy unit. The key can only be inserted/removed in the “off” position, and in this position the main power and control circuits are without electrical power. Power is required to move collimators, activate field lights, align system, etc. Requiring a single key would not allow the licensee to operate these powered systems.

The following license condition should be used:

“Notwithstanding the requirements of 10 CFR 36.23(a), the licensee may use separate keys to operate the lock on the personnel entrance door or barrier and to move the sources in accordance with procedures described in the letter/application dated **[insert date]**.”

D.2.2 10 CFR 36.23(b)

Regions may grant exemptions to 10 CFR 36.23(b), which states, in part, that, "...each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed..."

The Region may grant the licensee an exemption from this requirement, provided that the licensee has an electrical interlock system meeting all of the conditions specified in 10 CFR 35.615(b) on each entrance to the radiation room. Alterations of the electrical interlocks of the teletherapy unit to meet the requirements of 10 CFR 35.23(b) may cause the interlock system to function incorrectly. A working electrical interlock system on each entrance suffices to prevent personnel entry while the source is exposed. In addition, the licensee must commit to having an operator present during the entire irradiation who can visually observe the entrance and to having a radiation monitor that can be read prior to entering the radiation area.

The following license condition should be used:

"Notwithstanding the requirements of 10 CFR 36.23(b), the licensee is exempt from having an independent backup access control to detect personnel entry while sources are exposed, based on the commitments described in the letter/application dated **[insert date]**."

1 **D.2.3 10 CFR 36.23(c)**

Regions may grant exemptions to 10 CFR 36.23(c), which states, in part, that, “The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high...”

Alteration of the interlock system to meet this requirement could prevent entry to the treatment room to remove a patient in the event of a stuck source. The Region may grant the licensee an exemption from this requirement, provided that the licensee has an electrical interlock system that will retract the source upon opening access doors to the irradiation room and commits to its use. In addition, the licensee must commit to having an operator present and having a radiation monitor in the room.

The following license condition should be used:

“Notwithstanding the requirements of 10 CFR 36.23(c), the licensee is exempt from having the monitor integrated with personnel access door locks to prevent room access when radiation levels are high, based on the commitments described in the letter/application dated **[insert date]**.”

1 **D.2.4 10 CFR 36.23(d)**

Regions may grant exemptions to 10 CFR 36.23(d), which states, in part, that, "...the source control must automatically activate visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position..."

An acceptable justification is that an audible alarm within the treatment room may cause undue distress to the patients (human or animal). If the licensee commits to having a visual alarm provided on the outside of the treatment room and to having the operator visually check the room prior to starting treatments, the Regions may grant the licensee an exemption from this provision of the regulations.

The following license condition should be used:

"Notwithstanding the requirements of 10 CFR 36.23(d), the licensee is exempt from having a visible and audible alarm within the treatment area, based on the commitments described in the letter/application dated **[insert date]**."

1 **D.2.5 10 CFR 36.23(f)**

Regions may grant exemptions to 10 CFR 36.23(f), which states, in part, that, “Each radiation room at a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.”

Exemptions may be granted to licensees having teletherapy units that are being used for irradiation of materials only (non-human and non-animal use), provided the licensee commits to the operator visually verifying that the room is not occupied prior to closing the door, and that the converted teletherapy unit (irradiator) activates a visual and audible alarm in the teletherapy room for at least 15 seconds prior to moving the source from the shielded position. This visual and audible alarm must be interlocked with the teletherapy unit such that the source will not move to the exposed position until the visual and audible alarm has been activated and is finished alarming. The use of a visual and audible alarm in a patient treatment room may cause patient anxiety (human or animal). Object or material irradiation may be granted an exemption from 10 CFR 36.23(f) without the need to have a visual and audible alarm, if the licensee commits to having an operator visually verify that the room is not occupied prior to closing the door and if the licensee has a means of visual observation of the area, as required in 10 CFR 35.615(d). If the unit is not used for patients, then the visual and audible alarm described above is required.

The following license condition should be used:

“Notwithstanding the requirements of 10 CFR 36.23(f), the licensee is exempt from having a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time, based on the commitments described in the letter/application dated **[insert date]**.”

1 **D.2.6 10 CFR 36.27(a) and 10 CFR 36.27(b)**

Regions may grant exemptions to 10 CFR 36.27(a), which states, in part, that, “The sources must automatically become fully shielded if a fire is detected,” and 10 CFR 36.27(b), which states, “The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.”

The purpose of a fire extinguishing system is to prevent a fire from damaging the access control system or preventing the sources from being shielded. Most converted teletherapy units are designed to retract the source when the electrical power fails, as may occur during a fire. The licensee may be granted an exemption from these requirements by the Region, provided that the licensee commits to having smoke detectors, fire extinguishers, and a fire alarm at the site to detect and fight small fires, and to alert authorities of the fire; to have a means of measuring the radiation levels in the radiation room during an electrical failure; and to instruct the operators to retract the source prior to exiting for a fire involving major portions of the facility, provided this action does not jeopardize the operator’s safety.

The following license condition should be used:

“Notwithstanding the requirements of 10 CFR 36.27(a) and (b), the licensee is exempt from (as requested by licensee) based on the commitments described in the letter/application dated **[insert date]**.”

1 **D.2.7 10 CFR 36.31(a)**

Regions may grant exemptions to 10 CFR 36.31(a), which states, in part, that, “The key must be attached to a portable radiation survey meter by a chain or cable. . .The door to the radiation room must require the same key.”

Converted teletherapy units require that the source activation key be inserted in the console to provide power to the unit to activate field lights and align the head; therefore, the Region may grant the licensee an exemption from this requirement, provided that the licensee commits to having administrative controls in place to insure that personnel entering the radiation room use a portable survey meter to verify that the source has retracted. The licensee must also commit to attach the survey meter to the exposure room door key. This exemption refers specifically to converted teletherapy units that are now used as irradiators for non-medical purposes. When used for medical purposes, the key for the door and the teletherapy unit were **not** required to be the same because of the need to have access to the patient without having to first get the key from the unit. This exemption allows a teletherapy unit to be used as an irradiator under 10 CFR Part 36.

The following license condition should be used:

“Notwithstanding the requirements of 10 CFR 36.31(a), the licensee is exempt from the requirement to have the console key attached to a portable survey meter by a chain or cable and that the door to the radiation room require the same key, based on the commitments described in the letter/application dated **[insert date]**.” The radiation room door key must be attached to the portable survey meter.

1 **D.2.8 10 CFR 36.31(b)**

Regions may grant exemptions to 10 CFR 36.31(b), which states, in part, that, “The console of a panoramic irradiator must have a source position indicator that indicates . . . when they are in transit . . .”

In converted teletherapy units, the source is moved nearly instantaneously from the shielded to the exposed position. Most teletherapy units are designed with two indicator lights. The green light indicates the source is in the fully shielded position; the red light indicates the source is exposed. During transit, both lights are on, indicating that the source is in transit. To require that the licensee install an electronic system to indicate “in transit” for the period of time the source is in transit, less than a second, does not provide any additional protection. Illumination of both lights simultaneously accomplishes the same safety goal as an “in transit” indicator; therefore, the Region may grant this exemption, provided the licensee submits a description of its device indicators.

The following license condition should be used:

“Notwithstanding the requirements of 10 CFR 36.31(b), the licensee is exempt from the requirement to have a separate position indicator to indicate when the source is in transit, in accordance with letter/application dated **[insert date]**.”

1 **D.2.9 10 CFR 36.67(b)(2)**

Regions may grant exemptions to 10 CFR 36.67(b)(2), which states that a licensee must, “Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.”

Due to the risk of malfunction associated with alterations to the existing electrical interlocks of the teletherapy units required necessary to comply with this regulation and the licensee’s commitment to administratively control access to the room to meet the intent of this regulation, the Region may grant this an exemption if the licensee demonstrates that a retrofit to install such a control would not be possible with the teletherapy unit and if the licensee commits to the following:

- The operator will close the doors immediately upon completion of the visual inspection required by 10 CFR 36.67(b)(1).
- The operator will verify that each door has locked automatically before stepping to the control panel.

The following license condition should be used:

“Notwithstanding the requirements of 10 CFR 36.67(b)(2), the licensee is exempt from the requirement to have a control in the radiation room that must be activated prior to irradiation and that would not allow the source to be moved from the shielded position unless the door to the radiation room is locked within a present time, based on the commitments described in the letter/application dated **[insert date]**.”

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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 persons using byproduct materials, in accordance with 10 CFR 30.12, 10 CFR 40.11, and 10 CFR 70.11, when the prime contractor or subcontractor is performing work under their U.S. Department of Energy (DOE) at a location that is not considered a government-owned or controlled site.

The U.S. Nuclear Regulatory Commission (NRC) regulations in 10 CFR Parts 30, 40, and 70 describe exemptions to specified regulatory requirements to contractors under certain DOE and NRC contracts. For example, 10 CFR 30.12, which applies to persons using byproduct material, grants exemptions to provisions in Part 30 to certain DOE prime contractors or subcontractors to the extent that the contractor—under the prime contract—is involved in manufacturing, production, transfer, receipt, acquisition, owning, possessing, or using 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. [29 Fed. Reg. 14401 1964]¹

DOE or NRC contractors who do not satisfy the requirements described above will be exempt from the provisions under 10 CFR 30.12, 10 CFR 40.11, and 10 CFR 70.11 when the Commission determines (i) that the prime contractor or subcontractor is authorized by law; and (ii) 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 non-government-owned or controlled site is located in an Agreement State, the exemption process is set forth in a Commission Policy Statement². The NRC may issue case-by-case exemptions upon a joint determination with the Agreement State that the necessary findings have been made 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 States 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.

¹29 FR 14401 (1964)

²46 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 information contained in Attachment 1 “Application Form” for an exemption to the NRC. The exemption requester should 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 nongovernment owned or controlled site (not a DOE facility). If information is missing or the request is incomplete, the qualified regional license reviewer (hereafter to be referred to as license reviewer) should provide Attachment 1 to DOE as a Request for Additional Information 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 Division of Nuclear Materials Safety (DNMS) 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 Agreement State Programs Branch (ASPB)
 - The applicable RSAO if the activity will occur in an Agreement State
 - For a facility in NRC jurisdiction, the chief of the Materials Safety Licensing Branch (MSLB)
 - 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 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 that the exemption of the prime contractor or subcontractor is authorized by law. NMSS/MSST/ASPB or NMSS/MSST/MSLB point of contact (POC) and appropriate regional staff should be copied on the e-mail.

- 1 5. For a facility in an Agreement State jurisdiction, ASPB will
- 2 • Provide a POC from NMSS/MSST
- 3 • Inform NRC's Office of Nuclear Security and Incident Response (NSIR) and any other
- 4 office, as necessary
- 5 • Provide assistance to the Region and Agreement State, if needed
- 6 For a facility in an NRC jurisdiction, MSLB will
- 7 • Provide a POC from NMSS/MSST
- 8 • Inform NSIR and any other office, as necessary
- 9 • Provide assistance to the Region, if needed
- 10 6. The license reviewer will review the procedures in accordance with Attachment 2 "License
- 11 Reviewer Checklist." The reviewer should complete the License Reviewer Checklist, and,
- 12 review as necessary the relevant sections (e.g., operating and emergency procedures, leak
- 13 testing, and applicable security of radioactive material) of the appropriate NUREG-1556 series
- 14 (e.g., Volume 7) licensing guidance. Based on the review, the license reviewer will make a
- 15 determination whether the work thereunder provides reasonable assurance that the public
- 16 health and safety will be adequately maintained during the conduct of the activity.
- 17 7. The license reviewer will draft the Safety Evaluation (SE) and acceptance letter. The attached
- 18 draft SE and acceptance letter can be used as a template. If the request is similar to a previous
- 19 request, the license reviewer can use the previous SE as a template and update the SE with the
- 20 correct dates, location(s), contractor client(s), etc. The SE will serve to document whether there
- 21 is adequate assurance that the work thereunder can be accomplished without undue risk to the
- 22 public health and safety, and whether the exemption can be extended for the requested
- 23 work activity.
- 24 8. For a facility in Agreement State jurisdiction, once the license reviewer has their branch chief's
- 25 approval on the draft SE, the license reviewer will send the draft SE to the Agreement State with
- 26 a copy to the RSAOs. Typically, the Agreement State is provided 7 to 14 days to review the
- 27 request and will either request additional information from the DOE contractor or subcontractor
- 28 POC or inform the NRC that they have no objection to proceeding forward. If additional
- 29 information is needed, the Agreement State should request the information through the RSAO
- 30 and the NRC license reviewer will work with the DOE contractor to obtain the additional
- 31 information. Within 14 days, OGC should provide their decision regarding whether the activity is
- 32 authorized by law to the license reviewer. OGC's determination should be placed in ADAMS
- 33 and profiled as Non-Public; Official Use Only-Sensitive Internal Information (Management
- 34 Directive 3.4, Section A.7).
- 35 9. For a facility in an Agreement State jurisdiction, once the Agreement State Director has no
- 36 objection to the path forward and OGC acknowledged that the activity was authorized by law,
- 37 then the SE and acceptance letter should be reviewed by the regional DNMS Branch Chief or
- 38 by a qualified license reviewer. The DNMS Division Director will grant the approval, concur on
- 39 the SE, and sign the acceptance letter consistent with the delegation of authority.
- 40 For a facility in NRC jurisdiction, the SE and acceptance letter should be reviewed by the
- 41 regional DNMS Branch Chief or by a qualified license reviewer. The DNMS Division Director
- 42 will grant the approval, concur on the SE, and sign the acceptance letter consistent with their
- 43 delegation of authority.

- 1 10. After the proposed activity is completed, NMSS/MSST/MSLB or NMSS/MSST/ASPB POC will
2 enter the information in the DOE Exemptions SharePoint Tracking System. The NRC will keep
3 track of these requests in the Tracking System. The direct link to the tracking system is: [DOE](#)
4 [Exemptions Tracking System](#).

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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.

A request for withholding proprietary information from public disclosure should be reviewed in accordance with established regional instructions, which provide guidance to regional personnel on the review of a request to withhold proprietary information from public disclosure.

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 to 10 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)].

1

APPENDIX G

2

SAFETY CULTURE POLICY STATEMENT

Safety Culture

The safety culture policy statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011, and can be found at: <https://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf>. It is also posted in NRC's Agencywide Documents Access and Management System (ADAMS) Accession Number ML11146A047.

Safety Culture Policy Statement

The purpose of this Statement of Policy is to set forth the Commission's expectation that individuals and organizations establish and maintain a positive safety culture, commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees; certificate holders; permit holders; authorization holders; holders of quality assurance program approvals; vendors and suppliers of safety-related components; and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. The Commission encourages the Agreement States, Agreement State licensees, and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture, as articulated in this Statement of Policy.

Nuclear Safety Culture is defined as *the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment*. Individuals and organizations performing regulated activities bear the primary responsibility for safety and security. The performance of individuals and organizations can be monitored and trended and, therefore, may be used to determine compliance with requirements and commitments and may serve as an indicator of possible problem areas in an organization's safety culture. The NRC will not monitor or trend values. These will be the organization's responsibility as part of its safety-culture program.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal-conflict situations (e.g., production, schedule, and the cost of the effort versus safety). It should be noted that although the term "security" is not expressly included in the following traits, safety and security are the primary pillars of the NRC's regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

1 The following are traits of a positive safety culture:

- 2 (1) *Leadership Safety Values and Actions*—Leaders demonstrate a commitment to safety in
3 their decisions and behaviors;
- 4 (2) *Problem Identification and Resolution*—Issues potentially impacting safety are promptly
5 identified, fully evaluated, and promptly addressed and corrected, commensurate with
6 their significance;
- 7 (3) *Personal Accountability*—All individuals take personal responsibility for safety;
- 8 (4) *Work Processes*—The process of planning and controlling work activities is implemented
9 so that safety is maintained;
- 10 (5) *Continuous Learning*—Opportunities to learn about ways to ensure safety are sought out
11 and implemented;
- 12 (6) *Environment for Raising Concerns*—A safety conscious work environment is maintained
13 where personnel feel free to raise safety concerns without fear of retaliation, intimidation,
14 harassment, or discrimination;
- 15 (7) *Effective Safety Communication*—Communications maintain a focus on safety;
- 16 (8) *Respectful Work Environment*—Trust and respect permeate the organization; and
- 17 (9) *Questioning Attitude*—Individuals avoid complacency and continuously challenge
18 existing conditions and activities in order to identify discrepancies that might result in
19 error or inappropriate action.

20 There may be traits not included in this Statement of Policy that are also important in a positive
21 safety culture. It should be noted that these traits were not developed to be used for
22 inspection purposes.

23 It is the Commission's expectation that all individuals and organizations, performing or
24 overseeing regulated activities involving nuclear materials, should take the necessary steps to
25 promote a positive safety culture by fostering these traits as they apply to their organizational
26 environments. The Commission recognizes the diversity of these organizations and
27 acknowledges that some organizations have already spent significant time and resources in the
28 development of a positive safety culture. The Commission will take this into consideration as
29 the regulated community addresses the Statement of Policy.

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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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