

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About
Licenses of Broad Scope

Final Report

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Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Licenses of Broad Scope

Final Report

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ABSTRACT

This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses of broad scope. In particular, it describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

NUREG-1556, Volume 11, Revision 1, is not intended to be used alone. Because broad scope licensees may be involved in many different program areas (e.g., medicine, research and development, manufacturing and distribution), this document frequently refers the user to other relevant program-specific guidance documents in the NUREG-1556 series.

Paperwork Reduction Act Statement

This NUREG references information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0044, 3150-0014, 3150-0035, 3150-0017, 3150-0016, 3150-0001, 3150-0015, 3150-0007, 3150-0010, 3150-0158, 3150-0214, 3150-0130, 3150-0020, 3150-0021, 3150-0135, 3150-0009, 3150-0008, 3150-0123 and 3150-0120.

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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 11, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," is intended for use by applicants, licensees, and NRC staff. This revision provides a general update to the previous information contained in NUREG-1556, Volume 11, dated April 1999, to incorporate certain security requirements and other regulatory and policy changes that have been implemented since the last revision was published.

This report takes a risk-informed, performance-based approach to licensing the use of radioactive material under a broad scope authorization. A team composed of staff from NRC Headquarters, NRC regional offices, and Agreement States prepared this document, drawing on their collective experience in radiation safety in general and as specifically applied to users of radioactive material under a broad scope license.

NUREG-1556, Volume 11, Revision 1, is not a substitute for NRC or Agreement State regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable if applicants include a basis for the staff to make the determinations needed to issue or renew a license.

The comments received during the public comment period for NUREG-1556, Volume 11, Revision 1, were summarized and addressed in a document that can be located on the NRC's Agencywide Documents and Management System (ADAMS) under [ML15357A092](#). Access to ADAMS is available on the public Web site at: <http://www.nrc.gov/reading-rm/adams.html>. The comments received by NRC included general corrections, comments on training, and comments on safety culture.

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ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANSI	American National Standards Institute
bkg	background
Bq	becquerel
CFR	<i>Code of Federal Regulations</i>
Ci	curie
cm ²	square centimeter
cpm	counts per minute
DFP	decommissioning funding plan
DIS	decay-in-storage
DOT	U.S. Department of Transportation
dpm	disintegrations per minute
EA	environmental assessment
FA	financial assurance
FR	<i>Federal Register</i>
GBq	gigabecquerel
G-M	Geiger-Mueller
GPO	Government Printing Office
Gy	Gray
HAZMAT	hazardous materials
IAEA	International Atomic Energy Agency
IN	information notice
IP	inspection procedure
IROFS	items relied on for safety
ISG	Interim Staff Guidance
kBq	kilobecquerel
LLEA	Local law enforcement agency
LLW	low-level radioactive waste
LSA	low specific activity
LSC	liquid scintillation counting
MBq	megabecquerel
μCi	microcurie
μGy	microgray
μR	microrentgen
mCi	millicurie
MDA	minimum detectable activity
MDC	minimum detectable concentration
mGy	milligray
mrad	millirad
mrem	millirem
mSv	millisievert
ND	not detectable
NHPA	National Historic Preservation Act of 1966, as amended
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
N/A	not applicable

NRC	U.S. Nuclear Regulatory Commission
NSTS	National Source Tracking System
NSTTR	National Source Tracking Transaction Report
NVLAP	National Voluntary Laboratory Accreditation Program
OMB	Office of Management and Budget
PII	Personally Identifiable Information
PG	Policy and Guidance Directive
Q	quality factor
RG	regulatory guide
RIS	regulatory issue summary
RSC	radiation safety committee
RSO	radiation safety officer
SCO	surface contaminated objects
SSD	Sealed Source and Device [registration certificate]
SNM	special nuclear material
std	standard
Sv	sievert
TBq	terabecquerel
TEDE	total effective dose equivalent
U.S.C.	United States Code

1 PURPOSE OF REPORT

This NUREG provides guidance to an applicant applying for a broad scope license and also provides the U.S. Nuclear Regulatory Commission (NRC) staff with the criteria for evaluating such applications. This document uses the terms “byproduct material,” “licensed material,” and “radioactive material” interchangeably. Although the applicant for a limited scope license generally must submit to the NRC for review and approval the specific training and experience of each proposed user and the facilities and equipment available to support each proposed use, the applicant for a broad scope license normally must submit to the NRC for review and approval a description of the internal review process and criteria that will be used to approve users and uses. As opposed to limited scope licenses, which typically identify specific isotopes that may be possessed, the broad scope license typically authorizes the possession and use of a wide range of byproduct radioactive materials.

Because the NRC grants significant decision-making authority to broad scope licensees through the license, a broad scope license is not normally issued to a new licensee. An applicant for a broad scope license typically has several years of experience operating under a limited scope license and a good regulatory performance history. This document is intended to provide the additional guidance required by the experienced limited scope licensee to prepare an application for a broad scope license. Guidance related to specific program areas, which may not apply to all broad scope licensees, is not included in this document but can be found in other volumes of NUREG–1556, often referred to in this document as “the base NUREGs” or “the base documents,” or in guidance documents that have not yet undergone the consolidation process.

Applicants should have established limited scope licensed programs in accordance with the guidance described in the appropriate base NUREG(s) before they apply for a broad scope license. For example, applicants for a broad scope license that use byproduct material for research and development should review NUREG–1556, Volume 7, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers,” for guidance. Similarly, applicants for broad scope licenses that use byproduct material for medical purposes should review NUREG–1556, Volume 9, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.” A list of the currently available base NUREGs is included in the “Foreword” to this document.

Chapter 8, “Contents of an Application,” of this NUREG identifies the information needed to complete NRC Form 313, “Application for Materials License” (see Appendix A of this NUREG), for the use of byproduct material for licenses of broad scope. The Office of Management and Budget (OMB) has approved the information collection requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” and NRC Form 313 under OMB Clearance Nos. 3150-0017 and 3150-0120, respectively.

The format within this document for each item of technical information is as follows:

- Regulations—references the regulations applicable to the item
- Criteria—outlines the criteria used to evaluate the applicant’s response

- Discussion—provides additional information about the topic
- Response from Applicant—provides suggested response or responses, offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process

Notes and References are self-explanatory and may not be found for each item on NRC Form 313.

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11, as indicated on the form. Applicants should address those items on separate sheets of paper and submit them along with the completed NRC Form 313. For the convenience and streamlined handling of applications, Appendix B of this NUREG, “Suggested Format for Providing Information Requested in Items 5 through 11 of U.S. Nuclear Regulatory Commission Form 313,” may be used to provide supporting information. Appendices C through R of this NUREG contain additional information on various radiation safety topics.

In this document, “dose” or “radiation dose” means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE), as defined in 10 CFR Part 20, “Standards for Protection Against Radiation.” To describe units of radiation exposure or dose, rem and its International System of Units equivalent, sievert (Sv) (1 rem = 0.01 Sv), are used. This is done because 10 CFR Part 20 sets dose limits in terms of rem (Sv), rather than rad or roentgen. When the radioactive material emits beta and gamma rays, 1 roentgen is assumed to equal 1 rad, which is assumed to equal 1 rem. For alpha and neutron-emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from alpha particles and neutrons requires the use of an appropriate quality factor (Q) value. These Q values are used to convert absorbed dose (rad) to dose equivalent (rem). Tables 1004(b).1 and .2 in 10 CFR 20.1004, “Units of radiation dose,” address the Q values for alpha particles and neutrons.

Overview of Broad Scope Programs

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 33, “Specific Domestic Licenses of Broad Scope for Byproduct Material,” provides for three distinct categories of broad scope license (i.e., Type A, Type B, and Type C), which are defined in 10 CFR 33.11, “Types of Specific Licenses of Broad Scope.”

Type A licenses of broad scope are typically the largest licensed programs and encompass a broad range of uses. Type A broad scope licensees use a Radiation Safety Committee (RSC), radiation safety officer (RSO), and criteria developed and submitted by the licensee and approved by the NRC during the licensing process to review and approve all uses and users under the license. The requirements for issuance of a Type A broad scope license are described in 10 CFR 33.13, “Requirements for the Issuance of a Type A Specific License of Broad Scope.”

An applicant for a Type A broad scope license must establish administrative controls and provisions related to organization and management, procedures, recordkeeping, material

control, and accounting and management review necessary to ensure safe operations, including:

- establishment of an RSC
- appointment of a qualified RSO
- establishment of appropriate administrative procedures to ensure the following:
 - control of procurement and use of byproduct material
 - completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures
 - review, approval, and recording by the RSC of safety evaluations of proposed uses
- use of byproduct material only by, or under the direct supervision of, individuals approved by the licensee's RSC

Type B broad scope licensed programs are normally smaller and less diverse than Type A broad scope programs. Type B broad scope licensees use an RSO and criteria developed and submitted by the licensee and approved by the NRC during the licensing process to review and approve all uses and users under the license. Because the RSO reviews and approves all uses and users under the license, rather than a full RSC, as established for Type A broad scope programs, the types and quantities of byproduct material authorized by the Type B broad scope license are limited to those described in 10 CFR 33.11(b) and 10 CFR 33.100, "Schedule A," Column I. While the quantities of individual radionuclides described in Schedule A may be large, the "unity rule" further restricts total license possession limits (see Section 8.5.1, "Unsealed or Sealed Byproduct Material," of this NUREG volume for additional information on license possession limits and the unity rule). Generally, the scope of authorization for Type B licenses is limited to the experience and knowledge of the RSO. The requirements for issuance of a Type B broad scope license are described in 10 CFR 33.14, "Requirements for the Issuance of a Type B Specific License of Broad Scope."

An applicant for a Type B broad scope license must also establish administrative controls and provisions related to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to ensure safe operations, including:

- appointment of a qualified RSO
- establishment of appropriate administrative procedures to ensure the following:
 - control of procurement and use of byproduct material
 - completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures

- review, approval, and recording by the RSO of safety evaluations of proposed uses
- use of byproduct material only by, or under the direct supervision of, individuals approved by the licensee's RSO

Type C broad scope licensed programs typically are issued to institutions that do not require significant quantities of radioactive material but need the flexibility to possess a variety of different radioactive materials. Users of licensed material under these programs are approved by the licensee based on training and experience criteria described in 10 CFR 33.15(b). The types and quantities of byproduct material authorized by the Type C broad scope license are limited to those described in 10 CFR 33.11(c) and 10 CFR 33.100, Schedule A, Column II, again, considering the unity rule. The requirements for issuance of a Type C broad scope license are described in 10 CFR 33.15, "Requirements for the Issuance of a Type C Specific License of Broad Scope."

While 10 CFR 33.15 does not require Type C broad scope licensees to appoint an RSO, the licensee must establish administrative controls and provisions related to procurement of byproduct material, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations. This should include the appointment of someone responsible for the day-to-day operation of the radiation safety program, such as an RSO.

Except for activities specifically excluded from broad scope licenses by 10 CFR 33.17(a), a Type A broad scope license can include any licensed material the applicant needs and for which it qualifies. An application for a Type A broad scope license can include uses of source material and special nuclear material under the same program (e.g., laboratory-scale research and development or the use of uranium as shielding) as the byproduct material to be possessed under the provisions of 10 CFR 30.32(d). However, applicants should submit separate applications for the production of radioactive material in a cyclotron, or for the use of source and special nuclear materials for purposes not directly related to the use of byproduct material under the Type A broad scope license (e.g., use of source material in subcritical assemblies and special nuclear material in critical mass quantities).

In practice, 10 CFR Part 33 reduces the administrative burden for both licensees and the Commission without reducing the safety standards or lessening the licensing requirements for training, experience, facilities, and equipment. Both the NRC and the licensee benefit from the reduction in license amendments that might otherwise be needed to change authorized radionuclides, quantities, or names of individuals who may use, or supervise the use of, byproduct material.

Part 33 does not specifically permit a broad scope licensee to make other types of changes to the radiation program as described in the application, such as changing the dosimetry provider, without amendment of the license. However, the NRC has permitted broad scope licensees, on a case-by-case basis, to build in limited program flexibility during the licensing process.

For example, rather than requiring that the applicant identify the company that would provide personnel dosimetry, the broad scope licensee could specify that dosimetry would be provided by an organization holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology. The NRC will continue to allow licensees to build in this type of program flexibility.

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

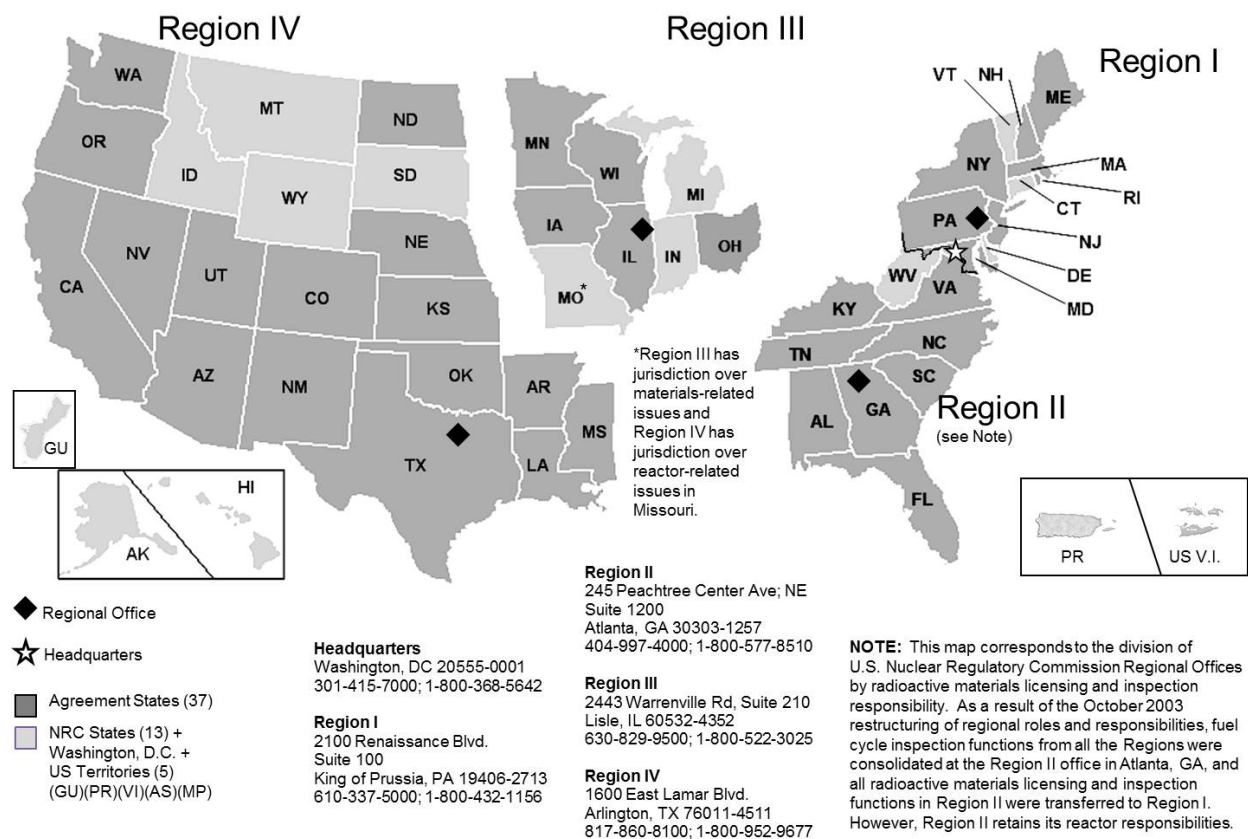


Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

In the special situation of work at federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement State has regulatory authority.

These areas can also include Tribal lands of federally recognized Indian Tribes.² The NRC has regulatory authority over land determined to be “exclusive Federal jurisdiction,” while the Agreement State may have jurisdiction over nonexclusive Federal jurisdiction land.

Applicants are responsible for determining, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. Additional guidance on determining jurisdictional status is found in the Office of Nuclear Material Safety and Safeguards (NMSS) procedures in the State Agreement series, SA-500, “Jurisdiction Determination,” which is available at <https://scp.nrc.gov>. Once on the Web site, use the link for “NMSS Procedures” in the left-hand column under “Resources & Tools.”

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

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with Title 10 of the <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
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

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 that wish to possess or use licensed material on Tribal lands should contact the appropriate NRC regional office to determine the jurisdictional status of the Tribal lands and identify the appropriate regulatory agency for licensing and reciprocity.

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.

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	Regulatory Agency
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 the NMSS public Web site, <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.

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

3 MANAGEMENT RESPONSIBILITY

The U.S. Nuclear Regulatory Commission (NRC) recognizes that effective radiation safety program management is vital to achieving safe, secure, and compliant operations. Consistent compliance with NRC regulations provides reasonable assurance that licensed activities will be conducted safely and that effective management will result in increased safety, security, and compliance.

“Management” as used in this volume refers to the processes for conduct and control of a radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

3.1 Commitments and Responsibilities

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 the 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 the behalf of the applicant or licensee. The signature on an application acknowledges the licensee’s commitments and responsibilities for the following:

- radiation safety, security and control of radioactive materials, and compliance with regulations
- completeness and accuracy of the radiation safety records and all information provided to the NRC (10 CFR 30.9, “Completeness and accuracy of information”)
- knowledge about the contents of the license and application
- compliance with current NRC and Department of Transportation regulations, the licensee’s operating, emergency, and security procedures, and NRC license commitments
- commitment to provide adequate resources (including space, equipment, personnel, time and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and compliance with regulations is maintained
- commitment to report defects, noncompliances, or reportable events in accordance with regulations
- selection and assignment of qualified individuals to serve on the radiation safety committee, if required, and to serve as radiation safety officer (RSO) for its licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities
- commitment to ensure that radiation workers have adequate training

- prevention of discrimination of employees engaged in protected activities and commitment to provide information to employees about employee protection provisions (10 CFR 30.7, 40.7, and 70.7, “Employee protection”)
- commitment to provide information to employees about deliberate misconduct provisions (10 CFR 30.10, 40.10, and 70.10, “Deliberate misconduct”)
- commitment to obtain NRC’s prior written consent before transferring control of the license (see Section 9.1, “Timely Notification of Transfer of Control,” of this NUREG)
- notification of the appropriate NRC regional administrator, in writing, immediately following the filing of petition for voluntary or involuntary bankruptcy [10 CFR 30.34(h), 40.41(f), and 70.32(a)(9)], as discussed further in Section 8.2.1, “Notification of Bankruptcy Proceedings,” of this NUREG

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of the NRC’s Enforcement Policy and Inspection Procedures available in the NRC’s online library, under “Document Collections,” at <http://www.nrc.gov/reading-rm.html>.

3.2 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 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 3-1 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 or may not be inherent to an organization's existing radiation safety practices and programs. For instance, laboratory facilities that perform iodinations require that air monitoring be performed of the effluents released through the stack. Developing and implementing procedures for monitoring effluent releases may correspond with the safety culture trait specified in Table 3-1 as "Work Processes" (the process of planning and controlling work activities is implemented so that safety is maintained). Another example would be that broad scope licensees are required to develop and implement an audit program. Development, implementation, and revision of an audit program to effectively and promptly address issues potentially impacting safety may correspond with the safety culture trait identified in Table 3-1 as "Problem Identification and Resolution." However, licensees should be aware that these are just examples, and should still consider reviewing their radiation safety programs in order to develop and implement a safety culture commensurate with the nature and complexity of their organizations and functions.

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

Table 3-1. 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 with a potential impact on 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

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of Title 10 of the *Code of Federal Regulations* (10 CFR) contain regulations applicable to the use of licensed material by broad scope licensees. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

The current versions of these parts can be found under the "Basic References" link at the U.S. Nuclear Regulatory Commission (NRC) online library at <http://www.nrc.gov/reading-rm.html>; for viewing in a browser, the following list includes direct links to the rules:

- [10 CFR Part 2](#) "Agency Rules of Practice and Procedure"
- [10 CFR Part 19](#) "Notices, Instructions and Reports to Workers: Inspection and Investigations"
- [10 CFR Part 20](#) "Standards for Protection Against Radiation"
- [10 CFR Part 21](#) "Reporting of Defects and Noncompliance"
- [10 CFR Part 30](#) "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- [10 CFR Part 33](#) "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- [10 CFR Part 37](#) "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- [10 CFR Part 51](#) "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"
- [10 CFR Part 71](#) "Packaging and Transportation of Radioactive Material"
- [10 CFR Part 170](#) "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"
- [10 CFR Part 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"

The following Parts of 10 CFR Chapter 1 contain regulations that, depending on the type or types of activities authorized by the license, may be applicable to the use of licensed material by broad scope licensees:

- [10 CFR Part 31](#) “General Domestic Licenses for Byproduct Material”
- [10 CFR Part 32](#) “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material”
- [10 CFR Part 34](#) “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations”
- [10 CFR Part 35](#) “Medical Use of Byproduct Material”
- [10 CFR Part 36](#) “Licenses and Radiation Safety Requirements for Irradiators”
- [10 CFR Part 39](#) “Licenses and Radiation Safety Requirements for Well Logging”
- [10 CFR Part 40](#) “Domestic Licensing of Source Material”
- [10 CFR Part 61](#) “Licensing Requirements for Land Disposal of Radioactive Waste”
- [10 CFR Part 70](#) “Domestic Licensing of Special Nuclear Material”
- [10 CFR Part 150](#) “Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274”

Copies of these documents may be obtained by calling the Government Publishing Office Customer Contact Center toll-free at 866-512-1800, in Washington, DC; calling 202-512-1800; or ordering online at <http://bookstore.gpo.gov>.

In addition, 10 CFR Parts 1 through 199 can be found on the NRC’s Web site at <http://www.nrc.gov/reading-rm/doc-collections/> under “Regulations (10 CFR).”

NRC regulations can also be accessed from the “NRC Library” link on the NRC’s public Web site at <http://www.nrc.gov>. Regulations are periodically amended, and the NRC (as well as all other Federal agencies) is required to publish notice of such amendments in the *Federal Register*.

5 HOW TO FILE

5.1 Application Preparation

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix A of this NUREG), Items 1 through 4, 12, and 13 on the form itself. A link to the form is available at <http://www.nrc.gov/reading-rm/doc-collections/forms/>.
- Complete NRC Form 313, Items 5 through 11, on supplementary pages or use Appendix B of this NUREG.
- Provide sufficient detail for the NRC to determine that the equipment, facilities, training, experience, and radiation safety program are adequate to protect health and safety and minimize danger to life and property.
- For each separate sheet other than NRC Form 313 and Appendix B pages, as applicable, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Avoid submitting proprietary information and personally identifiable information. If submitted, proprietary, personal privacy, security-related, and other sensitive information should be clearly identified according to Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, “Public inspections, exemptions, requests for withholding” (see Chapter 6, “Identifying and Protecting Sensitive Information”).

5.2 Where to File

Applicants wishing to possess or use licensed material in any State, U.S. territory, or U.S. possession subject to NRC jurisdiction must file an application with the NRC regional office for the locale in which the material will be possessed or used. Figure 2-1 identifies the NRC’s four regional offices and their respective areas for licensing purposes and the Agreement States. Note that all materials applications are submitted to Regions I, III, or IV. All applicants for materials licenses located in the Region II geographical area should send their applications to Region I.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State and not with the NRC. However, if work will be conducted at federally controlled sites, or federally recognized Indian Tribal lands, in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether the NRC or the Agreement State has regulatory authority. See Chapter 2, “Agreement States,” for additional information.

5.3 Paper Applications

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 8 ½ × 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).

Applications must be signed by the applicant, licensee, or a person duly authorized as required by 10 CFR 30.32(c) (see Section 8.13, "Certification").

5.4 Electronic Applications

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 <http://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.

6 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

All licensing applications, except for portions containing sensitive information, will be made available for review in the U.S. Nuclear Regulatory Commission (NRC) Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit www.nrc.gov.

The applicant or licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. License applications that contain sensitive information should be marked as indicated in the list that follows in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR 2.390) before the information is submitted to the NRC. Key examples are as follows:

- **Proprietary Information and Trade Secrets:** If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Appendix R of this NUREG provides a checklist for requests for withholding proprietary information from public disclosure.
- **Personally Identifiable Information:** Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" and "Information Notices," respectively: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.
- **Security-Related Information:** Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information and the top of every page of a document that contains such information should be clearly marked: "Security-Related Information—Withhold under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 22, 2005, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>. Additional

information on procedures and any updates is available at <http://www.nrc.gov/reading-rm/sensitive-info.html>.

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

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

In 10 CFR 2.390, NRC specifies the procedures and requirements for persons to submit sensitive information to NRC so that it may be properly protected from disclosure. This regulation is available electronically on the NRC Web site: <http://www.nrc.gov/reading-rm/doc-collections/cfr>.

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

If the request is denied, in whole or in part, NRC will give the applicant the option of withdrawing the information or application, as permitted in 10 CFR 2.390. If the applicant decides not to withdraw the information or application, NRC will notify the applicant in writing that the request for withholding has been denied and that NRC will disregard any references concerning the proprietary status of the information.

Any part of a license application or information provided by a licensee or applicant that the NRC determines should be withheld from public disclosure will be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program," and the licensee or applicant will be notified in writing that NRC plans to honor the request. Management Directive 12.6 is available electronically on the NRC Web site: <http://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.

7 APPLICATION AND LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to Title 10 of the *Code of Federal Regulations* (10 CFR) 170.31, "Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses," to determine the amount of the fee. The U.S. Nuclear Regulatory Commission (NRC) will not issue a license until the fee is received. Consult 10 CFR 170.11, "Exemptions," for information on exemptions from these fees. Once the technical review of an application has begun, no fees will be refunded. Application fees will be charged regardless of the NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16, "Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC." Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities." Note that in order to pay reduced fees, a licensee that qualifies as a "small entity" must provide proper certification of this status to the NRC each year along with its annual fee payment.

Direct all questions about the NRC's fees or completion of Item 12 of NRC Form 313 to the Office of the Chief Financial Officer at NRC Headquarters 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.

8 CONTENTS OF AN APPLICATION

The following information applies to the indicated items on U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix A of this NUREG).

All items in the application should be completed in enough detail for the NRC to determine whether the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect public health and safety and minimize danger to life and property. Consideration should be given, when developing the application, to the concepts of keeping exposure as low as is reasonably achievable (ALARA), minimizing contamination, and maintaining control of radioactive materials.

Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1101(b) states: "The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Regulatory Guide 8.10, Rev. 2, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," discusses the ALARA concept and philosophy. The application should document ALARA considerations, including establishing administrative action levels and monitoring programs.

10 CFR 20.1406, "Minimization of contamination," requires applicants for licenses to describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste. As with ALARA considerations, applicants should address these concerns for all aspects of their programs.

The application should include information on how the licensee will implement the security requirements in 10 CFR 20.1801, "Security of stored material," and 10 CFR 20.1802, "Control of material not in storage."

After an application for broad scope authority has been reviewed by the NRC staff and found to be generally complete and responsive to NRC Form 313 (Appendix A of this NUREG) and this guidance, a pre-licensing visit may be scheduled by the NRC at the licensee's facility. A visit or conference may also be scheduled as part of the license renewal process. A pre-licensing visit provides the NRC staff with an opportunity to better evaluate the proposed program and the necessity for a broad scope license. The pre-licensing visit also provides the NRC staff an opportunity to meet with licensee management and others responsible for the radiation protection program and stress the importance of their responsibilities under a broad license, as well as to discuss and agree on additional information and commitments that may be needed. If a broad license is not warranted, NRC staff may discuss the continuation of the program with an appropriate specific license.

Refer to Appendix P of this NUREG for guidance regarding the definition of construction and the consideration of activities that can be performed by materials license applicants and potential applicants and licensees before the NRC has concluded its environmental review of the proposed licensing action. The majority of materials licensing actions will meet the criteria in 10 CFR 51.22(c)(14) for a categorical exclusion. This means that the licensing action will not require an environmental assessment (EA) or environmental impact statement in accordance with 10 CFR 51.22(b), since the NRC has already determined that this type of licensing action does not have a significant impact on the environment. It is the applicant's responsibility to

review the guidance in Appendix P to determine whether the categorical exclusion applies to the licensing action.

All information submitted to the NRC during the licensing process may be incorporated as part of the license and will be subject to review during inspection.

8.1 **Item 1: License Action Type**

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

Type of Action	License No.
<input type="checkbox"/> A. New License	Not Applicable
<input type="checkbox"/> B. Amendment	XX-XXXXXX-XX
<input type="checkbox"/> C. Renewal	XX-XXXXXX-XX

Check Box A for a new license request. Note that a pre-licensing visit may be conducted prior to issuance of the license. Also note that an initial security inspection may be conducted in accordance with NRC Inspection Manual Chapter 2800, "Materials Inspection Program," before issuance of the license.

Check box B for an amendment to an existing license, and provide the license number.

Check box C for a renewal of an existing license, and provide the license number.

See "License Amendments and Renewals" in Chapter 9 of this NUREG.

8.2 **Item 2: Name and Mailing Address of Applicant**

List 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 may 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. Provide the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address.

Notify the NRC of changes in the mailing address. These changes do not require a fee.

Note: The NRC must be notified and the transfer approved before control of the license is transferred (see Section 9.1, "Timely Notification of Transfer of Control"). The NRC must also be notified when bankruptcy proceedings have been initiated (see Section 8.2.1, "Notification of Bankruptcy Proceedings").

8.2.1 **Notification of Bankruptcy Proceedings**

Regulation: 10 CFR 30.34(h), 10 CFR 40.41(f)(1), 10 CFR 70.32(a)(9)(i)

Criteria: Immediately following the filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the appropriate NRC regional administrator in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains subject to all applicable NRC regulatory requirements. The NRC must be notified when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). The NRC shares the results of its determinations with other involved entities (e.g., trustee), so that health and safety issues can be resolved before bankruptcy actions are completed and may request that the United States Department of Justice represent the NRC's interests in the bankruptcy proceeding.

Response from Applicant: None is required at the time of application for a new license. Licensees must immediately notify the NRC in writing following the filing of a voluntary or involuntary petition for bankruptcy by or against the licensee.

Reference: 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."

8.3 Item 3: Address(es) Where Licensed Material Will Be Used or Possessed

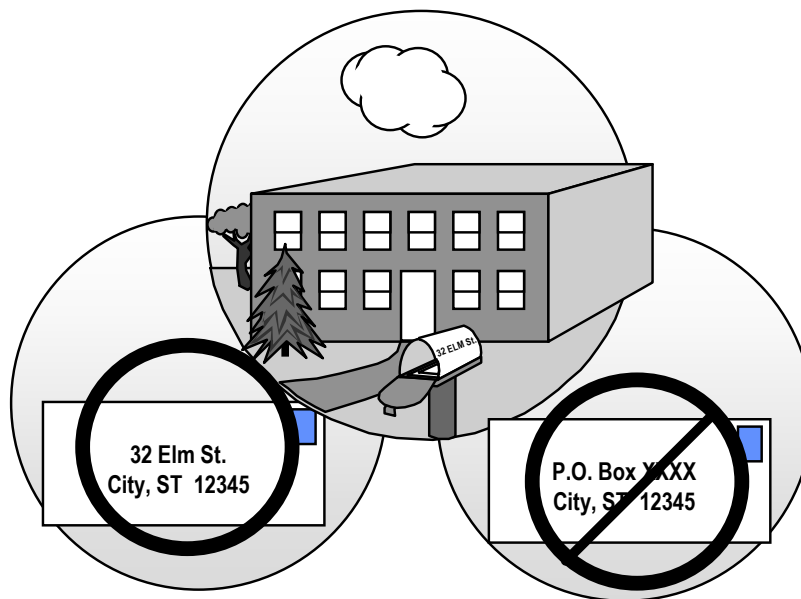
"Permanent Location"

With regard to areas where licensed materials are used or stored on a permanent basis, a "permanent location" may be:

- an individual building or facility at one address
- a contiguous, licensee-controlled geographic area, such as a campus or licensee-owned/operated/controlled business campus or park
- a designated area at sea or on board a ship if it is a permanent jobsite

Note: A temporary jobsite is not considered a "permanent location."

Specify 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) for each permanent location at which licensed material will be used or stored. Provide a list of activities to be conducted at each location. The descriptive address should be sufficient to allow an NRC inspector to find the permanent location. A post office box address is not acceptable. In addition, applicants are encouraged to provide global positioning system coordinates, as appropriate.



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An acceptable location of use or possession specifies street address, city, State, and zip code and does not include a post office box number.

Figure 8-1. Location of Use or Possession

If byproduct material is to be used at more than one permanent location, applicants should give the specific address of each location.¹ Applicants for a broad scope license need not identify each building or facility at a particular location. For example, applicants may specify that byproduct material will be used on the Main Campus of ABC University located in Anytown, State and at 123 First Street, Anothertown, State.

Applicants should identify the location of all facilities designed or established for special uses, e.g., panoramic irradiators, interim or long-term waste storage facilities, high activity laboratories, iodination facilities, alpha laboratories, incinerators, field studies and animal facilities.

If byproduct material (e.g., portable gauging devices, well logging tools and small quantities of sealed and unsealed material) will be used at temporary jobsites (i.e., areas where work is conducted for limited periods of time that may include uses at sea or on board a ship), the scope of these activities should be described and the address may be stated as “temporary jobsites anywhere in the U.S. where the NRC maintains jurisdiction.”

If byproduct material is to be used in field studies, the activities must be specifically identified and authorized on the license. Appendix C of this NUREG contains information required of applicants prior to granting authorization for field use of licensed material.

A license amendment is required before receiving, using, or storing licensed material at a permanent location not already listed on the license.

¹Exceptionally, large Federal licensees with more than 20 locations may generically request to use or store licensed material at any of their facilities instead of giving specific addresses for each location. Please note that such licensees must track their locations and that a list of these locations must be available during NRC inspections.

An NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements).

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.” See Chapter 6, “Identifying and Protecting Sensitive Information,” for more details.

Note: As discussed in Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning,” licensees must maintain permanent records describing where licensed material was used or stored while the license was in effect. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches, written descriptions of the specific locations, or room numbers where licensed material is used or stored and any records of spills or other unusual occurrences involving the possible spread of contamination in or around the licensee’s facilities.

8.4 Item 4: Person to be Contacted About This Application

Identify the individual who can answer questions about the application, and include a telephone number where the individual may be contacted as well as business cell phone numbers and e-mail addresses. This individual, usually the radiation safety officer (RSO), will serve as the point of contact during the review of the application. If this individual is not a full-time employee of the licensed entity, his or her position and relationship to the licensee should be specified. The NRC should be notified if the person assigned to this function changes or if his or her telephone number, cell phone number, or e-mail address changes. Notification of a contact change is only provided for informational purposes and would not be considered an application for license amendment, unless the notification involves a change in the contact person who is also the RSO.

As indicated on NRC Form 313 (see Appendix A of this NUREG), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix B of this NUREG for this purpose and should note that using the suggested wording of responses and committing to use the model procedures in this NUREG will facilitate the NRC’s review.

8.5 Item 5: Radioactive Material

8.5.1 Unsealed or Sealed Byproduct Material

Regulations: 10 CFR 30.32(d), 10 CFR 30.32(g), 10 CFR 30.32(i), 10 CFR 30.33(a), 10 CFR 30.72, 10 CFR 32.210, 10 CFR 33.11, 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15, 10 CFR 33.17, 10 CFR Part 37

Criteria: An application for a specific license will be approved if the requirements of 10 CFR 30.32; 10 CFR 30.33(a); 10 CFR 33.11; 10 CFR 33.12; 10 CFR 33.13; 10 CFR 33.14; 10 CFR 33.15, as appropriate; and 10 CFR 33.17 are met. Licensees must also protect aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5, from theft, diversion, and sabotage.

Discussion: Applicants for a Type A broad scope license typically request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the

maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. When establishing individual radionuclide and total cumulative quantities, all materials possessed under the license should be included (i.e., materials received awaiting use, materials in use/process, and those categorized as waste awaiting disposal). The maximum quantity for each individual radionuclide and total cumulative possession should be commensurate with the applicant's needs, facilities, procedures, and demonstrated experience/capability. If certain individual radionuclides will be needed in much larger quantities than described in the atomic number 1-83 request, they should be listed separately rather than increasing the possession limit for all radionuclides. Similarly, if applicants know that certain relatively more hazardous radionuclides (e.g., strontium-90) are needed only in smaller quantities, they should be listed separately.

If needed, an applicant for a Type A broad scope license may request authorization to possess byproduct materials with atomic numbers greater than 83 (e.g., atomic numbers 84 to 96). For this request, the applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides.

Note that authorization to possess byproduct materials with atomic numbers 84 through 96 does not authorize the possession of naturally occurring isotopes of uranium or thorium, or of plutonium because, even though these elements have atomic numbers within the range of 84 through 96, these materials are either source material or special nuclear material and not byproduct material. Licensees may request source material and special nuclear material when use of these materials is directly related to the use of byproduct material under the broad scope license (e.g., laboratory-scale research and development or the use of depleted uranium as shielding). Applicants should submit separate applications for the production of radioactive material in a cyclotron, or for the use of source material; and special nuclear materials for purposes not directly related to the use of byproduct material under the broad scope license (e.g., subcritical assemblies and critical mass quantities of special nuclear material).

A separate listing should also be submitted for sealed sources needed in quantities larger than that described in the atomic number 1-83 request (e.g., self-contained irradiators, instrument calibrators, sealed sources used for medical therapy, portable and non-portable gauging devices). Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that the NRC can verify that they have been evaluated in a Sealed Source and Device (SSD) registration certificate or provide the information requested by 10 CFR 30.32(g) to allow the NRC to conduct a case-by-case review. Sealed sources or devices containing sealed sources built to unique specifications of a given user (custom source) and that are intended for use solely under broad scope licenses, and are not transferred to another licensee, need not be evaluated by the NRC or Agreement State for registration if: (1) they contain less than 7.4 gigabecquerels (GBq) [200 millicurie (mCi)] of radioactive material or less than 740 GBq [20 curie (Ci)] of tritium, and (2) the licensee performs its own safety evaluation in accordance with the administrative procedures required by 10 CFR 33.13(c)(3)(ii) and 33.14(b)(2)(ii), as appropriate. Custom sources and devices which contain an activity greater than these values must be submitted to the NRC or Agreement State for evaluation and registration in accordance with the guidance provided in NUREG-1556, Volume 3. Table 8-1 provides a sample of how byproduct material should be requested.

Table 8-1. Sample Format for Providing Information About Requested Radioisotopes		
Byproduct material	Form	Amount
Any byproduct material with atomic numbers 3 through 83	Any	___ gigabecquerels (GBq) [millicuries (mCi)] per radionuclide and ___ GBq [curies (Ci)] total
Any byproduct material with atomic numbers 3 through 83 and a half-life less than or equal to 120 days	Any	___ GBq [mCi] per radionuclide and ___ GBq [Ci] total
Hydrogen 3	Any	___ GBq [Ci]
Carbon 14	Any	___ GBq [Ci]
Phosphorus 32	Any	___ GBq [mCi]
Sulfur 35	Any	___ GBq [mCi]
Nickel 63	Sealed sources (<i>insert manufacturer and model number</i>)	Not to exceed ___ GBq [mCi] per source and ___ GBq [mCi] total
Cobalt 60	Sealed sources (<i>insert manufacturer and model number</i>)	Not to exceed ___ GBq [mCi] per source and ___ GBq [mCi] total

Applicant and licensee information on manufacturers, model numbers, and possession limits is sensitive and should be marked accordingly (see Chapter 6, “Identifying and Protecting Sensitive Information”).

In most cases, the NRC or an Agreement State will perform a safety evaluation of sealed sources and devices before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in an SSD registration certificate. Paragraph (g) of 10 CFR 32.210 provides some exceptions to this requirement. For additional guidance related to sealed sources and devices, see NUREG–1556, Volume 3, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration.”

Possession requests should be categorized into: (1) general areas of use (e.g., research and development activities, teaching, training, animal studies, and environmental studies); and (2) special areas of use, (e.g., gauging activities, irradiators, instrument calibrators, and medical applications). See Section 8.6 for more details.

Applicants for Type A broad scope license should review the requirements for financial assurance (FA) and decommissioning before specifying possession limits for radionuclides with a half-life greater than 120 days. These requirements are discussed in Section 8.5.2 of this document.

Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in 10 CFR 33.100, Schedule A. The possession limit for a Type B broad scope license, if only one radionuclide is possessed, is the quantity specified for

that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows. For each radionuclide, determine the ratio of the quantity to be 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 may not exceed unity. The possession limit for a Type C broad scope license, if only one radionuclide is to be possessed, is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the sum of the ratios, determined in the same manner as discussed above, for all radionuclides possessed under the license may not exceed unity. This is sometimes referred to informally as the “unity rule” or the “rule of ratios.” Compliance with the unity rule and the Schedule A possession limits may be reviewed during inspection.

Type B and Type C broad scope applicants/licensees that require materials not specified in Schedule A should either: (1) develop Type A broad scope programs, or (2) carry these additional materials under a separate specific license of limited scope. For the latter option, the applicant should review the base NUREG related to the planned specific use of this material and submit the information needed by the license reviewer as described in that document. For example, applicants that require materials not specified in Schedule A for purposes of research and development should review NUREG–1556, Volume 7, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,” and submit the information described therein.

Type B licensees that require quantities of material in excess of that permitted by 10 CFR 33.11(b) should: (1) develop a Type A broad scope program and apply for a Type A license, or (2) apply for a separate specific license of limited scope for these additional quantities, as described in the previous paragraph. Type C licensees that require quantities of material in excess of that permitted by 10 CFR 33.11(c) should: (1) develop, as appropriate, a Type A or Type B broad scope program, and apply for such a license or (2) apply for a separate specific license of limited scope for these additional materials.

Applicants for Type B or Type C broad scope license may consider limiting their possession of isotopes described in Schedule A with half-lives greater than 120 days below that amount permitted by 10 CFR 33.11(b) or 33.11(c), respectively, to avoid being required to submit certification of FA or a decommissioning funding plan. See Section 8.5.2 of this document for a discussion of Financial Assurance and Recordkeeping for Decommissioning.

The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated “Category 1 quantity of radioactive material” or “Category 2 quantity of radioactive material.” These terms are defined in 10 CFR 37.5, and the radionuclides referenced in these 10 CFR 37.5 definitions are listed in Appendix A to 10 CFR Part 37. See Section 8.10.9, “Security Program for Category 1 and Category 2 Radioactive Material,” of this NUREG for more information on the applicability and requirements of 10 CFR Part 37.

Response from Applicant: Applicants for a Type A broad scope license should request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. The applicant should separately list individual radionuclides needed in much larger quantities or in much smaller quantities than that described in the atomic number 1 through 83 request. The maximum quantities of nuclides with atomic numbers above 83 also should be listed separately. A separate listing should also be submitted for sealed sources needed in larger quantities than that described in the atomic number 1

through 83 request. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that the NRC can verify that they have been evaluated in a SSD registration certificate or specifically approved on a license. Applicants must also provide the maximum activity per source and the total possession limit. For sources and devices not registered, as allowed by 10 CFR 32.210(g)(2), the applicant must have adequate training and experience and facilities and equipment to handle comparable quantities of material in any form under 10 CFR 30.33(a)(2) and (3) and must provide information about the unregistered sealed sources and devices in accordance with 10 CFR 30.32(g)(4).

Possession requests should be categorized into general areas of use (e.g., research and development activities, routine gauging activities, self-shielded irradiators, instrument calibrators, and medical applications).

In accordance with 10 CFR 30.32(i), applications to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities listed in 10 CFR 30.72 must include either of the following:

- an evaluation showing that the maximum offsite dose caused by a release of radioactive materials would not exceed 0.01 sievert (Sv) [1 rem] effective dose equivalent or 0.05 Sv [5 rem] to the thyroid; or
- an emergency plan for responding to the release of radioactive material in accordance with the criteria listed in 10 CFR 30.32(i)(3)

Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in 10 CFR 33.100, Schedule A. Type B applicants should request the quantity of material specified in 10 CFR 33.11(b). Type C applicants should request the quantity of material specified in 10 CFR 33.11(c).

8.5.2 Financial Assurance and Recordkeeping for Decommissioning

Regulations: 10 CFR 30.32(h), 10 CFR 30.34(b), 10 CFR 30.35, 10 CFR 30.36(e), 10 CFR 30.36(g)(4)(v), 10 CFR 30.51, 10 CFR 40.31(i), 10 CFR 40.36, 10 CFR 40.42(e), 10 CFR 40.42(g)(4)(v), 10 CFR 40.46, 10 CFR 40.61, 10 CFR 70.22(a)(9), 10 CFR 70.25, 10 CFR 70.36, 10 CFR 70.38(e), 10 CFR 70.38(g)(4)(v), 10 CFR 70.51

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25—all titled “Financial assurance and recordkeeping for decommissioning”—must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (FA) for decommissioning.

All licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site, or any area, is released for unrestricted use.

Before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and/or 10 CFR 70.36, licensees must transfer records important to decommissioning to the new proposed licensee in accordance with 10 CFR 30.35(g), 10 CFR 40.36(f) and/or 10 CFR 70.51(b)(3), respectively. Furthermore, before a license is terminated, the licensee must send records important to decommissioning that are required by 10 CFR 30.35(g), 10 CFR 40.36(f) and/or 10 CFR 70.25(g) to the appropriate NRC regional

office in accordance with 10 CFR 30.51(f), 10 CFR 40.61(f), and/or 10 CFR 70.51(a)(3), respectively.

Discussion: The NRC seeks to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. There are two parts to the rule: financial assurance, which applies to some licensees, and recordkeeping, which applies to all licensees.

Financial Assurance

NRC decommissioning FA regulations are designed to provide reasonable assurance that the decommissioning of licensed facilities will be accomplished in a safe and timely manner and that licensees will provide adequate funds to cover all costs associated with decommissioning. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee that funds will be available. Applicants are required to provide FA when the possession of radioactive material of half-life greater than 120 days exceeds certain limits. Criteria for determining if an applicant is required to submit a DFP or has an option of submitting either a DFP or a certification of FA are stated in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25. A DFP contains a site-specific cost estimate and a certification of FA. A certification of financial assurance includes a certification that the licensee has provided the required FA and an acceptable FA instrument.

Acceptable FA includes prepayment option of a trust fund; surety, insurance, or other guarantee methods (letters of credit, surety bonds, parent company guarantees, insurance policies), and statements of intent from Government entities. Criteria for parent company guarantees and self-guarantees can be found in 10 CFR Part 30, Appendix A, Appendix C, Appendix D, and Appendix E.

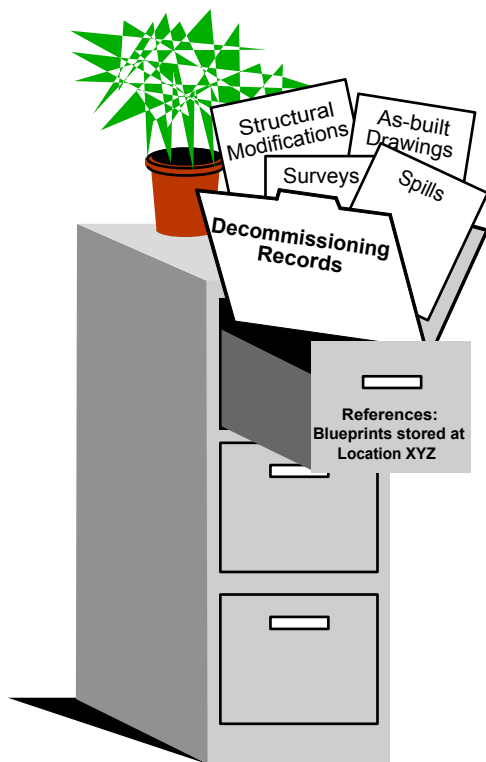
NUREG-1757, Volume 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness" (NUREG-1757, Vol. 3), provides guidance acceptable to the NRC staff on the information to be provided for establishing FA for decommissioning and a standard format for presenting the information. Note that FA is required for four types of licensed materials: unsealed byproduct material, sealed byproduct material, dispersible source material, and unsealed special nuclear material. The total amount of FA required to be provided is the sum of the FA required for each of these types of materials.

Recordkeeping for Decommissioning

The following regulations state the requirements for maintaining records important to decommissioning: 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g). All licensees are required to maintain these records in an identified location until the site is released for unrestricted use. Careful recordkeeping of radionuclides used, including form, amount, and area used, will facilitate area release and license termination. In the event that the licensed activities are transferred to another person or entity, these records must be transferred to the new licensee before the transfer of the licensed activities takes place.

In accordance with 10 CFR 30.35(g) and corresponding requirements in Parts 40 and 70, licensees must transfer records important to decommissioning to the new licensee before licensed activities are transferred or assigned according to 10 CFR 30.34(b) and corresponding requirements in Parts 40 and 70.

Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and/or 10 CFR 70.51(a)(3), prior to license termination, each licensee must forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f) and/or 10 CFR 70.25(g), respectively, to the appropriate NRC regional office.



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Figure 8-2. Types of Records That Must be Maintained for Decommissioning

Response from Applicant:

- State the following: “Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g) and 10 CFR 70.51(b)(3), we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and/or 10 CFR 70.36. Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and /or 10 CFR 70.51(a)(3), prior to license termination, we will forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g) to the appropriate NRC Regional Office.”

AND

- If financial assurance is required, submit evidence of financial assurance following the guidance of NUREG–1757, Volume 3, “Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness.”

8.5.3 Emergency Plan

Regulations: 10 CFR 30.32(i); 10 CFR 30.72

Criteria: Applicants who will be authorized to possess radioactive material in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities listed in 10 CFR 30.72 must be prepared for the potential release of radioactive material.

Discussion: When requesting authorization for possession limits in excess of the quantities listed in Schedule C of 10 CFR 30.72, the applicant must provide in conjunction with the license application either:

- an evaluation showing that the maximum offsite dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv [5 rem] to the thyroid; or
- an emergency plan for responding to the release of radioactive material in accordance with the criteria listed in 10 CFR 30.32(i)(3).

For NRC to grant authorization to possess quantities equal to the activities specified in Schedule C of 10 CFR 30.72, it is necessary to provide the information outlined in 10 CFR 30.32(i) sufficient to evaluate the need for an emergency plan.

Response from Applicant: If an emergency plan is required, provide either:

- an evaluation showing that the maximum offsite dose due to a release of radioactive materials would not exceed 0.01 Sv [1 rem] effective dose equivalent or 0.05 Sv [5 rem] to the thyroid; or
- an emergency response plan for responding to the release of radioactive material in accordance with the criteria listed in 10 CFR 30.32(i)(3).

References:

- Regulatory Guide 3.67, Rev. 1, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities."

8.6 Item 6: Purpose(s) for Which Licensed Material Will Be Used

Regulations, 10 CFR 30.32(d), 10 CFR 30.33(a)(1), 10 CFR 33.13, 10 CFR 33.14, or 10 CFR 33.15, as appropriate, 10 CFR 33.17(a)

Criteria: An application for a license will be approved if the proposed activity is authorized by the Atomic Energy Act of 1954, as amended. Sealed sources and devices containing licensed material must be used only for the purpose for which they are designed and according to the manufacturer's and distributor's instructions and recommendations for use, as specified in the SSD registration certificate, unless otherwise authorized in the license. Certain types of sealed sources and devices containing licensed material that are intended for use solely under broad scope licenses, and that will not be transferred to another licensee, need not be evaluated by the NRC prior to use if the licensee is authorized to possess the requested quantity of radioactive material in unsealed form and has administrative controls and provisions established for ensuring safety in accordance with 10 CFR 33.13, 10 CFR 33.14, or 10 CFR 33.15, as

appropriate. Additional licensing guidance for the possession and use of certain types of sealed sources and devices that are not required to have an SSD registration certificate is provided in Chapter 5 of NUREG–1556, Volume 3, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration.”

Note: Applicants desiring certain radionuclide activities and type of uses disallowed by 10 CFR 33.17(a) should apply for specific authorization. Refer to the “Discussion” section for further explanation.

Discussion: The applicant should describe in general terms the purposes for which the licensed material will be used. New applicants should describe why a broad scope license is needed rather than amendments to an existing limited scope license. The uses should be consistent with prior licensed activities. Sufficient information should be provided to enable the reviewer to have a clear understanding of each use and to determine the potential for exposure of workers and members of the public to radiation and radioactive materials. The information provided regarding “Purpose of Use” is understood by the NRC staff as a self-imposed limitation contained within the application. If a broad scope licensee desires to initiate a use other than those described in its application and committed to in its license, the licensee must submit an amendment to the license to modify or expand the “purpose.”

If the material will be used in tracer/field studies in which licensed material is deliberately released into the environment, or in animal studies that may result in the release of licensed material into the environment, an EA may be needed in accordance with 10 CFR 51.21. NUREG–1748, “Environmental Review Guidance for Licensing Actions Associated with NMSS Programs,” addresses procedures that staff should use in conducting environmental reviews. A memorandum dated October 20, 2009 (ADAMS Accession No. ML092321078), provides further guidance.

The exclusions stated in 10 CFR 33.17(a) provide that, unless specifically authorized by other parts of the regulations, persons licensed under broad scope licenses are not permitted to do any of the following:

- conduct tracer studies in the environment involving the direct release of radioactive material (applies to field users)
- receive, acquire, own, possess, use, transfer, or import devices containing 3.7×10^{15} becquerels (Bq) [100,000 Ci] or more of byproduct material in sealed sources for irradiation of materials
- conduct activities for which a specific license issued by the Commission under 10 CFR Part 32, “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material”; 10 CFR Part 34, “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations”; or 10 CFR Part 35, “Medical Use of Byproduct Material,” is required
- add or cause the addition of byproduct material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being

Applicants desiring these activities should review the appropriate base NUREG (i.e., that volume of NUREG–1556 that most closely applies) and request specific authorization in accordance with the guidance contained therein. For example, broad scope licensees that wish

to perform industrial radiography should review NUREG–1556, Volume 2, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Industrial Radiography Licenses,” and provide necessary information, as specified.

Response from Applicant: Describe in general terms the purposes for which the licensed material will be used.

8.7 Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

Executive management, the radiation safety committee (RSC), if required, and the RSO and his or her staff, as necessary, work as a team to oversee the broad scope program. Each plays a critical role within a given area of responsibility. The roles and responsibilities of executive management, the RSC, the RSO, and the radiation safety office staff are discussed in the sections that follow.

Note: NUREG–1516, “Management of Radioactive Material Safety Programs at Medical Facilities,” published May 1997, describes the role of executive management, the RSC, and the RSO at medical facilities but contains information pertinent to all broad scope programs.

8.7.1 Executive Management

Regulations: 10 CFR 20.1101(c), 10 CFR 33.13(c), 10 CFR 33.14(b), 10 CFR 33.15(c)

Criteria: The applicant must have administrative controls and provisions relating to organization and management and management review necessary to ensure safe operations.

Discussion: Executive management is the individual at the senior management level who is responsible for oversight of the facility’s radiation safety program and has the ultimate responsibility for the license and the activities associated with the license. Executive management has an important role in implementing and managing the radiation safety program.

Because of the various structures of different organizations, the NRC recognizes that executive management may need to delegate certain responsibilities to other managers for the day-to-day oversight of the program. For example, a large company may have several licenses issued to it for different facilities or for different activities. In this case, a company may choose to establish a senior level manager with responsibility for all of the licenses issued to that company, with the day-to-day responsibility for each license designated to the facility senior manager or program area senior manager. There are numerous ways in which an applicant may wish to structure its management oversight to meet the needs of the organization. However, there must still be one level of management, as the licensee’s representative, with ultimate responsibility for the radiation safety program.

In a Type A broad scope program, executive management or her or his delegate is a vital member of the RSC and should attend committee meetings. In all licensed programs, executive management should be knowledgeable of the results of periodic audits and the annual review of the licensed program to ensure all activities comply with regulatory requirements and the conditions of the license and that activities are being conducted in a safe manner. Annual reviews and audits are discussed in more detail in Section 8.10.1 of this guidance document.

The licensee should consider several factors when selecting executive management for the radiation safety program. This individual represents the highest level of facility management and has the authority to delegate resources for the program and appropriate funds in a timely manner. This individual must be available to facilitate effective and immediate action on behalf of management, the RSC (for Type A broad scope programs), and the RSO, particularly in the event of an emergency. Executive management must have the authority to make prompt decisions without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all radiation safety practices are in accordance with the regulations and conditions of the license.

Executive management is involved in selecting the chairperson and members of the RSC (for Type A broad scope) and the RSO (for Type A and Type B broad scope), and defines the role, duties, and responsibilities of each. Executive management should support the RSC and the RSO, creating an atmosphere of cooperation and professionalism such that individuals feel comfortable raising radiation safety concerns. Authority will be enhanced if authorized users clearly understand that there is strong management support for, and participation in, the licensed program. Many problems can be avoided if management takes proactive steps before radiation safety problems escalate. Individuals should understand management's expectations regarding internal enforcement of program requirements and the consequences for noncompliance.

NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," Chapter 1, describes the role of executive management at medical facilities, but it also contains information pertinent to all broad scope programs.

Response from Applicant: The applicant must describe administrative controls and provisions relating to organization and management and management review necessary to ensure safe operations. The applicant should submit an organizational chart that describes the management structure, reporting paths, and the flow of authority between executive management, the RSC (for Type A broad scope), and the RSO (For Type A and Type B broad scope).

8.7.2 Radiation Safety Committee

Regulations: 10 CFR 33.13(c)(1), 33.13(c)(3)(iii)

Criteria: Type A broad scope licensees must establish an RSC that works with executive management and the RSO in implementing the radiation safety program. Type B and Type C broad scope licensees are not required to establish an RSC.

Discussion: An applicant for a Type A broad scope license must establish an RSC pursuant to 10 CFR 33.13(c)(1). The RSC works with executive management and the RSO to implement the radiation safety program, and will be involved in establishing policies and procedures for managing the radiation safety program. The RSC, through the executive management, must have the authority and flexibility necessary to effectively fulfill its role in managing the radiation safety program.

The RSC for a Type A broad scope program is composed of such persons as the RSO, executive management, and persons trained and experienced in the safe use of radioactive material. Each area of use under the license should be represented on the RSC.

The licensee should select a chairperson for the committee. There are several factors to consider when making this selection. An individual with a knowledge of radiation safety issues, good leadership abilities, the authority and credibility by virtue of his or her position within the facility, and a desire to serve as chairperson will facilitate the effectiveness of the RSC. Additionally, the individual chosen as the chairperson must have the time to devote to the position in addition to other responsibilities he or she might have within the facility. Executive management should delegate a level of authority to the position so that the chairperson is effective. In general, the RSO should not be appointed as the chairperson of the committee, since the RSO is responsible for the day-to-day operation of the radiation safety program and may be too closely involved with the licensed activities to be objective.

The RSC should establish a quorum for RSC meetings. The NRC considers as acceptable the following: a quorum consisting of the chairperson of the committee (or his or her designee), the RSO, the executive management (or his or her alternate), a representative from each area of use from which specific issues will be discussed, and any other member whose field of expertise is necessary for the discussion.

Regulations in 10 CFR Part 33 do not specify the meeting frequency for RSC meetings for broad scope programs. The RSC should meet as often as needed to ensure the radiation safety program is operating in compliance with the license, established procedures, and the regulations. For most programs, quarterly RSC meetings are needed to adequately oversee the program.

The RSC should maintain minutes of its meetings. The minutes should include the date of the meeting, the members present and absent to demonstrate a quorum was present, a summary of the discussions, recommendations, and the results of votes. The RSC should also document its review of new users, uses, and program changes. The minutes should also include information related to the ALARA program reviews and the annual radiation safety program review.

Duties and Responsibilities

The radiation safety committee is required, pursuant to 10 CFR 33.13(c)(3)(iii), to review, approve, and record safety evaluations of proposed uses of byproduct materials. Pursuant to 10 CFR 33.17(b), the material possessed under the broad scope program may only be used by, or under the direct supervision of, individuals approved by the RSC. Therefore, one of the primary responsibilities of the RSC for a broad scope program is to evaluate new users and new uses of byproduct material. The RSC should consider all available information in making decisions. This includes evaluating the training and experience of applicants that request authorization to use radioactive material at the facility, using criteria developed by the RSC. The RSC members should be aware of the regulatory training and experience criteria that apply to each type of use at their institution. The criteria developed by the committee should include such things as the requester's training and experience, the proposed facilities, the protocol for using radioactive material to ensure that all procedures are in accordance with good radiation safety practices, and waste disposal.

Broad scope programs that also include activities that are under other NRC regulations must meet all applicable requirements of those regulations. Most common are medical licensees of broad scope, which must meet the requirements of 10 CFR Part 35, as well as those of Part 33. Broad scope licensees should review other base NUREGs that may apply to their licensed program, such as NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licensees: Program Specific Guidance About Medical Use Licenses," which provides guidance

for licensees that possess radioactive material for medical use. Similarly, guidance can be found for other uses of radioactive materials commonly found at broad scope programs, such as self-shielded irradiators (NUREG-1556, Vol. 5), use in animals including veterinary treatment (NUREG-1556, Vol. 7), and uses of small sealed sources in devices such as x-ray fluorescence devices or gas chromatographs (NUREG-1556, Vol. 7) or portable gauges (NUREG-1556, Vol. 1) and fixed gauges (NUREG-1556, Vol. 4).

In addition, the committee is responsible for reviewing personnel dosimetry results, and discussing the results of required radiation surveys and any significant incidents, including spills, contamination, and medical events. Since the licensee is required under 10 CFR 20.1101 to maintain a radiation program based upon sound radiation protection principles to achieve doses that are ALARA, the RSC should review the program for maintaining doses ALARA and provide any necessary recommendations to ensure this. The overall compliance status for authorized users should be thoroughly reviewed. The RSC, working with the executive management, shares responsibility with the RSO for conducting periodic audits of the radiation safety program. Additionally, the RSC reviews any consultant's audit findings and documents the acceptance or rejection of the consultant's findings in the RSC Committee minutes. The RSC also reviews the results of the annual review of the radiation safety program. Licensees should analyze possible trends and implement timely corrective actions as needed.

Problems should be clearly defined and reviewed in the future as open items. An assessment of the effectiveness of corrective actions is also helpful in deterring or eliminating future problems and violations.

For Type A broad scope licensees or applicants for a Type A broad scope license that desire the flexibility to make certain program changes and changes to certain procedures as discussed in Section 1 of this document, the RSC, along with executive management and the RSO, will review and approve program and procedural changes in accordance with criteria developed and approved by the RSC. The criteria for reviewing and approving such changes should include provisions for training staff before implementing new procedures and ensure that the proposed changes will not degrade the effectiveness of the currently approved program. Additionally, the audit program should include an evaluation process that will ensure that changes have been properly implemented by the staff and will determine the effectiveness of changes made in achieving program goals.

Response from Applicant: Applicants for a Type A broad scope license should submit the following:

- description of the duties and responsibilities of the RSC
- criteria used for selecting members of the RSC, including what members and the number of members constituting a quorum. Members should be indicated by position title, rather than by name
- criteria and procedure describing the approval process used by the RSC and RSO for authorizing new users and new uses

In addition, applicants for a Type A broad scope license that request the flexibility to make some program changes and revise some procedures previously approved by the NRC without amendment of the license should submit the following:

- a description of the duties and responsibilities of the RSC, including:
 - review and approval of permitted program and procedural changes prior to implementation
 - implementation of program and procedural changes
 - audit of licensed operations to determine compliance
 - appropriate actions taken when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence
- a description of the process for procedure and program review and approval, including documentation of the specific change (At a minimum, documentation should state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.)

8.7.3 Radiation Safety Officer

Regulations: 10 CFR 30.33(a)(3), 10 CFR 33.13(c)(2), 10 CFR 33.14(b)(1)

Criteria: 10 CFR Part 33, “Specific Domestic Licenses of Broad Scope for Byproduct Material,” requires that Type A and Type B broad scope licensees must have a radiological safety officer, more commonly known as an RSO, who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiological safety matters. The RSO’s training and experience should be applicable to and generally consistent with the types and quantities of licensed material listed on the license for which the individual’s authorization as an RSO is requested. While regulation does not require Type C broad scope licensees to have an RSO, 10 CFR 33.15, “Requirements for the issuance of a Type C specific license of broad scope,” requires that the licensee establish administrative controls and provisions related to procurement of byproduct material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations. Type C broad scope licensee management should appoint someone responsible for the day-to-day operation of the radiation safety program, who will be named as the RSO on the license.

Discussion: Each Type A and Type B program that uses byproduct materials must appoint an RSO who is responsible for radiation safety and compliance with the regulations for the use of byproduct material. Each Type C broad scope program should appoint an individual who is responsible for the day-to-day operation of the radiation safety program and who will be listed on the license as the RSO. In a Type A broad scope license, the RSO is a member of the RSC and works closely with the RSC and executive management to implement the radiation safety program. In a Type B or Type C broad scope license, the RSO is the individual responsible for implementing the radiation safety program.

Duties and Responsibilities

For all broad scope licenses, the RSO must ensure that the licensee’s radioactive material is used and stored safely and securely according to approved policies and procedures, and that all regulatory requirements are met. The RSO must have full access to all activities that involve the use of byproduct material and the authority to terminate any activity in which health and

safety appear to be compromised without consulting with executive management or the RSC. The applicant should submit a "Radiation Safety Officer Delegation of Authority" signed by executive management. Appendix D of this NUREG contains a model "delegation of authority" that the NRC considers acceptable.

- In a Type A broad scope licensed program, the RSO typically performs a preliminary review of proposed new uses and users, prior to formally discussing the proposal with the RSC. The RSC grants the formal approval of new users and uses in a Type A broad scope license.
- In a Type B broad scope licensed program, the task of reviewing and approving proposed uses and users is the responsibility of the RSO. The Type B broad scope RSO should be qualified by training and experience to provide advice and assistance to others working with materials under the Type B broad scope license. The Type B broad scope RSO also is required to perform the review, approval, and recording of safety evaluations of proposed uses prepared in accordance with 10 CFR 33.14(b)(2)(ii) before use of the byproduct material.
- In a Type C broad scope program, individuals are qualified as users if they meet the training and experience criteria described in 10 CFR 33.15(b). While no licensee, committee, or individual is required by regulation to make the determination that an individual is qualified to use the material possessed under the Type C broad scope license, or that a particular use of byproduct material is safe, licensee management ultimately is responsible for assuring safe operations. The licensee should designate one individual to be named as the RSO on the license. This individual will be the NRC's primary technical contact for matters related to the Type C broad scope license.

The RSO performs audits of all areas of use and individuals who are authorized to use byproduct material to ensure work is done in accordance with the license, regulations, and user permit conditions. Specific duties and responsibilities of the RSO include but are not limited to:

- monitoring and surveys of all areas in which radioactive material is used
- overseeing ordering, receipt, surveys, and delivery of byproduct material
- packaging, labeling, surveys, etc., of all shipments of byproduct material leaving the institution
- monitoring programs, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits
- developing and implementing an ALARA program
- training all personnel
- overseeing the waste disposal program
- monitoring inventory and leak tests of sealed sources
- overseeing decontamination

- investigating incidents, responding to emergencies and notifying the appropriate agencies
- for licensees possessing an aggregated Category 1 or Category 2 quantity of radioactive material, participating in the development and implementation of a security program for radioactive material in accordance with 10 CFR Part 37 (a “Category 1 quantity of radioactive material” and a “Category 2 quantity of radioactive material” are defined terms in 10 CFR 37.5, and the radionuclides referenced in these 10 CFR 37.5 definitions are listed in Appendix A to 10 CFR Part 37)
- maintaining all required records

The applicant or licensee may not transfer the responsibilities of the RSO to other individuals. Many tasks and duties associated with managing the program may be assigned or delegated to other qualified individuals. The responsibility for these tasks and duties, however, lies with the RSO. The NRC does recognize that a qualified individual will have to fill in for the RSO when the RSO will be away for short periods of time for professional conferences, vacation, or illness. However, this should not occur for extended or indefinite periods of time. The applicant or licensee should have a plan in place for contacting the RSO in the event of an emergency.

When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position and select an individual who is qualified to serve. The RSO will need sufficient technical knowledge to understand, in general, the majority of the work being done with byproduct materials under his or her responsibility. The NRC recognizes that an RSO may not be an expert in all areas that might be involved in a broad scope program. The RSO should be qualified by training and experience to perform the duties required for the position. Executive management should ensure that enough time is allocated to the individual selected as the RSO to carry out the responsibilities of the position.

RSO Qualifications and Training

In order to demonstrate adequate training and experience, the RSO should have: (1) at a minimum, a college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection and measurement instrumentation
- biological hazards of exposure to radiation (appropriate to types and forms of licensed material to be possessed and used)
- NRC regulatory requirements and standards
- hands-on use of radioactive materials commensurate with the uses proposed by the applicant

The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested. For instance, in addition to a college degree, RSOs at most broad scope licensees should be specialists in the field of radiation protection and may need at least 40 hours of radiation safety training specific to their job duties, as well as a year of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be an RSO.

The RSO designee should have obtained the above training in formal course(s) designed for RSOs, presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts. In addition, the proposed RSO's experience should be sufficient to identify and control the anticipated radiation hazards. For example, the RSO should have experience planning and conducting evaluations, surveys, and measurements similar to those required by the licensee's radiation safety program.

The applicant should also be aware of specific regulatory requirements for the RSO that may apply to its licensed program. For example, 10 CFR Part 35 contains specific requirements for an RSO in a medical program. However, an individual who qualifies as a medical RSO may not necessarily be qualified to be an RSO in a broad scope program.

Chapters 3 and 4 of NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," describe the role of the RSO and selection of the RSO at medical facilities, but it also contains information pertinent to all broad scope programs.

Response from Applicant:

For Type A, Type B, and Type C applicants:

- Submit the name of the proposed RSO.
- Describe the training for the proposed RSO that demonstrates the individual is qualified to perform the duties required under the license.
- Address the RSO's experience in performing each of the duties listed in the "Duties and Responsibilities" section, when and where the experience was gained, and the type, form, and quantity of radionuclides involved.
- Submit a statement delineating the RSO's duties and responsibilities.
- Submit a radiation safety officer delegation of authority memorandum signed by the licensee's executive management.

In addition, for Type B applicants, submit the criteria used by the RSO to approve new users and uses of byproduct material. Also, submit the criteria that the RSO will use to evaluate the radiation safety aspects of proposed uses, prior to approval.

Applicants should provide specific information about the proposed RSO's training and experience that is relevant to the requested licensed material types, forms, and quantities requested in the application.

Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. This only serves to slow down the review process.

Applicants should not submit personal information, such as birth dates, social security numbers, home addresses, personal telephone or cell phone numbers, for the proposed RSO. Such information is not required to be submitted and under the Privacy Act, documents containing such information must be handled separately, which may delay completion of the review process.

Note: Notify the NRC and obtain a license amendment before making changes in the designation of the RSO listed on the license. Applicants should review the regulations for specific program areas, such as medical uses, that have specific requirements regarding changes in the RSO.

8.7.4 Radiation Safety Office Staff

Criteria: Licensees should provide sufficient staff to assist the RSO in implementing the radiation safety program.

Discussion: The licensee should provide the RSO with a sufficient staff of professional and administrative support personnel. The number of staff and their qualifications will vary depending on the scope of the program. For small programs, the RSO may not require any assistance. Licensees should evaluate the licensed program and ensure that the RSO has adequate resources to effectively manage the program.

Chapters 6 and 7 of NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," discuss the subjects of radiation safety program resources and the use of consultants and service companies at medical facilities. However, these chapters also contain information pertinent to all broad scope programs.

Response from Applicant: No response is required.

8.8 Item 8: Training for Individuals Working in or Frequenting Restricted Areas

Regulations: 10 CFR 19.12, 10 CFR 19.13, 10 CFR 30.33(a)(3), 10 CFR 30.34(e), 10 CFR 37.5, 10 CFR 37.43

Criteria: Before beginning work with or in the vicinity of licensed material, all individuals who are likely to receive an occupational dose in excess of 1 millisievert (mSv) [100 millirem (mrem)] in a year must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training. Any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material (as defined in 10 CFR 37.5) must implement a training program for those individuals implementing the security program.

Discussion: Requirements in 10 CFR 19.12(a) establish the training that licensees are required to provide to individuals who, in the course of their employment, are likely to receive in a year an occupational dose in excess of 1 mSv [100 mrem]. Section 19.12(b) of 10 CFR requires that the licensee, in determining which individuals are subject to the training requirements of 19.12(a), consider assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during the life of a licensed facility. Many licensees can demonstrate that it is not likely during a normal situation for a laboratory worker, manufacturing technician, or environmental services worker at the facility to receive in a year an occupational dose in excess of 1 mSv [100 mrem]. However, such individuals could reasonably receive this level of exposure during abnormal situations (e.g., radioactive material left unsecured, a contamination event, or improper disposal of radioactive material in the regular trash) or, by their actions, cause others to receive this level of exposure. Untrained workers represent a potential hazard to themselves, other individuals, and property.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Practical, site-specific training should be provided for all individuals prior to beginning work with or in the vicinity of licensed material. Periodic refresher training should also be provided. Topics covered must, at a minimum, include those described in 10 CFR 19.12(a). The training may take any form. Many licensees use interactive media or offline computer programs to provide training. The licensee should determine if the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual who is familiar with the licensee's program.

Retraining should be performed whenever there is a change in duties or the work environment and at a frequency sufficient to ensure that all staff members are adequately trained.

Applicants should review the model training program described in the appropriate base NUREG corresponding to the particular type of licensed program. For example, NUREG-1556, Volume 7, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," describes a training program that is acceptable to the NRC for licensees that are involved in research and development, and Volume 9, "Consolidated Guidance About Materials Licensees: Program Specific Guidance About Medical Use Licenses," describes a training program that is acceptable to the NRC for licensees that possess radioactive material for medical use.

The applicant should also be aware of additional specific training requirements that may apply to their licensed program. For example, 10 CFR Part 35 contains specific requirements for the training of individuals who will work under the supervision of medical authorized users.

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must implement a training program in accordance with 10 CFR 37.43, "General security program requirements," and specifically, must comply with 10 CFR 37.43(c), "Training," to ensure that those individuals who may have a responsibility to implement portions of the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. Additionally, in accordance with 10 CFR 37.43(c)(3), refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant:

Applicants should do one of the following:

- Submit a description of the radiation safety training program developed for each group of workers, including: topics covered, qualifications of the instructors, method of training, method for assessing the success of the training, and the frequency of training and refresher training.
- Identify the model training program described in the appropriate base NUREG corresponding to the particular type of licensed program and submit a statement that this training program will be implemented.

In addition, Type A broad scope licensees or applicants that want the flexibility to revise their radiation safety training program without amendment of the license (as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this NUREG) should describe the process that will be used to revise and implement their submitted training programs.

8.9 Item 9: Facilities and Equipment

Regulations: 10 CFR 20.1101, 10 CFR 20.1406, 10 CFR 30.33(a)(2), 10 CFR 30.34(e), 10 CFR 30.35(g), 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15, 10 CFR Part 37, 10 CFR 37.5, 10 CFR 37.49, 10 CFR 37.53

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property and provide enhanced physical protection of aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5. They must minimize the possibility of contamination and keep exposures to workers and the public ALARA.

Discussion: Applicants for all broad scope licenses need to demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees, keep exposures to radiation and radioactive materials

ALARA, and minimize the danger to life and property from the types and quantities of radioactive materials to be used. Facilities and equipment designed to control exposure can range from a vial that contains licensed material to buildings, fences, or exclusion areas that are between the source and the maximally exposed member of the public. These facilities not only reduce the exposure from the source but may also limit access to the source. The licensee should list and describe these facilities for the following purposes:

- to show compliance with a regulation
- to demonstrate the use of the material will be within the ALARA concept
- to meet emergency response requirements

Licensees should consider controlling exposures through available engineering options, as well as through limiting the releases of effluents to the environment. The licensee should describe all facilities and equipment essential to achieving these goals. The licensee will also need to describe the criteria that will be used by the RSC and/or RSO, as appropriate, to review and approve proposed facilities. Facilities and equipment used for special applications in which the effect on workers or the public could be significant if radioactive material were to be released accidentally, should be specifically described. These would include, for example, self-shielded irradiators, specialized radio-labeling (iodination or tritiation) facilities, alpha laboratories, radioactive waste processing facilities (including incinerators, compactors, liquid reclamation processors, etc.), radioactive waste storage facilities (including decay-in-storage locations), individual laboratories processing 3.7 GBq [100 mCi] or more of radioactive materials per experiment or process, nuclear pharmacies, specially designed therapy rooms, and sealed source storage areas. Significant modifications that affect facilities and equipment should have prior RSO review and RSC approval before being adopted.

Also note that if radioactive materials will be used in or on animals, licensees should provide a description of the animal handling and housing facilities. NUREG-1556, Volume 7, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," provides guidance on the information that should be addressed concerning the use of radioactive materials in animals.

In discussing the criteria used to evaluate their facilities and equipment, applicants should include information on how a laboratory or facility classification scheme relates to toxicity and quantity of radioactive material and the facility and equipment requirements.

Appendix E of this NUREG provides additional guidance regarding facilities and equipment used to handle radioactive materials in a laboratory setting.

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other things,

- implement the physical protection requirements in 10 CFR Part 37 for material in use and storage, at both permanent and temporary jobsites; and
- in accordance with 10 CFR 37.49, be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones, including those surrounding mobile devices, and immediately detect any unauthorized removal of Category 1 quantities of radioactive material from the security zone. (Monitoring and detection systems may include, among other methods, monitored video surveillance systems and electronic devices for intrusion detection alarms.)
- for mobile devices containing Category 1 or Category 2 quantities of radioactive material, have two independent physical controls to secure the material from unauthorized removal when the device is not under direct control and constant surveillance in accordance with 10 CFR 37.53. "Mobile device" is defined in 10 CFR 37.5

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant: Describe the criteria the RSC or RSO, as appropriate, will use to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.). The description will need to include the method of classifying laboratories based on type, toxicity, and quantity of byproduct material being requested. Sample diagrams should be provided for each classification scheme that take into consideration shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When reviewing facilities where radioactive materials may become airborne, sample diagrams should take into consideration descriptions of the ventilation systems—including pertinent airflow rates, pressures, filtration equipment, and monitoring systems. For facilities and equipment used in special applications, such as those described above, the application will include their locations (i.e., buildings and room numbers) and special considerations that the RSC or RSO (or both) will use in authorizing byproduct material use. Also describe the procedures for control, review, and approval of significant facilities or equipment modifications.

Reference: For further information on facility design, see Chapter 4 of NCRP Report No. 127, "Operational Radiation Safety Program."

8.10 Item 10: Radiation Safety Program

8.10.1 Audit and Review of Program

Regulations: 10 CFR 33.13(c), 10 CFR 33.14(b), 10 CFR 33.15(c), 10 CFR 20.1101, 10 CFR 20.2102, 10 CFR 37.33, 10 CFR 37.55

Criteria: Applicants for Type A, Type B, and Type C broad scope licenses are required by 10 CFR 33.13(c), 33.14(b), and 33.15(c), respectively, to establish administrative controls and provisions related to management review necessary to ensure safe operations. 10 CFR 20.1101(c) requires the licensee to review the radiation program content and implementation, periodically (at least annually). 10 CFR 20.2102, "Records of radiation protection programs," requires licensees to maintain records of the radiation protection program, including: (1) the provisions of the program; and (2) audits and other reviews of the program contents and implementation. Licensees that are subject to the requirements in 10 CFR Part 37 must annually review their access authorization program and security program.

Discussion:

Management and Radiation Safety Committee Audits

The application for a Type A, B, or C broad scope license should discuss executive management oversight of the licensed program and the mechanisms they will use to ensure awareness of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program. This oversight may include independent audits of the program, frequent meetings with the RSC or RSO (or both), as appropriate, and periodic tours of selected facility areas.

In a Type A broad scope program, the RSC assists executive management in performing this oversight function. Detailed written procedures should be developed and implemented for the operation of the RSC to ensure that appropriate oversight is provided. The RSC should be fully aware of the operations and activities of the RSO. The RSC should conduct periodic interactive management audits and evaluations of the radiation safety program's performance, including: nonconformance reports, corrective action, status reports and audits, incident investigation reports, ALARA program development and implementation, effluent releases, qualification and radiological safety training, and performance of the RSO. Licensees should report results of the RSC's audit and program reviews to executive management to allow for timely remedial actions sufficient in scope to ensure safe operations and compliance with NRC regulations and license conditions.

Appendix F of this NUREG contains an annual audit program that the NRC finds acceptable for use in the review of most non-medical broad scope programs. Because all areas indicated in Appendix F may not be applicable to every licensee and all items may not need to be addressed during each audit, licensees may wish to develop a program-specific audit checklist.

10 CFR 20.1101(c) requires the licensee to review the radiation program content and implementation periodically (at least annually). Reviews should be conducted at least once every 12 months.

Internal Audits

The application should describe the audit mechanism implemented by the RSO and her or his staff, or other individual who is responsible for the day-to-day operation of the licensed program, to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC- or RSO-approved permits (as appropriate), good health physics practices, and ALARA principles. The audit program should include performance based routine unannounced inspections of each user's facility and practices to supplement and audit the routine monitoring performed by the user. Facility inspections should include the following:

- review of user inventory and survey records
- evaluation of user and technician training through discussion and observation of work practices
- performance of independent surveys of user work areas
- evaluation of compliance with NRC regulations, the conditions of the license, and the RSC and RSO permit and safety manual requirements
- evaluation of performance based instruction for users and technical-level staff

The types and frequencies of monitoring performed by the RSO should be indicated. The intervals of surveys and audits should be frequent enough to ensure close communications and proper surveillance of individual radioactive material users. Applicants should consider developing survey and audit schedules based on activity and use (e.g., high use facilities and users of volatile radioactive materials may be audited weekly or biweekly; intermediate use facilities may be audited monthly; and low-level facilities may be audited quarterly).

The NRC encourages licensee management to conduct performance-based reviews by observing work in progress, interviewing staff, and spot-checking required records. As part of the audit program, licensees should consider including unannounced audits of licensed material users to observe whether radiation safety procedures are being followed.

It is essential that once problems are identified, comprehensive corrective actions are taken in a timely manner. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. The NRC routinely reviews licensee's records to verify whether appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. The NRC can opt to exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented.

The NRC's Enforcement Policy may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The Enforcement Manual may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html>. For examples of the NRC's use of discretion in issuing a notice of violation, refer to the most recent version of NRC's enforcement documents at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

Recordkeeping

With regard to audit records, 10 CFR 20.2102 requires, in part, that licensees maintain records of “audits and other reviews of program content and implementation” for 3 years after the record is made. The NRC has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and followup.

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other things,

- in accordance with 10 CFR 37.33, review its access authorization programs at least annually to confirm compliance with the requirements of Subpart B of 10 CFR Part 37 and ensure that comprehensive actions are taken to correct any noncompliance that is identified; and
- in accordance with 10 CFR 37.55, review its security program at least annually to confirm compliance with the requirements of Subpart C of 10 CFR Part 37 and ensure that comprehensive actions are taken to correct any noncompliance that is identified.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, “Implementation Guidance for 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.”” Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, “Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material.”

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant:

- Describe the mechanisms executive management uses to ensure adequate oversight of the program. In addition, if a licensee is upgrading its limited scope license to a Type A broad scope license or is renewing its Type A broad scope license, describe the RSC’s involvement in these oversight mechanisms.
- Describe the audit mechanism implemented by the RSO or other responsible individual to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC- or RSO-approved permits (as appropriate), and good health physics practices.
- The applicant is not required to, and should not, submit its program for conducting the annual audit required by 10 CFR 20.1101, “Radiation protection programs,” to the NRC for review as part of a license application. The NRC will review this audit program during inspection.

In addition, Type A broad scope licensees or applicants that want the flexibility to revise the audit mechanism implemented by the RSO without amendment of the license, as discussed in Chapter 1, “Purpose of Report” and Section 8.7.2, “Radiation Safety Committee,” of this NUREG, should describe the process they will use to revise and implement their audit program.

References: The NRC's Enforcement Policy, which is located on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement.html>, and IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," which is available in the "NRC Library" under Document Collections/Generic Communications on the NRC's Web site, <http://www.nrc.gov>.

8.10.2 Radiation Monitoring Instruments

Regulations: 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2), 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15

Criteria: Pursuant to 10 CFR 20.1501, "General," licensees must possess and periodically calibrate radiation monitoring instruments that are necessary to protect health and minimize danger to life or property.

Discussion: Licensees must possess an adequate number of radiation detection and measurement instruments, as necessary, to maintain radiation safety and to comply with regulations. Licensees must ensure instruments are calibrated periodically for the radiation being measured. For purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. The choice of instrument needs to be appropriate for the type of radiation to be measured and for the type of measurement to be taken (count rate, dose rate, etc.).

The applicant should submit the criteria used in determining what radiation detection and monitoring equipment will be required for each type of use by authorized users and the availability of a sufficient quantity of these instruments to both the radiation safety office and authorized users (e.g., ionization chambers, Geiger-Mueller (G-M) detectors, air samplers, liquid scintillation counters).

The NRC requires that survey instruments used for quantitative measurements be calibrated periodically. Calibrations requiring the use of radioactive sources should be performed by the instrument manufacturer or persons specifically authorized by the NRC or an Agreement State. Survey instruments should be calibrated at least annually (every 12 months), unless another frequency is specified by regulation or license condition. Licensees seeking authorization to perform their own survey instrument calibrations will need to submit calibration procedures for review. The licensee may wish to review available industry standards for calibration of instruments, such as American National Standards Institute (ANSI) N323AB-2013, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts an authorized firm to perform calibrations, the licensee must retain records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made, in accordance with 10 CFR 20.2103(a). Appendix H of this NUREG provides useful information about instrument specifications and model calibration procedures that the NRC considers to be acceptable.

Some instruments may only need to be checked periodically for operability and response to radiation rather than receive full calibration. For example, G-M detection instruments used to identify contamination in laboratories may only need to be checked for ability to detect low-level contamination.

Applicants will need to submit their method for assuring that instruments are checked and calibrated at proper frequencies.

Response from Applicant:

- Provide the criteria used by the RSC or RSO (or both), as appropriate, to review and approve radiation monitoring instrumentation to ensure that appropriate radiation monitoring equipment will be used during licensed activities.
- Discuss how the RSC or RSO, as appropriate, will ensure that instruments are properly calibrated at prescribed frequencies.
- Submit procedures for instrument calibration or state that instruments will be calibrated by a vendor licensed by the NRC or an Agreement State to perform instrument calibrations. Licensees that want authorization to calibrate their own survey instruments may commit to implementing the model procedures published in Appendix H of this NUREG.
- State the frequency at which instruments will be calibrated.

In addition, Type A broad scope licensees or applicants that want the flexibility to revise their instrument specifications and procedure for calibration of instruments without amendment of the license, as discussed in Chapter 1, “Purpose of Report,” and Section 8.7.2, “Radiation Safety Committee,” of this NUREG, should describe the process that they will use to revise and implement these submitted procedures.

Note: If an applicant or licensee wishes to perform instrument calibration as a commercial service, they will need to either amend their existing broad scope license or apply for a new NRC license authorizing commercial calibration service.

8.10.3 Material Receipt and Accountability

Regulations: 10 CFR 20.1501(a), 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 20.2001, 10 CFR 20.2108(b), 10 CFR 20.2201, 10 CFR 20.2207, 10 CFR 30.34(e), 10 CFR 30.35(g), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15, 10 CFR 37.49, 10 CFR 37.71, 10 CFR 37.75, 10 CFR 37.77, 10 CFR 40.36(f), 10 CFR 70.25(g)

Criteria: Licensees must—pursuant to 10 CFR Parts 20, 30, and 33—develop, implement, and maintain written procedures for all of the following:

- purchasing and receipt of radioactive material
- safely receiving and opening packages
- ensuring control and accountability of licensed material

Licensees must also do the following:

- Maintain records of receipt, transfer, and disposal of licensed material.
- Update transactions in the National Source Tracking System (NSTS), including performing annual inventory reconciliation, if applicable.

- Before transferring aggregated Category 1 or Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37, use NRC's license verification system to verify that the recipient licensee is authorized to possess the radioactive material.
- Preplan, coordinate and provide advance notification of shipment of Category 1 quantities of radioactive material and coordinate shipment of Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37.

Discussion: Licensed materials must be tracked from receipt to transfer to ensure accountability at all times; identify when licensed material may be lost, stolen, or misplaced; and ensure that the possession limit stated on the license is not exceeded. The NRC requires applicants for a broad scope license to establish appropriate administrative controls and provisions that are necessary to ensure safe operations, including procedures to regulate the control of procurement and use of byproduct material. Administrative procedures must ensure that only authorized individuals receive radioactive materials and then only the types and quantities of radioactive material that they are authorized to receive.

Applicants for a broad scope license are strongly encouraged to develop an administrative procedure to control procurement and use of radioactive material that emphasizes centralized purchasing and receipt. The NRC has found centralized purchasing and receipt, involving the radiation safety officer as an active part of the process, to be effective in controlling licensed materials entering the licensed institution through normal commercial channels, particularly for larger institutions. Procedures must also be established to control licensed materials obtained outside of the normal channels (e.g., through the loan or transfer of materials without purchase or through surplus). Appendix I of this NUREG describes a model procedure for controlling procurement and use of specifically licensed and generally licensed radioactive material that is acceptable to the NRC.

Licensees are required to develop, implement, and maintain written procedures for safely receiving and opening packages in accordance with 10 CFR 20.1906, "Procedures for receiving and opening packages." Appendix I of this NUREG describes a model procedure for safely receiving and opening packages containing licensed materials that the NRC finds to be acceptable. Table 8-2 provides a list of package monitoring requirements.

Table 8-2. Package Monitoring Requirements (10 CFR 20.1906)			
Package	Contents	Survey Type	Survey Time*
Damaged	Licensed Material	Radiation Level and Radioactive Contamination [§20.1906(b)(3)]	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas nor Special Form Greater Than Type A†	Radiation Level [§20.1906(b)(2)] and Radioactive Contamination [§20.1906(b)(1)]	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater Than Type A†	Radiation Level [§20.1906(b)(2)]	As soon as practicable, but not later than 3 hours after receipt of package

Table 8-2. Package Monitoring Requirements (10 CFR 20.1906)			
Package	Contents	Survey Type	Survey Time*
Labeled (White I, Yellow II, Yellow III)	Not Gas nor Special Form Less Than or Equal to Type A [†]	Radioactive Contamination [§20.1906(b)(1)]	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less Than or Equal to Type A [†]	None [§20.1906(b)(1)]	None
Not Labeled	Licensed Material	None [§20.1906(b)]	None [‡]
<p>*Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has 3 hours after the beginning of the next work day to perform the required surveys [§20.1906(c)].</p> <p>[†]Type A Quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A₁ for special form radioactive material, or A₂, for normal form radioactive material, where A₁ and A₂ are given in Table A-1 of 10 CFR Part 71, or may be determined by procedures described in Appendix A of 10 CFR Part 71.</p> <p>[‡]Excepted Packages and limited quantity packages received by many laboratories are required to have the appropriate identification number from the Hazardous Materials Table in 49 CFR 172.101 (i.e., the “UN number”) on the outside of the box, identifying it as containing radioactive materials. It is good health physics practices to perform an incoming survey on these packages, even though transportation regulations do not require it.</p>			

Applicants for a broad scope license are required to establish appropriate administrative controls and provisions related to material control and accounting that are necessary to ensure safe operations. Licensees use various methods to account for receipt, use, transfer, disposal, and radioactive decay of unsealed licensed material (e.g., computer programs, manual ledgers, log books). These methods help to ensure that licensee and individual authorized user possession limits are not exceeded. Licensees that possess sealed sources are required to perform periodic inventories. The frequency of these inventories is normally established by license condition at intervals not to exceed 6 months; however, regulations may specify a different inventory frequency. For aggregated Category 1 and Category 2 quantities of radioactive material, licensees must, according to 10 CFR 37.49(a)(1), continuously monitor and detect, without delay, all unauthorized entries into security zones. Additionally, for Category 1 quantities of radioactive material, 10 CFR 37.49(a)(3)(i) requires immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. For Category 2 quantities of radioactive material, 10 CFR 37.49(a)(3)(ii) requires weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

The NRC considers licensed material to become part of the licensee's inventory at the time that it is received by the licensee, be it during normal working hours or after hours when delivered by the carrier in accordance with procedures established by the licensee. If through some error, the licensee receives material it is unauthorized to possess or receives quantities of material that would result in the total inventory being in excess of license possession limits, the licensee should place the package in secure storage and arrange for the return of these materials in a timely manner. If return of the materials is not possible, the licensee should contact the NRC regional office and request issuance of an expedited license amendment. The materials must not be used until the amendment is granted.

Licensees are required under 10 CFR 20.1801 and 20.1802 to secure radioactive materials from unauthorized removal or access while in storage in controlled or unrestricted areas and to

control and maintain constant surveillance over licensed material that is in a controlled or unrestricted area and is not in storage. Applicants should establish policies and procedures for ensuring accountability of licensed materials. Licensed materials should be tracked from receipt to transfer to ensure accountability at all times; to identify when licensed material may be lost, stolen, or misplaced; and to ensure that the possession limit stated on the license is not exceeded.

Licensees must maintain records of receipt, use, transfer, and disposal of all licensed material. Table 8-3 below lists each type of record and how long the record must be maintained.

Table 8-3. Record Maintenance	
Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed and for 3 years following the transfer or disposal of the material
Transfer	For 3 years after each transfer unless a specific requirement dictates otherwise
Disposal	Until the NRC terminates the license
Important to decommissioning*	Until the site is released for unrestricted use
*Information about locations where licensed material is used or stored are among the records important to decommissioning and required by 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g). See also the section on "Financial Assurance and Recordkeeping for Decommissioning."	

Category 1 and Category 2 sealed sources listed in Appendix E to 10 CFR Part 20 (i.e., nationally tracked sources) must be tracked in the National Source Tracking System (NSTS) in accordance with 10 CFR 20.2207. The regulations in 10 CFR 20.2207 require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NSTTR) to the NRC. The NSTTRs are maintained in the NSTS, a secure computer system that tracks Category 1 and Category 2 nationally tracked sources from the time they are manufactured or imported through the time of their disposal or export, or until the source activity decays to below Category 2.

There are additional security requirements for shipment and transfer of a Category 1 and Category 2 quantity of radioactive material listed in Appendix A to 10 CFR Part 37. Prior to transferring Category 1 or Category 2 quantities of radioactive material, licensees must use NRC's license verification system (or contact the licensing authority) to verify that the recipient licensee is authorized to possess the radioactive material. Licensees that ship Category 1 or Category 2 quantities of radioactive material must preplan and coordinate such shipments in accordance with 10 CFR 37.75. Shipments of Category 1 quantities are also subject to the 10 CFR 37.77 advance notification requirements. For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant:

- Describe the administrative procedures used to ensure control of procurement and use of byproduct material.
- While the applicant is required to develop and implement safe opening procedures for packages containing radioactive material, the applicant need not submit the procedures during the licensing process. The NRC will review activities subject to these procedures during inspection.
- Provide the following statement: "We will develop, implement and maintain procedures for ensuring accountability of licensed materials at all times."
- Describe the administrative controls and provisions related to materials control, accounting and security. Describe the method for maintaining accountability of licensed material at all times.
- If applicable, provide the following statement: "We will comply with the National Source Tracking System (NSTS) reporting requirement as described in 10 CFR 20.2207."

In addition, Type A broad scope licensees or applicants that want the flexibility to revise their administrative procedures concerning control of procurement and use of byproduct material without amendment of their licenses (as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this NUREG) should describe the process their RSC will use to revise these administrative procedures, controls, and provisions. Licensees and applicants should also do this when making revisions to their administrative controls and provisions related to material control, accounting, and security.

8.10.4 Occupational Dose

Regulations: 10 CFR 19.13, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1703, 10 CFR 20.2104, 10 CFR 20.2106, 10 CFR 20 Appendix B

Criteria: Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure.

The use of individual monitoring devices for external dose is required, pursuant to 10 CFR 20.1502(a), for:

- adults who are likely to receive an annual dose from sources external to the body in excess of any of the following (each evaluated separately):
 - 5 mSv [0.5 rem] deep-dose equivalent
 - 15 mSv [1.5 rems] lens (of the eye) dose equivalent
 - 50 mSv [5 rems] shallow-dose equivalent to the skin
 - 50 mSv [5 rems] shallow-dose equivalent to any extremity
- minors who are likely to receive an annual dose from sources external to the body in excess of any of the following (each evaluated separately):
 - 1.0 mSv [0.1 rem] deep-dose equivalent
 - 1.5 mSv [0.15 rem] lens (of the eye) dose equivalent
 - 5 mSv [0.5 rem] shallow-dose equivalent to the skin
 - 5 mSv [0.5 rem] shallow-dose equivalent to any extremity
- declared pregnant women who are likely to receive a dose from radiation sources external to the body during the entire pregnancy in excess of 1.0 mSv [0.1 rem] deep-dose equivalent
- individuals entering a high or very high radiation area

Internal exposure monitoring is required, pursuant to 10 CFR 20.1502(b), for the following:

- adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable annual limit on intake for ingestion and inhalation
- minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 1.0 mSv [0.1 rem] and declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv [0.1 rem]

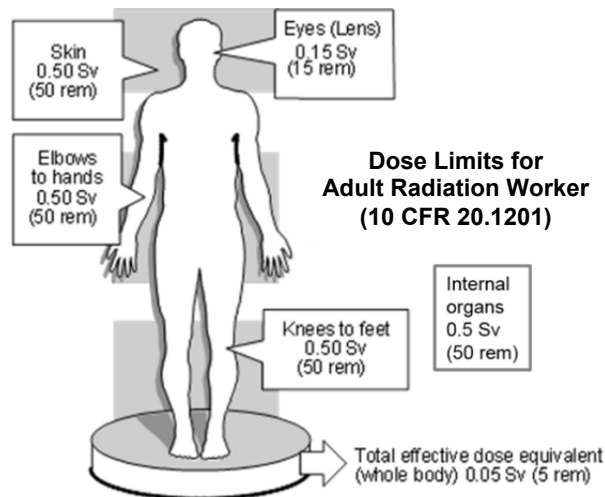


Figure 8-3. Annual Dose Limits for Adult Radiation Workers

Discussion:

Total effective dose equivalent (TEDE) equals the effective dose equivalent (for external exposures) plus the committed effective dose equivalent (for internal exposures).

If an adult radiation worker is likely to receive in 1 year a dose greater than 10 percent of any applicable limit (See Figure 8-2 for annual dose limits), monitoring for occupational exposure is required. Monitoring is required for minors and declared pregnant females as shown in the criteria section. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas. An example of such an evaluation for a licensee possessing only sealed sources in portable gauges is provided in Appendix H of NUREG-1556, Volume 1, Revision 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses." Also, an example of such an evaluation for a licensee possessing only sealed sources in fixed gauges is provided in Appendix G of NUREG-1556, Volume 4, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses."

If this prospective evaluation shows that an adult individual's dose is not likely to exceed 10 percent of any applicable limit, there are no recordkeeping or reporting requirements in regard to the individual's exposure. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring, and therefore, recordkeeping and reporting requirements. If it was determined that monitoring was not required and a subsequent evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received.

Licensees should use NRC Form 4, “Cumulative Occupational Dose History,” and NRC Form 5, “Occupational Dose Record for a Monitoring Period,” to record individual dose. If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter “N/A” for “not applicable” in the blocks on NRC Form 4, “Cumulative Occupational Dose History,” and NRC Form 5, “Occupational Dose Record for a Monitoring Period,” to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter “ND” for “not detectable.”

If the prospective evaluation shows that the individual adult is likely to exceed 10 percent of an applicable limit, then monitoring and reporting of the results of monitoring performed—regardless of the actual dose received—is required. If air sampling or bioassay is required, discussion of air sampling or bioassay should provide enough detail so that the NRC staff is assured that appropriate steps will be taken to manage and monitor such exposure. Licensees must provide individual radiation exposure data to each worker as required by 10 CFR 19.13.

Licensees should also perform prospective evaluations of the doses that may be received by occupationally exposed minors and declared pregnant women. As with individual adult workers, licensees must supply and require the use of individual monitoring devices to monitor external exposures and monitor the occupational intake of radioactive material when the results of prospective dose evaluations exceed the doses specified in 10 CFR 20.1502.

When personnel dosimeters that require processing to determine the radiation dose are used to comply with the individual monitoring requirement for external doses in 10 CFR 20.1502(a), licensees must use dosimeters supplied by a NVLAP-approved processor. The exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their NVLAP-approved processor for its recommendations for exchange frequency and proper use of the dosimeter.

For guidance about methodologies for determination of internal occupational dose and summation of occupational dose, refer to Table 8-4.

Table 8-4. Guidance on Personnel Monitoring and Bioassay	
Regulatory Guide 8.7, Revision 2	Instructions for Recording and Reporting Occupational Radiation Exposure Data
Regulatory Guide 8.9, Revision 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program
Regulatory Guide 8.20, Revision 2	Applications of Bioassay for Radioiodine
Regulatory Guide 8.21, Revision 1	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
Regulatory Guide 8.23, Revision 1	Radiation Safety Surveys at Medical Institutions
Regulatory Guide 8.25, Revision 1	Air Sampling in the Workplace
Regulatory Guide 8.32	Criteria for Establishing a Tritium Bioassay Program
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Radiation Doses

Table 8-4. Guidance on Personnel Monitoring and Bioassay	
Regulatory Guide 8.35, Revision 1	Planned Special Exposures
Regulatory Guide 8.36	Radiation Dose to the Embryo/Fetus
Regulatory Guide 8.37	ALARA Levels for Effluents from Materials Facilities
ANSI N13.30-2011	Performance Criteria for Radiobioassay
Information Notice 2000-10	Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits

Additional Reference for Further Reading:

U.S. Department of Energy G 441.1-1C, "Radiation Protection Programs Guide," May 19, 2008

Response from Applicant: Provide one of the following statements:

"We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502."

OR

"We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program—Occupational Dose' in NUREG–1556, Vol. 11, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.'"

OR, IN LIEU OF THESE STATEMENTS,

Provide a description of an alternative method for demonstrating compliance with the referenced regulations.

In addition, Type A broad scope licensees or applicants that want the flexibility to revise their personnel monitoring program without amendment of the license, as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this NUREG, should describe the process they will use to revise and implement their submitted personnel monitoring program.

Reference: The NIST maintains a directory of laboratories that are NVLAP-approved at <http://ts.nist.gov/standards/scopes/dosim.htm>.

8.10.5 Public Dose

Regulations: 10 CFR 20.1003, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2107

Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed in such a way that the total effective dose equivalent (TEDE) to members of the public will not exceed more than 1 mSv [100 mrem] in a year, and the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour.

Discussion: Public dose is defined in 10 CFR 20.1003 as “the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee.” Public dose excludes occupational doses or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 10 CFR 35.75, “Release of individuals containing unsealed byproduct material or implants containing byproduct material,” from voluntary participation in medical research programs, and from the licensee’s disposal of radioactive material into sanitary sewerage in accordance with 10 CFR 20.2003, “Disposal by release into sanitary sewerage.” Whether the dose to an individual is an occupational dose or a public dose depends on the individual’s assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) where the individual is in when he or she receives the dose.

There are both external exposure components and internal exposure components of public dose. The licensee should review all possible internal and external exposure pathways and decide which are applicable to its operations.

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1301. Specific requirements on demonstrating compliance with dose limits for individual members of the public are provided in 10 CFR 20.1302. The extent and frequency of monitoring will depend on the nature of the licensee’s operations, potential release pathways, and potential exposures that can contribute to public dose or environmental releases. For additional guidance on monitoring of effluents, refer to the section titled “Radiation Safety Program – Surveys.”

Regulations in 10 CFR 20.2107, “Records of dose to individual members of the public,” require that licensees maintain survey and monitoring records that demonstrate compliance with the dose limits for members of the public until the Commission terminates the license.

Response from Applicant: No response is required from the applicant, but records and written materials documenting compliance will be examined during inspection. During NRC inspections, licensees must be able to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public.

For guidance about accepted methodologies for determining doses to members of the public, see Appendix J of this NUREG, and, for examples of such methodologies as applied only to sealed sources in fixed gauges, see Appendix G of NUREG-1556, Volume 4, Revision 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses.”

8.10.6 Safe Use of Radionuclides and Emergency Procedures

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.1406; 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 30.32(i), 10 CFR 30.34(e), 10 CFR 30.50, 10 CFR 30.72, 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15, 10 CFR 37 (Subpart B), 10 CFR 37.21(a), 10 CFR 37.45, 10 CFR 37.49

Criteria: Licensees must, pursuant to the regulations stated above, keep radiation doses to workers and members of the public ALARA; ensure security of licensed material; and make required notifications to the NRC of events. Licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material, listed in Appendix A to 10 CFR Part 37, must also

establish, implement, and maintain its access authorization program; coordinate, to the extent practicable, with local law enforcement authorities for responding to threats to the licensee's facility; and be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones.

Discussion: Licensees are responsible for developing and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facilities until it is used, transferred, and/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

All licensed materials stored in controlled or unrestricted areas must be secured from unauthorized access or removal so that individuals who may not be knowledgeable about radioactive materials cannot be exposed to or contaminated by the material, and so that individuals cannot take the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material and prevent unauthorized persons from removing the material from the area.

Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include:

- storing and using licensed materials only in restricted areas
- limiting access to an entire facility or building or portion of the building to radiation workers
- providing storage areas that can be locked to prevent access to the material
- implementing procedures that require a radiation worker to be within "line of sight" of the materials whenever licensed materials are in use

Licensees should develop procedures that clearly state acceptable methods to secure licensed material at a facility. Particular attention may be required at facilities that have unusual needs because of the activities performed, such as hot cells, animal care facilities, and waste processing facilities. Security procedures may be in a separate document or included in the "General Safety Procedures."

Applicants should develop radionuclide-specific procedures based on the respective hazards associated with the radionuclides. Appendix K of this NUREG describes general safety guidelines. Licensees are encouraged to use these guidelines in developing procedures for the safe use of radionuclides.

Licensees must identify all areas that require posting in accordance with 10 CFR 20.1902, "Posting requirements," unless they meet the exemptions listed in 10 CFR 20.1903, "Exemptions to posting requirements." Also, containers of licensed material (including radioactive waste) must be labeled in accordance with 10 CFR 20.1904, "Labeling containers," unless they meet the exemptions in 10 CFR 20.1905, "Exemptions to labeling requirements."

Applicants need to establish written procedures to handle emergencies ranging from a minor spill to a major accident that may require intervention by outside emergency response

personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, individual users should have a clear understanding of their limitations in an emergency, with step-by-step instructions and clear direction for whom to contact. Appendix K of this NUREG describes model emergency procedures that the NRC considers acceptable.

Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished, as necessary. The licensee should also consider establishing an emergency response team composed of individuals experienced in various emergency response functions (e.g., radiological, medical, emergency management, security, and fire protection).

Regulations in 10 CFR 20.2201–20.2203, 10 CFR 21.21, “Notification of failure to comply or existence of a defect and its evaluation,” and 10 CFR 30.50, “Reporting requirements,” require certain incidents and emergencies be reported to the NRC. Appendix G of this NUREG provides examples of some events that require notification and/or reports. Note that Appendix G is not all inclusive, as there are other notification and/or reporting requirements that may apply to specific programs (e.g., 10 CFR Parts 32, 34, 35, 36, and 39).

If licensees submit a license application requesting to possess quantities of material in excess of the applicable amounts listed in 10 CFR 30.72, “Schedule C,” then they may also be required to submit an “emergency plan for responding to a release of radioactive material.” See Section 8.5.1, “Unsealed or Sealed Byproduct Material,” of this document for specific information related to this requirement.

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other things,

- in accordance with 10 CFR 37.21(a), establish, implement, and maintain its access authorization program in accordance with the requirements of 10 CFR Part 37, Subpart B;
- in accordance with 10 CFR 37.45, coordinate with their local law enforcement agency (LLEA) for responding to threats to a licensee’s facility; and
- in accordance with 10 CFR 37.49, be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones, including those surrounding mobile devices.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, “Implementation Guidance for 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.”” Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, “Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material.”

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant: Submit procedures for safe use of radionuclides and emergencies. Submissions should include procedures for maintaining security of licensed radioactive materials. As an alternative, state, “We will adopt the procedures for the safe use of radionuclides and emergencies as published in Appendix K of NUREG–1556, Volume 11, Revision 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.’”

In addition, Type A broad scope licensees or those applying for a Type A broad scope license that want the flexibility to revise their safe use and emergency procedures without amendment of the license, as described in Chapter 1, “Purpose of Report,” and Section 8.7.2, “Radiation Safety Committee,” of this NUREG, should discuss the process that will be used to revise and implement their submitted safe use and emergency procedures.

8.10.7 Surveys and Leak Tests

Regulations: 10 CFR 20.1501, 10 CFR 20.1906; 10 CFR 20.2103, 10 CFR 30.53, 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15, 10 CFR 35.67(d), 10 CFR 35.2067(a), 10 CFR 36.81(h), 10 CFR 39.35(a)

Criteria: Licensees are required, pursuant to the regulations listed above, to make surveys of potential radiological hazards in their workplace. The NRC requires testing to determine whether there is any radioactive leakage from sealed sources. Licensees must retain records of surveys and leak test results in accordance with license conditions and NRC regulations.

Discussion: Survey is defined as an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. These evaluations may be measurements (e.g., radiation levels measured with a survey instrument or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. Licensees should also use surveys to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public. In certain cases, environmental monitoring may be required to demonstrate compliance with 10 CFR Part 20.

Surveys are required when it is necessary for the licensee to comply with the regulations or to evaluate a radiological hazard. Many different types of surveys may need to be performed because of the particular use of licensed materials. Typical surveys may include:

- measurements of radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
- measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material or where licensed material is or could be released to unrestricted areas
- measurements of radioactive material concentrations in water that are released to the environment or to the sanitary sewer

- bioassays to determine the kinds, quantities, or concentration—and in some cases, the location of—radioactive material in the human body (A bioassay can be made by direct measurement, *in vivo* counting, or by analysis and evaluation of material excreted or removed from the human body.)
- measurements of external radiation exposure levels in both restricted and unrestricted areas

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above.

Appendix L of this NUREG describes survey procedures that are acceptable to the NRC.

The regulations in 10 CFR Part 20 do not specify limits for surface contamination. Each applicant should propose and justify which removable surface contamination limits will be allowable before decontamination will be performed in each work area. However, Subpart E of 10 CFR Part 20 specifies dose limits for residual contamination at the time of license termination. These criteria should also be used at the time of decommissioning of facilities that are to be released for unrestricted use, even as the license continues in effect at other locations. Guidance for survey criteria to meet the license termination criteria may be found in NUREG-1757, “Consolidated Decommissioning Guidance.”

Also, NUREG-1575, “Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM),” dated August 2000, contains additional guidance concerning surveys during the decommissioning of facilities. Licensees that have facilities to decommission should review this document.

Leak Test

When issued, a license will require performance of leak tests of sealed or plated foil sources at intervals as approved by the NRC or an Agreement State and specified by the SSD registration certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq [0.005 μ Ci (microcurie)] of radioactivity.

Because the types, forms, and quantities of licensed materials in sealed sources can vary significantly for applicants, leak test requirements usually are specified in a license condition. Typically, leak tests are not required if:

- sources contain only hydrogen-3 (tritium)
- sources contain only byproduct material with a half-life of less than 30 days
- sources contain only a radioactive gas
- sources contain 3.7 megabecquerels [100 μ Ci] or less of beta-emitting or gamma-emitting material or 370 kilobecquerels (kBq) [10 μ Ci] or less of alpha-emitting material

- sources are stored and are not being used (but must be leak tested before use or transfer, or if stored more than 10 years)

For more information regarding leak tests, see Appendix M of this NUREG.

Response from Applicant:

- Surveys

Submit procedures to evaluate radiological hazards, both external and internal. As an alternative, the applicant may state, "We will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix L of NUREG-1556, Volume 11, Revision 1, " Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.""

- Leak Testing

Submit leak test procedures. As an alternative, the applicant may state, "We will implement the model leak test program published in Appendix M of NUREG-1556, Volume 11, Revision 1, " Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.""

In addition, Type A broad scope licensees or those applying for a Type A broad scope license that want the flexibility to revise their survey or leak test program without amendment of the license, as described in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this NUREG, should discuss the process that will be used to revise and implement their submitted survey and leak test program.

8.10.8 Transportation

Regulations: 10 CFR 20.1101, 10 CFR Part 20, Appendix G, 10 CFR 30.41, 10 CFR 30.51, 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15, 10 CFR 34.35, 10 CFR Part 37 (Subpart D), 10 CFR 71.5, 10 CFR 71.12, 10 CFR 71.13, 10 CFR 71.14, 10 CFR 71.47, 10 CFR 71.87, 49 CFR Parts 171-185

Criteria: Broad scope licensees that will transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material to ensure compliance with NRC and U.S. Department of Transportation (DOT) regulations. In accordance with 10 CFR Part 37 (Subpart D), licensees must also preplan, coordinate and provide advance notification of the shipment of Category 1 quantities of radioactive material and coordinate the shipment of Category 2 quantities of radioactive material.

Discussion: DOT regulations [Title 49 of the *Code of Federal Regulations* (49 CFR), "Transportation"] were written to help ensure that hazardous materials in *commerce* were transported uniformly and safely. NRC licensees that transport byproduct material (hazardous material) in commerce are, therefore, required to comply with all applicable DOT regulations. However, many NRC licensees routinely transport byproduct material that is not in commerce. In 1979, 10 CFR 71.5, "Transportation of Licensed Material," was codified to ensure that all NRC licensees that transport byproduct material, in commerce or not, transport it in a uniformly

safe manner. Some broad scope licensees have applied for certain exemptions to 10 CFR 71.5; however, the NRC did not grant these exemption requests. The NRC's position regarding the transportation regulations in 49 CFR is that these regulations already allow for flexibility and are thus considered to be performance-based requirements rather than prescriptive requirements. For example, packages shipped by broad scope licensees frequently meet the "limited quantity" criteria as described in 49 CFR 173.421, "Excepted Packages for Limited Quantities of Class 7 (Radioactive) Materials," and are therefore excepted from certain DOT requirements, provided that certain other less-restrictive requirements are met. Appendix N of this NUREG provides an overview of the transportation requirements that commonly affect NRC licensees. Broad scope licensees' radiation safety staff should be thoroughly familiar with 10 CFR 71.5 and 49 CFR and how they interrelate in order to be able to comply with and to take full advantage of the flexibility inherent in DOT requirements.

Licensed material, including radioactive waste, must be packaged and transported in accordance with NRC and DOT requirements if the transportation involves the use of public highways. In addition, broad scope licensees should develop and maintain their own radiation safety procedures for transporting licensed material within their facilities if such transportation does not involve the use of public highways.

Licensees also should consider the safety of all individuals who may handle or may come in contact with the packages containing licensed material. Therefore, the licensee's primary concern in transporting licensed material should be to ensure that the package is properly prepared prior to transport, that package integrity is not compromised during transport and that the radiation levels (including removable contamination levels) not only meet the regulatory requirements of 10 CFR 71.47, "External radiation standards for all packages," but also are ALARA.

Licensees shipping radioactive waste for disposal must prepare appropriate documentation as specified in 10 CFR Part 20, Appendix G, "Requirements for transfers of low-level radioactive waste intended for disposal at licensed land disposal facilities and manifests."

Licensees shipping or transferring a Category 1 or Category 2 quantity of radioactive material are subject to the requirements in 10 CFR Part 37, Subpart D ("Physical Protection in Transit"). For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant: No response is needed from applicants during the licensing phase. Compliance with transportation requirements will be reviewed during NRC inspections.

Reference: "Radioactive Material Regulations Review (December 2008)" is available from the DOT at www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/RAM_Regulations_Review_12-2008.pdf. The Memorandum of Understanding with DOT on the Transportation of Radioactive Material (signed June 8, 1979) is available from the NRC on its public Web site under "Enforcement Guidance" at <http://www.nrc.gov/about-nrc/regulatory/enforcement/moudot.pdf>.

8.10.9 Security Program for Category 1 and Category 2 Radioactive Material

Regulations: 10 CFR Part 37

Criteria: Licensees must ensure the security of Category 1 and Category 2 radioactive material.

Note: The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material. The specific radionuclides subject to 10 CFR Part 37 requirements are listed in Table 1 of Appendix A to 10 CFR Part 37.

Discussion:

Requirements in 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"

In accordance with 10 CFR Part 37, licensees that possess aggregated Category 1 or Category 2 quantities of radioactive material must establish, implement, and maintain an access authorization program (Subpart B) and a security program (Subpart C) to ensure physical protection of the radioactive material.

Table 1 of Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR Part 37, lists Category 1 and Category 2 threshold quantities of radioactive material. The applicant should refer to this table to determine whether its proposed activities would be subject to the 10 CFR Part 37 requirements.

Before giving individuals unescorted access to Category 1 or Category 2 quantities of radioactive material (as defined in 10 CFR 37.5), licensees must conduct background investigations of these individuals, to determine that they are trustworthy and reliable, in accordance with 10 CFR 37.25.

In accordance with 10 CFR 37.41(b), licensees must establish a security program designed to monitor and, without delay, detect, assess, and respond to any actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material.

Per 10 CFR Part 37, Subpart D, licensees must provide for physical protection of Category 1 or Category 2 quantities of radioactive materials in transit. These requirements apply to licensees delivering such material to a carrier for transport, as well as cases in which licensees are transporting such material. Please note that the Subpart D requirements applicable to the transport of Category 1 quantities of radioactive material are more stringent than those applicable to Category 2 quantities.

Applicants and licensees are required to implement the 10 CFR Part 37 security requirements before they take possession of an aggregated Category 1 or Category 2 quantity of radioactive material.

Any licensee that has not previously been made subject to the provisions of 10 CFR Part 37, Subpart C must notify the NRC regional office specified in 10 CFR 30.6 in writing at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold. Pursuant to 10 CFR 37.43(b), as part of the security program, the licensee must develop and maintain written procedures that document how the requirements of Subpart C will be met. These written procedures may be subject to NRC review and inspection.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Response from Applicant:

No response is required from an applicant or licensee. Compliance with access authorization and security program requirements may be reviewed during NRC inspections.

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1501, 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2108, 10 CFR Part 20, Appendix B, 10 CFR 30.51, 10 CFR 37.11(c)

Criteria: Radioactive waste must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

Discussion: The applicant should discuss the methods for management and disposal of radioactive waste. The program should include procedures for the handling of waste, safe and secure storage, waste characterization, waste minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Licensees may not receive radioactive waste from other licensees for processing, storage, or disposal unless specifically authorized by the NRC.

The U.S. Environmental Protection Agency issued guidance for developing a comprehensive program to reduce hazardous waste. The NRC transmitted this guidance to licensees in IN-94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program," dated March 1994. NRC Regulatory Issue Summary 2011-09, "Available Resources Associated with Extended Storage of Low-Level Radioactive Waste," also contains useful information. Applications should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (radioactive from non-radioactive, short from long half-life, liquid from solid waste, etc.).

Waste Volume Reduction

Licensees may implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay-in-storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity or increased radiation levels) to workers, members of the public, and the environment. Safety procedures to address these concerns should be implemented. Applicants must describe in detail waste volume reduction operations that could create a radiological hazard to licensee employees or the general public. Appendix O of this NUREG describes a model procedure for waste compaction.

The following methods of waste disposal may be considered and should be addressed in the application, as appropriate.

Transfer to an Authorized Recipient

Waste may be transferred to a recipient (usually a waste disposal service company or the original supplier) that is properly licensed to receive such waste in accordance with 10 CFR 20.2001(a). Each shipment must comply with all applicable NRC and DOT requirements.

Decay-in-Storage

The NRC has concluded that materials with half-lives of less than or equal to 120 days are appropriate for decay-in-storage (DIS). The holding time of the waste should be based on the radionuclide(s), half-life, and the activity present when the waste was placed into storage. Such waste may be disposed of as ordinary trash if radiation surveys of the waste indicate that radiation levels are indistinguishable from background. The surveys should be performed with an appropriate radiation detection meter set on its most sensitive scale in a low background area and without any interposed shielding. In accordance with 10 CFR 20.1904(b), all radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed. Applicants must maintain accurate records of such disposals.

Appendix O of this NUREG provides a model procedure for DIS.

Extended Interim Storage

The NRC does not consider storage as a substitute for final disposal of radioactive wastes. Other than storage for radioactive decay, LLW should be stored only when disposal capacity is unavailable, and for no longer than is necessary. NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste for Fuel Cycle and Material Licensees," dated February 5, 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW. Regulatory Issue Summary 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated May 9, 2008, updates information provided in IN 90-09. In addition, the NRC issued Regulatory Issue

Summary 2011-09, “Available Resources Associated with Extended Storage of Low-Level Radioactive Waste,” dated August 16, 2011, which refers to other helpful guidance documents.

Release into Air and Water

Release of radioactive material into air and water must conform to the requirements described in 10 CFR 20.1302(b)(2). The applicant should discuss the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the “constraint” on air emissions of radioactive material required by 10 CFR 20.1101(d), which effectively reduces the limits specified in 10 CFR 20.1302(b)(2) for release of gaseous effluents. Applicants that are considering release of radioactive material into air and water should review Regulatory Guide 8.37, “ALARA Levels for Effluents from Materials Facilities,” dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring. Regulatory Guide 4.20, Rev. 1, “Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors,” dated April 2012, also contains useful information.

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of 10 CFR 20.2003. The regulations in 10 CFR 20.2003 authorize disposal of licensed material by release into a public sanitary sewerage system if certain conditions are met. Licensees are responsible for demonstrating that licensed materials discharged into the public sewerage system are readily soluble in water or are biological materials that are readily dispersible in water. NRC IN 94-07, “Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20,” dated January 1994, provides the criteria for evaluating solubility of waste. Licensees should carefully consider the possibility of reconcentration of radionuclides that are released into the sewer. The NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewage systems in IN 84-94, “Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted under 10 CFR 20.303 [now 10 CFR 20.2003],” dated December 1984.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in 10 CFR 20.2003 and do not exceed the monthly and annual limits specified in regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. Appendix O of this NUREG provides a model procedure for disposal of radioactive waste via sanitary sewer and maintenance of records.

If the applicant’s or licensee’s facility maintains a private sewerage treatment system, a septic system, or leach fields, the regulations of 10 CFR 20.2003 are not applicable for releases to these systems (see 10 CFR 20.1003, “Definitions,” for the definition of “sanitary sewerage”). Applicants may make releases of liquids to private sewerage systems, septic systems, or leach fields as effluents released to unrestricted areas pursuant to 10 CFR 20.1302(b)(2)(i).

If liquid releases are made to a private sewerage treatment system, septic system, or leach field, the sludges or other solids from these systems may become contaminated with radioactive material. Applicants should describe the monitoring planned for these systems in Item 8.10.7, “Surveys and Leak Tests,” of the application. Contaminated sludges will be required to be disposed of as radioactive waste using one of the methods described in this section. Applicants

may obtain approval of alternative disposal methods through application to the Commission, as described in 10 CFR 20.2002, "Method for obtaining approval of proposed disposal procedures."

Incineration

Applicants that wish to treat or dispose of licensed material by incineration must comply with the requirements of 10 CFR 20.2004, "Treatment or disposal by incineration." Applicants proposing incineration should be aware that a notice in the *Federal Register* may be required before disposal of ash as ordinary waste can be approved. However, approval of incineration pursuant to 10 CFR 20.2004 does not require notice in the *Federal Register* if the ash is disposed as radioactive waste or transferred to a specific licensee. Policy and Guidance Directive PG 8-10, "Disposal of Incineration Ash as Ordinary Waste," dated January 1997, provides guidance on the disposal of ash. Appendix O of this NUREG offers a model procedure for incineration of waste.

Applicants that are considering disposal of radioactive material by incineration should review Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring.

Disposal of Specific Waste as if it Were Not Radioactive

The following radioactive wastes may be disposed of as non-radioactive waste pursuant to 10 CFR 20.2005, "Disposal of specific wastes":

- liquid scintillation medium containing no more than 1.85 kBq [0.05 μ Ci] of H-3 or C-14 per gram of the medium
- animal carcasses or animal tissue containing no more than 1.85 kBq [0.05 μ Ci] of H-3 or C-14 per gram averaged over the weight of the entire animal

Applicants should have procedures to ensure that the above limits are not exceeded and that the disposal of animal tissue or carcasses containing licensed material is in a manner that will not permit their use either as food for humans or as animal feed. Applicants must maintain accurate records of these disposals.

Burial

Licensees previously authorized to bury radioactive materials pursuant to 10 CFR 20.304 before January 28, 1981, should describe the locations, condition, and current status of these former sites (i.e., controlled or uncontrolled, active monitoring of the site, and current condition of the burial site). If the licensee plans to decommission a burial site prior to termination of the license, the licensee may be required to notify the NRC and develop a decommissioning plan in accordance with 10 CFR 30.36. Additional guidance is provided in NUREG-1757, "Consolidated Decommissioning Guidance."

Other Methods Specifically Approved by the NRC Pursuant to 10 CFR 20.2002

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the

waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

The application should describe the ALARA considerations taken before disposal of radioactive materials. The request should discuss the potential for unmonitored or unanticipated release of radioactive materials to work areas and from release points (i.e., hoods and incinerator stacks). To be in compliance with the ALARA philosophy stated in 10 CFR 20.1101, "Radiation protection programs," radioactive material waste stream concentrations should be a fraction (generally 10 to 20 percent) of the limits specified in Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," Table II, 10 CFR Part 20.

Furthermore, because of the variability of inventory control programs for monitoring disposal and releases of byproduct material in use, a program for physically measuring releases should be in place whenever releases exceed the specified ALARA action point.

Note: Guidance concerning alternate waste disposal procedures that involve multiple jurisdictions has been provided in the State and Tribal Communication Letter FSME 12-025, dated March 13, 2012, "Clarification of the Authorization for Alternative Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR." (ADAMS Accession No. ML12065A038)

Note: Before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and/or 10 CFR 70.36, if licensees are authorized to possess byproduct material with a half-life greater than 120 days in an unsealed form, source material in an unsealed form, and/or special nuclear material, the licensees must, in accordance with 10 CFR 30.51(e), 10 CFR 40.61(e), and/or 10 CFR 70.51(b)(1)&(2), respectively, transfer the following records to the new licensee:

- records of disposal of licensed material made under:
 - 10 CFR 20.2002, "Method for obtaining approval of proposed disposal procedures"
 - 10 CFR 20.2003, "Disposal by release into sanitary sewerage"
 - 10 CFR 20.2004, "Treatment or disposal by incineration"
 - 10 CFR 20.2005, "Disposal of specific wastes"
- records required by 20.2103(b)(4) of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

In accordance with 10 CFR 37.11(c), a licensee that possesses radioactive waste that contains Category 1 or Category 2 quantities of radioactive material as defined in 10 CFR 37.5 is exempt from the requirements of 10 CFR Part 37, Subparts B, C, and D. However, any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg [4,409 lbs] is not exempt from the requirements of 10 CFR Part 37. For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

A licensee possessing radioactive waste that is exempt under 10 CFR 37.11(c) from the requirements of 10 CFR Part 37, Subparts B, C, and D must implement the following requirements to secure the radioactive waste:

- use continuous physical barriers that allow access to the radioactive waste only through established access control points;
- use a locked door or gate with monitored alarm at the access control point;
- assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and
- immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains Category 1 or Category 2 quantities of radioactive material.

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant:

Provide procedures for waste collection, storage, and the disposal by any of the authorized methods described in this section. Applicants should contact the appropriate regional office of the NRC for guidance to obtain approval of any method(s) of waste disposal other than those discussed in this section.

Note: Applicants do not need to provide information to the NRC if they plan to dispose of LLW through transfer to an authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14, as authorized by 10 CFR 20.2005.

References:

- Information Notice 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program," dated March 1994
- Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," dated January 1994

- Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984
- Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990
- Regulatory Issue Summary 2008-12, "Considerations For Extended Interim Storage Of Low-Level Radioactive Waste By Fuel Cycle And Materials Licensees"
- Regulatory Issue Summary 2011-09, "Available Resources Associated With Extended Storage Of Low-Level Radioactive Waste"
- Policy and Guidance Directive PG 8-10, "Disposal of Incineration Ash as Ordinary Waste," January 1997, ADAMS Accession Nos. ML003744979 and ML003752866 and Addendum, ADAMS Accession Nos. ML003744984 and ML003744988.
- NRC Regulatory Issue Summary 2004-17, Revision 1, "Revised Decay-In-Storage Provisions For The Storage Of Radioactive Waste Containing Byproduct Material," September 2005
- State and Tribal Communication Letter FSME 12-025 dated March 13, 2012 "Clarification of the Authorization for Alternative Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR" (ADAMS Accession No. ML12065A038)
- Division of Waste Management and Environmental Protection, Environmental and Performance Assessment Directorate, Operating Procedures, EPPAD 3.5 (Draft for Interim Use), "Review, Approval, and Documentation of Low-Activity Waste Disposals in Accordance with 10 CFR 20.2002 and 10 CFR 40.13(a)," dated August 2009
- Regulatory Issue Summary 2016-11, "Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002," November 13, 2016

8.12 Item 12: License Fees

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

Direct all questions about the NRC's fees or the completion of Item 12 of NRC Form 313 to the Office of the Chief Financial Officer at NRC Headquarters in Rockville, MD, 301-415-7554. Information about fees may also be obtained by calling the NRC's toll-free number, 800-368-5642, extension 415-7554. The e-mail address for fees questions is Fees.Resource@nrc.gov.

8.13 Item 13: Certification

A representative of the corporation or legal entity filing the application should sign and date NRC Form 313. The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed

previously in Chapter 3, “Management Responsibility,” signing the application acknowledges management’s commitment to and responsibility for the radiation protection program. The NRC will return all unsigned applications for proper signature.

Notes:

- It is a criminal offense to knowingly and willfully make a false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When an application references commitments, those items will be incorporated into the license and therefore become binding regulatory requirements.

9 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date [10 CFR 2.109(a), 10 CFR 30.36(a)].

Applicants for license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request.
- Submit either an U.S. Nuclear Regulatory Commission (NRC) Form 313 or a letter requesting amendment or renewal.
- Provide the license number and docket number.
- For renewals, provide a complete and up-to-date application including all required program elements outlined in Appendix B of this NUREG. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application.

9.1 Timely Notification of Transfer of Control

Regulations: 10 CFR 30.34(b), 10 CFR 40.46, 10 CFR 70.36.

Criteria: Licensees must provide all supporting information and obtain the NRC's prior, *written consent* before transferring control of the license, also referred to as a "change of ownership" and/or "transferring the license."

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not the NRC's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior NRC written consent to ensure the following:

- radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses or Agreement State licenses
- materials are properly handled and secured
- persons using these materials are capable, competent and committed to implementing appropriate radiological controls
- a clear chain of custody is established to identify who is responsible for disposition of records and licensed material
- the transferee has the financial resources to decommission the license, if necessary

- public health and safety are not compromised by the use of such materials
- adequate financial assurance is provided for compliance with the applicable NRC requirements, if required

Response from Applicant: No response is required from an applicant for a new license. However, current licensees should refer 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 more information about transfer of control (i.e., ownership).

Reference: 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, which can be found on the NRC’s Generic Communications Web page under “Regulatory Issue Summaries”: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.

10 APPLICATIONS FOR EXEMPTIONS

Regulations: 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 30.11

Criteria: Licensees may request exemptions from U.S. Nuclear Regulatory Commission (NRC) regulations. The licensee must demonstrate that the exemption is authorized by law; will not endanger life, property, or the common defense and security; and is otherwise in the public interest. Licensees may also use existing specific exemptions outlined in the Title 10 of the *Code of Federal Regulations* (10 CFR) regulations if they meet the established criteria.

Discussion: Various sections of the NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, "Application for exemptions"; 10 CFR 20.2301, "Applications for exemptions"; 10 CFR 30.11, "Specific exemptions"). These regulations state that the NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

Exemptions are not intended to revise regulations or apply to large classes of licensees and are generally limited to unique situations. Requests for exemptions submitted to the NRC must identify the regulation for which the exemption is being requested and include a justification for the requested exemption.

Unless the NRC has granted an exemption in writing, licensees must comply with all applicable regulations.

11 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36, 10 CFR 30.51, 10 CFR 40.36(f), 10 CFR 40.42, 10 CFR 40.46, 10 CFR 40.61, 10 CFR 70.25(g), 10 CFR 70.36, 10 CFR 70.38, 10 CFR 70.51

Criteria: The licensee must do the following:

- Notify the U.S. Nuclear Regulatory Commission (NRC), in writing, within 60 days of the occurrence of any of the following:
 - expiration of its license
 - a decision to permanently cease principal activities¹ at the entire site
 - for licensees subject to Title 10 of the *Code of Federal Regulations* (10 CFR) 30.36, a decision to permanently cease principal activities in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements
 - for licensees subject to 10 CFR 40.42 or 10 CFR 70.38, a decision to permanently cease principal activities in any separate building or outdoor area
 - no principal activities under the license have been conducted for a period of 24 months
 - no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release according to NRC requirements
- Submit a decommissioning plan, if required by 10 CFR 30.36(g), 10 CFR 40.42(g), and/or 10 CFR 70.38(g).
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j), 10 CFR 40.42(h) and (j), and/or 10 CFR 70.38(h) and (j).
- Submit to the appropriate NRC regional office a completed NRC Form 314, "Certificate of Disposition of Materials" (or equivalent information), and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final surveys and results of leak tests of sealed sources).
- Before a license is terminated, send records important to decommissioning that are required by 10 CFR 30.35(g), 10 CFR 40.36(f) and/or 10 CFR 70.25(g) to the

¹'Principal activities' are activities which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

appropriate NRC regional office in accordance with 10 CFR 30.51(f), 10 CFR 40.61(f), and/or 10 CFR 70.51(a)(3), respectively.

- Before a license is terminated, send records of disposal of licensed material made under 10 CFR 20.2002, 10 CFR 20.2003, 20.2004, 20.2005, and the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment to the appropriate NRC regional office in accordance with 10 CFR 30.51(d), 10 CFR 40.61(d), and/or 10 CFR 70.51(a)(1)&(2), if authorized to possess byproduct material with a half-life greater than 120 days in an unsealed form, source material in an unsealed form, and/or special nuclear material, respectively.

Discussion: To comply with the above criteria, before a licensee can decide whether it must notify the NRC under 10 CFR 30.36(d), 10 CFR 40.42(d), and/or 10 CFR 70.38(d), the licensee must determine whether residual radioactivity is present and, if so, whether the levels make the building or outdoor area unsuitable for release, according to NRC requirements. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

The permanent cessation of principal activities in an individual room or laboratory may require the licensee to notify the NRC if no other licensed activities are being performed in the building.

This requirement also applies to buildings that were approved by the broad scope licensee as locations of use but not specifically named on the broad scope license.

For information about requirements that apply to the timeliness of decommissioning, see Regulatory Issue Summary (RIS) 2015-19, Rev. 1, "Decommissioning Timeliness Rule Implementation and Associated Regulatory Relief," dated September 27, 2016, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2015/>.

For guidance on the disposition of licensed material, see Section 8.11 "Waste Management." For guidance on decommissioning records, see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

NUREG-1757, "Consolidated Decommissioning Guidance," contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Licensees that have large facilities to decommission should review NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)." The computer code "DandD" offers an acceptable method for calculating screening values to demonstrate compliance with the unrestricted dose limits. Supplemental information on the implementation of the final rule on radiological criteria for license termination was published in the *Federal Register* (63 FR 64132) on November 18, 1998.

Supplemental information on the implementation of the final rule on radiological criteria for license termination also was published in the *Federal Register* on December 7, 1999, (64 FR 68395) which addresses screening values in soils for the most common radionuclides, and in the *Federal Register* on June 13, 2000, (65 FR 37186) for screening values for building surfaces and soils contaminated with radionuclides not addressed in the prior *Federal Register* notices.

Response from Applicant: The applicant is not required to submit a response to the NRC during the initial application. The licensee's obligations in this matter begin when the license

expires or at the time the licensee ceases operations, whichever is earlier. These obligations are to undertake the necessary decommissioning activities, to submit NRC Form 314 or equivalent information, and to perform any other actions summarized in “Criteria” above.

Reference: NRC Form 314 is available at <http://www.nrc.gov/reading-rm/doc-collections/forms>.

APPENDIX A

U.S. NUCLEAR REGULATORY COMMISSION FORM 313

U.S. Nuclear Regulatory Commission Form 313

Please use the most current version of this form, which may be found at:
<http://www.nrc.gov/reading-rm/doc-collections/forms/>

NRC FORM 313 (06-2016) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE	APPROVED BY OMB: NO. 3150-0120 Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.																		
EXPIRES: 06/30/2019																				
INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.																				
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NRC FORM 313 (06-2016)

APPENDIX B

**SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN
ITEMS 5 THROUGH 11 OF
U.S. NUCLEAR REGULATORY COMMISSION FORM 313**

**Suggested Format for Providing Information Requested in
Items 5 Through 11 of
U.S. Nuclear Regulatory Commission Form 313**

Instructions:

If an applicant checks a box in the column marked "Description Attached," then they must provide that information on separate sheets.

Item No.	Suggested Response	Description Attached
5.	<p>RADIOACTIVE MATERIAL</p> <p>Unsealed and Sealed Byproduct Material</p> <p>Applicants for a Type A broad scope license should request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. The applicant should separately list individual radionuclides needed in much larger quantities or in much smaller quantities than that described in the atomic number 1 through 83 request. The maximum quantities of nuclides with atomic numbers above 83 also should be listed separately.</p>	[]
	<p>A separate listing should be submitted for sealed sources needed in larger quantities than described in the atomic number 1 through 83 request. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that the NRC can verify that they have been evaluated in a SSD registration certificate or specifically approved on a license. Applicants must also provide the maximum activity per source and the total possession limit. For sources and devices not registered, as allowed by 10 CFR 32.210(g)(2), the applicant must have adequate training and experience and facilities and equipment to handle comparable quantities of material in any form under 10 CFR 30.33(a)(2) and (3) and must provide information about the unregistered sealed sources and devices in accordance with 10 CFR 30.32(g)(4).</p>	[]

Item No.	Suggested Response	Description Attached
5.	<p>RADIOACTIVE MATERIAL (Cont'd)</p> <p>Unsealed and Sealed Sources (Cont'd)</p> <p>Possession requests should be categorized into general areas of use (e.g., research and development activities, routine gauging activities, self-shielded irradiators, instrument calibrators, and medical applications).</p> <p>Applicants for licenses to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities listed in 10 CFR 30.72 must include either of the following: (1) an evaluation showing that the maximum offsite dose caused by a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid, or (2) an emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3).</p> <p>Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in 10 CFR 33.100, Schedule A. Type B applicants should request the quantity of material specified in 10 CFR 33.11(b). Type C applicants should request the quantity of material specified in 10 CFR 33.11(c).</p>	

Item No.	Suggested Response	Description Attached
	<p>Financial Assurance and Recordkeeping for Decommissioning</p> <p>State the following: “Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g) and 10 CFR 70.51(b)(3), we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and/or 10 CFR 70.36. Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and /or 10 CFR 70.51(a)(3), prior to license termination, we will forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g) to the appropriate NRC Regional Office.”</p> <p>If financial assurance is required, submit evidence of financial assurance following the guidance of NUREG–1757, Volume 3, “Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness.”</p> <p>Emergency Plan</p> <p>If an emergency plan is required, provide either:</p> <p>an evaluation showing that the maximum offsite dose due to a release of radioactive materials would not exceed 0.01 Sv [1 rem] effective dose equivalent or 0.05 Sv [5 rem] to the thyroid; or</p> <p>an emergency plan for responding to the release of radioactive material in accordance with the criteria listed in 10 CFR 30.32(i)(3).</p>	<p>[]</p> <p>[]</p>
6.	<p>PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED</p> <p>Describe in general terms the purposes for which the licensed material will be used.</p>	<p>[]</p>
7.	<p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE</p> <p>Executive Management</p> <p>The applicant must describe administrative controls and provisions relating to organization and management and management review necessary to ensure safe operations. The applicant should submit an organizational chart that describes the management structure, reporting paths, and the flow of authority between executive management, the RSC (for Type A broad scope), and the RSO (For Type A and Type B broad scope).</p>	<p>[]</p>

Item No.	Suggested Response	Description Attached
7.	<p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Cont'd)</p> <p>Radiation Safety Committee</p> <p>Applicants for a Type A broad scope license should submit the following:</p> <ul style="list-style-type: none"> • description of the duties and responsibilities of the RSC • criteria used for selecting members of the RSC, including what members and the number of members constituting a quorum. Members should be indicated by position title rather than by name • criteria and procedure describing the approval process used by the RSC and RSO for authorizing new users and new uses <p>In addition, applicants for a Type A broad scope license that request the flexibility to make some program changes and revise some procedures previously approved by the NRC without amendment of the license should submit the following:</p> <ul style="list-style-type: none"> • a description of the duties and responsibilities of the RSC, including: <ul style="list-style-type: none"> – review and approval of permitted program and procedural changes prior to implementation – implementation of program and procedural changes – audit of licensed operations to determine compliance – the appropriate actions taken when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence • a description of the process for procedure and program review and approval, including documentation of the specific change. (At a minimum, documentation should state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.) 	<p>[]</p> <p>[]</p> <p>[]</p>

Item No.	Suggested Response	Description Attached
7.	<p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Cont'd)</p> <p>Radiation Safety Officer</p> <p>For Type A, Type B, and Type C applicants:</p> <ul style="list-style-type: none"> • Submit the name of the proposed RSO. • Describe the training for the proposed RSO that demonstrates the individual is qualified to perform the duties required under the license. • Address the RSO's experience in performing each of the duties listed in the "Duties and Responsibilities" section in section 8.7.3, "Radiation Safety Officer," when and where the experience was gained, and the type, form, and quantity of radionuclides involved. • Submit a statement delineating the RSO's duties and responsibilities. • Submit a radiation safety officer delegation of authority memorandum signed by the licensee's executive management. <p>In addition, for Type B applicants:</p> <ul style="list-style-type: none"> • Submit the criteria used by the RSO to approve new users and uses of byproduct material. • Submit the criteria that the RSO will use to evaluate the radiation safety aspects of proposed uses, prior to approval. 	<p>[]</p> <p>[]</p>

Item No.	Suggested Response	Description Attached
8.	<p>TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS</p> <p>Submit a description of the radiation safety training program developed for each group of workers, including: topics covered, qualifications of the instructors, method of training, method for assessing the success of the training, and the frequency of training and refresher training. Alternately, identify the model training program described in the appropriate base NUREG corresponding to the particular type of licensed program and submit a statement that this training program will be implemented.</p> <p>In addition, Type A broad scope licensees or applicants that want the flexibility to revise their radiation safety training program without amendment of the license (as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of NUREG-1556, Volume 11, Revision 1) should describe the process that will be used to revise and implement the submitted training programs.</p>	<p>[]</p> <p>[]</p>
9.	<p>FACILITIES AND EQUIPMENT</p> <p>Describe the criteria the RSC or RSO, as appropriate, will use to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.). The description will need to include the method of classifying laboratories based on type, toxicity, and quantity of byproduct material being requested. Sample diagrams should be provided for each classification scheme that take into consideration shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When reviewing facilities where radioactive materials may become airborne, sample diagrams should take into consideration descriptions of the ventilation systems—including pertinent airflow rates, pressures, filtration equipment, and monitoring systems. For facilities and equipment used in special applications such as those described in Section 8.9 of NUREG-1556, Volume 11, Revision 1, the application will include their locations, (i.e., buildings and room numbers) and special considerations that the RSC or RSO (or both) will use in authorizing byproduct material use. Also, describe the procedures for control, review, and approval of significant facilities or equipment modifications.</p>	<p>[]</p>

Item No.	Suggested Response	Description Attached
10.	<p>RADIATION SAFETY PROGRAM</p> <p>Audit and Review of Program</p> <p>Describe the mechanisms executive management uses to ensure adequate oversight of the program. In addition, if a licensee is upgrading its limited scope license to a Type A broad scope license or renewing its Type A broad scope license, describe the RSC's involvement in these oversight mechanisms.</p> <p>Describe the audit mechanism implemented by the RSO or other responsible individual to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC- or RSO-approved permits (as appropriate), and good health physics practices.</p> <p>The applicant is not required to, and should not, submit its program for conducting the annual audit required by 10 CFR 20.1101, "Radiation protection programs," to the NRC for review as part of a license application. The NRC will review this audit program during inspection.</p> <p>In addition, Type A broad scope licensees or applicants that want the flexibility to revise the audit mechanism implemented by the RSO without amendment of the license, as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of NUREG-1556, Volume 11, Revision 1, should describe the process they will use to revise and implement their audit program.</p>	[]

Item No.	Suggested Response	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Radiation Monitoring Instruments</p> <p>Provide the criteria used by the RSC or RSO (or both), as appropriate, to review and approve radiation monitoring instrumentation to ensure that appropriate radiation monitoring equipment will be used during licensed activities.</p> <p>Discuss how the RSC or RSO, as appropriate, will ensure that instruments are properly calibrated at prescribed frequencies.</p> <p>Submit procedures for instrument calibration or state that instruments will be calibrated by a vendor licensed by the NRC or an Agreement State to perform instrument calibrations. Licensees that want authorization to calibrate their own survey instruments may commit to implementing the model procedures published in Appendix H of NUREG-1556, Volume 11, Revision 1.</p> <p>State the frequency at which instruments will be calibrated.</p> <p>In addition, Type A broad scope licensees or applicants that want the flexibility to revise their instrument specifications and procedure for calibration of instruments without amendment of the license, as discussed in Chapter 1, "Purpose of the Report," and Section 8.7.2, "Radiation Safety Committee," of NUREG-1556, Volume 11, Revision 1, should describe the process that will be used to revise and implement these submitted procedures.</p>	<p>[]</p> <p>[]</p>

Item No.	Suggested Response	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Material Receipt and Accountability</p> <p>Describe the administrative procedures to ensure control of procurement and use of byproduct material.</p> <p>While the applicant is required to develop and implement safe opening procedures for packages containing radioactive material, the applicant need not submit the procedures during the licensing process. The NRC will review activities subject to these procedures during inspection.</p> <p>Provide the following statement: "We will develop, implement and maintain procedures for ensuring accountability of licensed materials at all times."</p> <p>Describe the administrative controls and provisions related to materials control, accounting, and security. Describe the method for maintaining accountability of licensed material at all times.</p> <p>If applicable, provide the following statement: "We will comply with the National Source Tracking System (NSTS) reporting requirement as described in 10 CFR 20.2207."</p> <p>In addition, Type A broad scope licensees or applicants that want the flexibility to revise their administrative procedures concerning control of procurement and use of byproduct material without amendment of their license should describe the process that their radiation safety committee will use to revise these administrative procedures, controls, and provisions. Licensees and applicants should also do this when making revisions to their administrative controls and provisions related to material control, accounting, and security. The flexibility to revise these administrative procedures is discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of NUREG-1556, Volume 11, Revision 1.</p>	[]

Item No.	Suggested Response	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Occupational Dose</p> <p>Provide one of the following statements:</p> <p>“We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502.”</p> <p style="text-align: center;">OR</p> <p>“We will monitor individuals in accordance with the criteria in the section titled, ‘Radiation Safety Program–Occupational Dose’ in NUREG–1556, Vol. 11, Revision 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.’”</p> <p style="text-align: center;">OR, IN LIEU OF THESE STATEMENTS,</p> <p>provide a description of an alternative method for demonstrating compliance with the referenced regulations.</p> <p>In addition, Type A broad scope licensees or applicants that want the flexibility to revise their personnel dosimetry program without amendment of the license, as discussed in Chapter 1, “Purpose of Report,” and Section 8.7.2, “Radiation Safety Committee,” of NUREG-1566, Volume 11, Revision 1, should describe the process they will use to revise and implement their submitted personnel dosimetry program.</p> <p>Public Dose</p> <p>No response is required from the applicant, but records and written materials documenting compliance will be examined during inspection. During NRC inspections, licensees must be able to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public.</p>	<p>[]</p> <p>[]</p>

Item No.	Suggested Response	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Safe Use of Radionuclides and Emergency Procedures</p> <p>Submit the procedures for safe use of radionuclides and emergencies. Submissions should include procedures for maintaining security of licensed radioactive materials. As an alternative, the applicant or licensee may state that, "We will adopt the procedures for the safe use of radionuclides and emergencies as published in Appendix K of NUREG-1556, Volume 11, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.""</p> <p>In addition, Type A broad scope licensees or those applying for a Type A broad scope license that want the flexibility to revise their safe use and emergency procedures without amendment of the license, as described in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of NUREG-1556, Volume 11, Revision 1, should discuss the process that will be used to revise and implement their submitted safe use and emergency procedures.</p> <p>Surveys</p> <p>Submit procedures to evaluate radiological hazards, both external and internal. As an alternative, the applicant may state, "We will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix L of NUREG-1556, Volume 11, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.""</p> <p>Leak Testing</p> <p>Submit leak test procedures. As an alternative, the applicant may state, "We will implement the model leak test program published in Appendix M of NUREG-1556, Volume 11, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.""</p> <p>In addition, Type A broad scope licensees or those applying for a Type A broad scope license that want the flexibility to revise their survey or leak test program without amendment of the license, as described in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of NUREG-1556, Volume 11, Revision 1, should discuss the process that will be used to revise and implement their submitted survey and leak test program.</p>	<p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p>

Item No.	Suggested Response	Description Attached
10.	RADIATION SAFETY PROGRAM (Cont'd) Transportation No response is needed from applicants during the licensing phase. Compliance with transportation requirements will be reviewed during NRC inspections.	
	Security Program for Category 1 and Category 2 Material No response is required from an applicant or licensee. Compliance with access authorization and security program requirements may be reviewed during NRC inspections.	
11.	WASTE MANAGEMENT Provide procedures for waste collection, storage, and the disposal by any of the authorized methods described in this section. Applicants should contact the appropriate regional office of the NRC for guidance to obtain approval of any method(s) of waste disposal other than those discussed in this section.	[]

APPENDIX C
INFORMATION NEEDED FOR FIELD USE OF BYPRODUCT MATERIAL

Information Needed for Field Use of Byproduct Material

Title 10 of the *Code of Federal Regulations* (CFR) 51.22(c)(14)(v) identifies as a categorical exclusion (from the requirement to prepare an environmental assessment (EA) or impact statement) the use of radioactive material for research and development and for educational purposes. However, this categorical exclusion does not encompass, among other things, performance of field studies in which licensed material is deliberately released directly into the environment for purposes of the study (e.g., tagging of animals or insects that remain in the wild, and use of tagged pesticides on crops grown outdoors in fields).

These types of requests may require an environmental report filed by the applicant and an EA by the U.S. Nuclear Regulatory Commission (NRC), pursuant to 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." Field studies that do not deliberately release radioactive material into the environment, such as tagging of animals and penning them to prevent escape or plant studies in greenhouse conditions, may be eligible for a categorical exclusion, pursuant to 10 CFR 51.22(c)(14)(xvi).

Applicants and licensees that desire to perform field studies in which licensed material is deliberately released to the environment for the purposes of studies should provide the following information:

1. a complete application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material
2. a complete experimental protocol
3. a description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment, if appropriate, and procedures for minimizing releases
4. a description of the expected radiation dose to humans
5. written permission from the property owner to use radioactive materials at the proposed site
6. a letter from the appropriate state health authorities indicating that they have reviewed the applicant's or licensee's application and concur with the request

APPENDIX D

MODEL DELEGATION OF AUTHORITY FOR RADIATION SAFETY OFFICER

Model Delegation of Authority for Radiation Safety Officer

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed radiation safety officer and are responsible for ensuring the safe and secure use of radiation. You are responsible for managing the Radiation Protection Program, identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads

APPENDIX E
FACILITIES AND EQUIPMENT CONSIDERATIONS

Facilities and Equipment Considerations

Below is a list of topics that should be considered when developing a description of the facilities and equipment that a broad scope applicant will use or otherwise have available. Not every applicant will need to address each topic in its application.

- Restricted areas are defined as areas where the licensee limits access to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.
- Security zones are defined as any temporary or permanent area determined and established by the licensee for the physical protection of aggregated Category 1 or Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37. The security zone should be designed so that the licensee can monitor, detect without delay, assess, and respond to any unauthorized entries into security zones and any unauthorized removal of radioactive material from the security zone. Monitoring and detection systems may include video surveillance systems and electronic devices for intrusion detection alarms.
- Bench top or open work areas may be used for sealed sources, small quantities of solid materials in a form not likely to become airborne or dispersed, and small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems. Surfaces should be smooth and non-porous to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems. Ventilation systems for these facilities should be designed so that airborne radioactive material work areas are at negative pressure compared to non-radioactive work areas.
- Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, unsealed volatile licensed materials, and processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, Appendix B.
- Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols.

Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- For the most efficient operation of hoods and glove boxes, minimize storage of materials and equipment inside the work areas.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity. If appropriate, supply and exhaust fans can be interlocked such that if exhaust fans shutdown, the shutdown of supply fans is also triggered, this interlock system to prevent laboratory and work areas from becoming positively pressurized with respect to the surrounding parts of the facility.
- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow, rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- To reduce radiation exposure from gamma-emitting radioactive materials, shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods, or in glove boxes.
- To reduce the exposure from high-energy beta-emitting materials, shielding of low atomic number material, such as high-density plastic, may be used.
- Shielded shipping containers frequently are used for continued storage after receipt of materials.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (as low as is reasonably achievable). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with low background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination buildup.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.

- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of 10 CFR Part 20, Subpart H, "Respiratory protection and controls to restrict internal exposure in restricted areas."
- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on the number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas and away from areas that personnel frequently occupy. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited. If radioactive waste materials are volatile, the containers should be stored in ventilated areas.
- If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per 10 CFR 20.1204, "Determination of internal exposure."
- Adequate air and/or water effluent monitoring equipment should be used to demonstrate compliance with the limits found in 10 CFR Part 20, Appendix B, if applicable, and tested for operability at the frequency established by the manufacturer.

APPENDIX F
SAMPLE AUDIT PROGRAM—NON-MEDICAL

Sample Audit Program–Non-medical

Licensees may use the following audit form to self-assess the adequacy of the licensed program, identify program weaknesses, and allow licensees to take early corrective actions [before an inspection by the U.S. Nuclear Regulatory Commission (NRC)]. This form is not intended to be all inclusive. During an audit, the auditor needs to keep in mind not only the requirements of the NRC's regulations, but also the licensee's commitments in its applications and other correspondence with the NRC. Licensees are encouraged to modify the audit form as needed to include items specific to their licensed program (e.g., implementation of a security program). The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement. This audit form includes references at the end.

1. **MANAGEMENT OVERSIGHT:**
[Management support to radiation safety, radiation safety committee, radiation safety officer (RSO), program audits (including annual reviews of program and ALARA reviews), control by authorized users, appropriate follow-up on events, implementation of corrective actions from previous audit/inspection findings, and active communication and interaction with other committees if conducting human and/or animal research]
2. **AMENDMENTS AND PROGRAM CHANGES:**
(Amendments to the license properly implemented; if applicable, program and procedural changes were approved and implemented in accordance with license condition)
3. **FACILITIES:**
(Facilities as described in license, uses, control of access, engineering controls, calibration facilities, shielding, and air flow)
4. **EQUIPMENT AND INSTRUMENTATION:**
[Operable and calibrated survey and effluent monitoring equipment, and Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21.21 requirements]
5. **MATERIAL USE, CONTROL, AND TRANSFER:**
(Materials and uses authorized, security and control of licensed materials, and procedures for receipt and transfer of licensed material)
6. **AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:**
(Radiological surveys, air sampling, leak tests, inventories, handling of radioactive materials, contamination controls, records, and public doses)
7. **TRAINING AND INSTRUCTIONS TO WORKERS:**
(Training and retraining requirements and documentation, interviews and observations of routine work, staff knowledge of all routine activities, requirements in 10 CFR Part 19 and 10 CFR Part 20, emergency situations, and supervision by authorized users)
8. **RADIATION PROTECTION:**
(Radiation protection program with ALARA provisions, external and internal dosimetry, exposure evaluations, dose and survey records and reports, annual notifications to workers, and bulletins and other generic communications)

9. **RADIOACTIVE WASTE MANAGEMENT:**
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents, and compactors; and license conditions for special disposal method)
10. **DECOMMISSIONING:**
(Records relevant to decommissioning; decommissioning plan and schedule, notification requirements, cost estimates, funding methods, financial assurance; “timeliness rule” requirements, and changes in radiological conditions since decommissioning plan was submitted—NUREG–1757, Volume 3, provides guidance on decommissioning)
11. **TRANSPORTATION:**
[Quantities and types of licensed material shipped, special form and packaging design requirements and documentation, shipping papers, hazardous materials (HAZMAT) communication procedures, return of sources, procedures for monitoring radiation and contamination levels of packages, HAZMAT training, and records and reports]
12. **NOTIFICATIONS AND REPORTS:**
(Reporting and follow-up of theft, loss, incidents, and overexposures. Notification of change in RSO or authorized user. Radiation exposure reports provided to individuals.)
13. **POSTING AND LABELING:**
(Notices; license documents; regulations; bulletins, and generic information; posting of radiation areas; and labeling of containers of licensed material)
14. **INDEPENDENT AND CONFIRMATORY MEASUREMENTS:**
(Areas surveyed, both restricted and unrestricted; measurements made; comparison of data with staff’s results and regulations)
15. **AUDIT FINDINGS:**

REFERENCES

- A. MANAGEMENT OVERSIGHT
 - 1. Radiation Safety Committee
Applicable license conditions
 - 2. Radiation Safety Officer
Applicable license conditions
 - 3. Audits, Reviews, or Inspections
10 CFR 20.1101, "Radiation protection programs"
10 CFR 20.2102, "Records of radiation protection programs"
Applicable license conditions
 - 4. ALARA
10 CFR 20.1101, "Radiation protection programs"
 - 5. Authorized Users
Applicable license conditions
- B. AMENDMENTS AND PROGRAM CHANGES
Applicable license conditions
- C. FACILITIES
 - 1. Access Control
10 CFR 20.1601, "Control of access to high radiation areas"
10 CFR 20.1602, "Control of access to very high radiation areas"
10 CFR 20.1801, "Security of stored material"
10 CFR 20.1802, "Control of material not in storage"
10 CFR Part 37, Subpart B, "Background Investigations and Access Authorization Program"
Applicable license conditions
 - 2. Engineering Controls
10 CFR 20.1101, "Radiation protection programs"
10 CFR 20.1701, "Use of process or other engineering controls"
10 CFR Part 37, Subpart C, "Physical Protection Requirements During Use"
Applicable license conditions
- D. EQUIPMENT AND INSTRUMENTATION
 - 1. Survey Instruments
10 CFR 20.1501, "General"
10 CFR 20.1701, "Use of process or other engineering controls"
10 CFR 20.2103, "Records of surveys"
Applicable license conditions

2. Safety Component Defects
 - 10 CFR 21.21, "Notification of failure to comply or existence of a defect and its evaluation"
- E. MATERIAL USE, CONTROL, AND TRANSFER
 1. License and Applicable License Conditions
 2. Security and Control
 - 10 CFR 20.1003, "Definitions"
 - 10 CFR 20.1801, "Security of stored material"
 - 10 CFR 20.1802, "Control of material not in storage"
 - 10 CFR Part 37, Subpart C, "Physical Protection Requirements During Use"
 3. Receipt and Transfer of Licensed Material
 - 10 CFR 20.1302, "Compliance with dose limits for individual members of the public"
 - 10 CFR 20.1906, "Procedures for receiving and opening packages"
 - 10 CFR 20.1501, "General"
 - 10 CFR 20.2103, "Records of surveys"
 - 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources"
 - 10 CFR 30.41, "Transfer of byproduct material"
 - 10 CFR 30.51, "Records"
 - 10 CFR Part 37, Subpart D, "Physical Protection in Transit"
 - 10 CFR 40.51, "Transfer of source or byproduct material"
 - 10 CFR 70.42, "Transfer of special nuclear material"
 - 10 CFR 74.13, "Material status reports"
 - 10 CFR 74.15, "Nuclear material transaction reports"
- F. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL
 1. Area Surveys
 - 10 CFR 20.1302, "Compliance with dose limits for individual members of the public"
 - 10 CFR 20.1501, "General"
 - 10 CFR 20.2103, "Records of surveys"
 - 10 CFR 20.2107, "Records of dose to individual members of the public"
 - Applicable license conditions
 2. Leak Tests and Inventories
 - Applicable license conditions
- G. TRAINING AND INSTRUCTIONS TO WORKERS
 1. General
 - 10 CFR 19.12, "Instruction to workers"
 - Knowledge of 10 CFR Part 20, "Standards for Protection Against Radiation"
 - Applicable license conditions
- H. RADIATION PROTECTION
 1. Radiation Protection Program
 - a. Exposure evaluation
 - 10 CFR 20.1501, "General"

- b. Programs
 - 10 CFR 20.1101, "Radiation protection programs"
 - 2. Dosimetry
 - a. Dose Limits
 - 10 CFR 20.1201, "Occupational dose limits for adults"
 - 10 CFR 20.1202, "Compliance with requirements for summation of external and internal doses"
 - 10 CFR 20.1207, "Occupational dose limits for minors"
 - 10 CFR 20.1208, "Dose equivalent to an embryo/fetus"
 - b. External
 - 10 CFR 20.1203, "Determination of external dose from airborne radioactive material"
 - 10 CFR 20.1501, "General"
 - 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose"
 - Applicable license conditions
 - c. Internal
 - 10 CFR 20.1204, "Determination of internal exposure"
 - 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose"
 - 10 CFR Part 20, Subpart H, "Respiratory protection and controls to restrict internal exposure in restricted areas"
 - 3. Source Security Protection
 - 10 CFR 37.43, "General security program requirements"
 - 4. Records
 - 10 CFR 20.2102, "Records of radiation protection programs"
 - 10 CFR 20.2103, "Records of surveys"
 - 10 CFR 20.2104, "Determination of prior occupational dose"
 - 10 CFR 20.2106, "Records of individual monitoring results"
- I. RADIOACTIVE WASTE MANAGEMENT
 - 1. Disposal
 - 10 CFR 20.1904, "Labeling containers"
 - 10 CFR 20.2001, "General requirements"
 - 10 CFR 20.2103, "Records of surveys"
 - 10 CFR 20.2108, "Records of waste disposal"
 - 10 CFR 20.2003, "Disposal by release into sanitary sewerage"
 - 2. Effluents
 - a. General
 - Applicable license conditions
 - b. Release to septic tanks
 - 10 CFR 20.1003, "Definitions" (sanitary sewerage)
 - 10 CFR Part 20, Appendix B, Table 2, "Effluent Concentrations"

- c. Incineration of waste
10 CFR 20.2004, "Treatment or disposal by incineration"
 - d. Control of air effluents and ashes
10 CFR 20.1201, "Occupational dose limits for adults"
10 CFR 20.1301, "Dose limits for individual members of the public"
10 CFR 20.1501, "General"
10 CFR 20.1701, "Use of process or other engineering controls"
Applicable license conditions
- 3. Waste Management
 - a. General
10 CFR 20.2001, "General Requirements"
Information Notice (IN) 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees"
 - b. Waste compacted
Applicable license conditions
 - c. Waste storage areas
10 CFR 20.1801, "Security of stored material"
10 CFR 20.1902, "Posting requirements"
10 CFR 20.1904, "Labeling containers"
Applicable license conditions
 - d. Packaging, control, and tracking
10 CFR Part 20, Appendix G, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests"
10 CFR 20.2006, "Transfer for disposal and manifests"
10 CFR 61.55, "Waste classification"
10 CFR 61.56, "Waste characteristics"
 - e. Transfer
10 CFR Part 20, Appendix G, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests"
10 CFR 20.2001, "General requirements"
10 CFR 20.2006, "Transfer for disposal and manifests"
 - f. Records
10 CFR 20.2103, "Records of surveys"
10 CFR 20.2108, "Records of waste disposal"
- J. DECOMMISSIONING
10 CFR Part 20, Subpart E, "Radiological Criteria for License Termination"
10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning"
10 CFR 30.36, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas"

K. TRANSPORTATION

1. General
10 CFR 71.5, "Transportation of licensed material"
2. Shippers—Requirements for Shipments and Packaging
 - a. General requirements
49 CFR Part 173, "Shippers—general requirements for shipments and packagings," Subpart I, "Class 7 (Radioactive) Materials"
49 CFR 173.24, "General requirements for packaging and packages"
49 CFR 173.448, "General transportation requirements"
49 CFR 173.435, "Table of A₁ and A₂ values for radionuclides"
 - b. Transport quantities
10 CFR 71.4, "Definitions"
 - i. All quantities
10 CFR 71.4, "Definitions"
49 CFR 173.410, "General design requirements"
49 CFR 173.431, "Activity limits Type A and Type B packages"
49 CFR 173.441, "Radiation level limitations and exclusive use provisions"
49 CFR 173.443, "Contamination control"
49 CFR 173.475, "Quality control requirements prior to each shipment of Class 7 (radioactive) materials"
49 CFR 173.476, "Approval of special form Class 7 (radioactive) materials"
 - ii. Limited quantities
49 CFR 173.421, "Excepted packages for limited quantities of Class 7 (radioactive) materials"
49 CFR 173.422, "Additional requirements for excepted packages containing Class 7 (radioactive) materials"
 - iii. Type A quantities
49 CFR 173.412, "Additional design requirements for Type A packages"
49 CFR 173.415, "Authorized Type A packages"
49 CFR 178.350, "Specification 7A; general packaging, Type A"
 - iv. Type B quantities
49 CFR 173.416, "Authorized Type B packages"
49 CFR 173.467, "Tests for demonstrating the ability of Type B and fissile materials packagings to withstand accident conditions in transportation"
 - v. Low specific activity (LSA) material and surface contaminated objects (SCOs)
49 CFR 173.403, "Definitions"

- 49 CFR 173.427, "Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO)"
- vi. International Atomic Energy Agency (IAEA) Code of Conduct
 - Category 1 and 2 materials including Highway Route Controlled quantities as defined in 49 CFR 173.403 or known radionuclides in forms listed as RAM-QC by the Nuclear Regulatory Commission
 - 49 CFR 172.802, "Components of a security plan"
- c. HAZMAT Communication Requirements
 - 49 CFR Part 172, "Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans"
 - 49 CFR Part 172, Subpart C, "Shipping Papers"
 - 49 CFR Part 172, Subpart D, "Marking"
 - 49 CFR Part 172, Subpart E, "Labeling"
 - 49 CFR Part 172, Subpart F, "Placarding"
 - 49 CFR Part 172, Subpart G, "Emergency Response Information"
- 3. HAZMAT Training
 - 49 CFR 172.702, "Applicability and responsibility for training and testing"
 - 49 CFR 172.704, "Training requirements"
- 4. Transportation by Public Highway
 - 49 CFR 171.15, "Immediate notice of certain hazardous materials incidents"
 - 49 CFR 171.16, "Detailed hazardous materials incident reports"
 - 49 CFR 177.800, "Purpose and scope of this part and responsibility for compliance and training"
 - 49 CFR 177.816, "Driver training"
 - 49 CFR 177.842, "Class 7 (radioactive) material"
- L. NOTIFICATIONS AND REPORTS
 - 10 CFR 19.13, "Notifications and reports to individuals"
 - 10 CFR 20.2201, "Reports of theft or loss of licensed material"
 - 10 CFR 20.2202, "Notification of incidents"
 - 10 CFR 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits"
 - 10 CFR 30.50, "Reporting requirements"
- M. POSTING AND LABELING
 - 10 CFR 19.11, "Posting of notices to workers"
 - 10 CFR 21.6, "Posting requirements"
 - 10 CFR 20.1902, "Posting requirements"
 - 10 CFR 20.1903, "Exemptions to posting requirements"
 - 10 CFR 20.1904, "Labeling containers"
 - 10 CFR 20.1905, "Exemptions to labeling requirements"

APPENDIX G

TYPICAL U.S. NUCLEAR REGULATORY COMMISSION (NRC) NOTIFICATION AND REPORTING REQUIREMENTS FOR INCIDENTS

Typical U.S. Nuclear Regulatory Commission (NRC) Notification and Reporting Requirements for Incidents

Note: The following list of notification and reporting requirements is provided to inform licensees about typical notification and reporting requirements that apply to their licensed activities. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, notification and reporting requirements change; therefore, licensees should consult the regulations for definitive information about current requirements.

Event	Telephone Notification	Written Report	Regulatory Requirement
Package received with removable radioactive surface contamination exceeding the limits of 10 CFR 71.87(i) or external radiation levels exceeding the limits of 10 CFR 71.47	immediate (NRC and final delivery carrier must be notified)	none	10 CFR 20.1906(d)
Theft or loss of licensed material	immediate	30 days	10 CFR 20.2201(a)(1)(i) 10 CFR 20.2201(b)(1)
Whole body dose greater than 0.25 Sv [25 rems]	immediate	30 days	10 CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Gy [250 rads]	immediate	30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 0.5 Sv [50 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems]	none	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv [0.1 rem]	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i) & (ii)
Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a) & (c)(2); 40.60(a) & (c)(2); and 70.50(a) & (c)(2)

Event	Telephone Notification	Written Report	Regulatory Requirement
Unplanned contamination event that requires restricted access for more than 24 hours and involves a quantity of material greater than five times the lowest annual limit on intake for the material as specified in Appendix B of 10 CFR Part 20 and requires the area to be restricted for a reason other than to allow radionuclides with half-lives less than 24 hours to decay	24 hours	30 days	10 CFR 30.50(b)(1) & (c)(2); 40.60(b)(1) & (c)(2); and 70.50(b)(1) & (c)(2)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2) & (c)(2); 40.60(b)(2) & (c)(2); and 70.50(b)(2) & (c)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4) & (c)(2); 40.60(b)(4) & (c)(2); and 70.50(b)(4) & (c)(2)
Determination that any licensee that has not previously implemented the Security Orders (i.e., orders issued by the NRC to require licensees to implement interim security measures) or been subject to the provisions of 10 CFR Part 37, Subpart C will aggregate radioactive material to a quantity that equals or exceeds the Category 2 threshold	none	90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold	10 CFR 37.41(a)(3)
Coordination with local law enforcement agency (LLEA) has failed, either because the LLEA has not responded or because the LLEA does not plan to participate	3 business days	Submittal of a written report concerning failures of coordination with LLEA as described in 10 CFR 37.45(b) is not required; however, licensees must document their efforts to coordinate with the LLEA and keep this documentation for 3 years	10 CFR 37.45(b)

Event	Telephone Notification	Written Report	Regulatory Requirement
Determination that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material	As soon as possible (but not at the expense of causing delay or interfering with the LLEA response), but no later than 4 hours after discovery	30 days	10 CFR 37.57(a)&(c)
Assessment of any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material	As soon as possible, but no later than 4 hours after notifying the LLEA	none	10 CFR 37.57(b)
Determination that a shipment containing a Category 1 quantity of material is lost or missing in transport	Within 1 hour of the determination . Also, notify LLEA within 1 hour of determination	30 days and periodic updates	10 CFR 37.81(a)&(g)
Determination that a shipment containing a Category 2 quantity of material is lost or missing in transport	Within 4 hours of the determination and again within 24 hours if the material has not yet been located and secured	30 days	10 CFR 37.81(b)&(g)
Discovery along the route of any actual or attempted theft or diversion, or suspicious activity, related to a Category 1 quantity of material in transport	Upon discovery, as soon as possible. Also, notify LLEA as soon as possible upon discovery	30 days (except no report for suspicious activity)	10 CFR 37.81(c)&(g)

Event	Telephone Notification	Written Report	Regulatory Requirement
Discovery of any actual or attempted theft or diversion, or suspicious activity, related to a Category 2 quantity of material in transport	As soon as possible	30 days (except no report for suspicious activity)	10 CFR 37.81(d)&(g)
Upon recovery of any lost or missing Category 1 quantity of material	As soon as possible. Also, notify LLEA as soon as possible	To be included in the 30-day report of an event described in 10 CFR 37.81(g), if recovered during that time	10 CFR 37.81(e)&(h)
Upon recovery of any lost or missing Category 2 quantity of material	As soon as possible	To be included in the 30-day report of an event described in 10 CFR 37.81(g), if recovered during that time	10 CFR 37.81(f)&(h)

Note: Telephone notifications must be made to the NRC Operations Center at 301-816-5100, except as noted. The Center is staffed 24 hours a day and accepts collect calls.

APPENDIX H

RADIATION MONITORING INSTRUMENT SPECIFICATIONS AND MODEL RADIATION SURVEY INSTRUMENT AND AIR SAMPLER CALIBRATION PROGRAM

Radiation Monitoring Instrument Specifications and Model Radiation Survey Instrument and Air Sampler Calibration Program

Radiation Monitoring Instrument Specifications

The specifications in Table H-1 will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility(ies). Additional information about instruments and their uses also can be found in NUREG-1575, "Multi Agency Radiation Survey and Sited Investigation Manual (MARSSIM)," Chapter 6 and Appendix H.

Table H-1. Typical Survey Instruments* (Instruments Used to Measure Radiological Conditions at Licensed Facilities)			
Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-ray	μR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
Nal Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
BF ₃ Proportional Tube*	Neutron	Thermal neutron	High
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (Nal)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%
*Table from "The Health Physics and Radiological Health Handbook, Revised Edition," edited by Bernard Shleien, 1992 (except for * items).			

In addition to selecting an instrument that is appropriate for the radiation(s) of interest, it is important to know if the instrument is sufficiently sensitive so as to make measurements at the required level. This is particularly important for measurements such as for leak test samples, bioassay measurement, and decommissioning of facilities or equipment. The “minimum detectable activity” (MDA) for the instrument should be a fraction (10 to 50 percent) of the criteria that must be met.

Example 1: A sealed source is considered to be leaking if a removable contamination exceeds 185 becquerels (Bq) [0.005 microcurie (μCi), or 11,100 disintegrations per minute (dpm)]. The instrument used to measure wipe test samples should have an MDA of 10 percent of that limit, or 1,100 dpm for the radionuclide being tested; this is usually easy to detect for cobalt-60 or cesium-137, but more difficult to detect for nickel-63, depending on the instrument used to analyze the sample.

Example 2: The licensee is closing a laboratory where uranyl acetate (generally licensed pursuant to 10 CFR 40.22, “Small quantities of source material”) was used. The total residual contamination screening value for uranium-238 is 101 dpm/100 square centimeters (cm²). The MDA for direct measurements of uranium-238 should be made at 10 to 50 percent of the screening value for uranium-238, or 10 to 50 dpm/100 cm².

When the sample count time and the background count time are the same, a simplified calculation can be used to determine the MDA for a static measurement. This simplified calculation assumes that the Type I error (false positive) and Type II error (false negative) are both selected to be equal in probability and at the 95 percent confidence error.

Note 1: This calculation can be modified for more complex situations as described in NUREG-1575, Chapter 6, “Field Measurements Methods and Instrumentation.”

Note 2: This equation applies only to instruments used in scalar mode, accumulating counts of radiation detected over a defined period of time. It is NOT applicable to survey instruments used in rate meter mode.

This simplified equation is:

$$MDA = \frac{2.71 + 4.65 \sqrt{bkg \times t}}{t \times E}$$

where: MDA = minimum detectable activity in disintegrations per minute (dpm)
 bkg = background count rate in counts per minute (cpm)
 t = background counting time and sample counting time in minutes (min)
 E = detector efficiency in counts per disintegration (c/d)

Example:

A gas-flow proportional counter is used in scalar mode to make 1-minute counts of samples.

background count rate (bkg) = 300 cpm

sample counting time (t) = 1 min

background counting time (t) = 1 min

efficiency (E) = 0.15 c/d

$$\text{MDA} = \frac{2.71 + 4.65 \sqrt{\text{bkg} \times t}}{t \times E} = \frac{2.71 + 4.65 \sqrt{300 \text{ cpm} \times 1 \text{ min}}}{1 \text{ min} \times 0.15 \text{ (c/d)}} = 555 \text{ dpm}$$

According to this calculation, the licensee would be confident that 95 percent of the time, the instrument can reliably detect measurements as low as 555 dpm. This is the minimum activity that the instrument can detect; results below this number are not reliable at the 95 percent confidence interval. However, all numerical results should be recorded. From the basic MDA, the licensee can determine the minimum detectable concentration (MDC) for the actual measurement conditions.

For example, suppose the above measurement was made with a radiation survey meter probe with a surface area of 15 square centimeters (cm²); then the MDC would be calculated as follows:

$$\text{MDC} = 555 \text{ dpm}/15 \text{ cm}^2 = 37 \text{ dpm/cm}^2 \text{ or } 3700 \text{ dpm}/100 \text{ cm}^2$$

Determining the MDA or MDC for instruments used in rate meter mode and for scanning surveys is more complicated. If the licensee will be performing surveys for decommissioning, which require direct measurement surveys, scanning measurement surveys, and surveys for removable contamination, they should review NUREG-1757, "Consolidated Decommissioning Guidance." Additional information related to determining the MDA and MDC for direct measurements and scanning measurements may be found in Chapter 6 and Appendix H of NUREG-1575.

Model Radiation Survey Instrument Calibration Program

Training

Before independently calibrating radiation survey instruments, an individual should complete both classroom and on-the-job training as follows:

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:
 - principles and practices of radiation protection
 - radioactivity measurements, monitoring techniques, and the use of radiation detection instruments
 - mathematics related to the use and measurement of radioactivity
 - biological effects of radiation
- On-the-job training will consist of the following:
 - observing authorized personnel performing radiation survey instrument calibration
 - conducting radiation survey meter calibrations under the supervision and in the physical presence of an individual already authorized to perform calibrations

Facilities and Equipment for Calibration of Dose and Dose Rate Measuring Instruments

To reduce doses received by individuals not calibrating radiation survey instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.

The calibration source should be well-collimated, and the calibration area should be designed to minimize scatter of radiation, which could affect the calibration process.

The calibration area should be appropriately controlled so that persons entering the area will be aware if a radiation source is in use.

Evaluate posting of the calibration area with appropriate radiation warning signs, as required by Subpart J of 10 CFR 20.

Individuals conducting calibrations of radiation survey instruments will wear assigned dosimetry.

Individuals conducting calibrations will use a calibrated and operable radiation survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Frequency of Calibration of Radiation Measurement Instruments and Equipment

A licensee committed to a routine or emergency radiation survey program should perform an acceptable calibration of all radiation measurement instruments and equipment at the frequency specified in U.S. Nuclear Regulatory Commission (NRC) regulations, annually, or at the frequency recommended by the manufacturer, whichever period is shorter.

Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a radiation measurement instrument have changed, by repair or alteration, or whenever system performance is observed to change significantly.

Routine maintenance of radiation measurement instruments should be performed as recommended by the manufacturer.

Primary or secondary standard instruments used to calibrate radiation measurement instruments should be inspected frequently for consistency of performance.

Calibration Sources for Dose and Dose Rate Measuring Instruments

A radioactive sealed source(s) will be used for calibrating dose and dose rate measuring radiation survey instruments, and this source will have the following characteristics:

- The source should approximate a point source.
- Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 microgray/hour ($\mu\text{Gy/h}$) [0.1 millirad/hour (mrad/h)] and 10 percent for dose rates less than 1.0 $\mu\text{Gy/h}$ [0.1 mrad/h].
- The source should contain a radionuclide that emits radiation of identical or similar type and energy as the environment in which the calibrated device will be used.
- The source should be strong enough to give an exposure rate of at least 7.7 microcoulomb per kilogram per hour [30 milliroentgen per hour] at 100 centimeters {e.g., 3.1 gigabecquerels [(85 mCi (millicuries))] of cesium-137 or 780 megabecquerels [21 mCi] of cobalt-60}.

Note: Inverse square and radioactive decay laws should be used to correct changes in exposure rate due to changes in distance or source decay.

Calibration of Dose or Dose Rate Measuring Instruments

There are three kinds of scales frequently used on dose and dose-rate survey meters. These are calibrated as follows:

- **Linear readout instruments** with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on each scale. After adjustment, check the response of the instrument at approximately 20 percent and 80 percent of full scale. Instrument readings should be within $\pm x$ of the conventionally true value for the following ranges:

- Background to 10 $\mu\text{Gy/h}$ [1.0 mrad/h]; $\pm x = \pm 30\%$
 - 10 $\mu\text{Gy/h}$ [1.0 mrad/h] to 1.0 mGy/h [100 mrad/h]; $\pm x = \pm 20\%$
 - 1.0 mGy/h [100 mrad/h] to 10 Gy/h [1,000 Rad/h]; $\pm x = \pm 10\%$
- **Logarithmic readout instruments**, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. Adjust the instrument for each scale according to site specifications or the manufacturer's specifications. After adjustment, check the calibration at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value as described for linear readout instruments.
 - **Digital readout instruments** should be calibrated the same as linear readout instruments.

Note: Readings above 2.58×10^{-4} coulomb/kilogram/hour [1 roentgen/h] need not be calibrated, unless the licensee expects to make measurements at higher dose rates; regardless, such scales should be checked for operation and response to radiation.

Calibration of Surface Contamination Measurement Instruments

Instruments used to detect surface contamination usually consist of a count-rate meter and a detector that is appropriate for the type of radiation(s) being measured.

The efficiency of radiation survey meters must be determined by using radiation sources with similar energies and types of radiation that users of the radiation survey instrument intend to measure.

If each scale has a calibration potentiometer, the reading should be adjusted to respond to the calibration source at approximately 80 percent of full scale, and the response at approximately 20 percent of full scale should be observed. If only one calibration potentiometer is available, the response should be adjusted at mid-scale on one of the scales, and response on the other scales should be observed. The instrument efficiency factor (e.g., cpm/dpm) thus obtained should have a signal-to-noise ratio, including the compilation of source and instrument uncertainties, of $\pm x$ for the following ranges:

- alpha measurement
 - 0.01 Bq/cm² to 2.0 Bq/cm² [60 to 12,000 dpm/100 cm²]; $\pm x = \pm 20\%$
 - 2.0 Bq/cm² to 200 Bq/cm² [12,000 to 1,200,000 dpm/100 cm²]; $\pm x = \pm 10\%$
- beta measurement
 - 0.05 Bq/cm² to 2.0 Bq/cm² [300 to 12,000 dpm/100 cm²]; $\pm x = \pm 20\%$
 - 2.0 Bq/cm² to 200 Bq/cm² [12,000 to 1,200,000 dpm/100 cm²]; $\pm x = \pm 10\%$

Calibration of Analytical Instruments Such As Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

Analytical instruments used to determine radioactivity in a sample may be specialized equipment according to the type of samples to be analyzed and the types and quantities of radioactivity to be measured. Typically, the sample sizes and activities are very small, and can

be difficult to measure. Sample collection and preparation may differ for the various analytical instruments, so manufacturer procedures and industry standard practices should be followed. Such analytical instruments should be calibrated in accordance with the manufacturer's instructions. Analytical instruments typically require routine maintenance and verification procedures to ensure that they are operating properly when used.

As with calibration of other radiation measurement instruments, calibration of analytical instruments use a radioactive sealed source(s). These should be suitable for the geometry of the sample(s) to be analyzed. The calibration source(s) should have a known activity(ies) and be of similar type and energy as the radioactive materials to be analyzed. The analysis should be sensitive enough to detect the lowest levels of radioactivity desired. Correction of results for quenching, self-absorption, and other factors may be required, depending on the analytical instrument, the samples type, and other environmental conditions.

Calibration Records

Calibration records for all radiation survey instruments should indicate the procedure used and the results of the calibration. The records should include the following:

- the owner or user of the radiation survey instrument
- a description of the radiation survey instrument that includes the manufacturer's name, model number, serial number, and type of detector
- a description of the calibration source, including the exposure rate at a specified distance or activity on a specified date
- for each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the radiation survey instrument
- the exposure reading indicated with the radiation survey instrument in the "battery check" mode (if available on the instrument)
- for radiation survey instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
- for radiation survey instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument
- for radiation detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure
- the exposure rate or count rate from a check source, if used
- the name and signature of the individual who performed the calibration and the date on which the calibration was performed

The following information will be attached to the radiation survey instrument as a calibration sticker or tag:

- for dose and dose rate measuring instruments, the source radionuclide used to calibrate the radiation survey instrument (with correction factors) for each scale
- for surface contamination measurement instruments, the efficiency of the radiation survey instrument, for each radionuclide the instrument will be used to measure (if efficiency is not calculated before each use)
- for each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
- the date of calibration and the next calibration due date
- the apparent exposure rate or count rate from the check source, if used

Air Sampler Calibration

To assess accurately the air concentration of radioactive materials in a given location, the volume of air sampled and the quantity of contaminant in the sample must be determined. Accurate determination of the volume of air sampled requires standard, reproducible, and periodic calibration of the air metering devices that are used with air sampling instruments.

Licensees can find guidance on total air sample volume calibration methods acceptable to NRC staff in the publication titled "Air Sampling Instruments," which can be found in the 9th Edition, American Conference of Governmental Industrial Hygienists, 2001. This information is supplemented below.

Frequency of Calibration of Air Sampling Equipment

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually (See Regulatory Guide 8.25, Rev. 1, "Air Sampling in the Workplace").
- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration, or whenever system performance is observed to have changed significantly.
- Routine instrument maintenance should be performed as recommended by the manufacturer.
- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit for Measurement of Air Sample Volume

Most methods of calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly

with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has been calibrated against a primary standard.

The following are significant errors associated with determining the total air volume sampled:

- E_C : The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)¹
- E_S : Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading.)
- E_t : The percentage error in measurement of sampling time that should be kept within 1 percent.
- E_V : The most probable value of the cumulative percentage error in the determination of the total air volume sampled. E_V can be calculated from the following equation, provided there are no additional significant sources of errors:

$$E_V = [E_S^2 + E_C^2 + E_t^2]^{1/2}$$

The most probable value of the cumulative error E_V , in the determination of total volume, should be less than 20%.

A sample calculation of the most probable value of the cumulative error in total volume measured is as follows: If accuracies of the scale reading, the calibration factor, and sample time are ± 4 , 2, and 1 percent, respectively, and there are no other significant sources of error, the cumulative error would be:

$$E_V = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\% \text{ or approx. } 5\%$$

If there are significant differences in pressure and temperature between the calibration site and the sampling site, appropriate corrections should be made using the ideal gas laws provided below:

$$V_s = V_1 * (P_1/760) * (273/T_1)$$

where V_s = volume at standard pressure and temperature (760 mm Hg and 273K

V_1 = volume measured at conditions P_1 and T_1

T_1 = temperature of V_1 in K

P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

¹The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factors to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20 percent, licensees should include an additional error term in the calculation above.

The licensee should maintain records of all routine and special calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed, and estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration and should include the appropriate correction factors to be used.

References:

- Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," June 1992
- NUREG-1400, "Air Sampling in the Workplace," September 1993 (available at the ADAMS Accession No. ML13051A671)
- Health Physics and Radiological Health, 4th Edition. Edited by Thomas E. Johnson and Brian Kent Birky, 2012
- American National Standards Institute (ANSI) N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments"
- "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 9th Edition, 2001

APPENDIX I
MATERIAL RECEIPT AND ACCOUNTABILITY

Material Receipt and Accountability

The broad scope licensee is authorized to possess only the radionuclides in the types and forms listed on the license, and the total quantity possessed under the license must not exceed the maximum possession limit listed on the license. Therefore, the radiation safety officer (RSO) must know how much material is possessed under the license, in all locations, at any time. The licensed inventory includes all radioactive materials in use, in storage, and in waste. The regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 30.51, 40.61, 70.51 and 10 CFR Part 74 require the licensee to maintain records of receipt, transfer, and disposal of all licensed materials.

Sample Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and do not exceed the possession limits.
- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the RSO (or designated receiving area).
- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

If the package appears to be damaged, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive between [state times (e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays)] must be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area. Security personnel (or other designated trained individual) should unlock the door, place the package in the designated secured storage area, and re-lock the door.

Radiation Safety Officer: _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries usually will be handled by security personnel (or other trained individuals), as described in the above procedures. Because certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. They should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.

If the instructions are not clear, or if there are questions regarding receiving packages containing radioactive material, please contact:

Name _____

Phone _____

For additional information on worker training, see the section titled, "Training for Individuals Working In or Frequenting Restricted Areas."

Materials Possessed Under a General License or Received from a General Licensee

Individuals at a licensee's facility may receive and use material pursuant to a general license as authorized in 10 CFR Parts 31, 40, or 70. Generally licensed materials are distributed by manufacturers authorized by the U.S. Nuclear Regulatory Commission (NRC) to distribute materials directly to the persons who will use them under a general license. Some common items include nickel-63 sources in electron capture detectors in certain gas chromatographs, tritium gas contained in self-luminous exit signs, calibration sources in liquid scintillation counters, and uranyl acetate used for staining electron microscope samples. The licensee should develop a policy for how their institution will require responsible use and tracking of this material.

If the licensee possesses generally licensed materials and wishes to transfer them to a specific license, they should review the regulations in 10 CFR Parts 30, 31, 40, or 70, as applicable, to determine how this may be done.

SAMPLE PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING LICENSED MATERIALS

For packages received under the specific license, authorized individuals must implement procedures for opening each package, as follows:

- Wear gloves to prevent hand contamination.
- Approach the package with a radiation survey meter to ensure that no unusual or unexpected radiation levels are present.
- Visually inspect the package for any sign of damage (e.g., crushed, punctured). If damage is noted, stop and notify the RSO.
- Check U.S. Department of Transportation (DOT) White I, Yellow II, or Yellow III label or packing slip for activity of contents so shipment does not exceed license possession limits.
- Monitor the external surfaces of a labeled package in accordance with 10 CFR 20.1906.
- Open the outer package (following supplier's directions, if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on the bottle or other container). Check integrity of the final source container (e.g., inspect for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Check again that the shipment does not exceed license possession limits. If an authorized individual finds anything other than expected, they should stop and notify the RSO.
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash.
- Maintain records of receipt, package survey, and wipe test results.
- Notify the final delivery carrier and the NRC Operations Center, 301-816-5100, by telephone when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) or the external radiation levels exceed the limits of 10 CFR 71.47.

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or laboratory or authorized user's control to another should have prior approval from the RSO. A written transfer procedure should be developed by the RSO to ensure that transfers are done in accordance with the conditions of the license. All transfers must be done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers.

External Transfers

Licensed material should not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance with DOT, NRC, or U.S. Postal Service Regulations, whichever is applicable. Prior to any transfer from the license, the licensee must verify that the recipient is authorized to receive the licensed material, as required by 10 CFR 30.41, 40.51 and 70.42.

Gifts

On occasion, licensees may be offered or have donated licensed materials by other individuals as gifts (e.g., a retiring medical practitioner donating his cesium needles to the university medical center). All such gifts of radioactive materials must be transferred to the licensee and handled in accordance with NRC requirements and the conditions of the license. In any case, the RSO should approve the gift prior to the transfer and package receipt and accountability procedures should be followed and documented as for all licensed material.

APPENDIX J
PUBLIC DOSE

Public Dose

This appendix describes methods for determining radiation doses to members of the public.

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in 1 calendar year resulting from the licensee's possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.
- Air emissions of radioactive materials do not result in doses greater than 0.1 mSv (10 mrem) per year total effective dose equivalent (TEDE). As required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1101(d), if the licensee exceeds the 10 mrem per year air emission dose constraint, the licensee must report the exceedance as provided in 10 CFR 20.2203, and promptly take appropriate corrective action to ensure against recurrence.

Members of the public include persons who live, work, study, or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of byproduct material but may work in the vicinity where such materials are used or stored.

Doses to Members of the Public	
<p>INCLUDE doses from:</p> <ul style="list-style-type: none"> • radiation and/or radioactive material released by a licensee • sources of radiation under the control of a licensee • effluents from sources of licensed radioactive materials • licensed material in transportation or storage at the licensee's facility 	<p>DO NOT INCLUDE doses from:</p> <ul style="list-style-type: none"> • sanitary sewerage discharges from licensee action taken in accordance with 10 CFR 20.2003 • natural background radiation • medical administration of radioactive material including patients released under 10 CFR 35.75 • voluntary participation in medical research

As defined in 10 CFR 20.1003, the term *unrestricted area* means “an area, access to which is neither limited nor controlled by the licensee.” For purposes of this definition in 20.1003, an “unrestricted area” is an area where access is neither limited nor controlled by the licensees for purposes of limiting exposures to radiation and radioactive materials. An “unrestricted area” for purposes of 20.1003 may be controlled for other purposes, such as for security purposes (see, for ex., 10 CFR 20.1801 and 20.1802), and still be considered an “unrestricted area” as long as it is not required to be controlled for limiting exposure to radiation and radioactive materials. Typical unrestricted areas may include offices, shops, areas outside buildings, property, and storage areas for non-radioactive materials, and other facilities and laboratories where licensed materials are not normally used or stored.

The licensee may show compliance with the annual dose limit for individual members of the public by:

- demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv [100 mrem] in a year
- demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in Table 2, “Effluent Concentrations,” of Appendix B, to

10 CFR Part 20 {The licensee also should show that if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv [2 mrem] in any one hour and 0.5 mSv [0.05 rem] in a year.}

To perform a dose assessment, the licensee should identify all potential sources of external and internal radiation exposure to members of the public and all locations of use, transport, and storage of radioactive material at the facility. The licensee must then take radiation measurements or perform calculations to demonstrate compliance.

Measurements

The licensee may use measurements to demonstrate that the average annual releases are within regulatory limits, as well as demonstrate that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv [100 mrem] in a year. These measurements may include:

- dose rate surveys for radiation exposures from external radiation sources
- measurements of radionuclides in air and water effluent

The method used to measure dose will depend on the nature of the radiation source. If the source of radiation is constant, it may be adequate to measure the dose rate and integrate it over time. If the source of radiation differs or changes over time, it may be necessary to perform continuous measurements.

Radioactivity releases may be determined by effluent monitoring or by effluent sampling and analysis. Airborne effluents may be discharged when volatile materials are used, such as during iodinations, but the discharge itself usually is not continuous since volatile materials often are used periodically rather than continuously. Liquid effluents may be discharged continuously

or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

Using a calculation method, the licensee must determine the highest dose an individual is likely to receive at the boundary of the unrestricted area. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. An extremely conservative calculation would assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see Table J–1). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further evaluation.

If, however, the licensee would rather choose a more realistic assumption of the individual's occupancy at the points of highest internal and external exposures, then the licensee may use the occupancy factors in Table J–1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table J–1. Standard Occupancy Factors	
Occupancy Factor	Description
1	Work areas such as offices, laboratories, shops, and occupied space in nearby buildings or outdoor areas
1/4	Corridors, lounges, elevators using operators, unattended parking lots
1/16	Waiting rooms, rest rooms, stairways, unattended elevators, janitor's closets, outside areas used only for pedestrians or vehicular traffic

Records

In accordance with 10 CFR 20.2107, the licensee must maintain records to demonstrate compliance with the dose limit for individual members of the public, until the Commission terminates the license. In general, survey and monitoring records of ambient radiation and effluent radioactivity should be adequate.

Records demonstrating the dose to an individual member of the public should identify the instruments used in the survey, the name of the surveyor, the date of the survey, the location of the survey(s) including a description or drawing of the area surveyed, survey results, and if applicable, the occupancy factors used and justification for their use. In addition, records

demonstrating the dose to an individual member of the public that involve effluent sampling analysis should include information on concentrations of specific radionuclides, minimum detectable activity of the system, and the estimated uncertainty of measurements.

APPENDIX K

**GENERAL TOPICS FOR SAFE USE OF RADIONUCLIDES
AND MODEL EMERGENCY PROCEDURES**

General Topics for Safe Use of Radionuclides and Model Emergency Procedures

General Topics for Safe Use of Radionuclides

Each laboratory or area where radioactive material is used or stored should have general rules so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used.
- Wear disposable gloves at all times when handling licensed materials.
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area.
- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Do not store food, drink, or personal effects in areas where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Store radioactive solutions in clearly labeled containers.
- Safely handle sealed sources.
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

Security of Radioactive Materials

- Licensed materials in use in controlled or unrestricted areas must be under constant surveillance
- Licensed materials will be secured by one or more of the following methods:
 - storing and using licensed materials only in restricted areas
 - limiting access to an entire facility or building or portion of the building to radiation workers
 - providing storage areas that can be locked to prevent access to the licensed material

- implementing procedures that require a radiation worker to be within “line of sight” of the materials whenever licensed materials are in use

Radionuclide-specific Procedures

Licensees should develop written procedures for use of different radionuclides so that users know the appropriate types of shielding, protective clothing, survey instruments, surveys, and decontamination activities that are required. Safety procedures may vary, depending on the chemical form of the radionuclide. See examples of such procedures included below.

Example 1:

If requesting more than 37 megabecquerels (MBq) [(1 millicurie (mCi))] of unbound (“free”) iodine-125 or iodine-131, special safety instructions should be provided to users, including the following:

- a mandatory radiation survey and wipe test for radioactive contamination after each use
- bioassay procedures for individuals working with mCi quantities of unbound radioiodine or volatile compounds labeled with radioiodine
- the use of vented hoods for iodination procedures and for the storage of millicurie quantities of potentially volatile forms radioiodine
- a dry run prior to the performance of unfamiliar procedures to preclude unexpected complications. In addition, the U.S. Nuclear Regulatory Commission (NRC) recommends that the radiation safety officer (RSO) be present during new procedures.
- procedures for measuring the concentration of radioiodine effluents from the hoods

Example 2:

If requesting more than 37 MBq [1 mCi] of phosphorus-32, special safety instructions should be provided to users, including the following:

- the use of shielding of low atomic number material, such as high-density plastic, to keep bremsstrahlung radiation to a minimum
- a mandatory radiation survey and wipe test for radioactive contamination after each use
- the use of extremity monitors for procedures that involve 37 MBq [1 mCi] or more
- a dry run prior to the performance of unfamiliar procedures to preclude unexpected complications. In addition, the NRC recommends that the RSO be present during new procedures.
- the use of eye protection for procedures that involve 370 MBq [10 mCi] or more

Sample Procedures for Handling Emergencies

Licensees should not neglect, delay, or ignore appropriate first aid and other immediate medical needs of injured individuals suspected of having been contaminated.

General Safety Procedures to Handle Spills

- Name and telephone number of RSO or an alternate person(s) should be posted conspicuously in areas of use so that they are readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:
 - disposable gloves
 - housekeeping gloves
 - disposable lab coats
 - disposable head coverings
 - disposable shoe covers
 - roll of absorbent paper with plastic backing
 - masking tape
 - plastic trash bags with twist ties
 - “radioactive material” labeling tape
 - marking pen
 - pre-strung “radioactive material” labeling tags
 - box of wipes
 - instructions for “emergency procedures”
 - clipboard with copy of the radioactive spill report form for the facility
 - pencil
 - appropriate survey instruments, including batteries (for radiation survey meters)

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, the likelihood of spread of contamination, the types of surfaces contaminated, and the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay. The applicant should establish criteria for determining when to use the major spill procedure versus the minor spill procedure

Minor Spills of Liquids and Solids

- Instructions to Workers
 - Notify persons in the area that a spill has occurred.
 - Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)
 - Clean up the spill, wearing disposable gloves and using absorbent paper.
 - Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.

- Survey the area with an appropriate low-range radiation survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.
- Promptly report the incident to the RSO.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with the RSO and the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Follow up on the decontamination activities and document the results.
 - As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
 - If necessary, notify the NRC.

Major Spills of Liquids and Solids

- Instructions to Workers
 - Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room.
 - Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened, if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
 - Shield the source only if it can be done without further contamination or significant increase in radiation exposure.
 - Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
 - Notify the RSO immediately.
 - Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap.
 - Allow no one to return to work in the area unless approved by the RSO.

- Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by perspiration.
 - Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results.
 - Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin.
 - If necessary, notify the NRC.

Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases

- Instructions to Workers
 - Notify all personnel to vacate the room immediately.
 - Shut down ventilation system, if possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.
 - Vacate the room. Seal the area, if possible.
 - Notify the RSO immediately.
 - Ensure that all access doors to the area are closed and posted with appropriate warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area.
 - Survey all persons who could possibly have been contaminated. Decontaminate as directed by the RSO.
 - Promptly report suspected inhalations and ingestions of licensed material to the RSO.
 - Decontaminate the area only when advised and/or supervised by the RSO.
 - Allow no one to return to work in the area unless approved by the RSO.
 - Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).

- Follow the instructions of the RSO and the RSO's staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).
- Reminders to RSO
 - Supervise decontamination activities.
 - Perform air sample surveys in the area before permitting resumption of work with licensed materials.
 - Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc.
 - Consider need for medical exam and/or whole body count before permitting involved individuals to return to work with licensed material.
 - Determine cause and corrective actions needed; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
 - If necessary, notify the NRC.

Minor Fires

- Instructions to Workers (Licensees should develop procedures and instructions in accordance with local fire safety requirements, Occupational Safety and Health Administration regulations, etc. and provide training as needed.)
 - Immediately attempt to put out the fire by approved methods (e.g., fire extinguisher) if other fire hazards or radiation hazards are not present.
 - Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department (as instructed by RSO).
 - Once the fire is out, isolate the area to prevent the spread of possible contamination.
 - Survey all persons involved in combating the fire for possible contamination.
 - Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap.
 - In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment necessary to decontaminate the area.
 - Allow no one to return to work in the area unless approved by the RSO.
 - Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).

- Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Supervise decontamination activities.
 - If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash affected area again to remove any contamination that was released by the perspiration.
 - Consult with fire safety officials to ensure that there are no other possibilities of another fire starting.
 - Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
 - If necessary, notify the NRC.

Fires, Explosions, or Major Emergencies

- Instructions to Workers
 - Notify all persons in the area to leave immediately.
 - Notify the fire department.
 - Notify the RSO and other facility safety personnel.
 - Upon arrival of firefighters, inform them where radioactive materials are stored or where radionuclides were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc.
 - Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
 - Allow no one to return to work in the area unless approved by the RSO.
 - Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Coordinate activities with facility's industrial hygienist or environmental health and safety office and with local fire department.

- Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished.
- Once the fire is extinguished, advise firefighters not to enter potentially contaminated areas where radioactive sources may be present or radiation areas until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas.
- Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary.
- Supervise decontamination activities.
- Consider bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- If necessary, notify the NRC.

Incidents Involving Sealed Sources

For an emergency situation that may occur concerning a sealed source that has been exposed unintentionally, is unshielded or compromised, the following safety instructions should be considered:

- Immediately secure and post the restricted area; maintain continuous surveillance and restrict access to the restricted area.
- Notify the RSO, RSO designee, and management personnel immediately.
- Retrieval operations should be supervised by the RSO.
- No source or suspected source should be handled directly with bare hands.
- Determine if additional dosimetry will be required during source retrieval.
- Appropriate survey instruments should be used for the response activity.
- Expedient methods of reducing unintended exposure to staff and the public, such as lead shot bags, sandbags, steel plates, and remote handling devices.
- The RSO should make required notifications to the NRC.

Copies of emergency procedures should be provided to all users. Post a current copy in each laboratory or other area where radioactive material is used.

Procedures for Collecting Bioassay Samples

In the event of an emergency in which an individual may become contaminated and radioactive material was taken into the body through skin absorption or other means, or is suspected of

having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. The following items should be considered in developing procedures for collecting bioassay samples:

- the type of bioassay that must be performed (direct or indirect)
- the number of samples or data points to be collected
- the frequency of sampling (e.g., hourly, daily, weekly, once)
- the size of the sample to be collected (e.g., 24-hour urine collection)
- the ease or difficulty of sample collection
- the need for written instructions to be provided to the sample collector, who may be the contaminated individual

APPENDIX L
RADIATION SAFETY SURVEY TOPICS

Radiation Safety Survey Topics

This appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits, and bioassays.

Training

Before independently performing radiation surveys, an individual should complete both classroom and on-the-job training as follows:

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:
 - principles and practices of radiation protection
 - radioactivity measurements, monitoring techniques, and using instruments
 - usage and basic mathematics and calculations for measuring radioactivity
 - biological effects of radiation
- Appropriate on-the-job-training consists of the following:
 - observing authorized personnel using survey equipment, collecting samples, and analyzing samples
 - using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- A gamma counter system with a single or multichannel analyzer can be used to count samples containing gamma-emitters (e.g., iodine-125, cesium-137, cobalt-60).
- A liquid scintillation counting (LSC) system can be used to count samples containing most beta-emitters and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements). The LSC is the most common instrument used for measurement of tritium (H-3) contamination and other low-energy beta-emitters commonly used in laboratory research and development, such as carbon-14, sulfur-35, and phosphorus-32.
- Licensees may use a gas-flow proportional counting system to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits or where an individual is working in a dose rate of 0.025 millisievert (mSv) [2.5 millirem/hour (mrem/h)] or more (50 mSv/year divided by 2,000 h/year).
- 10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv [0.1 rem] in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv [2 mrem] in any one hour.

The frequency of ambient surveys depends on the quantity and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker and members of the public from external exposure to radiation. While the regulations do not specify a specific survey frequency, the licensee must conduct such surveys as will ensure that the dose rate limits in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20 Subparts C and D are not exceeded.

Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys will be performed:

- to evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
- after any spill or contamination event
- when procedures or processes have changed
- to evaluate contamination of users and the immediate work area, at the end of the day or before leaving the area of use, when licensed material is used
- in unrestricted areas at frequencies consistent with the types and quantities of materials in use but generally not less frequently than quarterly
- in areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use. If the activity used is greater than or equal to the smallest annual limit on intake (ALI) (for either inhalation or ingestion) as identified in 10 CFR Part 20, Appendix B, then documented surveys should be performed at least daily and retain records accordance with 10 CFR 20.2103.

Table L–1 contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material “in use” at any one time at any particular location. If licensed material has not been used for a period of time greater than the required survey frequency, then it is considered to be “not in use.”

Table L–1. Suggested Contamination Survey Frequency			
	< 0.1 ALI	≥ 0.1 ALI < 1.0	≥ 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months		

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in Table L–2, taken from the “Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material” (August 1987) (ADAMS Accession No. ML030590504). Note that, for the purposes of release of facilities for unrestricted use or termination of the license, these values have been superseded by 10 CFR 20, Subpart E, “Radiological Criteria for License Termination,” and cannot be used for that purpose. In particular, the acceptable contamination levels listed below for most alpha emitters exceed the levels which will meet the 10 CFR 20, Subpart E criteria. Table L–2 levels can continue to be used for release of equipment and material from licensed material facilities during operational activities prior to license termination. (63 FR 64132; November 18, 1998)

Table L–2. Acceptable Surface Contamination Levels			
Nuclide¹	Average^{2, 3}	Maximum^{2, 4}	Removable^{2, 5}
U-nat, U-235, U-238, and associated decay products	83.3 Bq/100 cm ² (5,000 dpm/100 cm ²)	250 Bq/100 cm ² (15,000 dpm /100 cm ²)	16.7 Bq/100 cm ² (1,000 dpm/100 cm ²)
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-125, I-129	1.7 Bq/100 cm ² (100 dpm/100 cm ²)	5.0 Bq/100 cm ² (300 dpm/100 cm ²)	0.3 Bq/100 cm ² (20 dpm/100 cm ²)
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133	16.7 Bq/100 cm ² (1,000 dpm/100 cm ²)	50.0 Bq/100 cm ² (3,000 dpm/100 cm ²)	3.3 Bq/100 cm ² (200 dpm/100 cm ²)

Table L–2. Acceptable Surface Contamination Levels			
Nuclide¹	Average^{2, 3}	Maximum^{2, 4}	Removable^{2, 5}
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq/100 cm ² (5,000 dpm/100 cm ²)	250 Bq/100 cm ² (15,000 dpm /100 cm ²)	16.7 Bq/100 cm ² (1,000 dpm/100 cm ²)
¹ Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently. ² As used in this table, disintegrations per minute (dpm) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation. ³ Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object. ⁴ The maximum contamination level applies to an area of not more than 100 square centimeters (cm ²). ⁵ The amount of removable radioactive material per 100 cm ² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.			

For equipment that is potentially contaminated and is to be released for unrestricted use, Table L–2 provides the maximum acceptable residual levels for equipment. Additional guidance for release of equipment can be found in NUREG–1575, Supplement 1, “Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME).” Table L–2 values also may be acceptable criteria for contamination in facilities during facilities in operation.

A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm² is acceptable to indicate levels of removable contamination.

Decommissioning Surveys for Release for Unrestricted Use

When a facility will be closed and released for unrestricted use, the values in Table L–3 provide acceptable residual contamination levels, known as “screening values” for building surfaces. To the extent practicable facilities should be decontaminated to below these levels [as low as is reasonably achievable (ALARA)]. Surveys should be conducted for both removable contamination (not to exceed 10 percent of the values in Table L–3) and for total residual contamination before the facilities or equipment are released from restricted to unrestricted use, to ensure that they meet the applicable limits.

Table L–3. Screening Values for Building Surface Contamination*		
Radionuclide	Symbol	Screening levels for unrestricted release (dpm/100 cm²)
Hydrogen-3 (Tritium)	H-3	1.2×10^8
Carbon-14	C-14	3.7×10^6
Sodium-22	Na-22	9.5×10^3
Sulfur-35	S-35	1.3×10^7
Chlorine-36	Cl-36	5.0×10^5
Manganese-54	Mn-54	3.2×10^4
Iron-55	Fe-55	4.5×10^6
Cobalt-57	Co-57	2.1×10^5
Cobalt-60	Co-60	7.1×10^3
Nickel-63	Ni-63	1.8×10^6
Zinc-65	Zn-65	4.8×10^4
Strontium-90	Sr-90	8.7×10^3
Technetium-99	Tc-99	1.3×10^6
Iodine-129	I-129	3.5×10^4
Cesium-137	Cs-137	2.8×10^4
Europium-152	Eu-152	1.3×10^4
Tungsten-181	W-181	1.1×10^6
Iridium-192	Ir-192	7.4×10^4
Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100 percent of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10 percent to 100 percent range) may calculate site-specific screening levels using DandD, Version 1 computer code.		

Units are disintegrations per minute per 100 cm² (dpm/100 cm²). One dpm is equivalent to 0.0167 Bq. The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv [25 mrem] in a year unrestricted release dose limit in 10 CFR 20.1402, “Radiological criteria for unrestricted use.” For radionuclides in a mixture, the “sum of fractions” rule applies; see 10 CFR Part 20, Appendix B, Note 4 for an example of the “sum of fractions” calculation. Refer to NUREG–1757, “Consolidated Decommissioning Guidance,” for further information on application of the values in this table.

Table L–3 was derived using the DandD screening code, Version 1, (DandD, v1.0) and its default input parameters. Table L–3 provides criteria that permit licensees to demonstrate compliance with the unrestricted release dose criterion in the License Termination Rule in Subpart E of 10 CFR Part 20. Sites with building surface contamination levels below those listed in Table L–3 would be deemed acceptable for release for unrestricted use in accordance with the dose criteria in 10 CFR 20.1402, provided that residual radioactivity has been reduced to ALARA levels. The table is intended for use as criteria to facilitate license termination for many simple routine decommissioning cases without a site-specific dose assessment. For facilities with contamination levels above those in Table L–3, additional site-specific dose assessments may be necessary, and licensees should refer to NUREG–1757 regarding acceptable methods for conducting the appropriate dose assessment, such as using the current version of DandD to develop site-specific screening criteria. The most recent version of the DandD code can be installed by downloading the self-extracting program file, setup.exe, accessed through the Web site: http://www.marssim.com/Dose_Modeling.htm. Links to other useful software and guidance documents are also found at that Web site.

Table L-3 does not include screening values for radionuclides that emit alpha particles, or for soil contamination. Screening values for radionuclides not listed above may be found in “Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination” (63 FR 64132; November 18, 1998) for building surfaces; “Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination” (64 FR 68395; December 7, 1999) for soils; and “Use of Screening Values to Demonstrate Compliance With the Final Rule on Radiological Criteria for License Termination” (65 FR 37186; June 13, 2000), which references Tables 5.19 (surface contamination) and 6.91 (surface soil) from NUREG/CR-5512, Vol. 3, “Residual Radioactive Contamination from Decommissioning, Parameter Analysis, Draft Report for Comment, October 1999.” Tables 5.19 (surface contamination) and 6.91 (surface soil) are for use in determining acceptable screening values are for radionuclides not listed in the first two *Federal Register* notices.

The type of surveys to be performed for decommissioning of facilities, and the number and locations of survey points or samples to be collected, should be determined using guidance found in NUREG-1757. Many broad scope licensees will be able to use the “Simple Approaches for Conducting Final Radiological Surveys” found in Appendix B of NUREG-1757, Volume 2. If the decommissioning of a facility is too complex to allow use one of the “simple approaches,” then a licensee may have to develop a more formal decommissioning plan.

Survey Record Requirements

Each survey record will include the following:

- a diagram of the area surveyed
- a list of items and equipment surveyed
- specific locations on the survey diagram where wipe test was taken
- ambient radiation levels with appropriate units
- contamination levels with appropriate units
- make and model number of instruments used
- background levels
- name of the person making the evaluation and recording the results and date

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor’s signature. In addition, 10 CFR 30.35(g), 40.36(f) and 70.25(g) state, in part, that records of information important to the decommissioning of a facility, including records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site, must be maintained.

Air Monitoring in the Workplace

Air monitoring can be used to do the following:

- determine whether the confinement of radioactive materials is effective
- measure airborne radioactive material concentrations in the workplace
- estimate worker intakes of radioactive material
- determine posting requirements

- determine what protective equipment and measures are appropriate
- warn of significantly elevated levels of airborne radioactive materials

If bioassay measurements are used to determine worker doses of record, air sampling may be used to determine time of intake and to determine which workers should have bioassay measurements. The use of engineering controls and a good air sampling program can eliminate the need for bioassays.

Refer to Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992, and NUREG-1400, "Air Sampling in the Workplace," dated September 1993, which is available in the NRC Agencywide Documents Access and Management System at Accession No. ML13051A671, for further guidance on air sampling.

Airborne Effluent Release Monitoring

When practicable, airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration (at least annually) to ensure their reliability.

Regulatory Guide 4.20, Revision 1, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated April 2012, provides guidance on methods acceptable (calculation or COMPLY code) to NRC for compliance with the constraint on air emissions to the environment.

Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993, provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities.

For release points for which monitoring is not practicable, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur anytime unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in these areas, the number of procedures performed, or other appropriate methods. The unmonitored effluents should not exceed 30 percent of the total estimated effluent releases or 10 percent of the permissible air effluent concentrations found on column 1 of Table 2 in 10 CFR Part 20, Appendix B, whichever is greater.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (2011), "Sampling And Monitoring Releases Of Airborne Radioactive Substances From The Stacks And Ducts Of Nuclear Facilities," and ANSI N42.18 (2004), "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactivity in Effluents."

Liquid Effluent Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the sanitary sewer and to the environment. The licensee must show that these releases meet the limits in 10 CFR 20.2003 and 10 CFR 20.1302, respectively.

The topic of sanitary sewerage releases is more fully discussed in 10 CFR Part 20, Appendix B.

Bioassay Monitoring

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Consider the following elements:

- potential exposure of the individual
- retention and excretion characteristics of the radionuclides
- sensitivity of the measurement technique
- acceptable uncertainty in the estimate of intake and committed dose equivalent

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10 percent ALI criterion is consistent with 10 CFR 20.1502(b), which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10 percent of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements and special measurements further determine the frequency and scope of measurements.

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting, urinalysis, etc.) and the samples collected will vary according to the radionuclides and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment.

An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity since the most recent bioassay measurement is > 0.02 ALI (40 derived air concentration hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

When an individual is no longer subject to the bioassay program because of change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified.

Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- the presence of unusually high levels of facial and/or nasal contamination
- entry into airborne radioactivity areas without appropriate exposure controls
- operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity)
- known or suspected incidents of a worker ingesting radioactive material
- incidents that result in contamination of wounds or other skin absorption
- evidence of damage to or failure of a respiratory protective device

References:

- Regulatory Guide 4.20, Revision 1, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors," April 2012
- Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," July 1993
- Regulatory Guide 8.20, Revision 2, "Applications of Bioassay for Radioiodine," September 2014, ADAMS Accession No. ML14064A060
- Regulatory Guide 8.23, Revision 1, "Radiation Safety Surveys at Medical Institutions," January 1981
- Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," June 1992
- Regulatory Guide 8.32, "Criteria for Establishing a Tritium Bioassay Program," July 1988
- Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," July 1992
- Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," July 1993
- NUREG-1400, "Air Sampling in the Workplace," September 1993

- NUREG–1549, Draft Report for Comment, “Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination,” July 1998, ADAMS Accession No. ML993250291
- NUREG–1575, “Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM),” Revision 1, August 2000
- NUREG–1575, Supplement 1, “Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME),” January 2009
- NUREG–1757, “Consolidated Decommissioning Guidance,”
 - Volume 1, Decommissioning Process for Materials Licensees (Revision 2), September 2006
 - Volume 2, Characterization, Survey, and Determination of Radiological Criteria (Revision 1), September 2006
- NUREG/CR–4884, “Interpretation of Bioassay Measurements,” July 1987
- NUREG/CR–5512, Volume 2, “Residual Radioactive Contamination from Decommissioning: User’s Manual DandD Version 2.1,” April 2001, ADAMS Accession No. ML010940257
- NUREG/CR–5512, Volume 3, “Residual Radioactive Contamination from Decommissioning, Parameter Analysis, Draft Report for Comment,” October 1999 [containing Tables 5.19 (surface contamination) and 6.91 (surface soil)], ADAMS Accession No. ML082460902
- *Federal Register*: “Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination,” 63 FR 67132-34, November 18, 1998
- *Federal Register*: “Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination,” 64 FR 68395–96, December 7, 1999
- *Federal Register*: “Use of Screening Values to Demonstrate Compliance With the Final Rule on Radiological Criteria for License Termination,” 65 FR 37186, June 13, 2000
- ANSI N13.1-2011, “Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities,” 2011
- ANSI N13.30-2011, “Performance Criteria for Radiobioassay,” 2011
- ANSI N42.18-2004, “Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactivity in Effluents,” 2004
- NCRP Commentary No. 3, “Screening Techniques for Determining Compliance with Environmental Standards—Releases of Radionuclides to the Atmosphere,” published in January 1989, and the addendum published October 1989

- U.S. Department of Energy, DOE G 441.1-1C, Admin Chg 1, "Radiation Protection Programs Guide for Use with Title 10, Code of Federal Regulations, Part 835, Occupational Radiation Protection," July 8, 2011

APPENDIX M
MODEL LEAK TEST PROGRAM

Model Leak Test Program

Training

Before allowing an individual to perform leak testing, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak testing and sample analysis independently.

Classroom training may be in the form of lecture, online, video, hands-on, or self-study and should cover the following subject areas:

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and instrument use
- mathematics and calculations used for measuring radioactivity
- biological effects of radiation

Appropriate on-the-job-training consists of the following:

- observing authorized personnel collecting and analyzing leak-test samples
- collecting and analyzing leak-test samples under the supervision and in the physical presence of an individual authorized to perform leak testing and sample analysis

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, analyze leak tests in a low-background area.
- Use a calibrated and operable radiation survey instrument to check leak-test samples for gross contamination before they are analyzed.
- Analyze the leak-test sample using an instrument that is appropriate for the type of radiation to be measured [e.g., NaI (TI) well-counter system for gamma emitters, liquid scintillation for beta emitters, and gas-flow proportional counter for alpha emitters].
- If the sensitivity of the counting system is unknown, determine the minimum detectable activity (MDA). The MDA may be determined using the following formula:

$$MDA = \frac{2.71 + 4.65 \sqrt{bkg \times t}}{t \times E}$$

where: MDA = minimum detectable activity in disintegrations per minute (dpm)
 bkg = background count rate in counts per minute (cpm)
 t = background counting time in minutes
 E = detector efficiency in counts per disintegration

For example:

where: bkg = 200 cpm
 E = 0.1 counts per disintegration (10 percent efficient)
 t = 2 minutes

$$\begin{aligned} \text{MDA} &= \frac{2.71 + 4.65 \sqrt{200 \text{ cpm} \times 2 \text{ minutes}}}{2 \times 0.1} = \frac{2.71 + 4.65 \sqrt{400}}{0.2} \\ &= \frac{2.71 + 4.65(20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2} \\ &= \frac{478.55 \text{ disintegrations}}{\text{minute}} \end{aligned}$$

becquerels (Bq) = $\frac{1 \text{ disintegration}}{\text{second}}$

$$\text{MDA} = \frac{478.55 \text{ disintegration}}{\text{minutes}} \times \frac{\text{minute}}{60 \text{ seconds}} = 7.976 \text{ Bq}$$

Note: The MDA equation shown assumes that counting times for the background measurement and for the sample will be equal. MDA equations for non-equal counting times, as well as derivations of equations and discussions of limitations, can be found in “Decommissioning Health Physics—A Handbook for MARSSIM Users,” Eric W. Abelquist, published by Taylor & Francis Group, 2001.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective Sealed Source and Device Registration certificate. If a sealed source is not registered, leak tests should be conducted at 6 month intervals, unless a different interval is established during the licensing process. Leak testing of sealed sources may be required by license condition.

Procedure for Performing Leak Testing and Analysis

- For each sealed source to be tested, list identifying information such as the sealed source serial number, manufacturer, model number, radionuclide, and activity.
- Use a radiation survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking, but do not wipe the surface of a plated or foil source (see manufacturer’s instructions).
- Select instrumentation that is sensitive enough to detect 185 becquerels [0.005 microcurie] of the radionuclide contained in the sealed source.

- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. The calibration source should be in the same configuration as the sample. Accuracy of standards should be within plus or minus 5 percent of the stated value and traceable to primary radiation standards such as those maintained by the National Institute of Standards and Technology.
- Calculate the counting efficiency of the detector.

$$\text{Efficiency in cpm/Bq} = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}}$$

where: cpm = counts per minute
 std = standard
 bkg = background
 Bq = becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in Bq (or millicuries). The activity of the sample in becquerels may be calculated using the following formula:

$$\text{Activity of sample [Bq]} = \frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}}$$

- Sign and date the list of sources, data, and calculations. Retain records for 3 years [under Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2103(a)].
- If the wipe test activity is 185 Bq [0.005 microcurie] or greater, notify the radiation safety officer so that the source can be withdrawn from use and disposed of properly. Also notify the U.S. Nuclear Regulatory Commission.

Reference: See NUREG-1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," if the applicant wants to provide leak testing and sample analysis as a commercial service provider.

APPENDIX N

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS

U.S. Department of Transportation Regulations

Note: The following list of U.S. Department of Transportation (DOT) regulations is provided to inform licensees about typical requirements that apply to the transportation of licensed material including the preparation of shipments of licensed material. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, transportation requirements change; therefore, licensees should consult the regulations for definitive information about current requirements. Additional information on transportation requirements may be found at the DOT Web site: <http://www.dot.gov/>.

- Table of Hazardous Materials and Special Provisions—49 CFR 172, Subpart B
 - 49 CFR 172.101—Hazardous Materials Table [proper shipping name, hazard class, identification number]
 - 49 CFR 172.101—List of Hazardous Substances and Reportable Quantities, Table 2 to Appendix A—Radionuclides
- Shipping Papers—49 CFR 172, Subpart C
 - 49 CFR 172.201—Preparation and retention of shipping papers
 - 49 CFR 172.202—Description of hazardous material on shipping papers
 - 49 CFR 172.203—Additional description requirements
 - 49 CFR 172.204—Shipper's certification
- Marking—49 CFR 172, Subpart D
 - 49 CFR 172.300—Applicability
 - 49 CFR 172.301—General marking requirements for non-bulk packagings
 - 49 CFR 172.304—Marking requirements
 - 49 CFR 172.310—Class 7 (radioactive) materials
 - 49 CFR 172.324—Hazardous substances in non-bulk packagings [designation of "reportable quantities" with the letters "RQ"]
- Labeling—49 CFR 172, Subpart E
 - 49 CFR 172.400—General labeling requirements
 - 49 CFR 172.400a—Exceptions from labeling
 - 49 CFR 172.401—Prohibited labeling
 - 49 CFR 172.403—Class 7 (radioactive) material
 - 49 CFR 172.406—Placement of labels
 - 49 CFR 172.436—RADIOACTIVE WHITE-I label
 - 49 CFR 172.438—RADIOACTIVE YELLOW-II label
 - 49 CFR 172.440—RADIOACTIVE YELLOW-III label

- Placarding—49 CFR 172, Subpart F
 - 49 CFR 172.500—Applicability of placarding requirements
 - 49 CFR 172.504—General placarding requirements
 - 49 CFR 172.516—Visibility and display of placards
 - 49 CFR 172.556—RADIOACTIVE placard
- Emergency Response Information—49 CFR 172, Subpart G
 - 49 CFR 172.600—Applicability and general requirements
 - 49 CFR 172.602—Emergency response information
 - 49 CFR 172.604—Emergency response telephone number
- Training—49 CFR 172, Subpart H
 - 49 CFR 172.702—Applicability and responsibility for training and testing
 - 49 CFR 172.704—Training requirements
- Safety and Security Plans—49 CFR 172, Subpart I
 - 49 CFR 172.800—Purpose and applicability
 - 49 CFR 172.802—Components of a security plan
- Shippers—General Requirements for Shipments and Packagings—49 CFR Part 173
 - 49 CFR 173.25—Authorized packagings and overpacks
 - 49 CFR 173.403—Definitions
 - 49 CFR 173.411—Industrial packages
 - 49 CFR 173.412—Additional design requirements for Type A packages
 - 49 CFR 173.413—Requirements for Type B packages
 - 49 CFR 173.415—Authorized Type A packages
 - 49 CFR 173.416—Authorized Type B packages
 - 49 CFR 173.433—Requirements for determining basic radionuclide values, and for the listing of radionuclides on shipping papers and labels
 - 49 CFR 173.435—Table of A₁ and A₂ values for radionuclides
 - 49 CFR 173.441—Radiation level limitations and exclusive use provisions
 - 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission approved packages
 - 49 CFR 173.475—Quality control requirements prior to each shipment of Class 7 (radioactive) materials
 - 49 CFR 173.476—Approval of special form Class 7 (radioactive) materials

- Carriage by Public Highway—49 CFR Part 177
 - 49 CFR 177.817—Shipping papers
 - 49 CFR 177.842—Class 7 (radioactive) material [includes requirement for blocking and bracing during transport]

Note: The following reference charts are for reference only and are not a substitute for DOT and U.S. Nuclear Regulatory Commission transportation regulations.

1. Minimum Required Packaging for Class 7 (Radioactive) Material:^[1] (49 CFR 173 and 10 CFR 71)^[2]

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

Minimum Packaging Required for Radioactive Materials other than Low Specific Activity (LSA) Material and Surface Contaminated Objects (SCO) based on Activity of Package Contents

Radioactive Material Quantity ^[3]		Limited Quantities and Articles	Type A ^{[4] [9]}	Type B
Activity Restrictions		≤ the limits specified in Table 4 of § 173.425	≤ A ₁ for special form ≤ A ₂ for normal form	> A ₁ for special form > A ₂ for normal form
Contents of Package	Non-fissile and Fissile Excepted	Excepted Package	Type A Package	Type B(U) or Type B(M) package
	Fissile	N/A	Type AF ^[10] package	Type B(U)F or Type B(M)F package

Minimum Packaging Required for LSA Material and SCO^[5,6]

Type(s) of LSA and/or SCO	LSA-I	LSA-II	LSA-III	SCO-I	SCO-II
Category of Package for Domestic or International Transport ^[7,8]	Unpackaged ^[8] IP-1: solids or liquids/exclusive use IP-2: liquids/non-exclusive use	- - IP-2: exclusive use ^[9]	- - IP-2: exclusive use	Unpackaged ^[8] IP-1 -	- - IP-2
	Specification tank cars or cargo tank motor vehicles: liquids/exclusive use	IP-3: liquids or gases/non-exclusive use ^[9]	IP-3: non-exclusive use	-	-
Alternative Provisions for Domestic only Transport ^[8]	Packaging shall meet the requirements of §§ 173.24, 24a, and 173.410 . Transportation shall be an exclusive use shipment. Activity per shipment must be less than an A ₂ quantity (see § 173.427(b)(4)).				

- [1] Additional provisions may apply for radioactive materials that are pyrophoric, oxidizing, fissile excepted, or uranium hexafluoride.
- [2] Each NRC licensee shall comply with the applicable requirements of the DOT regulations in 49 CFR parts [107](#), [171](#) through [180](#), and [390](#) through [397](#) (see [§ 71.5](#)).
- [3] Materials that contain radionuclides, where both the activity concentration and the total activity in the consignment exceed either the values specified in the table in [§ 173.436](#) or the values derived according to the instructions in [§ 173.433](#), must be regulated in transport as Class 7 (radioactive) material.
- [4] Except for LSA material and SCO, a Type A package may not contain a quantity of Class 7 (radioactive) material greater than A₁ or A₂ (see [§ 173.431\(a\)](#)). See A₁ and A₂ definitions in [§ 173.403](#).
- [5] The external dose rate from LSA material or SCO in a single package may not exceed 10 mSv/h (1 rem/h) at 3 meters from the unshielded material or objects (see [§§ 173.427\(a\)\(1\) and \(d\)](#)).
- [6] LSA material and SCOs that are or contain fissile material in quantities that are not fissile excepted must be packaged in appropriate Type AF or Type BF packages, and not classified as LSA material or SCO. For alternate domestic transport provisions, see [§ 173.427\(b\)\(4\)](#). For comprehensive guidance on packaging and transportation of LSA material and SCO, see [NUREG-1608](#).
- [7] For the quantity of LSA material and SCO transported in a single conveyance, see the limits specified in [§ 173.427\(a\)\(2\)](#).
- [8] LSA material or SCO shall be appropriately packaged in accordance with [§ 173.427\(b\) or \(d\)](#). Certain LSA-I material and SCO-I may be transported unpackaged under the conditions in [§ 173.427\(c\)](#).
- [9] See [§§ 173.411\(c\) and 173.415\(a\)](#) for requirements related to package record retention (2 years) and associated documentation of physical tests.
- [10] See [§§ 71.22\(a\), 71.23\(a\) and 173.417\(a\)](#) for regulations regarding the use of non-AF packages for fissile materials.

2. Radiation Level, TI and CSI Limits for Transportation by Mode.^[1] (49 CFR 173 - 177, and 10 CFR 71)^[10]				
Type of Transport	Non-exclusive use	Exclusive use		
Mode of Transport	Road, Rail, Vessel and Air ^[9]	Road and Rail	Vessel	Air (cargo only)
Radiation Level Limits ^[2]				
Package Surface	2 mSv/h (200 mrem/h)	2 mSv/h (200 mrem/h): other than closed vehicles 10 mSv/h (1000 mrem/h): closed vehicles	2 mSv/h ^[11] (200 mrem/h)	2 mSv/h (200 mrem/h) ^[3]
Conveyance ^[4]	N/A	2 mSv/h (200 mrem/h): outer surfaces (sides, top and underside) of vehicle ^[5]	N/A	N/A
		0.1 mSv/h (10 mrem/h): at any point two (2) m (6.6 ft) from sides of the vehicle ^[5]	N/A	N/A
Occupied position	N/A	0.02 mSv/h (2 mrem/h): in any normally occupied area ^[6]	Requirements of § 176.708 apply	N/A
Transport Index (TI) Limits ^[2]				
Package ^[7]	3: passenger aircraft 10: road, rail, vessels and cargo aircraft	No limit		10
Conveyance ^[4]	50: road, rail and passenger aircraft 50 to No limit: vessels ^[8] 200: cargo aircraft	No limit		200
Overpack	N/A: for road, rail 50 to 200: vessel ^[8] 3: passenger aircraft; 10: cargo aircraft	N/A	No limit ^[8]	N/A
Criticality Safety Index (CSI) Limit for fissile material ^[2]				
Package ^[7]	50	100	100	100
Conveyance ^[4]	50: road, rail and air 50: for holds, compartments or defined deck areas of vessels ^[8] 200 to No limit: for a total vessel ^[8]	100	200 to No limit: for a total vessel ^[8]	100
Overpack	50: road, rail, vessels ^[8] and air	N/A		

[1] Radiation level, TI, and CSI are defined in § 173.403.

[2] In addition to any applicable radiation level, TI and CSI limits, separation distance requirements apply to packages, conveyances, freight containers and overpacks; to occupied positions; and to materials stored in transit. Separation distances are based on the sum of the TIs and, for fissile materials, the sum of the CSIs. [see applicable 49 CFR references for: Rail - § 174.700; Air – §§ 175.700 through 175.703; Vessel - §§ 176.700 through 176.708; and Highway - § 177.842].

[3] Higher package surface radiation levels may be allowed through an approved special arrangement.

[4] Conveyance is, for transport by public highway or rail, any transport vehicle or large freight container; and for transport by air, any aircraft. See definitions in § 173.403.

[5] The outer surfaces (sides, top and underside) of vehicles are specified for road and rail vehicles in § 173.441.

[6] For rail, normally occupied areas include the transport vehicle and adjacent rail cars. The 0.02 mSv/h (2 mrem/h) limit does not apply to carriers operating under a State or federally regulated radiation protection program where personnel wear radiation dosimetry devices.

[7] Additional TI and CSI limits apply for individual packages when non-fissile radioactive material packages are mixed with fissile material packages (see § 173.459).

[8] For details on TI and CSI limits for transport by vessel, see § 176.708.

[9] Only excepted packages and packages intended for use in research, medical diagnosis, and treatment are permitted on passenger aircraft (see §§ 173.448(f) and 175.700).

[10] The limits in this table do not apply to excepted packages. See the following references for the radiation level limits for: limited quantities, § 173.421; instruments and articles, § 173.424; articles containing natural uranium or thorium, § 173.426; or empty packaging, § 173.428.

[11] 2 mSv/h (200 mrem/h) other than intermodal transport of closed transport vehicles or exclusive use vessel.

3. Contamination Limits and Quality Control for Class 7 (Radioactive) Materials: (49 CFR 173.443 and 173.475, and 10 CFR 71)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

Maximum Permissible Limits for Non-fixed Radioactive Contamination on Packages When Offered for Transport

The level of non-fixed (removable) radioactive contamination on the external surface of each package, conveyance, freight container, and overpack offered for transport must be kept as low as reasonably achievable, and shall not exceed the values shown in the following table:

Contaminant	Maximum permissible limits (§ 173.443(a), Table 9)		
	Bq/cm ²	µCi/cm ²	dpm/cm ²
Beta and gamma emitters and low toxicity alpha emitters	4	10 ⁻⁴	240
All other alpha emitting radionuclides	0.4	10 ⁻⁵	24

The non-fixed contamination shall be determined by:

- (a) wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;
- (b) ensuring each wipe area is 300 cm² in size;
- (c) measuring the activity on each single wiping material and dividing that value by the surface area wiped and the efficiency of the wipe procedure, where an actual wipe efficiency may be used, or it may be assumed to be 0.10.

Alternatively, the contamination level may be determined using alternative methods of equal or greater efficiency.

A conveyance used for non-exclusive use shipments is not required to be surveyed unless there is reason to suspect that it exhibits contamination (see § 173.443(a)(2)).

Provisions for Control of Contamination on Radioactive Material Packages Offered for Transport and at the Time of Receipt

- When offered for transport, the non-fixed contamination on each package of radioactive material must be kept as low as reasonably achievable and may not exceed the limits set forth in § 173.443(a), Table 9 (as shown above).
- During transport, non-fixed contamination levels on packages transported as exclusive use by rail or highway may not exceed 10 times the limits in § 173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Excepted and Empty Radioactive Material Packages

- The non-fixed radioactive surface contamination on the external surface of excepted and empty packages shall not exceed the limits specified in § 173.443(a), Table 9 (as shown above).
- The internal contamination of an empty package must not exceed 100 times the limits in § 173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Packages and in Rail and Road Vehicles used for Exclusive Use Shipments of Radioactive Material

- The levels of non-fixed radioactive contamination on the packages (a) at the beginning of transport, may not exceed the levels prescribed in the above table, and (b) at any time during transport, may not exceed ten times the levels prescribed in § 173.443(a), Table 9 (as shown above) [see § 173.443(b)].
- Each conveyance, overpack, freight container, or tank used for transporting Class 7 (radioactive) material as an exclusive use shipment that utilizes the provisions of § 173.443(b) must be surveyed with appropriate radiation detection instruments after each exclusive use transport. If contamination values exceed acceptable levels, the transport vehicle may not be returned to exclusive use transport service, and then only for subsequent exclusive use shipment, unless the radiation dose rate at each accessible surface is demonstrated to be 0.005 mSv/h (0.5 mrem/h) or less, and that there is no significant non-fixed radioactive surface contamination as specified in § 173.443(a), Table 9 (as shown above) [see § 173.443(c)].

Provisions for Non-fixed (Removable) Contamination in Closed Rail and Road Vehicles that are used Solely for the Transportation of Radioactive Material (§ 173.443(d))

- The contamination levels must not exceed 10 times the levels prescribed in § 173.443(a), Table 9 (as shown above).
- Each vehicle is marked with the words "For Radioactive Materials Use Only" in letters at least 76 mm (3 in) high in a conspicuous place on both sides of the exterior of the vehicle.
- The vehicle must meet the placard requirements of Subpart F of Part 172.
- A survey of the interior surfaces of the empty closed vehicle must show that the radiation dose rate at any point does not exceed 0.1 mSv/h (10 mrem/h) at the surface or 0.02 mSv/h (2 mrem/h) at 1 m (3.3 feet) from the surfaces.
- Each vehicle shall be kept closed except for loading or unloading.

Provisions for Quality Control Prior to Each Shipment of Radioactive Material (§ 173.475)

- Before each shipment of any radioactive materials package, the offeror must ensure, by examination or appropriate tests, that:
 - (a) the packaging is proper for the contents to be shipped;
 - (b) the packaging is in unimpaired physical condition, except for superficial marks;
 - (c) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;
 - (d) for fissile material, each moderator and neutron absorber, if required, is present and in proper condition;
 - (e) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed;
 - (f) each closure, valve, or other opening of the containment system is properly closed and sealed;
 - (g) each packaging containing liquid in excess of an A₂ quantity and intended for air shipment has been tested to show that it will not leak under an ambient atmospheric pressure of not more than 25 kPa, absolute (3.6 psia), where the test must be conducted on the entire containment system, or on any receptacle or vessel within the containment system, to determine compliance with this requirement;
 - (h) the internal pressure of the containment system will not exceed the design pressure during transportation; and
 - (i) the external radiation and contamination levels are within the allowable limits specified in §§ 173.441 and 173.443.

4. Hazard Communications for Class 7 (Radioactive) Materials: Shipping Papers (49 CFR 172, Subpart C)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.^[1]

Shipping Paper Entries

Always Required	Sometimes Required	Optional Entries
<p><u>Basic description (in sequence):</u></p> <ul style="list-style-type: none"> • UN Identification number • Proper Shipping Name • Hazard Class (7) • Maximum activity contained in each package in SI units (e.g., Bq, TBq), or in both SI and customary units (e.g., Ci, mCi) with customary units in parentheses following the SI units • Number and type of packages <p><u>Additional description:</u></p> <ul style="list-style-type: none"> • Name of each radionuclide^[2] • Description of physical and chemical form (unless special form) • “Special form” when not in the proper shipping name • Category of label used • Transport index (TI) of each package bearing a Yellow-II or Yellow-III label <p><u>Additional entry requirements:</u></p> <ul style="list-style-type: none"> • 24 hour emergency telephone number • Shipper’s Certification shall be provided by each person offering radioactive material for transportation^[3] • Proper page numbering (e.g., Page 1 of 4) 	<p><u>Materials-based Requirements:</u></p> <ul style="list-style-type: none"> • The criticality safety index (CSI) or “Fissile Excepted” for fissile material • “Highway route controlled quantity” or “HRCQ” for highway route controlled quantities • The letters “RQ” entered either before or after the basic description for each hazardous substance [see § 171.8] • Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required • A hazardous waste manifest and the word “Waste” preceding the proper shipping name is required for radioactive material that is hazardous waste <p><u>Package-based Requirements:</u></p> <ul style="list-style-type: none"> • The applicable DOE or NRC package approval identification marking for each Type B(U), Type B(M), or fissile material package • The International Atomic Energy Agency (IAEA) Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package <p><u>Shipment- and Administrative-based Requirements:</u></p> <ul style="list-style-type: none"> • Specify “exclusive use shipment” as required • Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use • Specify the notation “DOT–SP” followed by the special permit number for a special permit shipment 	<ul style="list-style-type: none"> • The weight in grams or kilograms may be inserted instead of activity units for fissile radionuclides, except for Pu-239 and Pu-241 • The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units • Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information

Special Considerations/Exceptions for Shipping Papers

- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, or be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, or be designated by an “X” (or “RQ” if appropriate).
- Emergency response information consistent with §§ 172.600 – 172.606 shall be readily available on the transport vehicle.
- Shipments of excepted radioactive material in excepted packages, under UN2908, UN2909, UN2910, and UN2911, are excepted from shipping paper requirements if (a) the material is not a hazardous substance or hazardous waste and (b) the package does not contain fissile material or contain fissile material that is excepted by § 173.453.
- For road transport, the shipping papers shall be (a) readily available to authorities in the event of accident or inspection, (b) stored within the driver’s immediate reach while he is restrained by the lap belt, (c) readily visible to a person entering the driver’s compartment or in a holder which is mounted to the inside of the door on the driver’s side of the vehicle, and (d) either in a holder mounted to the inside of the door on the driver’s side of the vehicle or on the driver’s seat [see § 177.817(e)].



[1] International Atomic Energy Agency (IAEA); International Air Transportation Association (IATA); International Civil Aviation Organization (ICAO); International Maritime Organization (IMO).

[2] For mixtures of radionuclides, the radionuclides to be shown must be determined in accordance with § 173.433(g), which is commonly known as the 95% rule; abbreviations (symbols) are authorized.

[3] The Shipper’s certification shall satisfy the requirements of § 172.204.

5. Hazard Communication for Class 7 (Radioactive) Materials: Marking of Packages: (49 CFR 172, Subpart D; and 49 CFR 173.471, 178.3 and 178.350)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Markings on Packages		
Markings Always Required Unless Excepted ^[1]	Additional Markings Sometimes Required	Optional Markings
<p>For Non-bulk Packages:</p> <ul style="list-style-type: none"> • Proper shipping name • Identification number (preceded by "UN" or "NA," as appropriate) • Name and address of consignor or consignee, unless the package is: <ul style="list-style-type: none"> ▪ highway only and no motor carrier transfers; or ▪ part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee <p>For Bulk Packages:</p> <ul style="list-style-type: none"> • Identification number on orange panel or white square-on-point display [see §§ 172.332 or 172.336]: <ul style="list-style-type: none"> ▪ on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more^[2], or ▪ on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons)^[2] 	<p>Package-based marking requirements:</p> <ul style="list-style-type: none"> • Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 lb) • Package type as appropriate, i.e., "TYPE IP-1," "TYPE IP-2," "TYPE IP-3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"^[1] • Marked with international vehicle registration code of country of origin for IP-1, IP-2, IP-3 or Type A package design (e.g., "USA") • Radiation (trefoil) symbol^[3] on outside of outermost receptacle of each Type B(U) or Type B(M)  <ul style="list-style-type: none"> • Each NRC-approved package (e.g., Type AF, Type B(U), Type B(M), Type B(U)F, and Type B(M)F) must be marked with the identification marking indicated in the package approval • For Specification 7A packaging, mark on the outside with "USA DOT 7A Type A", and the name and address or symbol of the manufacturer satisfying §§ 178.3 and 178.350 <p>Materials-based requirements:</p> <ul style="list-style-type: none"> • For a non-bulk IP-1 package containing a liquid, use underlined double arrow symbol indicating upright orientation^[4], where the symbol is placed on two opposite sides of the packaging [see § 172.312]  <ul style="list-style-type: none"> • For a non-bulk package containing a hazardous substance, mark the outside of each package with the letters "RQ" in association with the proper shipping name <p>Administrative-based requirements:</p> <ul style="list-style-type: none"> • For each Type B(U), Type B(M) or fissile material package destined for export shipment, mark "USA" in conjunction with specification marking, or certificate identification; and package identification indicated in the U.S. Competent Authority Certificate • Mark "DOT-SP" followed by the special permit number assigned for each package authorized by special permit • Competent authority identification marking and revalidation for foreign made Type B(U), Type B(M), Type H(U), Type H(M), or fissile material package for which a Competent Authority Certificate is required 	<ul style="list-style-type: none"> • Both the name and address of consignor and consignee is recommended. • Other markings on packages such as advertising are permitted, but must be located away from required markings and labeling. <p>For marking exceptions for LSA material and SCO, [see § 173.427(a)(6)(vi)] (e.g., RADIOACTIVE-LSA, RADIOACTIVE-SCO, or RQ, as appropriate).</p> <p>For an overpack, the marking "OVERPACK" in lettering 12 mm (0.5 inches) high. This marking is not required if the package type contained in the overpack is visible from the outside [see § 173.25].</p>

Special Considerations for Marking Requirements

- All markings are to be (a) on the outside of each package, (b) durable and legible, (c) in English, (d) printed on or affixed to the surface of a package or on a label, tag, or sign, (e) displayed on a background of sharply contrasting color, and (f) unobscured by labels or attachments.
- When an overpack is used, see §§ 173.25 and 173.448(g) for marking requirements.

[1] Some marking exceptions exist for excepted packages, as specified in §§ 173.421, 173.422, 173.424, 173.426 and 173.428.

[2] If the identification number marking on a bulk package is not visible, the transport vehicle or freight container must be marked on each side and each end [see § 172.331].

[3] The radiation symbol shall be resistant to the effects of fire and water, plainly marked by embossing, stamping or other means resistant to the effects of fire and water and conform to the size requirements of Appendix B to Part 172.

[4] The arrows must be either black or red on white or other suitable contrasting background and commensurate with the size of the package; depicting a rectangular border around the arrows is optional.

6. Hazard Communications for Class 7 (Radioactive) Materials:




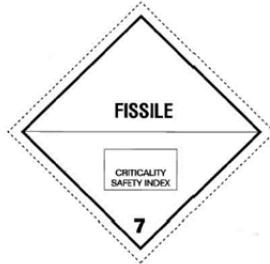
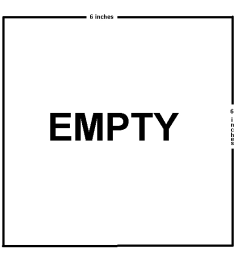
Labeling of Packages (49 CFR 172.400-450)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Requirements for Labels^[1]

- Label each package, except for (a) excepted packages of radioactive material; and (b) Low Specific Activity (LSA) material and Surface Contaminated Objects (SCO), packaged or unpackaged, when transported under exclusive use controls domestically and when the material or object contains less than an A_2 quantity.
- Labels are required to be (a) printed or affixed to a surface other than the bottom of the package, (b) placed near the proper shipping name marking, (c) printed or affixed to a background of contrasting color or have a dotted or solid line outer border, (d) clearly visible, (e) not obscured by markings or other attachments, (f) representative of the hazardous material content, and (g) in conformance with the label specifications of § 172.407.
- The appropriate radioactive label must be affixed to opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material.

Category of Radioactive Labels ^[3]			Other Radioactive Labels ^[2]	
				
White-I	Yellow-II	Yellow-III	Fissile	Empty
Maximum Radiation Surface Level (RSL)			Fissile labels required for each package containing fissile material, other than fissile-excepted material; and labels must be affixed adjacent to radioactive category labels.	Empty labels required for empty Class 7 (radioactive) packages satisfying § 173.428; and any previously-used labels must not be visible.
mSv/h	$RSL \leq 0.005$	$0.005 < RSL \leq 0.5$		
mrem/h	$RSL \leq 0.5$	$0.5 < RSL \leq 50$		
Transport Index (TI): ^[4]				
TI = 0	$0 < TI \leq 1$	$1 < TI \leq 10^{[5]}$		

Contents on Labels

- Each radioactive category label must contain: (a) Except for LSA-I material, the names of the radionuclides in the package where, for mixtures of radionuclides, the names listed must be in accordance with the 95% rule specified in § 173.433(g); and, for LSA-I material, the term "LSA-I"; (b) maximum activity in appropriate SI units (e.g., Bq, TBq), or appropriate customary units (e.g., Ci, mCi) in parentheses following SI units; and (c) for Yellow-II or Yellow-III labels the Transport Index (TI). Abbreviations and symbols may be used. Except for Pu-239 and Pu-241, the weight in g or kg of fissile radionuclides may be inserted instead of activity units; for Pu-239 and Pu-241, the weight in g of fissile radionuclides may be inserted in addition to the activity units [see § 173.403 for fissile material definition].
- Each fissile label must contain the relevant Criticality Safety Index (CSI) [see § 172.403(e)].

- [1] Additional labels may be required if the contents of a package contains material that also meets the definition of one or more other hazard class. See §§ 172.402 and 406(c) for details on additional labeling requirements. [See §§ 172.400a, 173.421 through 173.427 for details when labels are not required, and see § 172.407 for details on label durability, design, size, color, form identification, exceptions, and the trefoil symbol size].
- [2] A "Cargo Aircraft Only" label is required for each package containing a hazardous material which is authorized for cargo aircraft only [see § 172.402(c)].
- [3] The category of the label must be the higher of the two values specified for RSL and TI [see § 172.403(b)].
- [4] The TI is determined from the radiation level 1 meter from the package surface [see TI definition in § 173.403]. If the measured TI is not greater than 0.05, the value may be considered to be zero. When an overpack is used, it must be labeled in accordance with § 172.403(h).
- [5] Packages with a TI > 10 or an RSL > 2 mSv/h (200 mrem/h) must be transported under exclusive use provisions [see § 173.441(b)]. Any package containing a Highway Route Controlled Quantity (HRCQ) must be labelled as RADIOACTIVE YELLOW-III.

7. Hazard Communications for Class 7 (Radioactive) Materials: Placarding (49 CFR 172, Subpart F)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Conditions when Display of Placards is Required [§§ 172.504, 172.507(a), 172.508, and 172.512]

- Each bulk package, freight container, unit load device^[1], transport vehicle, or rail car containing any quantity of hazardous material must be placarded on each side and each end with the placards specified in § 172.504(e).
- Radioactive placards are required for: shipments that contain a package labeled as Radioactive Yellow-III; unpackaged LSA-I or SCO-I when transported under exclusive use provisions; shipments required by §§ 173.427, 173.441, and 173.457 to be operated under exclusive use; and closed vehicles marked "For Radioactive Materials Use Only" transported under § 173.443(d).
- The Radioactive placard is placed on a square background on any motor vehicle used to transport a package containing a Highway Route Controlled Quantity (HRCQ) Class 7 (radioactive) material^[2].

Visibility and Display of Radioactive Placards [§ 172.516]

- Placards are required to:
 - be clearly visible, on a motor vehicle and rail car, from the direction they face, except from the direction of another transport vehicle or rail car to which the motor vehicle or rail car is coupled^[3]
 - be securely attached or affixed thereto or placed in a holder thereon
 - be located clear of appurtenances and devices such as ladders, pipes, doors, and tarpaulins
 - be located, so far as practical, so dirt or water is not directed to it from the transport vehicle wheels
 - be located at least 3 inches (76.0 mm) away from any marking (e.g. advertising) that could reduce its effectiveness
 - have "RADIOACTIVE" printed on it displayed horizontally, reading from left to right
 - be maintained by the carrier so format, legibility, color, and visibility of the placard will not be substantially reduced due to damage, deterioration, or obscurement by dirt or other matter
 - be affixed to a background of contrasting color, or have a dotted or solid line outer border which contrasts with the background color.

Radioactive Placards

PLACARD (FOR OTHER THAN HRCQ)



White triangular background color in the lower portion with yellow triangle in the upper portion; trefoil symbol, text, class number and inner and outer borders in black.
[see § 172.556 and Appendix B of Part 172]

PLACARD FOR HRCQ



Square background must consist of a white square surrounded by one-inch black border. The placard inside the square is identical to that for other than HRCQ.
[see § 172.527]

General Specifications for Placards and Subsidiary Hazard Placarding

- Placards must conform to the specifications in § 172.519.
- A CORROSIVE placard is also required for each transport vehicle that contains 454 kg (1001 pounds) or more gross weight of non-fissile, fissile-excepted, or fissile uranium hexafluoride [see § 172.505(b)].
- Placards are also required for subsidiary hazards of POISON INHALATION HAZARD, POISON GAS, or DANGEROUS WHEN WET [see § 172.505].

[1] See § 172.512 for exceptions and variations to the placarding requirements for freight containers and aircraft unit load devices.

[2] See § 173.403 for the definition of Highway Route Controlled Quantity (HRCQ). A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels [see §§ 172.403(c) and 172.507(a)].

[3] Required placarding of the front of a motor vehicle may be on the front of a truck-tractor instead of or in addition to the placarding on the front of the cargo body to which a truck-tractor is attached § 172.516(b).

8. Requirements/Guidance for Registration, Emergency Response and Action for Class 7 (Radioactive) Materials: (49 CFR 107, Subpart G; 49 CFR 171.15; 49 CFR 172, Subparts F and G)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

Provisions for Persons Who Offer or Transport Class 7 (Radioactive) Materials (49 CFR 107, Subpart G)

- Any person, other than those excepted by § 107.606, who offers for transportation, or transports, in foreign, interstate or intrastate commerce any of the following Class 7 (radioactive) materials must satisfy registration and fee requirements of Part 107, Subpart G:
 - a highway route-controlled quantity of radioactive material;
 - a shipment in a bulk packaging with a capacity \geq 13,248 L (3,500 gallons) for liquids or gases, or $>$ 13.24 cubic meters (468 cubic feet) for solids; or
 - any quantity of radioactive material that requires placarding, under provisions of Part 172, Subpart F.
- Any person required to register must submit a complete and accurate registration statement on DOT Form F 5800.2 by June 30th for each registration year, or in time to have on file a current Certificate of Registration in accordance with § 107.620.
- Each registrant or designee must maintain for a period of 3 years from the date of issuance a copy of the registration statement and Certificate of Registration issued by PHMSA and must furnish its Certificate of Registration (or a copy thereof) and related records to an authorized representative or special agent of DOT upon request.
- Each motor carrier subject to registration requirements of this subpart must carry a copy of its current Certificate of Registration or another document bearing the registration number on board each truck and truck tractor, and the Certificate of Registration or document must be made available, upon request, to enforcement personnel.
- The amount of fees to be paid and procedures to be followed are found at §§ 107.612 and 107.616.

Provisions for Providing and Maintaining Emergency Response Information (49 CFR 172, Subpart G)

- When shipping papers for the transportation of radioactive materials are required [see Part 172, Subpart C], emergency response information shall
 - be provided and maintained during transportation and at facilities where materials are loaded for transportation, stored incidental to transportation, or otherwise handled during any phase of transportation;
 - be provided by persons who offer for transportation, accept for transportation, transfer or otherwise handle hazardous materials during transportation;
 - be immediately available for use at all times the hazardous material is present; and
 - include and make available the emergency response telephone number [see § 172.604] to any person, representing a Federal, State or local government agency, who responds to an incident involving the material or is conducting an investigation which involves the material.
- Emergency response information is information that can be used in mitigating an incident involving radioactive materials. It must contain at least the information specified in §§ 172.602 and 172.604; and includes an emergency response telephone number that is monitored at all times the material is in transportation by (a) knowledgeable person, or (b) a person who has immediate access to a knowledgeable person, or (c) an organization capable of accepting responsibility for providing the necessary detailed information concerning the material.
- Each carrier who transports or accepts for transportation radioactive material for which a shipping paper is required shall instruct, according to the requirements of § 172.606, the operator of a conveyance to contact the carrier in the event of an incident involving the material.

Actions to be Taken in the Event of Spillage, Breakage, or Suspected Contamination by Radioactive Material

- If there is evidence of a leaking package or conveyance, access to the package or conveyance must be restricted, the area impacted and the extent of the contamination must be determined, and appropriate measures must be taken to minimize impact to persons and the environment [see § 173.443(e)].
- Except for a road vehicle used solely for transporting Class 7 (radioactive) material [see § 173.443(d)], each aircraft used routinely, and each motor vehicle used for transporting radioactive materials under exclusive use, must be (a) periodically checked for radioactive contamination, (b) taken out of service if contamination levels are above acceptable limits, and (c) remain out of service until the radiation dose rates at accessible surfaces are less than 0.005 mSv/h (0.5 mrem/h) and non-fixed radioactive surface contamination levels are below the limits in §§ 173.443(a), Table 9; and 173.443(c) for exclusive use vehicle provisions [see Chart 3].
- Following any breakage, spillage, release or suspected radioactive contamination incident, any rail or air carrier shall notify, as soon as possible, the offeror (i.e. the consignor); special provisions apply for buildings, areas, and equipment that might become contaminated during rail transport. Alternative provisions may apply for motor vehicles transporting radioactive materials under exclusive use [see §§ 174.750(a), 175.705(e), and 177.843(b)].

Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (§§ 171.15 and 171.16)

- Each person in physical possession of radioactive material must provide notice in the event of a reportable incident (see § 171.15(b)) as soon as practical, but no later than 12 hours after the occurrence of the reportable incident, to the National Response Center (NRC) by telephone at 800-424-8802 (toll free) or 202-267-2675 (toll call) or online at <http://www.nrc.uscg.mil>.
- Each notice must include the information specified in § 171.15(a)(1) – (a)(7).
- A detailed incident report must also be submitted as required by § 171.16.

Guidance on Responding to Emergencies (Emergency Response Guidebook)

- The DOT issues guidance to aid first responders in quickly identifying the hazards of the dangerous goods involved in an accident or incident, and for protecting themselves and the general public during the initial response to the accident or incident. For each proper shipping name or UN ID Number, the user is led to a specific guide that provides insight into potential hazards and steps to be taken for public safety and emergency response.
- The current edition of the Emergency Response Guidebook is available at <http://phmsa.dot.gov/hazmat/outreach-training/erg>.



**9. Requirements for Training and Safety and Security Plans for Class 7 (Radioactive) Materials:
(49 CFR 172, Subparts H and I, 49 CFR 173, and 10 CFR 37)**

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

Training (49 CFR 172, Subpart H)

- For any person who is employed by an employer or is self-employed, and who directly affects hazardous materials transportation safety, a systematic program shall be established to ensure that the person:
 - has familiarity with the general provisions of [Part 172, Subpart H](#);
 - is able to recognize and identify radioactive materials;
 - has knowledge of specific requirements of [Part 172](#) that are applicable to functions performed by the employee;
 - has knowledge of emergency response information, self-protection measures and accident prevention methods and procedures; and
 - does not perform any function related to the requirements of [Part 172](#) unless instructed in the requirements that apply to that function.
- The person shall be trained pursuant to the requirements of [§ 172.704\(a\)](#) and [\(b\)](#), may be trained by the employer or by other public or private sources, and shall be tested by appropriate means. The training must include the following:
 - (a) general awareness training providing familiarity with applicable regulatory requirements;
 - (b) function-specific training applicable to functions the employee performs;
 - (c) safety training concerning emergency response information, measures to protect the employee from hazards, and methods and procedures for avoiding accidents;
 - (d) security awareness training providing awareness of security risks and methods designed to enhance transportation security; and
 - (e) in-depth security training if a security plan is required for the shipment(s) involved.
- Initial and recurrent training shall comply with the requirements of [§ 172.704\(c\)](#).
- Records of training shall be created and retained in compliance with the requirements of [§ 172.704\(d\)](#).

Security (49 CFR 172, Subpart I, 49 CFR 173, and 10 CFR 37)

- A security plan for hazardous materials that conforms to the requirements of [Part 172, Subpart I](#) must be developed and adhered to by each person who offers for transportation in commerce or transports in commerce in a motor vehicle, rail car, or freight container any of the following radioactive materials:
 - (a) IAEA Code of Conduct Category 1 and 2 materials (see [§§ 172.800\(b\)\(15\)](#) and [10 CFR 37](#));
 - (b) a highway route controlled quantity (HRCQ) of radioactive material as defined in [§ 173.403](#) [see [§ 172.800\(b\)\(15\)](#)];
 - (c) known radionuclides in forms listed as radioactive material quantities of concern (RAM-QC) by the NRC [see [§§ 172.800\(b\)\(15\)](#) and [10 CFR 37](#)]; or
 - (d) a quantity of uranium hexafluoride requiring placarding under [§ 172.505\(b\)](#) [see [§ 172.800\(b\)\(14\)](#)].
- The security plan must include an assessment of possible transportation security risks and appropriate measures to address the assessed risks.
- Specific measures put into place by the plan may vary commensurate with the level of threat at a particular time.
- At a minimum, a security plan must address personnel security, unauthorized access, and enroute security.
- The security plan must be
 - (a) in writing;
 - (b) retained for as long as it remains in effect;
 - (c) available as copies or portions thereof to the employees who are responsible for implementing it, consistent with personnel security clearance or background investigation restrictions and a demonstrated need to know;
 - (d) revised and updated as necessary to reflect changing circumstances; and
 - (e) maintained (all copies) as of the date of the most recent revision, when it is updated or revised.
- Security plans that conform to regulations, standards, protocols, or guidelines issued by other Federal agencies, international organizations, or industry organizations may be used to satisfy the requirements in [Part 172](#), provided such security plans address the requirements specified in [Part 172, Subpart I](#).
- Additional security planning requirements may apply for rail transport of a highway route controlled quantity of radioactive material [see [§§ 172.820](#) and [173.403](#)].

APPENDIX O

MODEL WASTE MANAGEMENT PROCEDURES

Model Waste Management Procedures

General Guidelines

- All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary “non-radioactive” waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- Remind workers that non-radioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the entire effect of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.
- The waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
- Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.
- A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest in accordance with Title 10 of the Code of Federal Regulations (10 CFR) Part 20, Appendix G, “Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests.”

Model Procedure for Disposal by Decay-in-Storage

Applicants should ensure that adequate space and facilities are available for the storage of waste for decay-in-storage (DIS). Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
- Short-lived waste should be segregated from long-lived waste.
- Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.
- Liquid and solid wastes should be stored separately.

- When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
- The identification label should include the date when the container was sealed, the longest-lived radionuclide in the container, total activity, and the name of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after many half-lives and persons performing surveys should be aware of the potential for measurable radiation.
- The contents of the container should be allowed to decay for a period of time after which it is expected that the radiation levels would not be distinguishable from background. The period of time depends on both the half-life of the radionuclide(s) and the original amount present.
- Prior to disposal as ordinary trash, each container should be monitored with an appropriate radiation detection instrument, on the lowest setting, as follows:
 - Check the radiation survey meter for proper operation.
 - Survey the contents of each container in a low background area.
 - Remove any shielding from around the container.
 - Monitor all surfaces of the container.
 - Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity (i.e., surface readings are indistinguishable from background).
 - If the surveys indicate residual radioactivity, return the container to DIS area and contact the radiation safety officer for further instructions.
 - If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (e.g., used or unused material, gloves, etc.), survey instrument used, and the name of the individual performing surveys and disposing of the waste.

In accordance with 10 CFR 20.1904(b), all radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed, provided that the following is done: waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility; labels are removed from the waste barrels/containers; waste is incinerated, not placed in a landfill; and the waste disposal firm is cautioned not to open the container prior to incineration.

Model Procedure for Disposal of Liquids into Sanitary Sewerage

- Confirm that the sewer system is a public system, not a private sanitary sewer, septic system or leach field.

- Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.
- Calculate the amount of each radionuclide that can be discharged by using the information from prior, similar discharges and the information in 10 CFR Part 20, Appendix B.
- Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR Part 20, Appendix B, Table 3.
- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 must not exceed unity.
- Confirm that the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 gigabecquerel (GBq) [5 Curies (Ci)] of H-3 (tritium), 37 GBq [1 Ci] of C-14, and 37 GBq [1 Ci] of all other radionuclides combined.
- Record the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the name of the individual discharging the waste.
- Liquid waste should be discharged only via designated sinks, toilets, or other release points.
- Discharge liquid waste slowly to minimize splashing with water running, to be sure that the material moves out of the sink and into the sewer system.
- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.
- Decontaminate all areas or surfaces if found to be contaminated.
- Maintain records of releases of licensed material to the sanitary sewer system. These records should include, for each release, the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the name of the individual discharging the waste. For the licensed facility as a whole, records should be maintained of the quantity and concentration of radionuclides that are released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Model Procedure for Incineration

These guidelines apply to non-commercial waste disposal, i.e., incineration of a licensee's own waste. An applicant or licensee does not need specific U.S. Nuclear Regulatory Commission (NRC) approval to incinerate certain categories of radioactive waste. For example, 10 CFR 20.2005 provides that tritium and carbon-14 in low level concentrations in liquid scintillation media and animal tissue may be disposed of without regard to radioactivity. After a licensee reviews their program and confirms that they have waste that requires specific NRC approval for incineration, please provide the following information:

- Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.
- Describe the waste that is proposed to be incinerated, to include: the chemical and/or physical form of the waste containing licensed material and a description of how the waste is segregated, packaged, and labeled for transfer from the generation site to the incinerator; the name of the radionuclide; concentration of radioactivity averaged over the weight of the material to be incinerated (microcuries per gram of waste medium) for each isotope to be incinerated; and the total radioactivity of each isotope per burn and the total number of burns per year. Describe procedures for ensuring that these frequencies and activities will not be exceeded.
- Describe the procedures for packaging, handling, securing, and monitoring of waste to prevent contamination and/or unnecessary exposure to personnel or property during the waste life cycle.
- Describe the method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe the procedures for collection, handling, and disposal of the ash residue.
- Describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incinerations, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records must be maintained in the same units as applicable regulations.
- Describe the characteristics of the incinerator and site location, including: height of the stack, rated air flow (cubic feet per hour or similar units), proximity of the stack or other discharge to occupied areas (e.g., residences, school, hospital), and distance to the nearest air intake ducts of adjacent buildings. Describe any scrubbers, filters, or air cleaning equipment that is present.
- State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined. Describe any stack monitoring that is planned.
- Provide a copy of the written safety analysis that demonstrates the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in 10 CFR Part 20.
- Provide a written commitment that the applicant or licensee has coordinated with appropriate State and local authorities and that they have obtained such permits and other authorizations as may be necessary.
- Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations and for monitoring all effluent generated by the incineration process. The procedures must ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant should describe the disposal method for any ash generated that exceeds regulatory limits.

Model Procedure for Compaction

The following information should be provided by licensees that propose to compact waste.

- Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations. Provide manufacturer's specifications, annotated sketches or photographs, and other information about the compactor design.
- Describe the type, quantities, and concentrations of waste to be compacted.
- Provide an analysis of the potential for airborne release of radioactive material during compaction activities.
- Provide the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtration systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange.
- Discuss the methods used to monitor worker breathing zones and/or exhaust systems.
- Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.
- Discuss the instruction provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

APPENDIX P

**COMMENCEMENT OF CONSTRUCTION AT EXISTING AND
PROPOSED BYPRODUCT (INCLUDING IRRADIATORS),
SOURCE, AND SPECIAL NUCLEAR MATERIAL FACILITIES WITH
SIGNIFICANT ENVIRONMENTAL IMPACTS**

Commencement of Construction at Existing and Proposed Byproduct (Including Irradiators), Source, and Special Nuclear Material Facilities With Significant Environmental Impacts

PURPOSE AND SCOPE

This appendix provides information concerning the definition of “construction,” and activities that may be performed by materials license applicants, potential applicants (hereinafter collectively referred to as “applicants”), and licensees before the U.S. Nuclear Regulatory Commission (NRC) staff has concluded its environmental review of the proposed licensing action.

This appendix applies to all Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30 (byproduct material), 36 (irradiators), 40 (source material) and 70 (special nuclear material [SNM]) facilities *except for* uranium recovery facilities, uranium hexafluoride conversion facilities, enrichment facilities, fuel fabrication facilities, uranium hexafluoride deconversion facilities, and facilities for SNM of greater than critical mass.

Except as noted in the previous paragraph, this appendix applies to licensing actions related to the receipt and possession of licensable byproduct, source, and SNM for the conduct of any activity which the NRC determines will significantly affect the quality of the environment. Except as noted in the previous paragraph, the information in this appendix should be reviewed by all holders of operating licenses for byproduct (including irradiators), source, and SNM facilities, and all persons who have submitted applications to construct byproduct, source, and SNM facilities, or have submitted letters of intent to submit such applications under 10 CFR Parts 30, 36, 40, and 70.

If a licensing action initiated pursuant to 10 CFR Parts 30, 40, or 70 meets any of the criteria in 10 CFR 51.20 or 51.21, then commencement of construction of a facility before the NRC staff has completed its environmental review process is grounds for denial of the license application, in accordance with 10 CFR 30.33(a)(5), 40.32(e), and 70.23(a)(7). However, if the licensing action meets the criteria in 10 CFR 51.22(c) for a categorical exclusion, and the NRC has not determined that an environmental assessment or an environmental impact statement is required in accordance with 10 CFR 51.22(b), then commencement of construction before the NRC staff concludes the environmental process should not be the sole basis for denial of the license application, as the NRC has already determined that this category of actions does not have a significant impact on the environment. In accordance with 10 CFR 36.15, commencement of construction of an irradiator will only be grounds for denial if the licensee or applicant has not submitted both an application and the requisite licensing fee.

BACKGROUND

The NRC amended its regulations in September 2011, by revising certain provisions applicable to the licensing and approval processes for byproduct (including irradiators), source, and SNM licenses in the final rule, “Licenses, Certifications, and Approvals for Materials Licensees” (76 FR 56951; September 15, 2011) (Material Licenses Construction Rule). The revisions contained in the Material Licenses Construction Rule revised the definitions of “construction” and “commencement of construction” for materials licensing actions.

The definitions of “commencement of construction” in 10 CFR 30.4, 36.2, 40.4, and 70.4 are identical.

Commencement of construction means taking any action defined as “construction” or any other activity at the site of a facility subject to the regulations in this part that has a reasonable nexus to:

1. radiological health and safety; or
2. common defense and security.

The definitions of “construction” in 10 CFR 30.4, 36.2, and 70.4 are identical.

Construction is defined as the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this part that are related to radiological safety or security. The term “construction” does not include:

- (1) changes for temporary use of the land for public recreational purposes;
- (2) site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (3) preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- (4) erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;
- (5) excavation;
- (6) erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
- (7) building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (8) procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
- (9) taking any other action that has no reasonable nexus to:
 - (i) radiological health and safety, or
 - (ii) common defense and security.

“Construction,” as defined in 10 CFR 40.4, also includes the installation of wells associated with radiological operations (e.g., production, injection, or monitoring well networks associated with *in-situ* recovery or other facilities).

The Atomic Energy Act of 1954, as amended, expressly limits the NRC’s regulatory authority to matters concerning the radiological public health and safety or common defense and security and non-radiological hazards to the extent such hazards result from the actual processing of by-product material. The NRC has determined that this authority does not extend to site preparation activities that do not have a nexus to radiological health and safety or common defense and security.

This appendix should be used to evaluate whether a particular construction activity has a nexus to radiological health and safety, and thus falls under the jurisdiction of the NRC for licensing purposes. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a materials facility is operating, or will operate, in accordance with the NRC’s regulations and in a manner that protects the public health and safety or the common defense and security from radiological hazards. The definitions of construction in 10 CFR 30.4, 36.2, 40.4, and 70.4 150.31 list activities that are not considered “construction.” This appendix provides examples of activities that fall under each of the excepted activities that do not constitute construction. Site preparation activities that are not considered “construction,” while not under NRC jurisdiction, may be subject to the regulatory authority of another Federal, State, or local agency which may require National Environmental Policy Act or state environmental review. NRC’s responsibilities under the National Historic Preservation Act of 1966, as amended (NHPA), must also be satisfied before a license is issued. Specifically, as noted in the statements by the NRC published with the final Material Licenses Construction Rule, under certain circumstances the NRC may be required to deny a license application if the NRC determines that the applicant intentionally significantly adversely affected, or allowed to be affected, a historic property with intent to avoid the requirements of §106 of the NHPA.

DISCUSSION OF EXAMPLES

In addition to the background discussion provided above, the following examples clarify the delineation of site preparation activities and construction activities. It is important to recognize that the NRC may have regulatory authority over activities that can occur before construction begins, such as procurement of basic components as defined in 10 CFR Part 21, the process of dedicating commercial grade items or basic components, or procurement of items relied on for safety (IROFS) as defined in 10 CFR Part 70. It should also be noted that, while site preparation activities may not require prior NRC approval, the approval of local, State, or other Federal agencies may be required.

BYPRODUCT MATERIAL (10 CFR PART 30)

Prior to the conclusion of the environmental review process, applicants for byproduct material licenses or license amendments should not perform construction activities that have a nexus to radiological health and safety or the common defense and security. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a licensed materials facility is operating, or will operate, in accordance with the NRC’s regulations and in a manner that protects the public health and safety or the common defense and security from radiological hazards.

Installation of foundations or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to 10 CFR Part 30 that are related to radiological health and safety or common defense and security should not be performed prior to the conclusion of the environmental review of a license application or amendment. Byproduct material license applicants subject to 10 CFR Part 30 may perform those site preparation activities identified in revised 10 CFR 30.4 before the NRC has completed its environmental review of the license application.

Excavation and other site preparation activities that do not have a reasonable nexus to radiological public health and safety or common defense and security, whether permanent or temporary, are not “construction” activities. For example, piles driven to support the erection of a bridge for a temporary or permanent access road to a new facility would not be considered as construction and may be performed prior to the NRC staff concluding its environmental review of a proposed action.

The installation of a temporary feature within an excavation for a building in which materials license activities will be conducted and that will be removed during construction is a site preparation activity. Such features include retaining walls, dewatering systems, ramps, and other structures that will have no physical presence following construction.

Construction includes installation of the foundation, including soil compaction; the installation of permanent drainage systems and geofabric; the placement of backfill, concrete (e.g., mudmats), or other materials that will not be removed before placement of the foundation of a structure; the placement and compaction of a subbase; the installation of reinforcing bars to be incorporated into the foundation of the structure; the erection of concrete forms for the foundations that will remain in place permanently (even if non-structural); and the placement of concrete or other material constituting the foundation of any safety-related feature.

The term “permanent” in this context includes anything that will exist in its final, in-place facility location after commencement of operations with licensed material. Construction also includes the “onsite, in-place” fabrication, erection, integration, or testing activities for any in-scope safety-related equipment. The terms “onsite, in place, fabrication, erection, integration, or testing” describe the process of constructing a facility in its final, onsite plant location, where components or modules are integrated into the final, in-plant location. The fabrication, assembly, and testing of components and modules in a shop building, warehouse, or laydown area, even if located onsite, is not construction. However, the installation or integration of the safety-related equipment into its final plant location is construction.

Construction also includes driving piles for safety-related equipment. Hence, an applicant must obtain a license before driving piles for safety-related equipment. However, driving piles that do not ensure the structural stability or integrity of a safety-related structure (e.g., piles driven to support the erection of a bridge for a temporary or permanent access road) is not construction; therefore, those piles may be driven prior to the NRC staff concluding its environmental review of a proposed action.

IRRADIATORS (10 CFR PART 36)

An applicant for a new irradiator license under 10 CFR Part 36 may perform the non-construction activities identified in revised 10 CFR 36.2 at any time. However, installation of foundations or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to 10 CFR Part 36 that has a reasonable nexus to

radiological safety or security should not be performed prior to the submission of an application for a license and the fee required by 10 CFR 170.31. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a licensed materials facility is operating, or will operate, in accordance with the NRC's regulations and in a manner that protects the public health and safety or the common defense and security from radiological hazards. Activities that have a reasonable nexus to radiological health and safety or common defense and security include, but are not limited to, construction of systems subject to 10 CFR Part 36, Subpart C, and the following:

- earthwork
- pool excavation
- footings and foundation for pool
- irradiator foundations and walls
- backfill pool
- install pool liner
- mechanical rough-in
- electrical rough-in
- shoring for roof
- form and place roof
- slab on grade

Subpart C of 10 CFR Part 36 lists the systems that have a nexus to radiological health and safety and defines the related engineering and safety concerns associated with each system:

- *access control:* adequacy of access control systems using interlocks and radiation monitors to prevent inadvertent entry to areas where radiation sources are unshielded; to provide emergency exits; and to ensure compliance with all the requirements of 10 CFR 36.23; (For computer-controlled access-control systems, licensing staff should consider expert evaluation of the software/system logic before operational testing.)
- *site:* potential need for protection against flooding and earth slides
- *base (soil, rock) for the pool and shielding structures:* strength, settlement, liquefaction, ground water, and soil compaction
- *footers and foundations for the pool and shielding structures:* strength and reinforcement, alignment with pool and shielding structures
- *pool and shielding structures:* strength and reinforcement, proper density of shielding materials, correct dimensions, minimization of voids in concrete or other shielding
- *pool liner:* contact with pool structure, penetrations in the liner, leak-tight welds
- *pool plumbing:* makeup water system; water cleanup system; effect of construction materials on pool-water chemistry; drainage system (potentially contaminated spilled water should flow into the pool); siphon breakers; radiation detection and alarm systems
- *penetrations through shielding:* any significant effect on structural strength, shielding, or both

- *source rack protection (if the product to be irradiated moves on a product conveyor system):* source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism
- *source-rack mechanical positioning system:* strength and stiffness of the rack and positioning cables or chains, source shroud will not interfere with source positioning, adequacy of motive power, potential for jamming
- *source-rack movement and position-sensing system:* structural attachments for electrical and mechanical transducers, adequacy of transducers for interacting with the source-rack control system
- *source-rack electrical control system:* adequacy of the design of logistical and operational electrical circuitry and electromechanical components, to ensure unambiguous response of the system, which includes programmable controllers or computers and their interaction with operations, interlocks, doors, signals, and alarms
- *source-leak detection:* adequacy of systems for detecting and isolating leaking sources
- *hard wiring:* adequacy of wire gauge and insulation to safely carry design currents and to withstand radiation and ozone damage if exposed; locating and attaching wiring to prevent fretting, wear, and exposure to potential fire hazards; accessibility to wiring for inspection and repair
- *uninterruptable electrical power supply:* adequate and reliable power capability to operate all electrical systems that are important to safety (including backup power sources); compatibility of the power supply with the electrical system
- *fire protection system:* adequacy to detect fire and smoke and to be manually as well as automatically initiated; must ensure that raised sources are immediately lowered into the pool
- *emergency systems for returning an up-stuck source rack to the pool:* capability of the electrical control system to sense and signal the occurrence of an up-stuck source-rack; adequacy of mechanical or electrical means for personnel to safely release and lower the rack; need for, and adequacy of, a system to cool the source-rack until it can be released and lowered
- *ozone ventilation system:* capability of the system to be properly initiated and to provide adequate volume flow rate of air to protect personnel and components
- *system for transferring sources from and to transport vehicles:* adequately sized openings in the shield-structure roof if sources are roof-loaded; structural adequacy of the roof-shield plug and its supports for its removal and replacement; structural and mechanical adequacy of systems for moving shipping containers into and out of the pool area

ACTIVITIES WHICH HAVE NO REASONABLE NEXUS TO RADIOLOGICAL SAFETY OR SECURITY

The NRC has determined that, in general, the following activities at byproduct (including irradiators), source, and SNM facilities listed in 10 CFR 30.4, 36.2, 40.4, and 70.4, do not have a reasonable nexus to radiological health and safety and the common defense and security may be performed by a licensee or applicant at any time. Note that in some circumstances, based on the specific licensing proposal, any of these activities could be determined to have a reasonable nexus to radiological health and safety or common defense and security and, based on that determination, these activities would be construction:

- (1) changes for temporary use of the land for public recreational purposes;
- (2) site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (3) preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- (4) erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to 10 CFR Parts 30, 36, 40, or 70;
- (5) excavation;
- (6) erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
- (7) building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (8) procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
- (9) taking any other action that has no reasonable nexus to:
 - (i) radiological health and safety, or
 - (ii) common defense and security.

While the above site preparation activities may not require prior NRC approval, the approval of local, State, or other Federal agencies may be required.

REFERENCES

- NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with Materials Facilities," August 2003
- DC/COL-ISG-4, "Interim Staff Guidance on the Definition of Construction and on Limited Work Authorizations," February 9, 2009, ML082970729

APPENDIX Q
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: <http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf>. It is also posted in the U.S. Nuclear Regulatory Commission (NRC) Agencywide Documents Access and Management System 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.

The following are traits of a positive safety culture:

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

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

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

APPENDIX R

CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)

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

In order to request that the U.S. Nuclear Regulatory Commission (NRC) withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:

<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 non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary 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 in 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.

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**Consolidated Guidance About Materials Licenses: Program-Specific
Guidance About Licenses of Broad Scope**

February 2017