U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

NUREG-1556
Volume 17, Rev. 1

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses

Final Report

Office of Nuclear Material Safety and Safeguards

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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 for special nuclear material of less than critical mass. 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.

Paperwork Reduction Act Statement

This NUREG contains 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; 3150-0010; 3150-0214; 3150-0135; 3150-0009; 3150-0008; 3150-0002; 3150-0123; 3150-0055; 3150-0032; 3150-0120; 3150-0003; 3150-0005; and 3150-0006. Send comments regarding this information collection to the Information Services Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0044; 3150-0014; 3150-0035; 3150-0017; 3150-0010; 3150-0214; 3150-0135; 3150-0009; 3150-0008; 3150-0002; 3150-0123; 3150-0055; 3150-0032; 3150-0120; 3150-0003; 3150-0005; and 3150-0006) Office of Management and Budget, Washington, DC 20503.

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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 17, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses," 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 17, issued November 2000.

This report takes a risk-informed, performance-based approach to licensing special nuclear material (SNM) of less than critical mass. 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 SNM. NUREG–1556, Volume 17, 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 they include a basis for the NRC staff to make the determinations needed to issue or renew a license.

The comments received during the public comment period for NUREG–1556, Volume 17, Revision 1, were summarized and addressed in a document that can be located on the NRC's Agencywide Documents and Management System (ADAMS) under ML18113A291. Access to ADAMS is available on the public Web site at: https://www.nrc.gov/reading-rm/adams.html. The comments received by NRC included general corrections, comments on examples in the NUREG, and comments regarding why sealed source and device information was contained throughout the document.

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ACKNOWLEDGMENTS

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ABBREVIATIONS

A	activity
ADAMS	Agencywide Documents Access Management System
AEA	Atomic Energy Act
ALARA	as low as is reasonably achievable
ALI	Annual Limit on Intake
ANSI	American National Standards Institute
AU	authorized user
Be	beryllium
bkg	background
Bq	becquerel
CEDE	Committed Effective Dose Equivalent
CFR	*Code of Federal Regulations*
Ci	curie
cpm	counts per minute
DFP	decommissioning funding plan
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
dps	decays per second
EPA	U.S. Environmental Protection Agency
FR	*Federal Register*
g	grams
GBq	gigabecquerel
GPS	global positioning system
h	hour
IN	Information Notice
L/C	license condition
LLEA	local law enforcement agency
LLW	low-level radioactive waste
LSC	liquid scintillation counter
MDA	minimum detectable activity
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
mol	mole
mR	milliroentgen
mrem	millirem
mSv	millisievert
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
NMMSS	Nuclear Materials Management and Safeguards System
NRC	United States Nuclear Regulatory Commission
NSSDR	National Sealed Source and Device Registry
NSTTR	National Source Tracking Transaction Report
NSTS	National Source Tracking System
NVLAP	National Voluntary Laboratory Accreditation Program
OMB	Office of Management and Budget
PII	Personally Identifiable Information
Pu	plutonium
Pu-236	plutonium-236
Pu/Be	plutonium/beryllium

Q	quality factor
QA	quality assurance
rad	radiation absorbed dose
rem	roentgen equivalent man
RG	Regulatory Guide
RIS	Reporting Identification Symbol
RQ	reportable quantities
RSO	radiation safety officer
SA	State Agreement
SNM	special nuclear material
SSD	sealed source and device
std	standard
Sv	sievert
$T_{1/2}$	radioactive material half-life
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeter
U-233	uranium-233
U-235	uranium-235
U-238	uranium-238
U.S.C.	United States Code
yr	year
ZnS	zinc sulfide

1 PURPOSE OF REPORT

This report provides guidance to an applicant in preparing a license application for a specific license for receipt, possession, use, and transfer of special nuclear material (SNM) in quantities that are not sufficient to form a "critical mass," as well as U.S. Nuclear Regulatory Commission (NRC) criteria for evaluating a license application for such SNM. Within this NUREG, the terms "SNM," "licensed material," and "radioactive material" are used interchangeably.

SNM, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70.4, means (i) plutonium, uranium 233 (U-233), uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, determines to be SNM but does not include source material; or (ii) any material artificially enriched by any of the foregoing but does not include source material.

SNM in quantities not sufficient to form a critical mass, as defined in 10 CFR 150.11(a), "Critical Mass," means uranium enriched in the isotope uranium-235 (U-235) in quantities not exceeding 350 grams of contained U-235; U-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them.

For each kind of SNM, the applicant should determine the ratio between the requested quantity of that SNM and the quantity specified above for the same kind of SNM. The sum of such ratios for all kinds of SNM, in combination, should not exceed unity. For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

$$.5 + .25 + .25 = 1$$

As defined in 10 CFR 150.11(b), determine whether the exemption granted in 10 CFR 150.10 applies to the receipt, possession, or use of SNM at any particular plant or other authorized location of use; a person shall include in the quantity computed according to 10 CFR 150.11(a) the total quantity of SNM a person is authorized to receive, possess, or use at the plant or other location of use at any one time.

This guidance is also intended for applicants requesting authorization to possess and use sealed plutonium/beryllium (Pu/Be) neutron sources. Applicants requesting authorization to possess and use Pu/Be neutron sources can have a mass quantity up to 2,000 grams of Pu with a Pu/Be ratio that is less than or equal to 1,000, if the request is for Pu/Be sources only. Agreement States may also allow possession and use of Pu/Be sources using the criteria noted above. The technical basis for such quantity can be found in document titled, "Technical Basis for 2,000 g Pu/Be Sealed Neutron Source Mass Limit," Agencywide Documents Access and Management System (ADAMS) Accession No. ML16190A294. If the request to possess and use Pu/Be neutron sources includes other types of SNM, then 10 CFR 150.11(a) applies.

After calculating the amount of SNM to confirm that it is within exemption for SNM not exceeding a critical mass as authorized in 10 CFR 150.11, the applicant should determine the level of security required to adequately protect the material at its site. See Section 8.10.11 of this NUREG.

Typical uses of SNM (see Figure 1-1) include:

- experiments using subcritical assemblies
- foil activation experiments using Pu/Be sources
- instrument calibration
- student instruction in radiation detection and measurement
- nuclear pacemakers
- U-235 target foils experiments
- low-enriched uranium sources for radiation detection testing

Figure 1-1. A Typical Research Use of Special Nuclear Material.

An example of how to convert activity to grams for a given radioisotope is provided below.

Example Calculation to Convert Activity of a Radioisotope to Grams*

It may first be necessary to convert the activity (A) in curies to disintegrations (or decays) per second (dps). For example:

$A = 0.963 \text{ curies} \times 3.7 \times 10^{10} = 3.56 \times 10^{10}$ dps

In the formula, $A = \lambda \times N$, the value of A is equal to 3.56×10^{10} dps. The value of $\lambda = .693/T_{1/2}$, where $T_{1/2}$ for U-233 equals 1.59×10^{5} yr $\lambda = [.693/(1.59 \times 10^{5} \text{ yr} \times 3.16 \times 10^{7} \text{ seconds/yr})] = 1.38 \times 10^{-13}$

$$N = 3.56 \times 10^{10} \text{ dps} / 1.38 \times 10^{-13} = 2.58 \times 10^{23} \text{ atoms} \times \frac{233.0 \text{ g/mol}}{6.02 \times 10^{23} \text{ atoms/mol}}$$

$$2.58 \times 10^{23} \text{ atoms} \times 3.87 \times 10^{-22} \text{ g/atoms} = 100 \text{ grams}$$

*The activity of the radioisotope can also be divided by the specific activity of the radionuclide to obtain the quantity of the material in grams [Example: Using a Specific Activity of U-233 = 0.0095 curies/g, A/Specific Activity = 0.963 curies/0.0095 curies/g = 101 grams (g)]

This NUREG is not intended to address the following issues:

- possession of quantities of SNM in excess of critical mass

- applications for licenses authorizing manufacturing and distribution of SNM (NUREG–1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility")

If an applicant or licensee needs authorization to possess a quantity of SNM equaling or exceeding critical mass, they should contact a member of the NRC staff in the Office of Nuclear Material Safety and Safeguards (NMSS) for details on SNM licensing.

Because some licensees subject to this report possess aggregated Category 1 or Category 2 quantities of radioactive material subject to 10 CFR Part 37, this NUREG additionally addresses security requirements associated with possession of that material.

Chapter 8, "Contents of an Application" of this guide identifies the information needed to complete NRC Form 313, "Application for Materials License," (see Appendix A of this NUREG) or letter of application for the use of unsealed and sealed SNM. The Office of Management and Budget (OMB) has approved the information collection requirements in 10 CFR Part 70 and NRC Form 313 under OMB Clearance Nos. 3150-0009 and 3150-0120, respectively.

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

- Regulations—references the regulations applicable to the item.

- Criteria—outlines the criteria used to evaluate of the applicant's response.

- Discussion—provides additional information about the topic.

- Response from Applicant—provides suggested response(s), 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. Sentences in this NUREG containing "must" and "will" are usually associated with NRC regulations. If these sentences are not tied to a regulatory requirement, they likely refer to a license condition or other obligation associated with the license. See NUREG–1556, Volume 20, "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures," for further information on license conditions.

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 SNM applications, Appendix B of this NUREG may be used to provide supporting information.

Appendix B of this NUREG is also a checklist that NRC staff use to review applications and applicants can use to check for completeness. Appendices C through N of this NUREG contain additional information on various radiation safety topics, including model procedures. Appendix L of this NUREG includes a table of NRC incident notification and reporting

requirements applicable to SNM. Appendix O of this NUREG provides a checklist for requesting the withholding of proprietary information from public disclosure, and Appendix P contains the NRC's Safety Culture Policy Statement.

In this NUREG, "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 (Gray). 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.

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 (SNM), 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. Since under Title 10 of the *Code of Federal Regulations* (10 CFR) 150.11 Agreement States can only regulate SNM in less than critical mass quantities, if an applicant or licensee needs authorization to possess a quantity of SNM equaling or exceeding critical mass, they should contact an NRC staff member in Office of Nuclear Material Safety and Safeguards (NMSS) for SNM licensing. Such an applicant or licensee should submit an application to NMSS, and if its application is granted, its Agreement State license should be terminated.

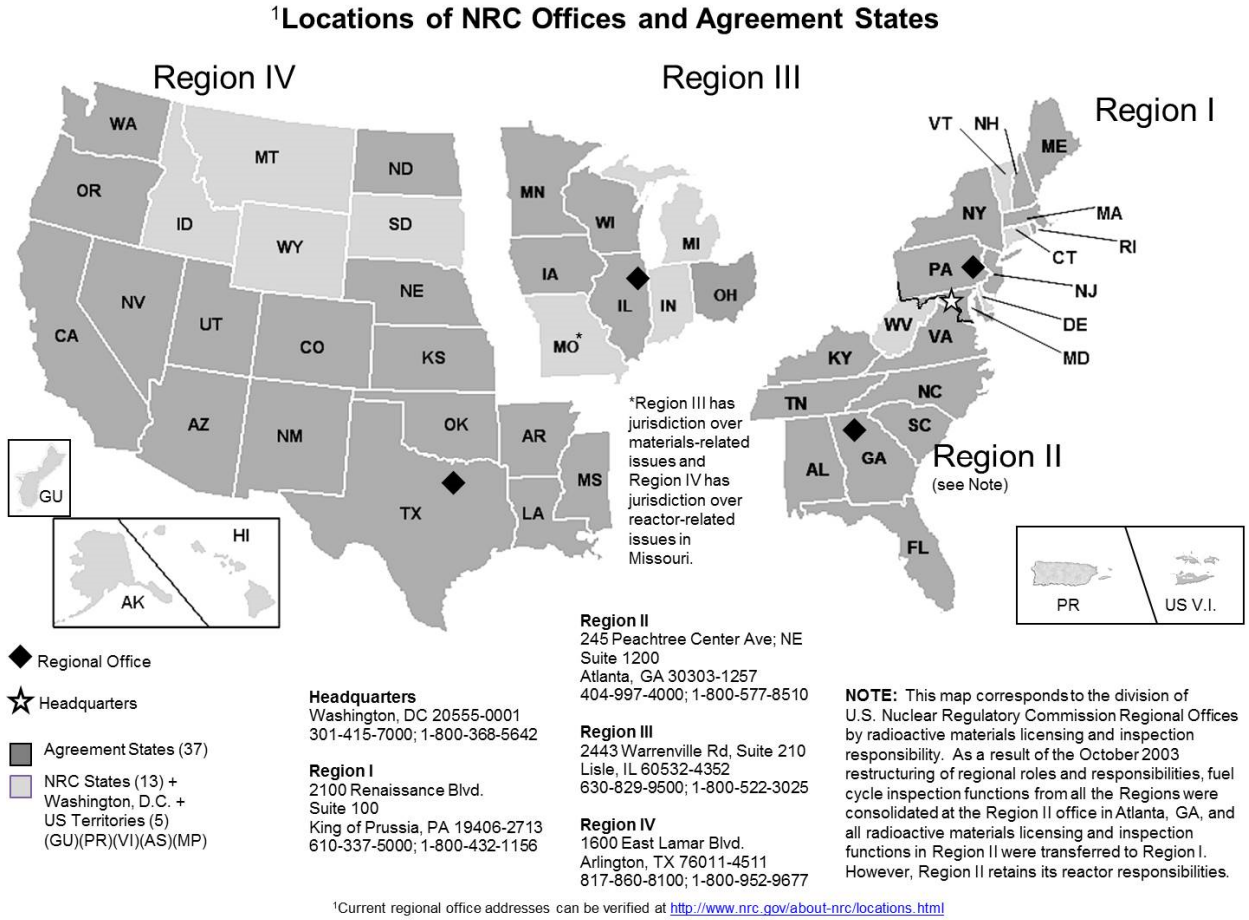


Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

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 NMSS procedures in the State Agreement (SA) 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 the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with 10 CFR 70.11, "Persons using special nuclear material under certain Department of Energy and Nuclear Regulatory Commission contracts")	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

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

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

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	**Regulatory Agency**
Non-Federal entity in Agreement State	Agreement State[4]
Non-Federal entity in Agreement State at federally controlled site not subject to exclusive Federal jurisdiction	Agreement State[4]
Non-Federal entity in Agreement State at federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with 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 Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	Agreement State[4]

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

2.2 Reciprocal Recognition of Specific Licenses

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

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

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

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

3 MANAGEMENT RESPONSIBILITY

The U.S. Nuclear Regulatory Commission (NRC) recognizes that effective management of radiation safety programs 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) 70.22(d), each application must be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee. If it is not clear whether the application was signed by someone duly authorized to act for and on behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual who signed the application is duly authorized to act for and on the behalf of the applicant or licensee. The signature on an application acknowledges the applicant's or licensee's commitments and responsibilities, including 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 70.9, "Completeness and accuracy of information")
- knowledge about the contents of the license and application
- compliance with current NRC and U.S. Department of Transportation (DOT) 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
- selection and assignment of a qualified individual to serve as the radiation safety officer (RSO) for 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
- ensure that radiation workers have adequate training
- prevention against discrimination of employees engaged in protected activities and commitment to provide information to employees about the employee protection provisions (10 CFR 70.7, "Employee protection")

- commitment to provide information to employees about deliberate misconduct provisions (10 CFR 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 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 https://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 be inherent to an organization's existing radiation safety practices and

programs. For instance, for calibration or reference sources containing plutonium, quality control and prototype testing procedures are required (for sources containing more than 0.005microcuries of plutonium) so that the plutonium contained in the source will not be released or removed from the source under normal conditions of use resulting in the spread of plutonium contamination. The need for quality control and prototype testing procedures for calibration or reference sources 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). However, licensees should be aware that this is just an example and should 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 P of this NUREG for the NRC's safety culture policy statement. More information on NRC activities relating to safety culture can be found at https://www.nrc.gov/about-nrc/regulatory/enforcement/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 potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected, commensurate with their significance.	All individuals take personal responsibility for safety.
Work Processes	**Continuous Learning**	**Environment for Raising Concerns**
The process of planning and controlling work activities is implemented so that safety is maintained.	Opportunities to learn about ways to ensure safety are sought out and implemented.	A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.
Effective Safety Communications	**Respectful Work Environment**	**Questioning Attitude**
Communications maintain a focus on safety.	Trust and respect permeate the organization.	Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

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 special nuclear material (SNM) of less than critical mass. 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 10 CFR regulations can be found under the "Basic References" link at the U.S. Nuclear Regulatory Commission's (NRC's) online library at https://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 37	"Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
10 CFR Part 70	"Domestic Licensing of Special Nuclear Material"
10 CFR Part 71	"Packaging and Transportation of Radioactive Material"
10 CFR Part 73	"Physical Protection of Plants and Materials"
10 CFR Part 74	"Material Control and Accounting of Special Nuclear Material"
10 CFR Part 150	"Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters under Section 274"
10 CFR Part 170	"Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services 0nder 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"

Copies of the above 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 https://bookstore.gpo.gov.

In addition, 10 CFR Parts 1 through 199 can be found on the NRC's Web site at https://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 https://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 the 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 https://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 8½ × 11-inch or legal-sized paper that will feed easily into a document scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura.
- Use an 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 corporate officer thereof, as required by 10 CFR 70.22(d) (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 https://www.nrc.gov/site-help/e-submittals.html. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic 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. Licensing applications that contain sensitive information should be marked as indicated below 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 O includes a checklist for requests for withholding information from public disclosure.

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

- Security-Related Information: Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive, unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities and associated security measures are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information, and the top of every page of a document that contains such information should be clearly marked: "Security-Related Information—Withhold under 10 CFR 2.390." 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 Regulatory Issue Summary 2005-31, Rev. 1, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated

December 26, 2017, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": https://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Additional information on procedures and any updates is available at https://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, or 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: https://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: https://www.nrc.gov/reading-rm/doc-collections/management-directives/.

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

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

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

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, Maryland, 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 the 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 and security programs 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 store material," and 10 CFR 20.1802, "Control of material not in storage."

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.
[ ] A. New License	Not Applicable
[ ] B. Amendment	XX-XXXXX-XX
[ ] C. Renewal	XX-XXXXX-XX

Check Box A for a new license request. Note that a prelicensing visit may be required prior to issuance of the license. Also note that an initial on-site security review 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 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 70.32(a)(9)

Criteria: Immediately following the filing of a voluntary or involuntary petition for bankruptcy by 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.

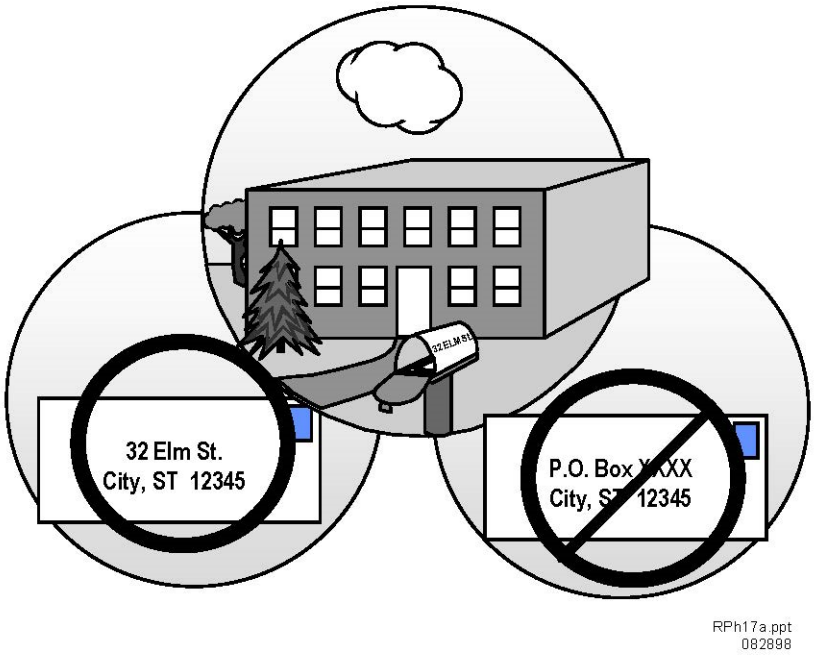
Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains subject to all applicable NRC regulatory requirements. The NRC must be notified when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled 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 the NRC may request that the U.S. 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

Specify the street address, city, and State or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable (see Figure 8-1). In addition,



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

applicants are encouraged to provide global positioning system coordinates, as appropriate. A license amendment is required before receiving, using, or storing licensed material at an address or location not already listed on the license.

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

To conduct operations at temporary job sites (i.e., locations where work is conducted for limited periods of time), the address may be stated as "temporary job sites anywhere in the United States where the NRC maintains jurisdiction."

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 later 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 special nuclear material was used or stored, and any records or information relevant to damaged devices or leaking radioactive sources, 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. Also include 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 Sealed Sources and Devices or Unsealed Radioactive Material

Regulations: 10 CFR 20.2207, 10 CFR Part 37, 10 CFR 70.22, 10 CFR 70.23, 10 CFR 70.39

Criteria: An application for a license will be approved if the requirements of 10 CFR 70.23, "Requirements for the approval of applications," are met. In addition, licensees will be authorized to possess and use only those sources and devices that are specifically approved or registered by NRC or an Agreement State. 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: Each authorized radioisotope is listed on the NRC license by its element name, chemical and/or physical form, and the maximum possession limit, including the percentage of enrichment and quantity in grams (or milligrams). Table 8-1 below shows the type of radioactive material covered by this NUREG.

Table 8-1. Types of Radioactive Materials

Type of Material	Covered By This Report	Examples
Byproduct (reactor-produced)	No	H-3, C-14, I-131, I-125, S-35, P-32, P-33, Ca-45, Ni-63, Cd-109, Cs-137
Source material	No	U, Th
Special nuclear material	Yes	U-233, U-235, and Pu
Naturally occurring radioisotopes	No	Ra-226
Accelerator-produced radioisotopes	No	Co-57, Na-22, Tl-201, Ga-67

The applicant should list each requested radioisotope by its element name and its mass number [e.g., uranium-233 (U-233)] in item 5. Identify the chemical and physical form of each requested radioisotope. Identify the quantities of material in milligrams or grams (g), and microcuries. If applicable, identify the percent enrichment of uranium-235 (U-235). If applicable, identify the National Sealed Source and Device Registry (NSSDR) number.

Note: Applicants seeking authorization to use a sealed source and device, without an associated NSSDR registry number, issued by the NRC or Agreement State, should submit all of the applicable procedures and information as described in 10 CFR 70.39. Lacking this information, the encapsulated source will be regulated as unsealed radioactive material until the applicant provides sufficient safety-related information demonstrating that the source can be licensed as a sealed source.

Applicants requesting an authorization to use unsealed radioactive material, including volatile, aerosol, or fine-particulate forms, must provide appropriate facilities, engineering controls, and radiation safety procedures for handling of such material.

The anticipated possession limit in milligrams (or grams), percent enrichment, and microcuries for each radioisotope should also be specified. Possession limits must cover the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radioisotope with a half-life greater than 120 days. These requirements are discussed in Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

A safety evaluation of sealed sources and devices may have been performed by the NRC or an Agreement State that authorizes a manufacturer (or distributor) to distribute the sealed source and device to specific or general licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) registration certificate. Information on SSD registration certificates may be obtained by contacting the U.S. Nuclear Regulatory Commission, Materials Safety Licensing Branch, Division of Materials Safety, State, Security, and Tribal Programs, Washington, DC 20555-0001. Guidance on the SSD registration process is provided in NUREG–1556, Volume 3, "Consolidated Guidance on Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration." If applicable, the license applicant should identify 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 an SSD registration certificate or specifically approved on a license.

Licensees should consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the sealed source and device designations registered with the NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates without obtaining the NRC's prior permission in a license amendment. To ensure that applicants use sources and devices according to the registration certificates, they may want to get a copy of the certificate and review it or discuss it with the manufacturer. 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").

Certain types of special nuclear material (SNM) less that critical mass sources can be at or above Category 2 quantities of radioactive material. "Category 2 quantity of radioactive material" is defined in 10 CFR 37.5, and the radionuclides referenced in the 10 CFR 37.5 definition is listed in Appendix A to 10 CFR Part 37. See Section 8.10.11.2, "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:

- For unsealed materials:
  - — Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit in milligrams (or grams), percent enrichment, and microcuries for each radioisotope.
- For sealed sources:
  - — Identify each radionuclide (element name and mass number) that will be used in each sealed source and specify the maximum quantity [mass in milligrams (or grams)], percent enrichment, and microcuries per source. Also, specify the maximum number of sources or total quantity for each radionuclide.
  - — Provide the manufacturer's or distributor's name and model number for each sealed source and device requested.
  - — Confirm that each sealed source, device, and source and device combination is registered as an approved sealed source or device by the NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available.
  - — Confirm that the activity per source and maximum quantity in each device will not exceed the maximum quantity listed on the approved certificate of registration issued by the NRC or by an Agreement State.
- For unregistered sealed sources:
  - — Identify each radionuclide (element name and mass number) that will be used and specify the maximum quantity [mass in milligrams (or grams)], percent enrichment, and microcuries per source. Also, specify the maximum number of sources or total quantity for each radionuclide.
  - — Provide source drawings, the form of the source itself, its containment structure, and a hazards analysis (e.g., what is the annual limit of intake for the source) for any sources not registered in the SSD registration.
  - — Provide clear limitations on the use of the source.
  - — Confirm that the activity per source and maximum quantity will not exceed the maximum quantity requested.
- Provide an emergency plan (if required).

8.5.2 Financial Assurance and Recordkeeping for Decommissioning

Regulations: 10 CFR 70.22(a)(9), 10 CFR 70.25, 10 CFR 70.38, 10 CFR 70.51

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

All licensees are required by 10 CFR 70.25(g) to maintain records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Licensees must transfer these records either to the new proposed licensee before licensed activities are transferred or assigned in accordance with 10 CFR 70.51(b), or to the appropriate NRC regional office before the license is terminated.

Financial Assurance

Discussion: NRC regulations requiring financial assurance or a DFP 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 such that unrestricted use of the facilities is possible at the conclusion or termination of licensed activities.

These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee through a third party that funds will be available (see Figure 8-2). Applicants are required to submit a certification of financial assurance or a DFP when the license authorizes possession of radioactive material of half-life ($T_{1/2}$) greater than 120 days and exceeds certain limits. Criteria for determining whether an applicant is required to submit a DFP or has the option of submitting either a DFP or a certification of financial assurance are stated in 10 CFR 70.25, "Financial assurance and recordkeeping for decommissioning." A DFP contains a site-specific cost estimate and a certification of financial assurance. A certification of financial assurance includes a certification that the licensee has provided the required financial assurance and an acceptable financial assurance instrument.

Applicants should consider encapsulated sources and certain custom sources as unsealed material if it is not registered in the sealed source and device registry. See 10 CFR 70.25 (b) regarding the DFP or certification of financial assurance for decommissioning for unsealed SNM.

The NRC wants to ensure that decommissioning will be carried out with minimum impact on the public, occupational health and safety, and the environment (53 FR 24018; June 27, 1988). There are two parts to this decommissioning rule: financial assurance that applies to some licensees and recordkeeping that applies to all licensees.

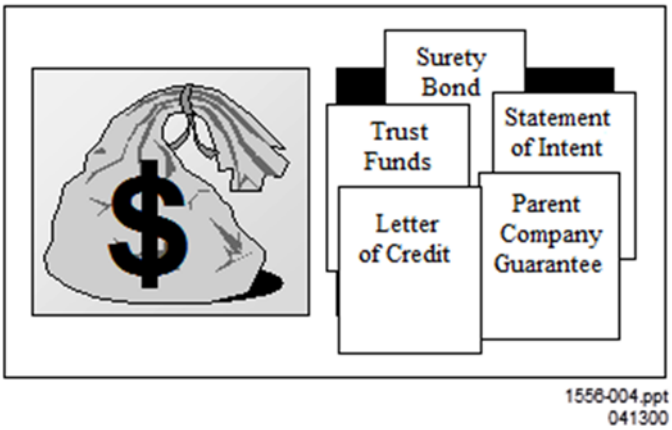


Figure 8-2. Methods of Certification of Financial Assurance for Decommissioning

NUREG–1757, Volume 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," provides a comprehensive listing of financial assurance mechanisms, including (i) Trust Fund, (ii) Surety Bond, (iii) Letter of Credit, (iv) Insurance Policy, (v) Parent Company Guarantee, (vi) Self-Guarantee, (vii) External Sinking Fund, (viii) Statement of Intent (in the case of Federal, State, or local government licensees), or (ix) Special Arrangements with a government entity that assumes custody and ownership of the site.

Recordkeeping for Decommissioning

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in 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 (see Figure 8-3). Before the licensed activities are transferred or assigned in accordance with 10 CFR 70.36 to another person or entity, these records must be transferred to the new proposed licensee prior to transfer of the licensed activities under 10 CFR 70.51(b). The new licensee is responsible for maintaining these records until the license is terminated. Also, before a license is terminated, these records must be transferred to the appropriate NRC regional office in accordance with 10 CFR 70.51(a).

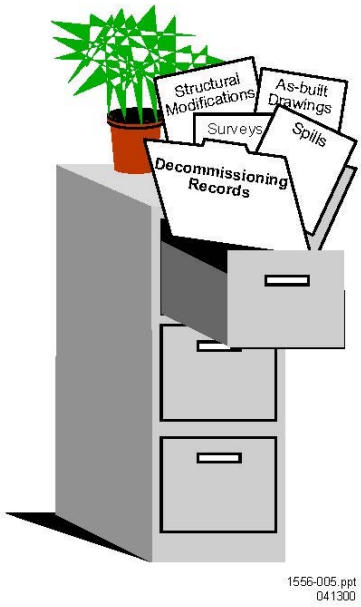


Figure 8-3. Types of Records That Must be Maintained for Decommissioning

Response from Applicant: No response is needed from most applicants requesting only sealed sources. However, if a certification of financial assurance or a DFP is required, submit the following:

- A statement that: "Pursuant to 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 70.36. Furthermore, pursuant to 10 CFR 70.51(a)(3), we will forward the records required by 10 CFR 70.25(g) to the appropriate NRC regional office before the license is terminated."

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."

References:

Regulatory Guide 3.65, Revision 1, "Standard Format and Content of Decommissioning Plans for Materials Licensees"

NUREG–1757, Volume 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness"

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

Regulations: 10 CFR 70.23(a)(1), 10 CFR 70.22(a)(2), 10 CFR 70.4

Criteria: The possession or use of requested radioisotopes must be authorized by the Atomic Energy Act of 1954, as amended. All sealed sources and devices containing licensed material

must be used only for the purpose for which they are designed, and according to manufacturer's and distributor's instructions and recommendations for use as specified in the SSD registration certificate, unless otherwise authorized in the license.

Discussion: Applicants should clearly specify the purpose for which each radioisotope will be used and a general plan for carrying out the activity should be described. Each individual use should be described.

A typical license authorizes persons to perform research and development and student instruction using plutonium/beryllium (Pu/Be) sealed sources in a neutron howitzer, experiments using subcritical assemblies, calibration of radiation-detection instruments and others described in Section 1.0. Nontypical uses will be evaluated on a case-by-case basis, and the authorized use condition will reflect approved uses.

The described uses should contain sufficient information to enable the reviewers to have a clear understanding of each use and determine the potential for exposure of workers and members of the public to radiation and radioactive materials.

Response from Applicant: List the specific use or purpose of each radioisotope.

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

8.7.1 Radiation Safety Officer

Regulation: 10 CFR 20.1101, 10 CFR 70.22(a)(6), and 10 CFR 70.23(a)(2)

Criteria: RSOs must have training and specific experience appropriate for the types and quantities of licensed material to be authorized on the license.

Discussion: The person responsible for the radiation protection program is the RSO. The RSO should have independent authority to stop operations that he or she considers unsafe. He or she should have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are illustrated in Figure 8-4 and described in Appendix C of this NUREG.

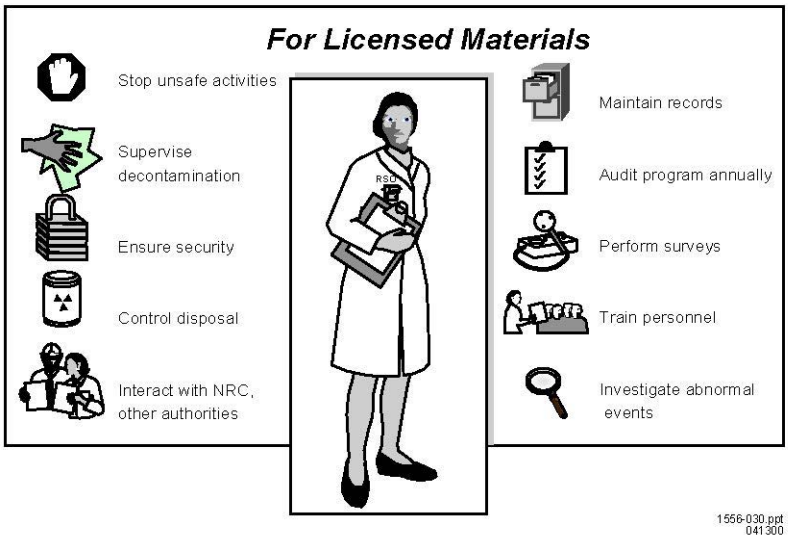


Figure 8-4. RSO Responsibilities
Typical duties and responsibilities of RSOs

The RSO should have (i) sufficient knowledge of physical, chemical, or biological sciences, or engineering, and (ii) 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 special nuclear material to be used)
- NRC and U.S. Department of Transportation (DOT) regulatory requirements and standards commensurate with the uses proposed by the applicant
- hands-on use of radioactive materials

The length of training and experience described above will depend upon the type, form, quantity, and proposed use of the licensed material requested. Ultimately, the proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards.

Response from Applicant: Provide the following:

- name of the proposed RSO
- information demonstrating that the proposed RSO is qualified by training and experience.

Applicants should provide information about the proposed RSO's training and experience relative to the licensed material requested in the application. Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, and committee and society memberships. The applicants should identify, mark, and protect sensitive information against unauthorized disclosure to the public and refrain from submitting personally identifiable information (PII) when possible (see Chapter 6, "Identifying and Protecting Sensitive Information," of this document). Submittal of unrelated material serves only to slow 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.

8.7.2 Authorized Users and Radiation Workers

Regulations: 10 CFR 19.11, 10 CFR 19.12, 10 CFR19.13, 10 CFR 20.1101, 10 CFR 70.22(a)(6), and 10 CFR 70.23(a)(2)

Criteria: Authorized users (AUs), including radiation workers working under their supervision, must have adequate training and experience to safely possess and use licensed radioactive materials.

For the purposes of discussion in this NUREG, the applicant (and members of the applicant's staff) will be denoted as AU. An AU is a person who, before using licensed material, is qualified by reason of training and experience to use the radioactive material for the purpose requested in accordance with the regulations of 10 CFR 70.22(a)(6) and 10 CFR 70.23(a)(2).

Radiation workers must receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12, "Instruction to workers," for individuals whose assigned duties involve exposure to radiation or radioactive material, and individuals who in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 millisievert (mSv) [100 millirem (mrem)].

Examples of the training and experience, which will be reviewed and authorized by the NRC during licensing actions, such as new licenses and amendments or renewals to existing NRC licenses are described in the discussion paragraphs.

Discussion: An AU is a person whose training and experience have been reviewed and approved by the NRC, who is named on the license, and who uses or directly supervises the use of licensed material. The AU's primary responsibility is to ensure that radioactive materials used in his or her particular lab or area, are used safely and according to regulatory requirements (see Figure 8-5). The AU also is responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

Figure 8-5. Authorized User
The authorized user is responsible for the safe use of licensed material in his or her laboratory or area.

AUs should have adequate and appropriate training to provide reasonable assurance that they will use licensed material safely. Training should include maintaining security of and access to, licensed material and responding appropriately to events or accidents involving licensed material to prevent the spread of contamination.

To demonstrate adequate training and experience, the AU should have (i) sufficient knowledge of physical, chemical, biological sciences, or engineering and (ii) training and experience commensurate with the scope of proposed activities. Training should include the following topics:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection instrumentation
- biological hazards of exposure to radiation (appropriate to the types and forms of special nuclear material to be used)
- hands-on use of radioactive materials

The length of training and experience described above will depend upon the type, form, quantity, and proposed use of the licensed material requested.

An AU is considered to be supervising the use of radioactive materials when the AU is directing personnel in operations involving the licensed material. Although the AU may delegate specific

tasks to supervised users (e.g., conducting surveys, keeping records), the AU is responsible for the safe use of radioactive material to assure that areas are not contaminated.

Applicants should name at least one qualified authorized user. In general, AUs should demonstrate training and experience with the type and quantity of material that they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or more times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high energy beta emitters.

Training may be in the form of lecture, demonstrations, videotape, or self-study and should emphasize practical subjects important to the safe use of licensed material. Emergency drills should be conducted on the likely scenarios that may be encountered. The guidance in Appendix M of this NUREG may be used to develop a training program. The program should consider both the topics pertinent for each group of workers and the method and frequency of training.

Response from Applicant: Provide the following:

- name of each proposed AU with the types and quantities of licensed material to be used

AND

- information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials.

Applicants should provide information about the proposed AU's training and experience relative to the licensed material requested in the application. Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. The applicants should identify, mark, and protect sensitive information against unauthorized disclosure to the public and refrain from submitting PII when possible (see Section 6, "Identifying and Protecting Sensitive Information," of this document). Submittal of unrelated material serves only to slow the review process.

OR

- A statement that: "Before using licensed material, authorized users will receive the training described in Appendix M in NUREG–1556, Volume 17, Revision 1, "Consolidated Guidance About Materials Licenses: Special Nuclear Material of Less Than Critical Mass Licenses."

Note: Alternative responses will be evaluated using the guidance in this section.

8.8 Item 8: Training for Individuals Working in or Frequenting Restricted Areas (Instructions to Occupationally Exposed Workers and Ancillary Personnel)

Regulations: 10 CFR 19.11, 10 CFR 19.12, 10 CFR 19.13, 10 CFR 37.43, 10 CFR 70.9, 10 CFR 70.23(a)(2)

Criteria: Individuals whose assigned duties involve exposure to radiation or radioactive material (from both licensed and unlicensed sources), and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv [100 mrem], must receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12, "Instruction to workers." Also, 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: 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 mSv [100 mrem] per year must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual also should receive periodic (for example annual) refresher training.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals. Particular attention should be given to persons performing work with radioactive materials that may require special procedures, such as hot cell work and waste processing. Also, ancillary personnel (e.g., clerical, housekeeping, security), whose duties may require them to work in the vicinity of radioactive material (whether escorted or not), need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately.

Training may be in the form of lecture, demonstrations, videotape, or self-study and should emphasize practical subjects important to the safe use of licensed material. The program should consider both the topics pertinent for each group of workers and the method and frequency of training.

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for an RSO or AU on the license and is familiar with the licensee's program).

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: Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training and refresher training.

8.9 Item 9: Facilities and Equipment

Regulations: 10 CFR 20.1101, 10 CFR 20.1406, 10 CFR Part 37, 10 CFR 37.5, 10 CFR 37.49, 10 CFR 37.53, 10 CFR 70.22(a)(7), 10 CFR 70.23(a)(3), 10 CFR 70.25(g), 10 CFR 70.41(a)

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. Facilities and equipment must also provide enhanced physical protection of aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5. Applicants must 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.

Discussion: Applicants must demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the uses of the types and quantities of radioactive materials to be used. These requirements are addressed in 10 CFR Part 20, Subpart E. Specifically, 10 CFR 20.1402, "Radiological criteria for unrestricted use," specifies that a site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a total effective dose equivalent (TEDE) to an average member of the critical group that does not exceed 0.25 mSv [25 mrem] per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA. Determination of the levels that are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

Applicants requesting authorization for an unregistered or custom sealed source should provide adequate information on facilities, equipment, operating and emergency procedures associated with a risk-based assessment of the containment structure.

Applicants may delay completing facilities and acquiring equipment until after the application review is completed and the license is issued, in case changes are required as a result of the application review. In all cases, the applicant cannot possess or use radioactive material until after the facilities are completed in accordance with the license, equipment is procured, and a prelicensing assessment has been performed by the NRC.

Applicants are reminded that records important to decommissioning include the following:

- as-built drawings and modifications of structures and equipment in restricted areas
- as-built drawings and modifications of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination
- records of spills and unusual occurrences that may result in contamination of the facility or site

These records are required to be maintained in an identifiable location under 10 CFR 70.25(g). Facilities will be considered acceptable for unrestricted use if the NRC release criteria are met as required by 10 CFR Part 20, Subpart E requirements. Therefore, careful facility design is important to prevent contamination, facilitate decontamination, and reduce the costs needed for decommissioning. For further information, see Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning.”

For additional guidance regarding facilities and equipment, refer to Appendix D of this NUREG.

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 facilities and equipment to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, security, preparation, and measurement of radioactive materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted. Also describe procedures for control, review, and approval of significant facilities or equipment modifications.

Reference: For further information on facility design, see Chapter 4 of National Council on Radiation Protection and Measurements (NCRP) Report No. 127, "Operational Radiation Safety Program."

8.10 Item 10: Radiation Safety Program

Regulations: 10 CFR 20.1101, 10 CFR 20.2102, 10 CFR 70.23

Criteria: A radiation safety program should be established by the applicant. The program should be commensurate with the scope and extent of activities for the use of licensed materials

for special nuclear material of less than critical mass. Each applicant for a SNM of less than critical mass license should develop, document, and implement a radiation protection program containing the following elements:

- steps to keep radiation exposures ALARA
- description of equipment and facilities adequate to protect personnel, the public, and the environment
- conduct of licensed activities by individuals qualified by training and experience
- written operating and emergency procedures to address all likely scenarios
- description of the organizational structure and of the individuals responsible for ensuring implementation of the radiation safety and security program
- records management
- implementation of an audit program to ensure that the radiation safety and security program are reviewed at least annually

Discussion: The specific components of the applicant's radiation safety and security program are detailed as separate topics in the remainder of this section. Some topics do not require a response from an applicant but are intended to provide guidance to the applicant on acceptable methods of compliance with specific NRC requirements.

8.10.1 Audit and Review of Program

Regulations: 10 CFR 20.1101, 10 CFR 20.2102, 10 CFR 21.21(a), 10 CFR 37.33, 10 CFR 37.55

Criteria: Licensees must review the content and implementation of their radiation protection programs at least annually to ensure the following:

- compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license
- occupational doses and doses to members of the public are ALARA (10 CFR 20.1101, "Radiation protection programs")
- access authorization program is effective and complies with 10 CFR Part 37, if required
- security program is effective and complies with 10 CFR Part 37, Subpart C, if required
- records of audits and other reviews of program content are maintained for 3 years after the record is made

Discussion: Appendix E of this NUREG contains a suggested audit program that is applicable to special nuclear material of less than critical mass licensees and is acceptable to the NRC. Because all areas indicated in Appendix E 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.

The NRC encourages licensee management to conduct performance-based reviews by observing work in progress, interviewing staff, and spot-checking required records. As a part of the audit program, licensees should consider including unannounced audits of users of SNM of less than critical mass to determine whether radiation safety procedures are being followed. Licensees should consider providing specialized audit training, if staff other than the RSO are used to conduct audits of the performance of licensed materials users. See Appendix E of this NUREG for applicable audit program areas for potential specialized training.

It is essential that, once identified, problems are corrected comprehensively and in a timely manner. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," 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 https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The Enforcement Manual may be found online at https://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 https://www.nrc.gov/reading-rm/doc-collections/enforcement/.

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record, in accordance with 10 CFR 20.2102. The NRC has found audit records that contain the following information acceptable:

- date of audit
- name of person or persons who conducted the audit
- names of persons contacted by the auditor or auditors
- areas audited
- audit findings and corrective actions
- follow-up

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: The applicant is not required to, and should not, submit its audit program to the NRC for review as part of a license application. However, the audit program may be reviewed during NRC inspections.

References:

- Enforcement guidance and policy, available online at https://www.nrc.gov/reading-rm/doc-collections/enforcement/

- Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996

The information above is available on the NRC Web site at https://www.nrc.gov/.

8.10.2 Radiation Monitoring Instruments

Regulations: 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 70.22(a)(7)

Criteria: Pursuant to 10 CFR 20.1501, "General," licensees must possess, or have access to, radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: Licensees must possess, or have access to, calibrated radiation detection and measurement instruments or licensed services to perform, as necessary, the following:

- package surveys
- contamination surveys
- sealed source leak tests
- air sampling measurements

- bioassay measurements
- effluent release measurements
- unrestricted area dose rate measurements

For the purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the survey instruments that may be used to perform the above functions include:

- portable or stationary count rate meters
- portable or stationary dose rate or exposure rate meters
- single or multichannel analyzers
- liquid scintillation counters (LSCs)
- gamma counters
- proportional counters
- zinc sulfide (ZnS) detectors
- neutron detectors
- solid state detectors

Other equipment and instrumentation associated with the radiation hazard assessment also should be periodically calibrated. This includes equipment used to collect radiological samples to perform assessments of airborne hazards, and other radiological hazards that cannot be directly assessed, such as:

- rotameters
- anemometers
- air pump flow rate or volumes
- liquid volume collection and measurement device

The choice of instrument should be appropriate for the type of radiation to be measured, and for the type of measurement to be taken (e.g., count rate, dose rate). The majority of the radioactive emissions from special nuclear material are alpha emissions; therefore, the applicant's instrumentation should include instrumentation capable of detecting alpha emissions, such as ZnS detectors. Applications should include descriptions of the instrumentation available for use and any instrumentation applicants intend to purchase prior to starting licensed activities. The description should include type of instrument and probe and the instrument's intended purpose.

Instruments used for qualitative surveys are only intended to detect contamination in the laboratory. Such instruments should be checked for operational response with an appropriate check source containing radioactive material, and can be calibrated with an electronic pulser instead of a radioactive source. However, these instruments cannot be used for *measurement* of surface contamination or radiation levels without a calibration with appropriate radioactive sources.

Under 10 CFR 20.1501, 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, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations will need to submit procedures for review. Appendix F of this NUREG provides information about instrument

specifications and model calibration procedures. Regardless of whether an applicant is authorized to calibrate radiation survey meters or contacts 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).

Response from Applicant: Provide one of the following:

- A description of the instrumentation that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F to the current version of NUREG–1556, Volume 17, "Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses." We reserve the right to upgrade our survey instruments as necessary."

OR

- A description of the instrumentation that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F to the current version of NUREG–1556, Volume 17, "Program-Specific Guidance About Special Nuclear Material of Less Than a Critical Mass Licenses." Additionally, we will implement the model survey meter calibration program published in Appendix F to current version of NUREG–1556, Volume 17, "Program-Specific Guidance about Special Nuclear Material of Less Than Critical Mass Licenses." We reserve the right to upgrade our survey instruments as necessary."

OR

- A description of alternative equipment or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. Further, a statement that: "We reserve the right to upgrade our survey instruments as necessary" should be added to the response.

***Note**:* Alternative responses will be evaluated using the guidance in this section.

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 20.2201, 10 CFR 20.2207, 10 CFR 37.49, 10 CFR 37.71, 10 CFR 37.75, 10 CFR 37.77, 10 CFR 70.22(a)(8), 10 CFR 70.23(a)(4), 10 CFR 70.25(g), 10 CFR 70.51, 10 CFR 70.56, 10 CFR 74.15, 10 CFR 75.34

Criteria: Licensees must do the following:

- Develop, implement, and maintain written procedures for safely opening packages.

- Develop, implement, and maintain procedures to ensure control and accountability of licensed material.

- 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, if required.

Discussion: Licensees must (i) track licensed materials from receipt to transfer to ensure accountability at all times; (ii) identify when licensed material may be lost, stolen, or misplaced; and (iii) ensure that the possession limit stated on the license is not exceeded.

Licensees are further 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." Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

SNM licensees should provide their Reporting Identification Symbol (RIS) to their supplier. A RIS allows the applicant to report nuclear material information to the Nuclear Materials Management and Safeguards System (NMMSS) database. The RIS would allow the company to report an export, import, domestic shipment, domestic receipt, and annual physical inventory report of one gram or more of special nuclear materials (plutonium, U-233, or U-235 contained in enriched uranium) required by NRC regulation (10 CFR 150.16 and 17) or one kilogram or more of source material (natural uranium, depleted uranium, or thorium) required by NRC regulations (10 CFR 150.16 and 17) to be reported to NMMSS. An RIS can only be obtained after the NRC license is issued. Once the license is issued, the licensee should e-mail the NRC at NMMSS.Resource@nrc.gov to obtain an RIS. In order to process the request to be assigned an RIS, the following information will be requested: NRC License Number, address where the material will be used and stored, business address of the licensee, and name and telephone number of a contact person. The NMMSS database applies to both NRC and Agreement State licensees.

If applicants have materials that are nationally tracked sources, they should report them to the NSTS. Applicants that have less than critical mass and have plutonium sources (greater than 16 Ci) or Pu/Be sources must report them to the NSTS.

Licensees need to make arrangements to receive radioactive packages when they are delivered or to be notified when radioactive packages arrive at the carrier's terminal so that the licensee can pick up the packages expeditiously.

In limited scope radiation safety programs, the RSO usually receives the incoming package directly from the carrier and performs all verification, surveying, opening, and documentation for inventory. The package is then delivered to the AU, or the AU retrieves the package from the RSO. If the package is transported over public roads by the licensee, it must be repackaged and transported in accordance with DOT regulations.

If the package of licensed material is delivered to the licensed facility's receiving department (Receiving), individuals working in that department should be trained to do the following:

- Identify the package as containing radioactive material by labeling and shipping papers.
- Segregate the package from other incoming items in a secured area until released by the RSO.
- Notify the RSO.

When notified that a package of licensed material has arrived, the RSO or AU should retrieve the package and follow the safe opening procedures.

NRC regulations in 10 CFR 20.1906(b) and (c) state the requirements for monitoring packages containing licensed material. These requirements are described in Table 8-2, below.

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
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†

*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)].

†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. "UN number") on the outside of the box, identifying it as containing radioactive materials. It is a good health physics practice to perform an incoming survey on these packages, even though transportation regulations do not require it.

Regulations in 10 CFR 20.1906(d) require that the licensee immediately 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 external radiation

levels exceed the limits of 10 CFR 71.47, “External radiation standards for all packages.” As illustrated in Figure 8-6, licensed materials must be tracked from “receipt to disposal” in order to ensure accountability at all times; identify when licensed material may be lost, stolen, or misplaced; and to ensure that possession limits listed on the license are not exceeded.

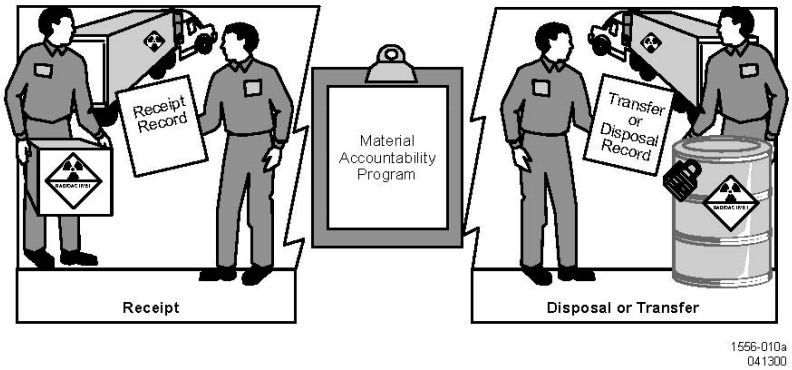


Figure 8-6. Material Receipt and Accountability
Licensees must maintain records of receipt, transfer, and disposal of licensed material

It is recognized that loss, theft, or misplacement of licensed material can occur; however, licensees must have in place an accountability and control system for promptly detecting losses of licensed material.

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. Some sealed sources may not be in use or are rarely used and are placed in storage. In these cases, licensees should confirm that these sealed sources have not been disturbed at least every 6 months. 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.

With regard to unsealed licensed material, licensees use various methods (e.g., computer programs, manual ledgers, log books) to account for receipt, use, transfer, disposal, and radioactive decay. These methods help to ensure that possession limits are not exceeded.

SNM licensees are required to comply with 10 CFR 74.15, “Nuclear material transaction reports,” and 10 CFR 75.34, “Inventory change reports.” These regulations require licensees to submit U.S. Department of Energy (DOE)/NRC Form 741. NUREG/BR–0006 Revision 8, “Instructions for Completing Nuclear Material Transaction Reports (DOE/NRC Forms 741 and 740M),” provides step-by-step instructions for filling out the form.

To ensure that only trained, experienced, and authorized individuals use or supervise the use of licensed material, the RSO should know who has requested an order of licensed material and the types and amounts of licensed materials requested. Control procedures should also be

established for the procurement of licensed materials that may be obtained outside the normal channels (e.g., through the loan or other transfer of materials without purchase or through surplus).

The NRC regulations applicable to transfers are stated in 10 CFR 70.42, “Transfer of special nuclear material.” Transfer of licensed materials within the facility may require special procedures to ensure proper control. In many facilities, pieces of laboratory equipment or components, including refrigerators and freezers, will become contaminated. Removal of these items for maintenance, repair, or disposal should also be carefully controlled.

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.

Licensees must maintain records of receipt, use, transfer, and disposal (as waste) of all licensed material. Table 8-3 below lists each type of record and how long the record must be maintained. Other records such as transfer records could be linked to radioactive material inventory records. Receipt records should also document cases where excessive radiation levels or radioactive contamination were found on packages or containers of material received and describe the action taken.

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
Inventory	For 3 years from the date of the inventory in accordance with license conditions
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 70.25(g). See also Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

Category 1 and Category 2 sources listed in Appendix E to 10 CFR Part 20 (i.e., nationally tracked sources) must be tracked in the 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.

Receipt, inventory, transfer, and disposal records typically contain the following information:

- radionuclide and quantity and date of measurement of SNM
- for each sealed source, manufacturer, model number, location, and, if needed for identification, serial number, and as appropriate, manufacturer and model number of device containing the sealed source
- date of the transfer and name and license number of the recipient, and description of the affected radioactive material (e.g., radionuclide, quantity, manufacturer's name and model number, serial number)
- for licensed materials disposed of as waste, include the radionuclide, quantity, date of disposal, and method of disposal (e.g., decay, sewer)

See the Section 8.11, "Waste Management," for additional information.

Information about locations where licensed material is used or stored are among the records important to decommissioning and required by 10 CFR 70.25(g). Also see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

***Note**:* If applicant has enriched uranium in quantities of low and moderate strategic significance as defined in 10 CFR 70.4, additional material control and accounting requirements apply per 10 CFR 70.22(b) and 10 CFR Part 74, "Material control and accounting of special nuclear material."

Response from Applicant:

- Submit a procedure(s) for ensuring material accountability.

OR

- Provide a statement that "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times."

AND

- If applicable, provide the following statement: "We will comply with the NSTS reporting requirement as described in 10 CFR 20.2207."

AND

- Provide either of the following:

  — A statement that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventories will be maintained for 3 years from the date of each inventory and will include the radionuclides, quantities, manufacturer's name, model numbers, and the date of the inventory."

OR

— A description of procedures for ensuring that no sealed sources have been lost, stolen, or misplaced and how often this will be done.

Notes:

- No response is needed from applicants for package opening procedures. Package opening procedures will be reviewed during NRC inspections.

- Alternative responses will be evaluated using the guidance in this section.

Reference:

- NUREG/BR–0006, Revision 8, "Instructions for Completing Nuclear Material Transaction Reports (DOE/NRC Forms 741 and 740M)

8.10.4 Occupational Dose

Regulations: 10 CFR 19.13, 10 CFR 20.1101, 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 20.2104, 10 CFR 20.1703, 10 CFR 20.2106, 10 CFR 20 Appendix B

Criteria: 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.

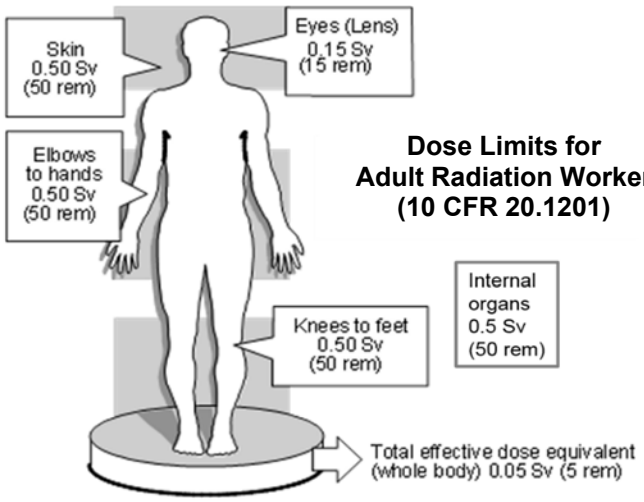
- declared pregnant women who are likely to receive a dose from radiation sources external to the body during the entire pregnancy in excess of 1.0 mSv [0.1 rem] deep-dose equivalent

- 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 a year, an intake in excess of 10 percent of the applicable Annual Limit on Intake (ALI) for ingestion and inhalation

- minors likely to receive, in a 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 1.0 mSv [0.1 rem].



Total effective dose equivalent (TEDE) = the effective dose equivalent (for external exposures) + the committed effective dose equivalent (CEDE) (for internal exposures)

Figure 8-7. Annual Dose Limits for Occupationally Exposed Adults

Discussion: Under 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," if an adult (individual) is likely to receive, in a year, a dose greater than 10 percent of any applicable limit (see Figure 8-7 for annual dose limits), monitoring for occupational exposure is required. Monitoring is required for minors and declared pregnant women as shown in the criteria section. The licensee should perform an evaluation of the dose the individual is likely to receive before 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. Further guidance on evaluating the need to provide monitoring is provided in Appendix G of this NUREG and Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," dated July 1992.

If this prospective evaluation shows that an individual's dose is not likely to exceed 10 percent of any applicable regulatory 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. When determining the need for monitoring and associated recordkeeping and reporting, only dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. If it was determined that monitoring was not required and a subsequent evaluation shows that the 10 percent regulatory threshold has or will be exceeded, the dose received by an individual when monitoring was not provided should be estimated, recorded, and reported (if required). These estimates can be based on any combination of work

location radiation monitoring, 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—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), dosimeters must be processed by a National Voluntary Laboratory Accreditation Program (NVLAP)-accredited processor (10 CFR 20.1501(d)). The exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their NVLAP-accredited 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 Regulatory Guide 8.7, “Instructions for Recording and Reporting Occupational Radiation Exposure Data;” Regulatory Guide 8.34, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses;” and Regulatory Guide 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program.” For copies of these guidance documents, contact the appropriate NRC regional office or access NRC’s Web site at https://www.nrc.gov.

Response from Applicant: Provide either of the following:

- A statement that: “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

- A statement that: “We will monitor individuals in accordance with the guidance in the section entitled, ‘Radiation Safety Program - Occupational Dose’ in NUREG–1556, Volume 17, Rev. 1, “Consolidated Guidance About Materials Licenses:

Program-Specific Guidance About Special Nuclear Material of Less than Critical Mass Licenses."

OR, IN LIEU OF THESE STATEMENTS

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

***Note**:*

- Alternative responses will be evaluated using the guidance in this section.
- Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with NRC requirements (e.g., to respond to worker requests).

8.10.5 Public Dose

Regulations: 10 CFR 20.1003, 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.2107

Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv [100 mrem] in a year, that air emissions of radioactive material to the environment, excluding radon-222 and its daughters, will not result in exposures to individual members of the public in excess of 0.1 mSv [10 mrem] TEDE in a year from those emissions, and the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour, from licensed operations. In addition, licensees must strive to maintain doses to members of the public that are ALARA.

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 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 and medical procedures. 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) the individual is in when the dose is received.

Figure 8-8 shows the steps to calculate the annual dose to an individual member of the public.

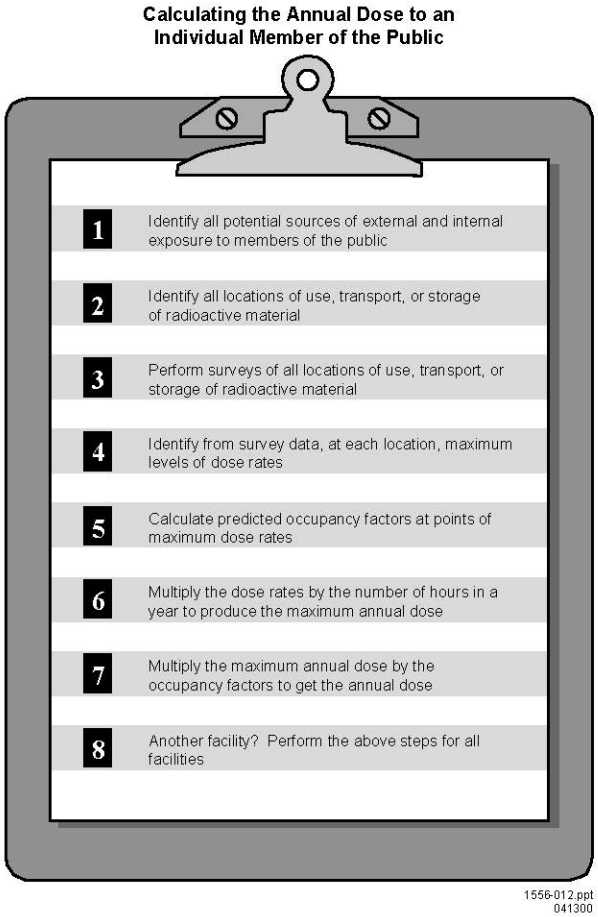


Figure 8-8. Calculating Public Dose
Steps to calculate the annual dose to an individual member of the public (see Appendix H for more information about occupancy factors.)

There are many possible dose pathways that contribute to the TEDE. The TEDE can, however, be broken down into three major dose pathway groups:

- airborne radioactive material (e.g., inhalation)
- waterborne radioactive material (e.g., ingestion)
- external radioactive exposure (e.g., source)

The licensee should review these major pathways and decide which are applicable to its operations.

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1302(b). The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to Section 8.10.8, "Radiation Safety Program—Surveys."

Under 10 CFR 20.2107, "Records of dose to individual members of the public," licensees must maintain records sufficient to demonstrate compliance with the dose limits for members of the public until the Commission terminates the license. Refer to Appendix H of this NUREG for additional guidance regarding compliance with the recordkeeping requirements.

Response from Applicant: No response is required from the applicant in a license application, but compliance will be examined during NRC inspections.

Note: Licensees must be able to demonstrate, by measurement or calculation, that the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public.

8.10.6 Operating 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 Part 37 (Subpart B), 10 CFR 37.21(a), 10 CFR 37.45, 10 CFR 37.49, 10 CFR 70.22(a), 10 CFR 70.23(a)(4), 10 CFR 70.50

Criteria: Each licensee should develop, implement, and maintain operating and emergency procedures that include the following provisions:

- instructions to keep radiation doses to workers and members of the public ALARA
- instructions for conducting operations to minimize the introduction of residual radioactivity into the site
- instructions for maintaining security during storage and transportation
- instructions to maintain accountability during use
- instructions for the proper storage and disposal of radioactive waste
- use of personnel monitoring and radiation survey equipment
- instructions for packaging and transporting licensed material
- instructions on how to respond and whom to contact when an emergency occurs
- instructions for identifying and reporting to the NRC defects and noncompliance, as required by 10 CFR 21.21
- instructions for maintaining records, in accordance with the NRC regulations and any license conditions

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: Operating and emergency procedures should be developed, maintained, and implemented to ensure that all licensed material are used in a secure and safe manner in accordance with licensed activities, control and accountability are maintained, and radiation doses received by occupational workers and members of the public are ALARA. The operating

procedures should include a description of the operations involving the SNM and a general plan for carrying out the activity. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public. Each licensee should develop, implement, and maintain operating and emergency procedures containing the following elements:

- contamination controls
- personnel and area monitoring (including frequency and limits)
- use of protective clothing and equipment
- recording requirements
- reporting requirements
- actions to be taken in case of an emergency (e.g., spill, fire, ventilation system failure)
- waste disposal practices

A copy of the operating and emergency procedures should be posted in all laboratory or work areas where radioactive materials are used. If posting of procedures is not practicable, the licensee may post a notice that describes the documents and states where they may be examined. Also, copies of operating and emergency procedures should be provided to all authorized users. These instructions should describe immediate action to be taken in case of an emergency in order to prevent release of radioactive material or further contamination of work areas and personnel. Examples of emergency procedures are (i) turning off the ventilation systems, (ii) evacuation of the area, (iii) reentry, and (iv) procedures for containment of spills. The instructions should specifically state the names and telephones numbers of responsible persons to be notified.

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 unauthorized 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.

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 and waste processing facilities. Security procedures may be in a separate document or included in the “General Safety Procedures.”

The NRC must be notified when licensed material is lost, stolen, or other related conditions occur. The RSO must be proactive in evaluating if NRC notification is required. Refer to Appendix L and the regulations (10 CFR 20.2201-20.2203, 10 CFR 70.50, and 10 CFR 21.21) for a description of when and where notifications are required.

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.

- 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 to be submitted to the NRC, but may be subject to review and inspection.

Response from Applicant: The applicant must provide a statement that: "Procedures for safe and secure use of materials and emergencies have been developed or will be developed before receipt of licensed material." If the applicant wants the option to make changes in the procedures, include a statement that: "Procedures may be revised only if:

- the changes are reviewed and approved by the licensee management and the RSO in writing;

- the licensee staff is provided training in the revised procedures prior to implementation;

- the changes are in compliance with the NRC regulations and the license; and

- the changes do not degrade the effectiveness of the program."

8.10.7 Leak Tests

Regulations: 10 CFR 20.1501, 10 CFR 20.2103, 10 CFR 70.39, 10 CFR 70.56

Criteria: The NRC requires testing to determine whether there is any radioactive leakage from the sealed sources. Records of test results must be maintained in accordance with license conditions and NRC regulations.

Discussion: When issued, a license will require performance of leak tests at intervals approved by the NRC or an Agreement State and specified in 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 becquerel (Bq) [0.005 microcurie] of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by the NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample using the instructions from the leak test kit supplier. The licensee returns the sample to the leak test service provider for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves.

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

Response from Applicant: Provide one of the following:

- A statement that: "Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the SSD registration certificate. Leak tests will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee using a leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services."

OR

- A statement that: "Leak tests will be performed at intervals approved by NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee using a leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services. As an alternative, we will implement the model leak test program published in Appendix J to the current version of NUREG–1556, Volume 17, "Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses."

OR

- Provide a description of alternative equipment or procedures for determining whether there is radioactive leakage from sealed sources.

***Note**:*

- Alternative responses will be evaluated using the guidance in this section.

- If a sealed source is added to an existing license, that license might already authorize the licensee to perform the entire leak test sequence. In this case, the licensee may perform the leak testing on the sealed source according to the procedures previously approved on its license.

8.10.8 Surveys

Regulations: 10 CFR 20.1501, 10 CFR 20.1906, 10 CFR 20.2103

Criteria: 10 CFR 20.1501 and 10 CFR 20.2103 contain general survey and survey recordkeeping requirements. 10 CFR 20.1906 contains general survey requirements for receiving and opening packages.

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 (See Figure 8-9). These evaluations may be measurements (e.g., radiation levels measured with a survey instrument or results of wipe tests for contamination), calculation, 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. To meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, gamma, and neutrons) and compared to the appropriate limits. 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.

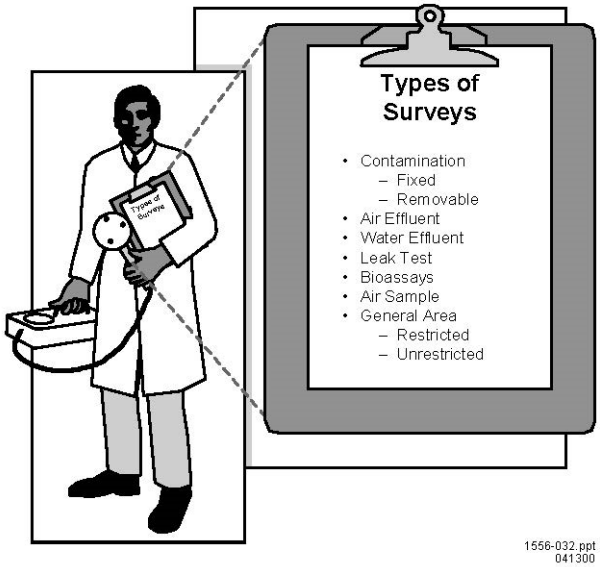


Figure 8-9. Types of Surveys
There are many different types of surveys performed by SNM licensees.

Radiation surveys are used to detect and evaluate contamination of:

- facilities
- equipment
- personnel (during use, transfer, or disposal of licensed material) (See Figure 8-10)
- restricted and unrestricted areas
- packages

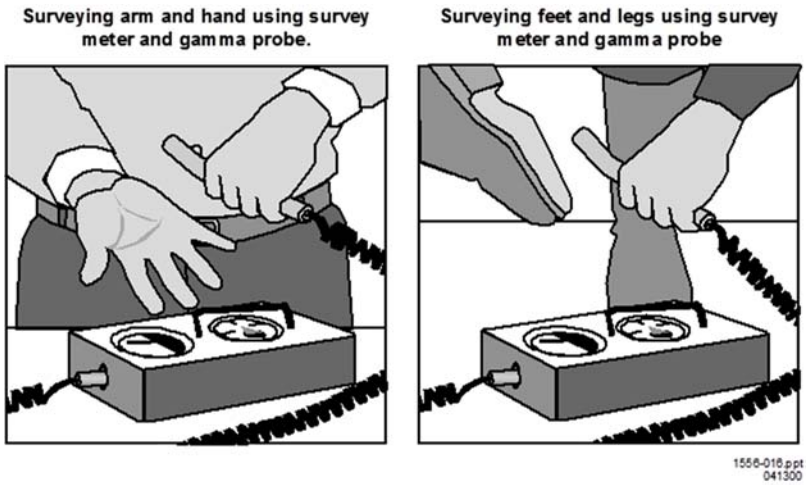


Figure 8-10. Personnel Surveys
Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the laboratory.

Under 10 CFR 20.1501(a), surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard. Many different types of surveys may need to be performed due to the particular use of licensed materials. Typical surveys may include:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, equipment, and packages of radioactive material received or prepared for shipment.

- 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 is 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.)

- Surveys 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 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 (see Appendix I of this NUREG).

Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any radiation safety program.

10 CFR Part 20 does not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area. Table I–2 in Appendix I of this NUREG contains contamination limits that are acceptable to the NRC. Note that Subpart E of 10 CFR Part 20 contains the radiological criteria for license termination and that these criteria are acceptable to the decommissioning of facilities that are to be released for unrestricted use, even if 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.

Response from Applicant: Provide one of the following:

- A statement that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix I to the current version of NUREG–1556, Volume 17, 'Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses.'"

OR

- Submit description of alternative equipment or procedures to evaluate a radiological hazard.

***Note**:* Alternative responses will be evaluated using the guidance in this section.

8.10.9 Transportation

Regulations: 10 CFR 20.1101, 10 CFR Part 37 (Subpart D), 10 CFR 70.42, 10 CFR 70.51, 10 CFR 71.5, 10 CFR 71.14, 10 CFR 71.22, 10 CFR 71.37, 10 CFR 71.38, 10 CFR 71.47, 10 CFR 71.63, 10 CFR 71.64, 10 CFR 71.81, 10 CFR 71.83, 10 CFR 71.85, 10 CFR 71.87, 10 CFR 71.88, 10 CFR 71.89, 10 CFR 71.91, 10 CFR 71.95, 10 CFR 71.97, 10 CFR Part 71 (Subpart H), 49 CFR Parts 171-180, 49 CFR Parts 390-397

Criteria: Licensees and applicants who will transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with NRC and 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: 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. Appendix K of this NUREG contains a list of major DOT regulations applicable to transportation of SNM of less than critical mass. Licensees and applicants also should consider the safety of all individuals who may handle or may come in contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that the package integrity is not compromised during transport and

that the radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of 10 CFR 71.47, “External radiation standards for all packages,” but also are ALARA.

The general licenses in 10 CFR 71.17, “General license: NRC-approved package,” and, 10 CFR 71.22, “General license: Fissile material,” provide the authorization used by most SNM of Less than Critical Mass licensees to transport, or offer for transport, packages of radioactive material and specify certain conditions. Most packages offered by such NRC licensees contain quantities of radioactive material that require using a Type A package. However, before offering any fissile material packages for shipment under the provisions of a general license, the licensee is required to implement an NRC-approved quality assurance (QA) plan. For information about QA plans, see Revision 3 of Regulatory Guide 7.10, “Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material,” dated June 2015.

Each licensee must also assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless the provisions of 10 CFR 71.88, “Air transport of plutonium;” 10 CFR 71.63, “Special requirements for plutonium shipments;” and 10 CFR 71.64, “Special requirements for plutonium air shipments,” are fully satisfied.

For additional guidance regarding the transportation of radioactive material, refer to NUREG–1660, “U.S. Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments.”

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.”

During its inspections, the NRC uses the provisions of 10 CFR 71.5, “Transportation of licensed material,” and a Memorandum of Understanding with DOT on the Transportation of Radioactive Materials (44 Fed. Reg. 38690, July 2 1979) to examine whether licensees are in compliance with the applicable DOT requirements referenced in 10 CFR 71.5.

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 to be 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.

References:

- "Radioactive Material Regulations Review" is available from DOT at www.phmsa.dot.gov.
- 1979 Memorandum of Understanding with DOT on the Transportation of Radioactive Material.
- Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material."
- NUREG–1660, "U.S. Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments."

8.10.10 Minimization of Contamination

Regulation: 10 CFR 20.1406

Criteria: Applicants must 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.

Discussion: When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination during operation, decontamination and decommissioning efforts, and radioactive waste generation. When submitting new applications, applicants should consider the following:

- implementation of and adherence to good health physics practices in operations
- minimization of areas, to the extent practicable, where licensed materials are used and stored
- maximization of the frequency of surveys, within reason, to enhance detection of contamination
- choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition
- appropriate filtration of effluent streams
- use of nonporous materials for laboratory bench tops, flooring, etc.
- ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction
- use of appropriate plumbing materials with minimal pipe lengths and traps
- minimization of the number of disposal sites (sinks) where liquid waste is disposed

SNM sealed sources and devices that are approved by the NRC or an Agreement State and located and used according to their SSD registration certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD registration certificate should identify defective sources. Leaking sources must be withdrawn immediately from use and decontaminated, repaired, or disposed of in accordance with the disposal requirements in Subpart K of 10 CFR Part 20. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Note: An unregistered custom or encapsulated source should be treated as unsealed material, and licensees should maintain appropriate facilities and safety equipment to minimize contamination.

Response from Applicant: The applicant does not need to provide a response to this item if the applicant provides responses to the following sections of this NUREG that meet the "Response from Applicant" criteria from those sections: Section 8.5.1, "Radioactive Material—Sealed Sources and Devices or Unsealed Radioactive Material;" Section 8.9, "Facilities and Equipment;" Section 8.10.6, "Radiation Safety Program—Operating and Emergency Procedures;" Section 8.10.7, "Radiation Safety Program—Leak Tests;" Section 8.10.8, "Radiation Safety Program—Surveys;" and Section 8.11, "Waste Management."

8.10.11 Security Program for Special Nuclear Material of Less Than Critical Mass

The regulations requiring control, security, and physical protection of SNM are graded based on the risk of the SNM to be used for malicious purposes. Basic control of licensed material is covered in 10 CFR Part 20, Subpart I. Subpart I requires licensees to secure licensed materials in storage from unauthorized removal or access, and to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

The existing SNM physical protection regulatory requirements applicable at fixed sites and to material in transit are located in 10 CFR Part 73 as discussed below, and are graded using a material categorization approach. The existing material categorization approach places uranium and plutonium into one of three risk categories ("formula quantity" of strategic SNM, SNM of "moderate strategic significance," and SNM of "low strategic significance," as defined in 10 CFR 73.2), depending on the type, quantity (i.e., mass) and enrichment of the SNM. The 10 CFR Part 37 requirements described in Section 8.10.11.2 are also applicable to licensees possessing plutonium-238 or plutonium 239/Be with an aggregated quantity of total activity greater than or equal to the amounts listed in Appendix A to 10 CFR Part 37.

Applicants and licensees should review its types and forms of SNM to determine which security or physical protection requirements apply.

8.10.11.1 Physical Protection System for Special Nuclear Material of Low Strategic Significance

Regulations: 10 CFR 70.22, 10 CFR 73.67, 10 CFR 150.14

Criteria: Licensees must ensure the security of special nuclear material of low strategic significance. Also, 10 CFR 150.14 requires that Agreement State licensees that

possess, use, or transport special nuclear material of low strategic significance, in quantities specified in 10 CFR 150.14, implement the requirements of 10 CFR 73.67.

Note: The regulations in 10 CFR Part 73 provide SNM physical protection requirements based on its category. The categories are based primarily on the ability of an adversary to create an improvised nuclear device using SNM. However, the regulations contain exemptions and exceptions, where material is not required to be protected within the three-category approach. With respect to 10 CFR Part 73, this guidance only addresses the physical protection requirements for SNM of low strategic significance.

Discussion: A quantity of SNM of low strategic significance relevant to this guidance means more than 15 grams of uranium-235 (U–235) (contained in uranium enriched to 20 percent or more) or 15 grams of uranium–233 (U–233) or 15 grams of plutonium or the combination of 15 grams when computed by the equation, grams = (grams contained U–235) + (grams plutonium) + (grams U–233).

10 CFR 73.67(b)(1) states that a licensee is exempt from the requirements in 10 CFR 73.67 for certain types and forms of SNM.

In accordance with 10 CFR 73.67, licensees authorized to possess SNM of low strategic significance must establish, implement, and maintain a physical protection system that will minimize the possibilities for unauthorized removal of SNM and facilitate the location and recovery of missing SNM. To achieve these objectives, the physical protection system must provide: (i) early detection and assessment of unauthorized access or activities by an external adversary within the controlled access area containing SNM, (ii) early detection of removal of SNM by an external adversary from a controlled access area, (iii) assure proper placement and transfer of custody of SNM, and (iv) respond to indications of an unauthorized removal of SNM and then notify the appropriate response forces of its removal to facilitate its recovery.

NRC Regulatory Guide 5.59, "Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance," contains additional guidance on developing a low strategic significance SNM physical protection system.

Physical Protection Requirements at Fixed Sites

In accordance with 10 CFR 73.67(f), licensees must only possess, store or use low strategic significance SNM at a fixed site or contiguous sites within a controlled access area. A controlled access area is any temporarily or permanently established area that is clearly demarcated, typically with a barrier (e.g., fence or wall), access to which is controlled, and which affords isolation of the material or persons within the controlled access area. The controlled access area shall be monitored with an intrusion alarm or other device or procedures to detect unauthorized penetrations or activities. Licensees shall assure that a watchman or offsite response force will respond to all unauthorized penetrations or activities in the controlled access areas, and shall also establish and maintain written response procedures for dealing with threats of thefts or thefts of SNM of low strategic significance.

Physical Protection Requirements in Transit

In accordance with 10 CFR 73.67(g)(1), licensees that transport or deliver to a carrier for transport SNM of low strategic significance shall provide advance notification to the receiver of

any planned shipments specifying the mode of transport, estimated time of arrival, location of the nuclear material transfer point, name of carrier, and transport identification. Prior to commencing the shipment, licensees shall receive from the receiver (i) confirmation that the receiver will be ready to accept the shipment at the planned time and location and (ii) an acknowledgment of the specified mode of transport. Transport of SNM of low strategic significance shall be in a tamper indicated sealed container. Prior to shipment, licensees shall check the integrity of the container and locks or seals. Licensees that transport or deliver to a carrier for transport SNM of low strategic significance shall arrange for the in-transit physical protection of the material unless the receiver is a licensee and has agreed in writing to make such arrangements.

Per 10 CFR 73.67(g)(2), licensees receiving quantities and types of SNM of low strategic significance shall (i) check the integrity of the containers and seals upon receipt of the shipment, (ii) notify the shipper of receipt of the material, and (iii) arrange for the in-transit physical protection of the material unless the shipper is a licensee and has agreed in writing to arrange for the in-transit physical protection.

In accordance with 10 CFR 73.67(g)(3), each licensee, either shipper or receiver, who arranges for the physical protection of SNM of low strategic significance shall establish and maintain response procedures for dealing with threats of thefts or thefts of this SNM. Licensees shall also make arrangements to be notified immediately of the arrival of the shipment at its destination, or of any such shipment that is lost or unaccounted for after the estimated time of arrival at its destination. Additionally, licensees shall conduct immediately a trace investigation of any shipment that is lost or unaccounted for after the estimated arrival time and notify the NRC Operations Center within one hour after the discovery of the loss of the shipment and within 1 hour after recovery of or accounting for such lost shipment.

The licensee must retain procedures and records as required by 10 CFR 73.67.

Response from Applicant: No response is required from an applicant or licensee.

8.10.11.2 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: The NRC issued 10 CFR Part 37 to establish security requirements for the use and transport of Category 1 and Category 2 quantities of radioactive material that are widely used in the U.S. by industrial, medical, and academic institutions. The theft or diversion of risk-significant quantities of radioactive materials could lead to their use in a radiological dispersal device or a radiological exposure device. The security of plutonium-238 material and

plutonium/beryllium encapsulated or sealed sources is addressed by Part 37. However, other plutonium isotopes or unsealed material are not addressed by Part 37.

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 70.5 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 20.1904, 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 37.11(c), 10 CFR 70.51, 10 CR 71.43

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

Discussion: Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material or unusable items contaminated with radioactive material (e.g., absorbent paper, gloves). Licensees may not receive radioactive waste from other licensees for processing, storage, or disposal, unless specifically authorized to do so by the NRC.

All radioactive waste should be stored in appropriately labeled containers until it is disposed. During the period between storage and disposal, waste container integrity must be assured. All radioactive waste must be secured against unauthorized access or removal by unauthorized personnel. In accordance with regulations in 10 CFR 20.2001-20.2007, the NRC requires licensees to dispose of radioactive waste generated at their facilities by one or more of the following methods:

- transfer to an authorized recipient
- release into sanitary sewerage
- extended interim storage
- obtaining prior approval of the NRC of any alternate method
- release in effluents to unrestricted areas, other than into sanitary sewerage
- incineration

Licensees may choose any one or more of these methods to dispose of their radioactive waste. It has been the NRC's experience that many of the facilities dispose of SNM by the first method. Applicants wanting to dispose of radioactive waste by incineration should contact the appropriate regional office of the NRC for guidance.

> ***Note***: Compliance with NRC regulations does not relieve a licensee of the responsibility of complying with any other applicable Federal, State, or local regulations. Furthermore, some radioactive waste called "mixed waste" may include additional hazards (e.g., biohazard or chemical hazard). The storage and disposal of "mixed waste" must also comply with all other applicable Federal, State, and local regulatory requirements.

Applicants should describe their program for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, waste characterization, waste minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. In accordance with 10 CFR 20.2108, licensees must maintain all appropriate records of radioactive waste disposal. The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce

hazardous waste that, in many instances, may also include radioactive waste. The NRC transmitted these guidelines 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.

Release Into Sanitary Sewerage

Regulations in 10 CFR 20.2003, "Disposal by release into sanitary sewerage," authorize disposal of radioactive waste by release into a public sanitary sewerage system if each of the following conditions is met:

- Material is readily soluble (or is readily dispersible biological material) in water.
- Quantity of licensed material or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer does not exceed the concentration specified in 10 CFR Part 20, Appendix B, Table 3.
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3, cannot exceed unity.
- Total quantity of licensed material and other radioactive material released into the sanitary sewerage system in a year does not exceed 185 gigabecqueral (GBq) [5 curie (Ci)] of H-3, 37 GBq [1 Ci] of C-14, and 37 GBq [1 Ci] of all other radioisotopes (including SNM) combined.

Licensees are responsible for demonstrating that licensed materials discharged into the public sewerage system are indeed readily soluble in water. The NRC's IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994, provides acceptable criteria for evaluating solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be "readily dispersible." Many chemical forms of special nuclear material are not soluble [e.g., uranium dioxide (UO_2), plutonium trifluoride (PuF_3), and uranium oxide (U_3O_8)][1] or are very slightly soluble [e.g., uranium tetrafluoride (UF_4)][1] in water. Careful consideration should be given to the possibility of reconcentration of radioisotopes 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, "Disposal by release into sanitary sewerage"), dated December 1984.

The regulations in 10 CFR 20.2003 are not applicable to releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas under 10 CFR 20.1301, "Dose limits for individual members of the public." However, if licensed material is released to a private sewerage treatment system, septic system, or leach field, the sludge or other solids from these

[1]From CRC Handbook of Chemistry and Physics, Table of Physical Constants of Inorganic Compounds.

systems may become contaminated with radioactive material. Such sludge may be required to be disposed of as radioactive waste, using one of the methods described in this section.

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. A model program for disposal of radioactive waste via sanitary sewer is described in Appendix N of this NUREG.

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. It is the licensee's responsibility to verify that the intended recipient is authorized to receive the radioactive waste prior to making any shipment. The radioactive waste must be packaged in approved containers for shipment, and each container must identify the radioisotopes and the amounts contained in the waste. Additionally, packages must comply with the requirements of the license for a particular burial site and State requirements. Each shipment must comply with all applicable NRC and DOT requirements. In some cases, the waste handling contractor may provide guidance to the licensee for packaging and transportation requirements; however, the licensee is ultimately responsible for ensuring compliance with all applicable regulatory requirements.

The shipper must provide all information required by the NRC's "Uniform Low-Level Radioactive Waste Manifest," and transfer this recorded manifest information to the intended recipient in accordance with 10 CFR Part 20, Appendix G, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests." Each shipment manifest must include a certification by the waste generator, as specified in Section II of the appendix. Each person involved in the transfer for disposal and disposal of waste, including waste generator, waste collector, waste processor, and disposal facility operator, must comply with requirements specified in Section III, "Control and Tracking," of Appendix G.

Licensees should 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) to workers and members of the public. The program should include adequate safety procedures to protect workers, members of the public, and the environment.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal.

Alternate Methods

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, in accordance with 10 CFR 20.2002. 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

operating and emergency procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

Extended Interim Storage

Licensees should exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site extended interim storage of radioactive waste only as a last resort. The protection of workers and the public is enhanced by disposal rather than storage of waste. Licensees may also find it more economical to dispose of radioactive waste than to store it on-site because as the available capacity decreases, the cost of disposal of radioactive waste may continue to increase. 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 by Fuel Cycle and Materials Licensees," dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

***Note**:* Before licensed activities are transferred or assigned in accordance with 10 CFR 70.36, if licensees are authorized to possess special nuclear material, the licensees must, in accordance with 10 CFR 70.51(b)(1) and (2), transfer the following records to the new licensee, as follows:

- 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 10 CFR 20.2103(b)(4) of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment

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 a statement that: "We will ensure that all licensed Special Nuclear Material will be disposed of in accordance with the requirements of 10 CFR Part 20 Subpart K."

OR

- If needed, the applicant should request authorization for extended interim storage of waste. Applicants should use the references at the end of Section 8.11, "Waste Management," of this NUREG, for guidance and submit the required information with the application.

OR

- State that: "We will use the model waste procedures published in Appendix N in NUREG–1556, Volume 17, Revision 1, "Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses.""

OR

- If the applicant wishes to use only selected model procedures, state that: "We will use the [specify either (i) disposal of liquids into sanitary sewerage or (ii) compaction] model waste procedures that are published in Appendix N in NUREG–1556, Volume 17, Revision 1, "Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses.""

***Note**:* Applicants do not need to provide information to the NRC if they plan to dispose of LLW via transfer to an authorized recipient.

Alternative responses will be evaluated using the guidance in this section.

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 20.303 (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," dated May 2008.
- Regulatory Issue Summary 2011-09, "Available Resources Associated With Extended Storage Of Low-Level Radioactive Waste," dated August 2011.
- Regulatory Issue Summary 2016-11, "Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002," November 13, 2016

Information Notices and Regulatory Issue Summaries are available at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

Additional Reference:

- Policy and Guidance Directive PG 8-10, "Disposal of Incineration Ash as Ordinary Waste," dated January 1997, ADAMS Accession Nos. ML003744979 and ML003752866 and Addendum, ADAMS Accession Nos. ML003744984 and ML003744988.

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 the application references commitments, those items will be incorporated into the license and therefore, will become binding and conditions to the license.

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 under Title 10 of the *Code of Federal Regulations* (10 CFR) 2.109(a), 10 CFR 70.33, 10 CFR 70.38(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 a 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

Regulation: 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" 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, under 10 CFR 70.36 and the Atomic Energy Act, licensees must obtain prior NRC written consent before transferring control of the license 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.

- Adequate financial assurance is provided for compliance with applicable NRC requirements, if required.

- Public health and safety are not compromised by the use of such materials.

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 (e.g., ownership).

Reference: For further information, see Regulatory Issue Summary 2014-08, Revision 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licenses," dated May 5, 2016. This Regulatory Issue Summary can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": https://www.nrc.gov/reading-rm/doc-collections/gen-comm/

10 APPLICATIONS FOR EXEMPTIONS

Regulations: Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 70.11, 10 CFR 71.12, 10 CFR 71.14

Criteria: Licensees may request exemptions from the 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 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 70.11, "Persons using special nuclear material under certain Department of Energy and Nuclear Regulatory Commission contracts;" 10 CFR 71.12, "Specific exemptions;" and 10 CFR 71.14, "Exemption for low-level material"). 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 to 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: Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 70.25(g), 10 CFR 70.38, 10 CFR 70.51(b)

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
  - — decision to permanently cease principal activities[1] at the entire site
  - — for licensees subject to 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 70.38(g).
- Conduct decommissioning, as required by 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 a demonstration 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 the records important to decommissioning that are required by 10 CFR 70.25(g) to the appropriate NRC regional office in accordance with 10 CFR 70.51(a)(3).
- Before a license is terminated, send records of disposal of licensed material made under 10 CFR 20.2002, 20.2003, 20.2004, and 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 70.51(a)(1) and (2), if authorized to possess special nuclear material.

Discussion: To comply with the above criteria, before a licensee can decide whether it must notify the NRC under 10 CFR 70.38(d), the licensee must determine whether residual

[1]Principal activities' are activities that 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.

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[1] 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 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": https://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" of this NUREG. For guidance on decommissioning records, see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning" of this NUREG.

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 FR 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 https://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:
https://www.nrc.gov/reading-rm/doc-collections/forms/

NRC FORM 313 (10-2017) 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 **EXPIRES: 06/30/2019**

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 Information Services Branch (T-2 F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.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.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

IF YOU ARE LOCATED IN:

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - ☐ A. NEW LICENSE
   - ☐ B. AMENDMENT TO LICENSE NUMBER _____
   - ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include zip code)*

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

BUSINESS TELEPHONE NUMBER | BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS E-MAIL ADDRESS

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)*
***Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.**
FEE CATEGORY _____ AMOUNT ENCLOSED $ _____

PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE | SIGNATURE | DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

NRC FORM 313 (10-2017)

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

The table below is designed to help applicants develop their applications. In some instances it is acceptable to simply indicate, by checking the box in the third column (Yes), that applicant commits to adopting the model procedures that are referenced. If the third column contains a asterisk (*), the licensee is expected to describe its program or submit its procedures for the particular item. In this instance, the applicant is requested to check the box in the fourth column indicating that the described program and/or procedures are attached to the application [U.S. Nuclear Regulatory Commission (NRC) Form 313]. If the third column contains a "Need Not be Submitted with Application" the licensee is not required to describe or submit its programs and/or procedures during the licensing phase. However, these program areas may be reviewed during an inspection.

The table below may also be used as a License Reviewer checklist for applications for special nuclear material licenses.

Table B–1. Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313.

Item No.	Suggested Response	Yes	Description Attached
5.	**RADIOACTIVE MATERIAL**		
	Unsealed and Sealed Sources		
	• For unsealed materials:		
	— Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit in milligrams (or grams), percent enrichment, and microcuries for each radioisotope	*	❒
	• For sealed materials:		
	— Identify each radionuclide (element name and mass number) that will be used in each sealed source and specify the maximum quantity [mass in milligrams (or grams)], percent enrichment, and microcuries per source. Also, specify the maximum number of sources or total quantity for each radionuclide.	*	❒
	— Provide the manufacturer's or distributor's name and model number for each sealed source and device requested.	*	❒
	— Confirm that each sealed source, device, and source and device combination is registered as an approved sealed source or device by the NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available.	❒	

Table B–1. Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313. (Continued)			
Item No.	**Suggested Response**	**Yes**	**Description Attached**
5.	**RADIOACTIVE MATERIAL (Continued)** **Unsealed and Sealed Sources (Continued)** — Confirm that the activity per source and maximum quantity in each device will not exceed the maximum quantity listed on the approved certificate of registration issued by the NRC or by an Agreement State.	❒	
	• For unregistered sealed materials: — Identify each radionuclide (element name and mass number) that will be used and specify the maximum quantity [mass in milligrams (or grams)], percent enrichment, and microcuries per source. Also, specify the maximum number of sources or total quantity for each radionuclide.	*	❒
	— Provide source drawings, the form of the source itself, its containment structure, and a hazards analysis (e.g., what is the annual limit of intake for the source) for any sources not registered in the SSD registration.	*	❒
	— Provide clear limitations on the use of the source.	*	❒
	— Confirm that the activity per source and maximum quantity will not exceed the maximum quantity requested.	❒	
	• Provide an Emergency Plan (if required).	*	❒
	Financial Assurance and Recordkeeping for Decommissioning No response is needed from most applicants requesting only sealed sources. However, if a certification of financial assurance or a decommissioning funding plan (DFP) is required, submit the following:		
	• A statement that: "Pursuant to 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 70.36. Furthermore, pursuant to 10 CFR 70.51(a)(3), we will forward the records required by 10 CFR 70.25(g) to the appropriate NRC regional office before the license is terminated."	❒	

Table B–1. Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313. (Continued)			
Item No.	**Suggested Response**	**Yes**	**Description Attached**
5.	**RADIOACTIVE MATERIAL (Continued)** **Financial Assurance and Recordkeeping for Decommissioning (Continued)** **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."	*	❒
6.	**PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED** List the specific use or purpose of each radioisotope.	*	❒
7.	**INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE** **Radiation Safety Officer (RSO)** • Provide the name of the proposed RSO. • Provide information demonstrating that the proposed RSO is qualified by training and experience. **Authorized Users (AUs) and Radiation Workers** • Provide the name of each proposed AU with the types and quantities of licensed material to be used. **AND** • Provide information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials. **OR** • Provide a statement that: "Before using licensed material, authorized users will receive the training described in Appendix M in NUREG–1556, Volume 17, Revision 1, "Consolidated Guidance About Materials Licenses: Special Nuclear Material of Less Than Critical Mass Licenses."	* * * * ❒	❒ ❒ ❒

Table B–1. Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313. (Continued)			
Item No.	**Suggested Response**	**Yes**	**Description Attached**
8.	**TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Instructions to Occupationally Exposed Workers and Ancillary Personnel)** Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training and refresher training.	*	❒
9.	**FACILITIES AND EQUIPMENT** Describe the facilities and equipment to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, security, preparation, and measurement of radioactive materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted. Also describe procedures for control, review, and approval of significant facilities or equipment modifications.	*	❒
10.	**RADIATION SAFETY PROGRAM** **Audit Program** The applicant is not required to, and should not, submit its audit program to NRC for review during the licensing phase. The audit program may be reviewed during NRC inspections.	Need Not be Submitted with Application	

Table B–1. Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313. (Continued)			
Item No.	**Suggested Response**	**Yes**	**Description Attached**
10.	**RADIATION SAFETY PROGRAM (Continued)** **Radiation Monitoring Instruments**		
	Provide a description of the instrumentation that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F to the current version of NUREG–1556, Volume 17, "Program Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses." We reserve the right to upgrade our survey instruments as necessary."	❒	❒
	OR		
	Provide a description of the instrumentation that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F to the current version of NUREG–1556, Volume 17, "Program Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses." Additionally, we will implement the model survey meter calibration program published in Appendix F to current version of NUREG–1556, Volume 17, "Program Specific Guidance about Special Nuclear Material of Less Than a Critical Mass Licenses." We reserve the right to upgrade our survey instruments as necessary."	❒	❒
	OR		
	Provide a description of alternative equipment or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. Further, a statement that: "We reserve the right to upgrade our survey instruments as necessary" should be added to the response.	❒	❒
	Material Receipt and Accountability		
	Submit a procedure(s) for ensuring material accountability.	*	❒
	OR		
	Provide a statement that "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times."	❒	

Table B–1. Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313. (Continued)			
Item No.	**Suggested Response**	**Yes**	**Description Attached**
10.	**RADIATION SAFETY PROGRAM (Continued)** **Material Receipt and Accountability (Continued)** **AND** 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." **AND** Provide either of the following: A statement that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventories will be maintained for 3 years from the date of each inventory and will include the radionuclides, quantities, manufacturer's name, model numbers, and the date of the inventory." **OR** A description of procedures for ensuring that no sealed sources have been lost, stolen, or misplaced and how often this will be done.	❒ ❒ *	 ❒
	Occupational Dose Provide a statement that: "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** Provide a statement that: "We will monitor individuals in accordance with the guidance in the section entitled, 'Radiation Safety Program Occupational Dose' in NUREG–1556, Volume 17, Rev. 1, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Special Nuclear Material of Less than Critical Mass Licenses." **OR, IN LIEU OF THESE STATEMENTS** Provide a description of an alternate method for demonstrating compliance with the referenced regulations.	❒ ❒ *	 ❒

Table B–1. Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313. (Continued)			
Item No.	**Suggested Response**	**Yes**	**Description Attached**
10.	**RADIATION SAFETY PROGRAM (Continued)** **Public Dose** No response is required from the applicant in a license application, but compliance will be examined during NRC inspections.	Need Not be Submitted with Application	
	Operating and Emergency Procedures Provide a statement that: "Procedures for safe and secure use of materials and emergencies have been developed or will be developed before receipt of licensed material." In addition, if the applicant wants the option to make changes to the operating and emergency procedures, provide a statement that: "Procedures may be revised if: • the changes are reviewed and approved by the licensee management and the RSO in writing; • the licensee staff is provided training in the revised procedures prior to implementation; • the changes are in compliance with the NRC regulations and the license; and • the changes do not degrade the effectiveness of the program."	❒ ❒	
	Leak Tests Provide a statement that: "Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee using a leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services." **OR** Provide a statement that: "Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee using a leak test kit supplier's	❒	

Table B–1. Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313. (Continued)			
Item No.	**Suggested Response**	**Yes**	**Description Attached**
10.	**RADIATION SAFETY PROGRAM (Continued)** **Leak Tests (Continued)** instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services. As an alternative, we will implement the model leak test program published in Appendix J to the current NUREG–1556, Vol. 17, "Program Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses."" **OR** Provide a description of alternative equipment or procedures for determining whether there is radioactive leakage from sealed sources.	 *	 ❒
	Surveys Provide a statement that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix I to the current NUREG–1556, Vol. 17, "Program Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses."" **OR** Submit a description of alternative equipment or procedures to evaluate a radiological hazard.	❒ *	 ❒
	Transportation No response is needed from applicants during the licensing phase. Compliance with transportation requirements will be reviewed during NRC inspections.	Need Not Be Submitted with Application	
	Minimization of Contamination The applicant does not need to provide a response to this item if the applicant provides responses to the following sections of this NUREG that meet the "Response from Applicant" criteria from those sections: (i) Section 8.5.1, "Radioactive Material—Sealed Sources and Devices or Unsealed Radioactive Material;" (ii) Section 8.9, "Facilities and Equipment;" (iii) Section 8.10.6, "Radiation Safety Program—Operating and Emergency Procedures;" (iv) Section 8.10.7, "Radiation Safety Program—Leak Tests;" (v) Section 8.10.8, "Radiation Safety Program—Surveys;"	Need Not Be Submitted with Application	

Table B–1. Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313. (Continued)			
Item No.	**Suggested Response**	**Yes**	**Description Attached**
10.	**RADIATION SAFETY PROGRAM (Continued)** **Minimization of Contamination (Continued)** and (vi) Section 8.11, "Radiation Safety Program—Waste Management."	Need not be submitted with application.	
	Security Program No response is required from an applicant or licensee. Compliance with access authorization and security program requirements may be reviewed during NRC inspections.	Need not be submitted with application.	
11.	**WASTE MANAGEMENT** Provide a statement that: "We will ensure that all licensed Special Nuclear Material will be disposed of in accordance with the requirements of 10 CFR Part 20, Subpart K."	❒	
	OR		
	If needed, the applicant should request authorization for extended interim storage of waste. Applicants should use the references at the end of Section 8.11, "Waste Management," of this NUREG, for guidance and submit the required information with the application.	❒	❒
	OR		
	State that: "We will use the model waste procedures published in Appendix N in NUREG–1556, Volume 17, Revision 1, "Program Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses.""	❒	
	OR		
	If the applicant wishes to use only selected model procedures, state that: "We will use the [specify either (i) disposal of liquids into sanitary sewerage or (ii) compaction] model waste procedures that are published in Appendix N in NUREG–1556, Volume 17, Revision 1, "Program Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses.""	❒	

APPENDIX C

TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

Typical Duties and Responsibilities of the Radiation Safety Officer

The radiation safety officer's (RSO's) duties and responsibilities include ensuring radiological safety, security, and compliance with the U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Transportation (DOT) regulations and the conditions of the license. See Figure 8-4. Typically, these duties and responsibilities include the following:

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of special nuclear material listed on the license.

- Ensure documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20.1301, "Dose limits for individual members of the public."

- Properly secure radioactive material.

- Ensure documents are posted as required by 10 CFR 19.11, "Posting of notices to workers" (10 CFR Part 19, license documents, operating procedures; NRC Form 3, "Notice to Employees"); and 10 CFR 21.6, "Posting Requirements" (10 CFR Part 21 Section 206 of the Energy Reorganization Act of 1974, procedures adopted under Part 21), or a note is posted indicating where these documents can be examined.

- Ensure that licensed material is transported in accordance with all applicable NRC and DOT requirements.

- Ensure that radiation exposures are kept as low as is reasonably achievable (ALARA).

- Oversee all activities involving radioactive material, including monitoring and surveying all areas in which radioactive material is used.

- Ensure that up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed, as appropriate.

- Safety consequences of nonroutine operations are analyzed before conducting any such activities that have not been previously analyzed.

- Nonroutine operations are performed by the manufacturer, distributor, or person specifically authorized by the NRC or an Agreement State.

- Serve as a point of contact for the NRC's, Agreement State's, and licensee's management during routine operations, emergencies, or incidents.

- Notify proper authorities of incidents, such as damage to sources/devices, loss of licensed material, fire, theft, etc.

- Investigate unusual occurrences, identify cause(s) and appropriate corrective action(s), and take timely corrective action(s) to prevent recurrence.

- Ensure that possession; installation; relocation; use; storage; repair; and maintenance of sealed sources, devices, and radioactive wastes are consistent with the limitations in the license, individual sealed source and device registration certificate(s), and the manufacturer's specific recommendations and instructions.

- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Part 19 and 20 and any other applicable regulations.

- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the facility, as well as packaging and labeling all radioactive material leaving the facility.

- Prospective evaluations are performed to demonstrate that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a) or that personnel monitoring devices are provided.

- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action. Record and maintain the results of such monitoring.

- Ensure that individuals involved with using radioactive materials are properly trained and evaluated.

- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records.

- Ensure licensed material is disposed of properly.

- Oversee the storage of radioactive material not in current use, including waste.

- Perform/oversee the inventory and leak testing on all sealed sources.

- Perform/oversee the inventory and calibration of radiation survey instruments.

- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license.

- Stop activities involving licensed material that the RSO considers unsafe.

- Supervise decontamination and recovery operations.

- For licensees possessing an aggregated Category 1 or Category 2 quantity of radioactive material, participate 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.

- Maintain required records that are necessary to support the license and satisfy NRC or Agreement States regulations.

- Perform periodic audits, at least annually, of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license.

- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for 3 years after the record is made) and provided to management for review; ensure that prompt action is taken to correct deficiencies.

- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.

- When the licensee identifies violation(s) of regulations or license conditions or program weaknesses, corrective action(s) are developed, implemented, and documented.

- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or 10 CFR Part 20 limits are investigated and reported to NRC and other appropriate authorities, if required, within the required time limits.

- Maintain understanding of and up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to the NRC during the licensing process.

- Submit amendment and renewal requests in a timely manner.

- Develop, implement, maintain, and distribute, as appropriate, up-to-date operating, emergency (if required), and security procedures.

Model Delegation of Authority to RSO

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 D

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 licensee will use, or otherwise have available. Not every applicant will need to address each topic in their application.

- Restricted areas are defined as areas to which access is limited by the licensee 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 Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37, Appendix A. 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, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays or 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, for unsealed volatile licensed materials, and for 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 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.

- 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.

- 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 frequently occupied by personnel. 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.

- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). 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 only appropriate devices. Pipetting by mouth should be strictly forbidden.

- 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 is to prevent laboratory and work areas from becoming positively pressurized with respect to the surrounding parts of the facility.

- Designated areas should be provided for coats and personal belongings, to avoid contamination.

- Areas with 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 build-up.

- 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.”

- 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 E

SUGGESTED AUDIT CHECKLIST

Suggested Audit Checklist

An audit is conducted, in part, to fulfill the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1101 for an annual review of the content and implementation of the licensee's radiation protection program. Audits should also identify program weaknesses and allow licensees to take early corrective actions (before a U.S. Nuclear Regulatory Commission (NRC) inspection). During an audit, the auditor needs to keep in mind not only the requirements of NRC's regulations, but also the licensee's commitments in its applications and other correspondence with NRC. 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.

The form in this appendix can be used to document the annual audit of the radiation protection program. Guidance follows on completing each section of the form. In the "remarks" portions of the form, note any deficiencies that were identified and the corrective actions taken or to be taken.

Section 1, Audit History. Enter the date of the last audit, whether any deficiencies were identified, and whether actions were taken to correct the deficiencies.

Section 2, Organization and Scope of Program. Give a brief description of the organizational structure, noting any changes in personnel. Describe the scope of licensed activities at the audited location. Check whether the Radiation Safety Officer (RSO) is the person identified in the license and fulfills the duties specified in the license. Ensure use by authorized individuals.

Section 3, Training, Retraining, and Instructions to Workers. Ensure that workers have received the training required by 10 CFR 19.12. Be sure that, before being permitted to use licensed material, the user has received training and has a copy of the licensee's safe use and emergency procedures. Note whether refresher training is conducted in accordance with licensee commitments. By interview or observation of selected workers, ensure that each has a copy of the licensee's procedures and can implement them properly.

Section 4, Operating and Emergency Procedures. Verify that operating and emergency procedures are current, contain specified information, and were submitted to the NRC. Determine if any accidents occurred. If accidents occurred, determine if they were handled properly, and if corrective actions and notifications or reports were required and made.

Section 5, Audits. Verify that audits fulfill the requirements of 10 CFR 20.1101, are conducted in accordance with licensee commitments, and are properly documented.

Section 6, Facilities. Verify that the licensee's facilities are as described in its license documents.

Section 7, Materials. Verify that the license authorizes the quantities and types of material that the licensee possesses.

Section 8, Leak Tests. Verify that all sealed/plated foil sources are tested for leakage at the prescribed frequency and in accordance with licensee commitments. Records of results should be maintained.

Section 9, Inventories. Verify that inventories are conducted at least once every 6 months to account for all sources; inventory records should be maintained and include the radionuclides, nominal activity (or quantity), manufacturer's name and model number, serial number, location of each source, name of individual who performed inventory and the date of the inventory.

Section 10, Radiation Surveys. Verify that the licensee has appropriate, operable and calibrated survey instruments available, that the instruments are calibrated (at the required frequency) in accordance with license conditions and in accordance with 10 CFR 20.2103. Calibration records must be retained for 3 years after the record is made. Verify compliance with 10 CFR 20.1301. Check that radiation levels in areas adjacent to use are within regulatory limits and records are in accordance with 10 CFR 20.2103. Records of surveys must be retained for 3 years after the record is made.

Section 11, Receipt and Transfer of Radioactive Material (Includes Waste Disposal). Verify that packages containing licensed material received from others are received, opened, and surveyed in accordance with 10 CFR 20.1906. Ensure that transfers of material are performed in accordance with 10 CFR 70.42. Records of surveys, receipt, and transfer must be maintained in accordance with 10 CFR 20.2103 and 10 CFR 70.51.

Section 12, Transportation (10 CFR 71.5(a) and 49 CFR 170-189). Determine compliance with U.S. Department of Transportation (DOT) requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with 49 CFR Parts 172 and 173 requirements. Verify that shipping papers are prepared, that they contain all needed information, and that they are readily accessible during transport (49 CFR 172.200, 201, 202, 203, 204, and 177.718).

Section 13, Personnel Radiation Protection. ALARA considerations are incorporated into the Radiation Protection Program as required in 10 CFR 20.1101(b). Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits in 10 CFR 20.1501(c). Alternately, if personnel dosimetry is provided and required, verify that it complies with 10 CFR 20.1501(c) and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with 10 CFR 20.1208. Check whether records are maintained as required by 10 CFR 20.2101, 10 CFR 20.2102, 10 CFR 20.2103, 10 CFR 20.2104, 10 CFR 20.2106, and 10 CFR 20.2201.

Section 14, Auditor's Independent Measurements (If Applicable). Make independent survey measurements and compare the results with those made or used by the licensee.

Section 15, Radioactive Effluents, Waste Management, and Disposal. Determine if radioactive effluents and radioactive waste are properly disposed and records maintained.

Section 16, Notification and Reports. Check on the licensee's compliance with the notification and reporting requirements in 10 CFR Parts 19, 20, and 70. Ensure that the licensee is aware of the telephone number for NRC's Emergency Operations Center, which is 301-816-5100.

Section 17, Posting and Labeling. Check for compliance with the posting and labeling requirements of 10 CFR 19.11, 10 CFR 20.1902, 10 CFR 20.1904, and 10 CFR 21.6.

Section 18, Recordkeeping for Decommissioning. Check to determine compliance with 10 CFR 70.25(g).

Section 19, NRC Correspondence. Check to determine if all NRC correspondence (e.g., regulatory issue summaries, bulletins, information notices, Office of Nuclear Material Safety and Safeguards newsletters) issued since the previous audit and applicable to special nuclear material of less than critical mass licenses have been reviewed. Check whether the licensee took appropriate action (e.g., training, updating procedures) in response to this NRC correspondence.

Section 20, Special License Conditions or Issues. Verify compliance with any special conditions on the licensee's license. If the licensee has any unusual aspect of its work, review and evaluate compliance with regulatory requirements.

Section 21, Continuation of Report Items. This section is self-explanatory.

Section 22, Problems or Deficiencies Noted; Recommendations. This section is self-explanatory.

Section 23, Evaluation of Other Factors. Evaluate licensee management's involvement with the radiation safety program, whether the RSO has sufficient time to perform his or her duties, and whether the licensee has sufficient staff to handle the workload and maintain compliance with regulatory requirements.

Section 24, Security of Radioactive Materials (if applicable). Review the Physical Protection Program to verify compliance with 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Also, review the physical protection system to ensure compliance with 10 CFR 73.67, if the 10 CFR Part 73, "Physical Protection of Plants and Materials" requirements are applicable (see Section 8.10.11.1 of this NUREG).

Section 25, Performance-based Review. Performance-based reviews may be conducted by observing work in progress, interviewing staff, and spot-checking required records. As a part of the audit program, consider performing unannounced audits to determine if, for example, procedures are available and are being followed for certain activities.

***Note**:* All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

SAMPLE CHECKLIST

Audit Report No._____ License No. _____

Licensee's name and mailing address:

_____

_____

_____

_____

Audit of activities at (Address):

_____

_____

_____

_____

Contact at Audit Location _____ Telephone No. _____

Date of this Audit _____

Summary of Findings and Action:

❒ No deficiencies

❒ Deficiencies

❒ Action on previous deficiencies

Recommendations:

Auditor _____ Date _____
(Signature)

Note: Except where noted, references in brackets are to Title 10 of the *Code of Federal Regulations* (10 CFR).

1. AUDIT HISTORY ❒ N/A (N/A means "Not applicable" – Initial Audit)

A. Last audit of this location conducted

B. Problems/deficiencies identified during last two audits or two years, whichever is longer ❒ Y ❒ N

C. Open problems/deficiencies from previous audits:

Status Requirement Prob./Def. Corrective Action Taken (Y/N) Open/Closed

_____

_____

_____

_____

_____

D. Any previous problem/deficiency not corrected or repeated ❒ Yes ❒ No ❒ N/A

Explain:

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Briefly describe organizational structure and note any personnel changes.

1. Structure is as described in license documents? ❒Yes ❒ No

2. Multiple authorized locations of use? ❒ Yes ❒ No

3. Briefly describe scope of activities involving licensed material, frequency of use, staff size, etc.

B. Radiation Safety Officer ❒ Yes ❒ No

1. Authorized on license ❒ Yes ❒ No

2. Fulfills duties as RSO ❒ Yes ❒ No

C. Use only by authorized individuals ❒Yes ❒ No

D. Commensurate security program implemented ❒Yes ❒ No

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

A. Instructions to workers per [19.12] ❒ Yes ❒ No

B. Training program required ❒ Yes ❒ No

C. Training records maintained ❒ Yes ❒ No

D. Evaluation of individuals' understanding of procedures and regulations based on interviews, observation of selected workers ❒ Yes ❒ No

1. Each has an up-to-date copy of the licensee's safe use and emergency procedures ❒ Yes ❒ No

2. Adequate understanding of:

a. Current safe use procedures ❒ Yes ❒ No

b. Emergency procedures ❒ Yes ❒ No

E. 10 CFR Part 20

Workers cognizant of requirements for:

1. Radiation Protection Program [20.1101] ❒ Yes ❒ No

2. Annual dose limits [20.1301, 20.1302, 20.1207] ❒ Yes ❒ No

3. NRC Forms 4 and 5 ❒ Yes ❒ No

4. 10 percent monitoring threshold [20.1502] ❒ Yes ❒ No

5. Dose limits to embryo/fetus and declared pregnant women [20.1208] ❒ Yes ❒ No

6. Procedures for opening packages [20.1906] ❒ Yes ❒ No

Remarks:

4. OPERATING AND EMERGENCY PROCEDURES

A. Procedures current? ❒ Yes ❒ No

B. Procedures contain information specified ❒ Yes ❒ No

C. Procedures submitted to the NRC ❒ Yes ❒ No

D. Did any incidents or events occur? ❒ Yes ❒ No

1. If so, were they handled properly? ❒ Yes ❒ No ❒ N/A

2. Were appropriate corrective actions taken? ❒ Yes ❒ No ❒ N/A

3. Was NRC notification or reporting required? [20.2201, 20.2202, 20.2203 and 30.50] ❒ Yes ❒ No ❒ N/A

Remarks:

5. INTERNAL AUDITS, REVIEWS OR INSPECTIONS

A. Audits are conducted ❒ Yes ❒ No

1. Audits conducted by _____

2. Frequency _____

B. Content and implementation of the radiation protection program reviewed annually [20.1101(c)] ❒ Yes ❒ No

C. Records maintained [20.2102] ❒ Yes ❒ No

6. FACILITIES

A. Facilities as described in license application ❒ Yes ❒ No

B. Access to restricted area/licensed material [20.1801,20.1802] ❒ Yes ❒ No

Remarks:

7. MATERIALS

A. Isotopes, quantities, and use as authorized on license ❒ Yes ❒ No

B. Using NUREG–1757, Volume 3: Financial Assurance is current [30.35, 70.25] ❒ Yes ❒ No ❒ N/A

Remarks:

8. LEAK TESTS

A. Leak test performed as described in correspondence with NRC (consultant; leak test kit; licensee performed) ❒ Yes ❒ No

B. Frequency: every 6 months or other interval, as approved by NRC or Agreement State ❒ Yes ❒ No

C. Records with appropriate information maintained ❒ Yes ❒ No

Remarks:

9. INVENTORIES

A. Conducted at 6-month intervals ❒ Yes ❒ No

B. Visual verification confirmed or security seal still in place ❒ Yes ❒ No

C. Transactions entered into the National Source Tracking System, Including annual reconciliation [20.2207] ❒ Yes ❒ No ❒ N/A

D. Records with appropriate information maintained ❒ Yes ❒ No

Remarks:

10. RADIATION SURVEYS

A. Instruments and Equipment: ❒ Yes ❒ No

1. Appropriate operable survey instrumentation possessed or readily available ❒ Yes ❒ No

2. Calibrated as required [20.1501] ❒ Yes ❒ No

3. Calibration records maintained [20.2103(a)] ❒ Yes ❒ No

B. Briefly describe survey requirements [20.1501(a)]:

C. Performed as required [20.1501(a)] ❒ Yes ❒ No

1. Radiation levels within regulatory limits ❒ Yes ❒ No

2. Corrective action taken and documented ❒ Yes ❒ No

D. Records maintained [20.2103] ❒ Yes ❒ No

E. Protection of members of the public

1. Adequate surveys made to demonstrate either (a) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (b) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 50 mrem in a year [20.1301(a)(1), 1302(b)] ❒ Yes ❒ No

2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)] ❒ Yes ❒ No

3. Records maintained [20.2103, 2107] ❒ Yes ❒ No

Remarks:

11. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL (INCLUDES WASTE DISPOSAL)

A. Describe how packages are received and by whom:

B. Written package opening procedures established and followed [20.1906(e)] ❒ Yes ❒ No

C. If package shows evidence of degradation, monitor for contamination and radiation levels ❒ Yes ❒ No ❒ N/A

D. Monitoring of degraded packages performed within time specified [20.1906(c)] ❒ Yes ❒ No ❒ N/A

E. Transfer(s) between licensees (including "disposal") performed per 10 CFR 70.36 and 10 CFR 70.42 ❒ Yes ❒ No ❒ N/A

F. Records of receipt/transfer maintained [20.2103(a), 70.51(b)(1)] ❒ Yes ❒ No

G. Transfers within licensee's authorized users or locations performed as required [L/C[1]] ❒ Yes ❒ No ❒ N/A

H. Special nuclear material transactions and status reports submitted to the Nuclear Materials Management Safeguards System (NMMSS) database [150.16, 150.17] ❒ Yes ❒ No ❒ N/A

I. Package receipt/distribution activities evaluated for compliance with 10 CFR 20.1301 [20.1302] ❒ Yes ❒ No ❒ N/A

Remarks:

12. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 170-180) ❒ N/A

A. Licensee shipments are:

1. Delivered to common carriers ❒ Yes ❒ No ❒ N/A
2. Transported in licensee's own private vehicle ❒ Yes ❒ No ❒ N/A
3. No shipments since last audit ❒ Yes ❒ No ❒ N/A

[1]L/C refers to license condition.

B. Hazmat Training

1. Applicability and responsibility for training and testing [49 CFR 172.702] ❒ Yes ❒ No ❒ N/A

2. Training requirements [49 CFR 172.704] ❒ Yes ❒ No ❒ N/A

C. Packages ❒ N/A

1. Authorized packages used [49 CFR 173.415, 416(b)] ❒ Yes ❒ No ❒ N/A

2. Closed and sealed during transport [49 CFR 173.475(f)] ❒ Yes ❒ No

3. Properly labeled and marked [49 CFR 172.403, 441, 173.471] ❒ Yes ❒ No ❒ N/A

D. Shipping Papers ❒ N/A

1. Prepared and used [49 CFR 172.200(a)] ❒ Yes ❒ No

2. Included [Shipping name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Cargo Aircraft Only" (if applicable)] [49 CFR 172.200-204] ❒ Yes ❒ No

3. Readily accessible during transport [49 CFR 177.817(e)] ❒ Yes ❒ No

E. Vehicles ❒ Yes ❒ No

1. Cargo blocked and braced [49 CFR 177.842(d)] ❒ Yes ❒ No

2. Placarded, if needed [49 CFR 172.504] ❒ Yes ❒ No

3. Proper overpacks, if used (shipping name, UN Number, labeled, statement indicating that inner package complies with specification package) [49 CFR 173.25] ❒ Yes ❒ No

F. Security Plans ❒ N/A

1. Components of a security plan [49 CFR 172.802] ❒ Yes ❒ No

G. Any incidents reported to DOT [49 CFR 171.15, 171.16] ❒ Yes ❒ No

Remarks:

13. PERSONNEL RADIATION PROTECTION

A. ALARA considerations are incorporated into the Radiation Protection Program [20.1101(b)] ❒ Yes ❒ No

B. Adequate documentation of determination that unmonitored occupationally individuals are not likely to receive >10% of allowable limit [20.1502(a)] ❒ Yes ❒ No ❒ N/A

OR

C. External dosimetry provided and required ❒ Yes ❒ No ❒ N/A

1. Supplier_____ Frequency_____

2. Supplier is NVLAP-accredited [20.1501(c)] ❒ Yes ❒ No

3. Dosimeters exchanged at required frequency [L/C]] ❒ Yes ❒ No

D. Occupational intake monitored and assessed [20.1502(b)] ❒ Yes ❒ No ❒ N/A

E. Reports ❒ N/A

1. Reviewed by_____ Frequency_____

2. Auditor reviewed personnel monitoring records for period_____ to_____

3. Prior dose determined for individuals likely to receive doses [20.2104] ❒ Yes ❒ No

4. Maximum exposures TEDE_____ Other_____

5. NRC Forms or equivalent [20.2104(d), 2106(c)]

   a. NRC Form 4 “Cumulative Occupational Exposure History” ❒ Yes ❒ No

      Complete: ❒ Yes ❒ No

   b. NRC Form 5 “Occupational Exposure Record for a Monitoring Period” ❒ Yes ❒ No

      Complete: ❒ Yes ❒ No

6. Worker declared her pregnancy in writing during inspection period (review records) ❒ Yes ❒ No ❒ N/A

   If yes, determine compliance with [20.1208] ❒ Yes ❒ No

   Check for records per [20.2106(e)] ❒ Yes ❒ No

F. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 2103, 2106, L/C] ❒ Yes ❒ No

Remarks:

14. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)

A. Survey instrument Serial No. Last calibration

_____

B. Auditor's measurements compared to licensee's ❒ Yes ❒ No

C. Describe the type, location, and results of measurements:

15. RADIOACTIVE EFFLUENTS, WASTE MANAGEMENT, AND DISPOSAL

A. Licensed material released into sanitary sewerage: ❒ N/A

1. Material is readily soluble (or is readily dispersible biological material) in water [20.2003(a)(1)] ❒ Yes ❒ No

2. Monthly average release concentrations do not exceed Appendix B values [20.2003(a)(2,3)] ❒ Yes ❒ No

3. Procedures for ensuring adequate sample representativeness and analysis properly implemented [20.1501, L/C] ❒ Yes ❒ No

4. Records maintained [20.2108] ❒ Yes ❒ No

Remarks:

B. Transfers for disposal at land disposal facilities: ❒ N/A

1. Waste transferred to person specifically licensed to receive waste [20.2001(b), 70.42] ❒ Yes ❒ No

2. Each shipment accompanied by a shipment manifest prepared as specified in Section I of Appendix G to 10 CFR Part 20 [20.2006(b) and Section III.A.4 of Appendix G to 10 CFR Part 20] ❒ Yes ❒ No

3. Shipment manifests certified as specified in Section II if Appendix G to 10 CFR Part 20 [20.2006(c)] ❒ Yes ❒ No

4. Compliance with Section III of Appendix G to 10 CFR Part 20 [20.2006(d)]

a. Liquid wastes solidified [61.56(a)] ❒ Yes ❒ No

b. Volume of solid wastes contain less than 1% free standing liquid [61.56(a)(3)] ❒ Yes ❒ No

c. Waste does not generate harmful vapors [61.56(a)] ❒ Yes ❒ No

d. Waste structurally stable (i.e., will maintain its physical dimensions and form under expected disposal conditions [61.56(b)] ❒ Yes ❒ No

e. Void spaces within the waste and between the waste and its package minimized [61.56(b)] ❒ Yes ❒ No

5. Waste packages labeled to identify their proper class [Section III.A.2 of Appendix G to 10 CFR Part 20] ❒ Yes ❒ No

6 Licensee conducts a Quality Assurance program to ensure compliance with 10 CFR 61.55 and 10 CFR 61.56, and which includes management evaluation of audits [Section III.A.3 of Appendix G to 10 CFR Part 20] ❒ Yes ❒ No

7. For shipments not acknowledged by recipient within 20 days after transfer, incident investigated and reported [Section III.A.9 of Appendix G to 10 CFR Part 20] ❒ Yes ❒ No

8. Records maintained [20.2108] ❒ Yes ❒ No

Remarks:

C. Waste compaction operations: ❒ N/A

1. Airborne releases evaluated and controlled [20.1501, 20.1701, L/C] ❒ Yes ❒ No

2. Internal exposures evaluated and controlled [20.1201, 20.1501, 20.1204, 20.1702, 20.1703] ❒ Yes ❒ No

3. Compliance with 20.1301 evaluated [20.1302] ❒ Yes ❒ No

D. Waste storage areas: ❒ N/A

1. Adequate protection from the elements (floods, tornadoes, hurricanes, etc.) and fire [L/C] ❒ Yes ❒ No

2. Adequate control of waste in storage [20.1801] ❒ Yes ❒ No

3. Containers properly labeled and area properly posted [20.1902, 20.1904] ❒ Yes ❒ No

4. Package integrity adequately maintained [L/C] ❒ Yes ❒ No

5. Adequate records of surveys and material accountability maintained [20.2103, 20.2108] ❒ Yes ❒ No

16. NOTIFICATION AND REPORTS ❒ N/A

A. Licensee in compliance with [19.13, 70.50] (reports to individuals, public and occupational, monitored to show compliance with Part 20) ❒ Yes ❒ No ❒ N/A

B. Licensee in compliance with [20.2201] (theft or loss) ❒ Yes ❒ No ❒ None

C. Licensee in compliance with [20.2202, 70.50] (incidents) ❒ Yes ❒ No ❒ None

D. Licensee in compliance with [20.2203, 70.50] (overexposures and high radiation levels) ❒ Yes ❒ No ❒ None

E. Licensee aware of telephone number for NRC Emergency Operations Center [301–816–5100] ❒ Yes ❒ No

17. POSTING AND LABELING

A. NRC Form 3 “Notice to Workers” is posted [19.11] ❒ Yes ❒ No

B. 10 CFR Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to 10 CFR Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted [19.11, 21.6] ❒ Yes ❒ No

C. Other posting and labeling per [20.1902, 20.1904] and the license is not exempted by [20.1903, 20.1905] ❒ Yes ❒ No

Remarks:

18. RECORDKEEPING FOR DECOMMISSIONING

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination ❒ Yes ❒ No

B. Records include all information outlined in [70.25(g)] ❒ Yes ❒ No

Remarks:

19. NRC CORRESPONDENCE

A. All NRC Correspondence (e.g., Regulatory Issue Summaries, Bulletins, Information Notices, NMSS Newsletters) issued since last audit and applicable to special nuclear material less than critical mass have been reviewed. ❒ Yes ❒ No

B. Appropriate action taken (e.g., training, updating procedures), as necessary, in response to NRC Correspondence ❒ Yes ❒ No

Remarks:

20. SPECIAL LICENSE CONDITIONS OR ISSUES ❒ N/A

A. Review special license conditions, NRC/Agreement State violations, Orders, Confirmatory Action Letters, or other safety or security issues, and describe findings:

B. Problems/deficiencies identified at licensee facilities other than at audit location:

C. Evaluation of compliance:

21. CONTINUATION OF REPORT ITEMS ❒ N/A
(If more space is needed, use separate sheets and attach to report.)

22. PROBLEMS OR DEFICIENCIES NOTED; RECOMMENDATIONS ❒ N/A

Note: Briefly state (a) the requirement and (b) how and when violated. Provide corrective actions or recommendations for improvement and preventive measures implemented to prevent recurrence.

23. EVALUATION OF OTHER FACTORS

A. Senior licensee management is appropriately involved with the radiation safety program and RSO oversight ❒ Yes ❒ No

B. RSO has sufficient time to perform his/her radiation safety duties and is not too busy with other assignments ❒ Yes ❒ No

C. Licensee has sufficient staff ❒ Yes ❒ No

D. Performance-based review (observation of licensed activities conducted) ❒ Yes ❒ No

Remarks/recommendations:

24. SECURITY OF RADIOACTIVE MATERIALS [10 CFR PART 37] ❒ N/A

A. Background investigations and access control program [10 CFR Part 37, Subpart B] ❒ Yes ❒ No

B. Physical protection requirements during use [10 CFR Part 37, Subpart C] ❒ Yes ❒ No

C. Physical protection in transit [10 CFR Part 37, Subpart D] ❒ Yes ❒ No

D. Records [10 CFR Part 37, Subpart F] ❒ Yes ❒ No

E. Security of special nuclear material of low strategic significance [73.67] ❒ N/A

1. Physical protection requirements at fixed sites [73.67(f)] ❒ Yes ❒ No

2. Physical protection requirements in transit [73.67(g)] ❒ Yes ❒ No

25. PERFORMANCE-BASED REVIEW ❒ N/A

A. Conduct performance-based reviews of radiation workers performing licensed activities:

1. to assess the capability of the radiation workers to maintain exposures ALARA;

2. to assess that radiation workers follow the operating procedures;

3. to assess the effectiveness of the operating procedures and compliance with the regulations, license conditions and the licensee commitments submitted in support of a license (and incorporated by “tie-down” conditions);

4. to ensure the safe and secure use of radioactive material;

5. to verify that radiation workers are cognizant of the emergency procedures and, if necessary, would be able to implement them and maintain exposures ALARA; and

6. to ensure that emergency procedures have been developed for all likely scenarios.

B. Take the necessary actions to address programmatic and performance deficiencies with radiation workers and facilitate immediate corrective actions.

APPENDIX F

MODEL RADIATION SURVEY INSTRUMENT CALIBRATION PROGRAM

Model Radiation Survey Instrument Calibration Program

The specifications in Table F–1 will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facilities. 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 F–1. Typical Survey Instruments[1].
(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	Micro-Roentgen to Roentgen (μ R-R)	N/A
Count Rate Meters			
Geiger Mueller (GM)	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	<1%
Remball detector	Neutron	All energies (dependent on size of the ball)	
High-purity Germanium detector	Gamma	All energies	High
Sodium Iodide (NaI) Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Zinc Sulfide (ZnS)	Alpha	All energies	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Liquid Scintillation Counting*	Alpha	All energies	High
	Beta	All energies	High
	Gamma	All energies	Moderate
NaI detector*	Gamma	All energies	High
High-purity Germanium detector	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High

Table F–1. Typical Survey Instruments[1]. (Continued)
(Instruments used to measure radiological conditions at licensed facilities.)

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Count Rate Meters			
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

[1]Table adapted 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 to be met.

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 authorized to perform calibrations

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

- Individuals conducting radiation survey instrument calibrations 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.

- 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 Part 20.

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

Radioactive sealed sources will be used for calibrating dose and dose rate measuring radiation survey instruments; these sources will have the following characteristics:

- The sources 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 (μGy/h) [0.1 millirad/hour (mrad/h)] and 10 percent for dose rates less than 1.0 μGy/h [0.1 mrad/h].

- The sources 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 sources 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 ±x (noted below) of the conventionally true value for the following ranges:

  — Background to 10 µGy/h [1.0 mrad/h]; ±x = ±30%

  — 10 µGy/h [1.0 mrad/h] to 1.0 mGy/h [100 mrad/h]; ±x = ±20%

  — 1.0 mGy/h [100 mrad/h] to 10 Gray/h [1,000 Rad/h]; ±x = ±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.

Note: Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured.

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 types of radiation 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 ±x for the following ranges:

- alpha measurement
    - — 0.01 Bq/cm^2 to 2.0 Bq/cm^2 [60 to 12,000 dpm/100 cm^2]; ±x = ±20%
    - — 2.0 Bq/cm^2 to 200 Bq/cm^2 [12,000 to 1,200,000 dpm/100 cm^2]; ±x = ±10%
- beta measurement
    - — 0.05 Bq/cm^2 to 2.0 Bq/cm^2 [300 to 12,000 dpm/100 cm^2]; ±x = ±20%
    - — 2.0 Bq/cm^2 to 200 Bq/cm^2 [12,000 to 1,200,000 dpm/100 cm^2]; ±x = ±10%

Model Procedures for Calibrating, 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 radioactive sealed sources. These should be suitable for the geometry of the samples to be analyzed. The calibration sources should have a known activity 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, including 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 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 radiation flux field and a specified surface of the instrument
- for radiation detectors with removable shielding, an indication 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, Revision 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 percent.

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:

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

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 273° K)
V_1 = volume measured at conditions P_1 and T_1

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[1]The 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, an additional error term should be included in the calculation above.

T_1 = temperature of V_1 in K
P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

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 (ADAMS Accession No. ML13051A671).
- The Health Physics & Radiological Health Handbook, 4th Edition, Edited by Thomas E. Johnson and Brian K. Birky, 2012.
- American National Standards Institute (ANSI) N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be obtained from the American National Standards Institute (ANSI) at www.ansi.org.
- "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 9th Edition, 2001.

APPENDIX G

GUIDANCE FOR DEMONSTRATING THAT UNMONITORED INDIVIDUALS ARE NOT LIKELY TO EXCEED 10 PERCENT OF THE ALLOWABLE LIMITS

Guidance for Demonstrating that Unmonitored Individuals are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individual adults likely to receive, in 1 year from sources external to the body, an occupational dose in excess of 10 percent of the applicable regulatory limits in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201. To demonstrate that dosimetry is *not* required, a licensee needs to perform a prospective evaluation to demonstrate that its adult workers are not likely to exceed 10 percent of the applicable limits.

The most common way that individuals might exceed 10 percent of the applicable limits is by being involved in the processing of sealed sources or unsealed material, (e.g., assembly lines, manufacturing processes and quality control activities). This could include internal radioactive uptake, as well as external radiation exposure. However, for many processes, even these activities result in the individual receiving minimal doses. Before allowing workers to perform these tasks, a licensee will need to evaluate the doses that its workers might receive to assess whether dosimetry is required. This is known as a prospective evaluation.

Example

One university has estimated the doses to the extremities and whole body of a person conducting foil activation experiments using plutonium-238 (Pu-238)/beryllium (Be) sources. Each Pu-238/Be source is authorized to contain up to 200 grams of plutonium. The university based its estimate on observations of individuals performing the recommended procedure according to accepted radiation safety practices. The university had the following types of information:

- Time needed to perform the entire procedure (e.g., 15 minutes)
- Expected dose rate received by the whole body of the individual, associated with the shielded source, and determined using measured or manufacturer-determined data {e.g., 0.02 mSv/h [2 mrem/h] at 46 cm [18.1 in] from the shield}
- Time the hands were exposed to the shielded source (e.g., 6 min)
- Expected dose rate received by the extremities of the individual, associated with the shielded source and determined using measured or manufacturer-determined data on contact with the shield {e.g., 0.15 mSv/h [15 mrem/h]}

From this information, the university estimated that the individual performing each foil activation experiment could receive the following:

- Less than 0.005 mSv [0.5 mrem] total effective dose equivalent (TEDE) (whole body) and
- 0.015 mSv [1.5 mrem] to the hands

The applicable TEDE (whole body) limit is 50 mSv [5 rem] per year and 10 percent of that value is 5 mSv [500 mrem] per year. If one of these procedures delivers 0.005 mSv [0.5 mrem], then an individual could perform 1,000 of these experiments each year and remain within 10 percent of the applicable limit.

The applicable shallow-dose equivalent (SDE) (extremities) is 500 mSv [50 rem] per year and 10 percent of that value is 50 mSv [5 rem or 5,000 mrem] per year. If one of these experiments delivers 0.015 mSv [1.5 mrem], then an individual could perform 3,333 of these procedures each year and remain within 10 percent of the applicable limit.

Based on the above specific situation, no dosimetry is required if an individual performs fewer than 1,000 foil activation experiments per year.

Guidance to Licensees

Licensees who wish to demonstrate that they are *not* required to provide dosimetry to their workers need to perform prospective evaluations similar to the example provided above. The expected dose rates, times, and distances used in the above example may *not* be appropriate to all licensees. In their evaluations, licensees need to use information appropriate to the type(s) of processes they intend to use.

Table G–1 may be helpful in performing a prospective evaluation and provides an example of the documentation to show that unmonitored individuals will not exceed 10 percent of the allowable dose limits.

Licensees should review evaluations periodically and revise them, as needed. Licensees need to check assumptions used in their evaluations to ensure that they are up-to-date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, utilize a new sealed source containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to conduct a new evaluation.

Table G–1. Dosimetry Evaluation			
Dosimetry Evaluation for _____			
A.	Time needed to perform the entire work activity	_____ minutes	_____ hour (divide # of minutes by 60)
B.	Expected whole body dose rate that the individual will encounter, determined using measured or manufacturer-provided data	_____ millirem/hour	
C.	Time the extremities were exposed to the unshielded source (if applicable)	_____ minutes	_____ hour
D.	Expected extremity dose rate that the individual will encounter, determined using measured or manufacturer-provided data for the unshielded source at the typical distance from the hands to the unshielded source	_____ millirem/hour	
Estimated Whole Body Dose Equivalent* Formula: (_____hours in Row A) × (_____millirem/hour in Row B) = (_____estimated millirem) × (_____# times conducted each year) = _____ millirem			
Estimated Extremity Dose Equivalent† Formula: (_____hours in Row C) × (_____millirem/hour in Row D) = (_____estimated millirem) × (_____# of times conducted each year) = _____ millirem			
*An expected Whole Body Dose Equivalent less than 500 millirem requires no dosimetry. †An expected Extremity Dose Equivalent less than 5,000 millirem requires no dosimetry.			

APPENDIX H

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 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 to the environment, excluding radon-222 and its daughters, 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 0.1 mSv [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 licensed material but who may work in the vicinity where such materials are used or stored.

Doses to Members of the Public	
INCLUDE doses from	DO NOT INCLUDE doses from
• radiation 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	• 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, e.g., 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 nonradioactive materials, and other facilities and laboratories where licensed materials are not normally used or stored.

The licensee must 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, in an unrestricted area from licensed operations, does not exceed 1 mSv [100 mrem] in a year, or

- 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 must also 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.) and

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 effluents
- use of environmental dosimeters in unrestricted areas

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 in an unrestricted area from licensed operations. 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. The occupancy factor for an area is defined as the average fraction of time the maximally exposed individual is present and exposed to a radiation source. If a source is used intermittently, the occupancy factor is a fraction of the hours in a week that a given person would occupy the area. 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 H–1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present. The occupancy factors in Table H-1 are general guidance values and may be used if more detailed information is not available.

Table H–1. Standard Occupancy Factors[1]	
Occupancy Factor	**Description**
1	Full occupancy areas such as administrative and clerical offices, receptionist areas, laboratories, pharmacies and other work areas fully occupied by an individual, attended waiting rooms, and occupied space in nearby buildings
1/2	Rooms where individuals are present for a major part of the day
1/5	Corridors, employee lounges, staff rest rooms, and class rooms
1/20	Unattended waiting rooms, public rest rooms, unattended vending rooms, storage areas, janitor's closets, attics, outdoor areas with seating, and recreational areas
1/40	Outdoor areas with only transient pedestrian or vehicular traffic, unattended parking lots, vehicular drop off areas (unattended), stairways, and unattended elevators

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 surveys including a description or drawing of the areas 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.

[1]Adapted from NCRP Report No. 147, "Structural Shielding Design for Medical X-Ray Imaging Facilities," issued November 19, 2004 and NCRP Report No. 151, "Structural Shielding Design and Evaluation for MegaVoltage X- and Gamma-Ray Radiotherapy Facilities," issued December 31, 2005

APPENDIX I

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., plutonium, cesium-137, uranium-233, uranium-235).

- A liquid scintillation counting 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 liquid scintillation counter (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 and sulfur-35.

- 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 TEDE 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 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 must be made as required by 10 CFR 20.1501. Surveys are usually 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 (see Table I–1). 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 in accordance with 10 CFR 20.2103.

Table I–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 I–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 I–2, taken from "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 Part 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 that will meet the 10 CFR Part 20 Subpart E criteria. Table I–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 I–2. Acceptable Surface Contamination Levels			
Nuclide[1]	**Average[2,3,6]**	**Maximum[2,4,6]**	**Removable[2,5,6]**
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 I–2. Acceptable Surface Contamination Levels

Nuclide[1]	Average[2,3,6]	Maximum[2,4,6]	Removable[2,5,6]
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]
Other alpha emitters[7]	8.33 Bq/100 cm^2 (500 dpm/100 cm^2)	25 Bq/100 cm^2 (1,500 dpm /100 cm^2)	1.67 Bq/100 cm^2 (100 dpm/100 cm^2)
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 a 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.
[6]The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/h at 1 cm and 1.0 mrad/h at 1 cm, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

For equipment that is potentially contaminated and is to be released for unrestricted use, Table I–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 I–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 cm^2 is acceptable to indicate levels of removable contamination.

[7]Surface contamination levels derived using one order of magnitude less than the values for beta-gamma emitters

Decommissioning Surveys for Release for Unrestricted Use

When a facility will be closed and released for unrestricted use, the values in Table I–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 I–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 I–3. Screening Values for Building Surface Contamination*

Radionuclide	Symbol	Screening levels for unrestricted release (dpm/100 cm^2)
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 the DandD, Version 1 computer code.

Units are disintegrations per minute per 100 cm^2 (dpm/100 cm^2). 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 I–3 was derived using the screening criteria in the DandD, Version 1, (DandD, v1.0) computer code and its default input parameters. Table I–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 I–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 I–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 I–3 does not include screening values for radionuclides that emit alpha particles, or for soil contamination. Screening values for radionuclides not listed in the table 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, Volume 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 of one of the "simple approaches," then a licensee may have to develop a more formal decommissioning plan.

Survey Record Requirements

Each survey record should include the following:

- a diagram of the area surveyed
- a list of items and equipment surveyed
- specific locations on the survey diagram where wipe tests were 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 70.25(g) requires, 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 may 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 are available in the NRC Agencywide Documents Access and Management System (ADAMS) at Accession No. ML003739616 and ML13051A671, respectively, 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, "Constraints 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 in 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 must evaluate the concentrations of radioactive material in water that is released to the sanitary sewer and to the environment. These releases must 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. The licensee should consider the following elements when determining the frequency of routine bioassay measurements:

- 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 bioassay measurements, and special bioassay measurements further determine the frequency and scope of measurements.

Routine Bioassay 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) 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 is the predominate exposure pathway.

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 Bioassay 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
- elevated air monitoring results

References:

Regulatory Guide 4.20, Revision 1, "Constraints 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 in 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 J

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 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 (Tl) well-counter system for gamma-emitters, liquid scintillation counters for beta-emitters, gas-flow proportional counters 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

$$MDA = \frac{2.71 + 4.65\sqrt{200\ cpm \times 2\ minutes}}{2 \times 0.1} = \frac{2.71 + 4.65\sqrt{400}}{0.2}$$

$$= \frac{2.71 + 4.65(20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2}$$

$$= \frac{478.55\ disintegrations}{minute}$$

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

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

Note: The MDA equation shown assumes that counting times for the background measurement and for the sample will be equal. MDA equations for nonequal 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 source to be tested, list identifying information such as the sealed source serial number, manufacturer, model number, radionuclides, and activity of the sealed sources.
- 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 an instrument that is sensitive enough to detect 185 becquerels (Bq) [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 Bq 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.

APPENDIX K

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 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: https://www.dot.gov/.

Title 10 of the *Code of Federal Regulations* (10 CFR) 71.5 requires compliance with DOT regulations in 49 CFR Parts 107, 171 through 180 and 390 through 397, appropriate to the mode of transport. The following are the major areas in DOT regulations most relevant for transporting radioactive materials as Type A or Type B quantities:

- 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 nonbulk 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 **Specification tank cars or cargo tank motor vehicles:** liquids/exclusive use	- - **IP-2:** exclusive use[9] **IP-3:** liquids or gases/non-exclusive use[9]	- - **IP-2:** exclusive use **IP-3:** non-exclusive use	Unpackaged[8] IP-1 - -	- - IP-2 -
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 A_1 or A_2 (see § 173.431(a)). See A_1 and A_2 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 cm^2 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 A_2 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
Basic description (in sequence): • **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** Additional description: • **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 Additional entry requirements: • 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)	Materials-based Requirements: • 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 Package-based Requirements: • 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 Shipment- and Administrative-based Requirements: • 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	• 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]

For Non-bulk Packages:

- Proper shipping name
- Identification number (preceded by "UN" or "NA," as appropriate)
- Name and address of consignor or consignee, unless the package is:
  - 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

For Bulk Packages:

- Identification number on orange panel or white square-on-point display [see §§ 172.332 or 172.336]:
  - 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]

Additional Markings Sometimes Required

Package-based marking requirements:

- 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) packaging design

- 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

Materials-based requirements:

- 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]

- 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

Administrative-based requirements:

- 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

Optional Markings

- 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.

For marking exceptions for LSA material and SCO, [see § 173.427(a)(6)(vi)] (e.g., RADIOACTIVE-LSA, RADIOACTIVE-SCO, or RQ, as appropriate).

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].

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]

White-I

Yellow-II

Yellow-III

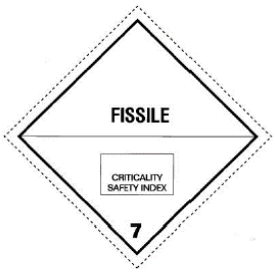
Maximum Radiation Surface Level (RSL)

mSv/h	**RSL** ≤ 0.005	0.005 < **RSL** ≤ 0.5	0.5 < **RSL** ≤ 2[5]
mrem/h	**RSL** ≤ 0.5	0.5 < **RSL** ≤ 50	50 < **RSL** ≤ 200[5]

Transport Index (TI):[4]

TI = 0	0 < **TI** ≤ 1	1 < **TI** ≤ 10[5]

Other Radioactive Labels[2]



Fissile

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

Empty labels required for empty Class 7 (radioactive) packages satisfying § 173.428; and any previously-used labels must not be visible.

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 § 72.403(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)	PLACARD FOR 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]	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 ≥ 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

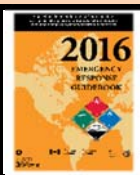
- If there is evidence of a leaking package or conveyance, access to the package or conveyance must be restricted, the area impacted and the extent of the contamination must be determined, and appropriate measures must be taken to minimize impact to persons and the environment [see § 173.443(e)].
- Except 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 https://www.nrc.uscg.mil.
- Each notice must include the information specified in § 171.15(a)(1) – (a)(7).
- A detailed incident report must also 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 https://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 L

NRC INCIDENT NOTIFICATIONS

NRC Incident Notifications

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 Requirements
Package received with removable radioactive surface contamination exceeding the limits of Title 10 of the *Code of Federal Regulations* (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 material	immediate	30 days	10 CFR 20.2201(a)(1)(i); 10 CFR 20.2201(b)(1); 10 CFR 70.50
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); 10 CFR 70.50
Extremity dose greater than 2.5 Gray [250 rads]	immediate	30 days	10 CFR 20.2202(a)(1)(iii); 10 CFR 20.2203(a)(1); 10 CFR 70.50
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); 10 CFR 70.50
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); 10 CFR 70.50
Whole body dose greater than 0.05 Sv [5 rems]	None	30 days	10 CFR 20.2203(a)(2)(i); 10 CFR 70.50
Dose to individual member of public greater than 1 mSv [100 mrems]	None	30 days	10 CFR 20.2203(a)(2)(iv)

Event	Telephone Notification	Written Report	Regulatory Requirements
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i) & (ii); 10 CFR 70.50
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 70.50(a) & (c)(2)
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 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 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 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)

Event	Telephone Notification	Written Report	Regulatory Requirements
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 attempts at 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)&(c)
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 (if subsequent substantive information)	10 CFR 37.81(a)(g)&(h)

Event	Telephone Notification	Written Report	Regulatory Requirements
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 and periodic updates (if subsequent substantive information)	10 CFR 37.81(b)(g)&(h)
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	As soon as possible upon discovery; also, notify LLEA as soon as possible upon discovery	30 days (except no report for suspicious activity) and periodic updates after report (if subsequent substantive information)	10 CFR 37.81(c)(g)&(h)
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) and periodic updates after report (if subsequent substantive information)	10 CFR 37.81(d)(g)&(h)
Upon recovery of any lost or missing Category 1 quantity of material	As soon as possible; also notify the 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 or in a subsequent update	10 CFR 37.81(e)&(h)

Event	Telephone Notification	Written Report	Regulatory Requirements
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 or in a subsequent update	10 CFR 37.81(f)&(h)

Note: Telephone notifications must be made to the NRC Operations Center at 301-816-5100 or by facsimile to 301-816-5151, except as noted. The Center is staffed 24 hours a day and accepts collect calls. NRC notification is required when licensed materials are lost or stolen or are involved in an incident that may have resulted in doses in excess of NRC limits.

APPENDIX M

CRITERIA FOR ACCEPTABLE TRAINING AND EXPERIENCE FOR AUTHORIZED USERS

Criteria for Acceptable Training and Experience for Authorized Users

This appendix is intended only as a guide for developing a training program. Individuals working with radionuclides may not require training on every topic provided. For example, housekeeping staff may need to know only what symbols to look for, which waste cans to empty, or which areas to enter or avoid. Conversely, laboratory technicians may require detailed information on particular topics. As a result, instruction for some individuals may be provided through a simple hand-out, whereas others may require extensive training, including a written exam to assess retention of the topics presented.

Classroom Training

Classroom training may be in the form of lecture, videotape, or self-study that emphasizes practical subject matter important to the safe handling of licensed materials. Duration and technical level of training should be commensurate with the expected hazards encountered during routine and emergency conditions. Training records should be kept in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2102 and be available for inspection.

Frequency of Training

- Before assuming duties with, or in the vicinity of, radioactive materials
- Whenever there is a significant change in duties, regulations, or the terms and conditions of the license
- Annually for refresher training

Suggested Radiation Safety Topics

- Fundamentals of Radiation Safety
  - — Characteristics of radiation
  - — Units of radiation dose and quantity of radioactivity
  - — Hazards of exposure to radiation
  - — Levels of radiation from licensed material
  - — Methods of controlling radiation dose (time, distance, and shielding)
  - — Radiation safety practices, including prevention of contamination, and methods of decontamination
  - — Discussion of internal exposure pathways
- Radiation Detection Instruments
  - — Use, operation, calibration, and limitations of radiation detection instruments
  - — Radiation survey techniques for measuring radiation field

- — Radiation survey techniques for measuring removable/fixed contamination
- — Handling and proper use of personnel monitoring equipment

- Radiation Protection Equipment and Use
  - — Proper use of protective equipment
  - — Decontamination of contaminated protection equipment
  - — Maintenance of equipment
- Storage, control, and disposal of licensed material
- U.S. Nuclear Regulatory Commission (NRC) regulations (10 CFR Parts 19, 20, and 70)
- NRC regulations (10 CFR Parts 21, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, 71, and 73), as applicable
- Licensee's operating and emergency procedures
- Case histories relevant to operations
- Course Examination (Didactic)
  - — Successful completion of closed-book written/oral examination, depending on the complexity and hazards of authorized activities
  - — Review of incorrect answers with student
- On-the-job Training and Examination (Practical)
  - — On-the-job training completed under the supervision of a qualified individual [authorized user (AU), radiation safety officer (RSO), or manufacturer's representative authorized by the NRC or an Agreement State] that includes supervised hands-on experience performing the task authorized on the license that are commensurate with the expected hazards during routine and emergency conditions
  - — Practical examination consisting of an assessment by the RSO to ensure that each proposed AU is qualified to work independently and that each individual is knowledgeable of the radiation safety aspects of licensed activities. This may be demonstrated by observing the proposed AU perform licensed activities.
- Discussion or drill on all applicable emergency procedures annually
- Retraining on areas found to be deficient in both the practical and didactic areas

Classroom Course Instructor Qualifications

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or AU on the license and is familiar with the licensee's program). Instructors who provide classroom training to individuals in the principles of radiation and radiation safety should have knowledge and understanding of these principles beyond those

obtainable in a course similar to the one given to prospective authorized users. Individuals who provide instruction in the hands-on use of licensed materials should have training and experience that would qualify them to be authorized users, or should possess a thorough understanding of the licensee operations.

APPENDIX N

MODEL WASTE DISPOSAL PROGRAM

Model Waste Disposal Program

General Guidelines

- All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary "nonradioactive" waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

- Remind workers that nonradioactive waste such as leftover reagents, boxes, and packaging material will 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 impact 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, inflammability), 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 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 curie (Ci)] of H-3 (tritium), 37 GBq [1 Ci] of carbon-14 (C-14), and 37 GBq [1 Ci] of all other radioisotopes 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 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's 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 any compactors 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 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 method of examining containers for defects.

APPENDIX O

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:

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

APPENDIX P

SAFETY CULTURE POLICY STATEMENT

Safety Culture

The safety culture policy statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011 and can be found at: https://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf. It is also posted in the U.S. Nuclear Regulatory Commission's (NRC's) Agencywide Documents Access and Management System (ADAMS) Accession No. 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.

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This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for licenses to receive, possess, use, and transfer special nuclear material in quantities less than "critical mass." 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.

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