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

NUREG-1556
Volume 18, Rev. 1

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Service Provider Licenses

Final Report

Office of Nuclear Materials Safety and Safeguards

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Final Report

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ABSTRACT

This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses for service providers. 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, 3150-00016, 3150-0001, 3150-0010, 3150-0214, 3150-0130, 3150-0009, 3150-0008, and 3150-0120.

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The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

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 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider 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 18, issued November 2000 to incorporate certain security requirements and other regulatory and policy changes that have been implemented since the last revision was published.

This report takes a risk-informed, performance-based approach to licensing service providers. 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 service providers. NUREG–1556, Volume 18, 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 18, Revision 1, were summarized and addressed in a document that can be located on the NRC's Agencywide Documents and Management System (ADAMS) under ML16036A128. Access to ADAMS is available on the public Web site at https://www.nrc.gov/reading-rm/adams.html. The comments NRC received included general corrections and comments on security of nuclear materials.

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ACKNOWLEDGMENTS

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ABBREVIATIONS

ADAMS	Agencywide Document and 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
bkg	background
Bq	becquerel
CEDE	committed effective dose equivalent
CFR	*Code of Federal Regulations*
Ci	curie
cpm	counts per minute
DFP	decommissioning funding plan
DIS	decay-in-storage
DOT	U.S. Department of Transportation
dpm	disintegrations per minute
EA	environmental assessment
FA	financial assurance
FR	Federal Register
GBq	gigabecquerel
Gy	gray
HDR	high dose rate
HEPA	high efficiency particulate air
IN	Information Notice
ISO	International Organization for Standardization
LLEA	local law enforcement agency
LLW	low-level radioactive waste
MARSAME	Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MBq	megabecquerel
mCi	millicuries
MDA	minimum detectable activity
MDC	minimum detectable concentration
mrem	millirem
mSv	millisievert

NaI	sodium iodide
NCRP	National Council on Radiation Protection and Measurements
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NSTS	National Source Tracking System
NSTTR	National Source Tracking Transaction Reports
NVLAP	National Voluntary Laboratory Accreditation Program
OEM	Original Equipment Manufacturer
OMB	Office of Management and Budget
PIC	Pocket Ionization Chamber
PII	Personally Identifiable Information
Q	quality factor
QA	quality assurance
RG	regulatory guide
RIS	regulatory issue summary
RQ	reportable quantities
RSO	radiation safety officer
RSRM	Risk Significant Radioactive Material
SA	State Agreement
SNM	special nuclear material
SSD	sealed source and device
std	standard
Sv	sievert
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeter
U.S.C.	United States Code

1 PURPOSE OF REPORT

This report provides guidance to an applicant in preparing a service provider license application based on the risk significance of the proposed activity, as well as providing the U.S. Nuclear Regulatory Commission (NRC) staff with the appropriate criteria for evaluating such applications.

Service providers offer a variety of commercial services to both specific and general licensees, ranging from low- to high-risk activities, and in some instances, recover both licensed and unlicensed material from the public domain. Customers who possess such radioactive material may require commercial services to manage materials at concentrations and activities they are not authorized to handle. In these unique situations, a service provider licensee is authorized to possess these radioactive materials under its license incident to performing specific services required by its customers. Optionally, customers may elect to transfer licensed material, such as radioactive waste and contaminated materials, to service providers (e.g., radioactive waste brokers, decontamination and decommissioning service providers, or nuclear laundry operators).

Service providers who, in the course of doing business, receive physical samples and possess equipment containing licensed materials related to the performance of commercial service activities—such as leak test and environmental sample analyses and survey instrument and dosimetry calibration services—are also included in this category.

Service providers addressed in this NUREG are limited to licensed entities providing the following types of commercial services based on low- or high-risk activities. These commercial services were subjectively categorized in this NUREG as low- or high-risk activities solely for the purpose of licensing guidance for service provider applicants and licensees in order to clarify for the applicant the type of information that needs to be submitted to support the request for the commercial service(s) being licensed.

LOW RISK—Possession or use incidental to performing the following commercial services:

- analysis of leak-test samples (no collection of leak-test samples)
- analysis of environmental samples (no collection of environmental samples)
- training/instruction to individuals on radiation safety-related topics
- packaging for shipment of radioactive materials in less than U.S. Department of Transportation (DOT) Type A quantities
- service or repair of gas chromatographs and X-ray fluorescent analyzers
- calibration of nuclear medicine/cardiology instruments using low-activity sources
- calibration of survey instruments and personnel dosimetry equipment using check or reference sources
- other low-risk services not identified above, where radioactive material is used for commercial service activities

HIGH RISK—Possession or use incidental to performing the following commercial services utilizing unsealed or uncontained radioactive material, and high-activity radioactive sealed sources:

- service or repair of portable nuclear gauges (including removal of source rod)
- service or repair of fixed gauges
- service or repair of fixed gauges mounted on a mobile object such as a truck or railcar
- storage of radioactive material for other entities
- use of unsealed material in tracer studies (example: use inside pipes in a refinery)
- use of remote activated robotics in radioactive contaminated areas
- calibration of survey instruments and personnel dosimetry equipment as a service for others
- installation; radiation surveys; routine and preventive maintenance; adjustment or repair of high dose rate (HDR) remote afterloaders, teletherapy, or gamma stereotactic radiosurgery units that require access to the sealed source(s), driving units, or other electronic components that could expose the sealed source, reduce the shielding, or compromise the radiation safety of the device or safety systems
- installation, relocation, removal from service, disposal, radiation surveys, routine or preventive maintenance, adjustment, training or repair of
  - — self-shielded irradiators [American National Standards Institute (ANSI) Category I irradiators]
  - — Title 10 of the *Code of Federal Regulations* (10 CFR) Part 36, “License and Radiation Safety Requirements for Irradiators,” (ANSI Categories II, III, and IV irradiators)
- nuclear laundry services
- retrieval of industrial radiography sealed sources
- decontamination and decommissioning services (NUREG–1757, Volume 1)
- packaging for shipment of radioactive materials, including the use of DOT Type B Packages
- waste management services including: packaging and repackaging of radioactive waste for transportation, commercial incineration, compaction, super compaction, solidification, or vitrification
- other high-risk services not identified above, excluding activities involving critical mass quantities of special nuclear material

Chapter 8, “Contents of an Application,” of this NUREG identifies the information needed to complete NRC Form 313, “Application for Materials License” (see Appendix A of this NUREG). The Office of Management and Budget (OMB) has approved the information collection requirements in 10 CFR Part 20, “Standards for Protection against Radiation,” and 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” and NRC Form 313 have been approved under OMB Clearance Nos. 3150-0014, 3150-0017, 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 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 necessary for each item on NRC Form 313.

NRC Form 313 does not provide sufficient space for applicants to include 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 of applicants and for streamlined handling of applications for service provider licenses, Appendix B, “Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313,” of this NUREG may be used to provide supporting information.

In this NUREG, “dose” or “radiation dose” means either absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE), as defined terms in 10 CFR Part 20. Roentgen equivalent man (rem) and its International System of Units equivalent, sievert (Sv) {1 rem =[0.01 Sv]}, are used to describe units of radiation exposure or dose. 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, in quantities not sufficient to form a critical mass, which are used or possessed within their borders. Any applicant, other than a Federal entity, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with the NRC. In areas under exclusive Federal jurisdiction within an Agreement State, NRC continues to be the regulatory authority.

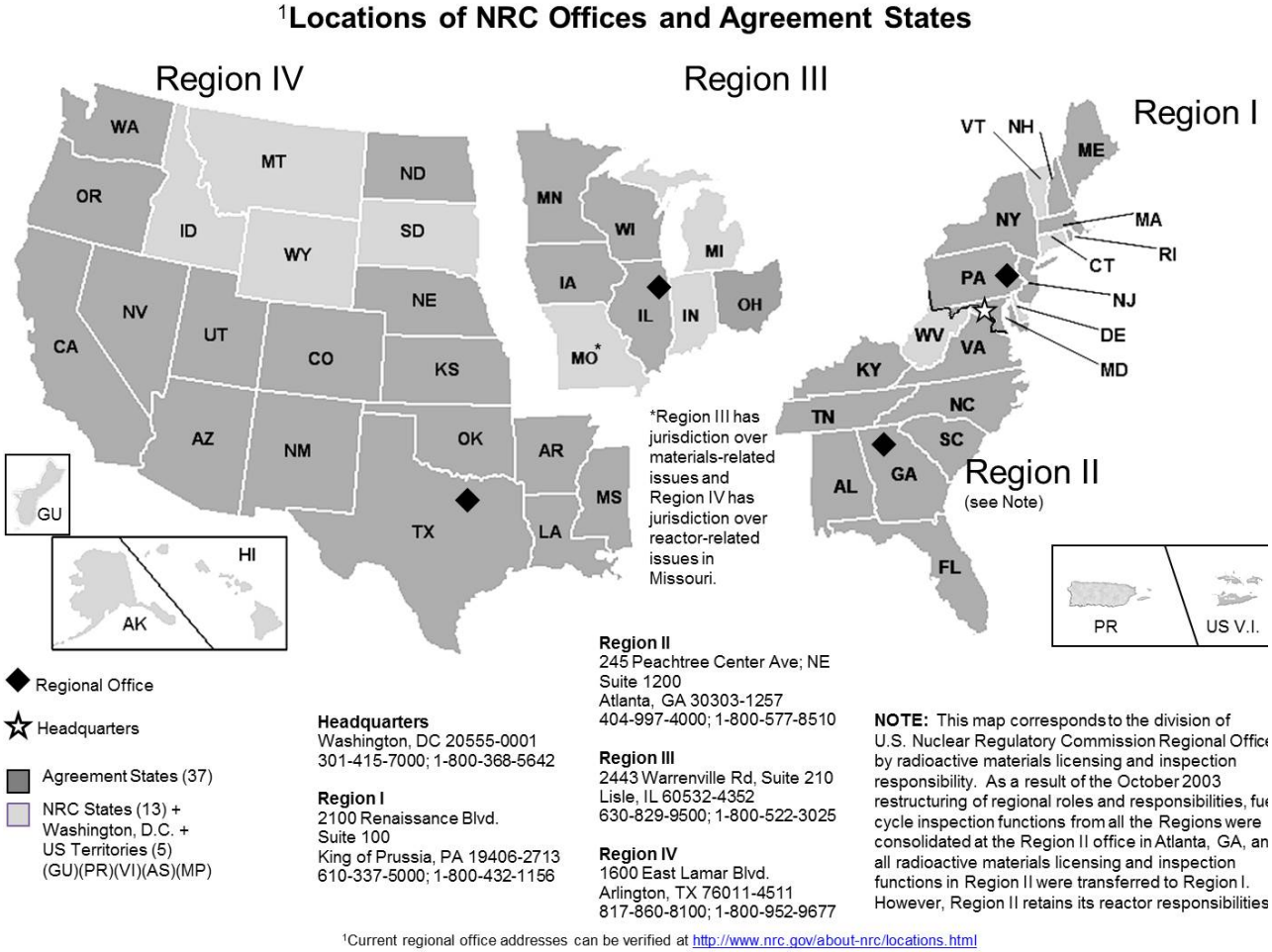


Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

In the special situation of work at federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement State has regulatory authority. These areas can also include Tribal lands of federally recognized Indian Tribes.[2]

The NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State may have jurisdiction over nonexclusive Federal jurisdiction land. Applicants are responsible for determining, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. Additional guidance on determining jurisdictional status is found in the Office of Nuclear Material Safety and Safeguards (NMSS) procedures in the State Agreement (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 that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.12, "Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts"; also, see 10 CFR 40.11 and/or 10 CFR 70.11, if applicable)	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or Tribal member on Indian Tribal land	NRC
Non-Federal entity on federally recognized Indian Tribal land	NRC[3]
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State.	Agreement State
Non-Federal entity in Agreement State	Agreement State[4]

[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.

[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, which NRC usually evaluates on a case-by-case basis.) Individuals or companies wishing to possess or use licensed material should contact the licensee to determine the jurisdictional status for specific AEA radioactive materials they intend to possess or use.

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	**Regulatory Agency**
Non-Federal entity in Agreement State at federally controlled site **not** subject to exclusive Federal jurisdiction	Agreement State[4]
Non-Federal entity in Agreement State at federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	NRC
Non-Federal entity in Agreement State using radioactive materials **not** directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	Agreement State[4]

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

2.2 Reciprocal Recognition of Specific Licenses

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

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

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

3 MANAGEMENT RESPONSIBILITY

The U.S. Nuclear Regulatory Commission (NRC) recognizes that effective 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) 30.32(c), 10 CFR 40.31(b), and 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 30.9, 10 CFR 40.9, and 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 and 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
- commitment to ensure that radiation workers have adequate training

- prevention of discrimination of employees engaged in protected activities and commitment to provide information to employees about employee protection provisions (10 CFR 30.7, 10 CFR 40.7, and 10 CFR 70.7, "Employee protection")

- commitment to provide information to employees about deliberate misconduct provisions (10 CFR 30.10, 10 CFR 40.10, and 10 CFR 70.10, "Deliberate misconduct")

- commitment to obtain the NRC's prior written consent before transferring control of the license (see Section 9.1, "Timely Notification of Transfer of Control")

- notification of the appropriate NRC regional administrator, in writing, immediately following the filing of a petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h), 10 CFR 40.41 (f), and 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 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, the 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, service providers following operating and emergency procedures to ensure that activities are conducted safely may be taking actions that correspond with the safety culture trait specified in Table 3-1 as "Work Processes" (the process of planning and controlling work activities to ensure that safety is maintained). These procedures allow the service provider to focus on the high-risk processes, while performing the maintenance activities to maintain safety. 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 N of this NUREG for the NRC's safety culture policy statement. More information on NRC activities relating to safety culture can be found at https://www.nrc.gov/about-nrc/safety-culture.html.

Table 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 service providers. 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 (NRC) 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 31 "General Domestic Licenses for Byproduct Material"
- 10 CFR Part 32 "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 33 "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- 10 CFR Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- 10 CFR Part 40 "Domestic Licensing of Source Material"
- 10 CFR Part 51 "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"
- 10 CFR Part 61 "Licensing Requirements for Land Disposal of Radioactive Waste"
- 10 CFR Part 70 "Domestic Licensing of Special Nuclear Material"
- 10 CFR Part 71 "Packaging and Transportation of Radioactive Material"
- 10 CFR Part 110 "Export and Import of Nuclear Equipment and 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 Under the Atomic Energy Act of 1954, as Amended"
- 10 CFR Part 171 "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC"

Copies of the above documents may be obtained by calling the Government Publishing Office order desk toll-free at 866-512-1800; in Washington, DC, at 202-512-1800; or 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 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 by 11-inch or legal sized paper that will feed easily into a document scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura.
- Use 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 person duly authorized, as required by 10 CFR 30.32(c), 40.31(b), and 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 non-public information.

6 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

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

The applicant or licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. License applications that contain sensitive information should be marked as indicated 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 of this NUREG 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 (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice (IN) 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" and "Information Notices," respectively, at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

- Security-Related Information: Following the events of September 11, 2001, 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—Withhold under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 22, 2005, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at 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 intragency 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 at 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 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 at https://www.nrc.gov/reading-rm/doc-collections/management-directives/.

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

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

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

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, licensees that qualify as "small entities" must provide proper certification of this status to the NRC each year, along with its annual fee payment.

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

8 CONTENTS OF AN APPLICATION

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

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

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

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

After an application for service provider authority has been reviewed by the NRC staff and found to be generally complete and responsive to NRC Form 313 (Appendix A of this NUREG) and this guidance, a pre-licensing visit may be scheduled by the NRC at the licensee's facility. A visit or conference may also be scheduled as part of the license renewal process. A pre-licensing visit provides the NRC staff with an opportunity to better evaluate the proposed program. The pre-licensing visit also provides the NRC staff an opportunity to meet with licensee management and others responsible for the radiation protection program and stress the importance of their responsibilities under a broad license, as well as to discuss and agree on additional information and commitments that may be needed.

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

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 pre-licensing visit may be required prior to issuance of the license. Also note that an initial security visit 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 "Amendments and Renewals to a License" in Chapter 9 of this NUREG.

8.2 Item 2: Name and Mailing Address of Applicant

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

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

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

8.2.1 Notification of Bankruptcy Proceedings

Regulations: 10 CFR 30.34(h), 10 CFR 40.41(f), 10 CFR 70.32(a)

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

"Permanent Location"

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

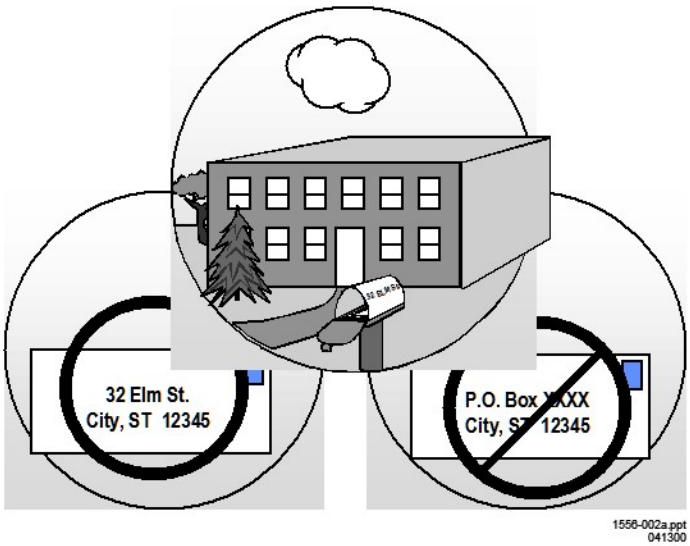
- an individual building or facility at one address
- a contiguous, licensee-controlled geographic area, such as a campus or licensee-owned/operated/controlled business campus or park
- a designated area at sea or on board a ship if it is a permanent jobsite

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

Specify the street address, city, and State or other descriptive address (e.g., Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each 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. In addition, 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.

Service providers who perform work activities at temporary jobsites should ensure that they are authorized to perform work at each location. To conduct operations at temporary jobsites (i.e., locations where work is conducted for limited periods of time), the address may be stated as "temporary jobsites anywhere in the United States where the NRC maintains jurisdiction." See Table 2-1 to determine the appropriate regulatory jurisdiction.



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

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

If an applicant submits documents that give the exact location of use and storage for any amount of radioactive material, the applicant should mark these documents as "Security-Related Information—Withhold under 10 CFR 2.390." See Chapter 6, "Identifying and Protecting Sensitive Information," for more details.

Note: As discussed in Section 8.5.3, "Recordkeeping for Decommissioning," licensees must maintain permanent records that describe where licensed material was used or stored while the license was in effect. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches, written descriptions of the specific locations or room numbers where licensed material is used or stored and any records of 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 in order to provide information 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

Regulations: 10 CFR 30.3, 10 CFR 30.32(g), 10 CFR 31.5, 10 CFR 31.12, 10 CFR 32.210, 10 CFR Part 37

Criteria: Applicants must provide the manufacturer's name, model number, radionuclide, quantity, and nominal activity for each requested sealed source and manufacturer and model number for each device that they will possess, use, and service in accordance with 10 CFR 30.32(g). Service provider licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State.

Discussion: The NRC or an Agreement State performs safety evaluations of sealed sources and devices before authorizing manufacturers to distribute to licensees. This safety evaluation is documented in a Sealed Source and Device (SSD) registration certificate. 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. Such changes may necessitate a custom registration review, increasing the time needed to process a licensing action. SSD registration certificates contain sections on "Conditions of Normal Use" and "Limitation and Other Considerations of Use." These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce the radiation safety of the device, or by circumstances unique to the sealed source or device. For example, the working life of the device, the appropriate temperature, and other environmental conditions may be specified. Except as specifically approved by the NRC, licensees are required to use sealed sources and devices according to their respective SSD registration certificates. Accordingly, applicants should obtain a copy of the certificate. Service providers, when possessing, using, or servicing sealed sources or devices, should consult with the manufacturer or distributor to ensure that requested sources and devices are compatible and conform to the SSD designations registered with 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.

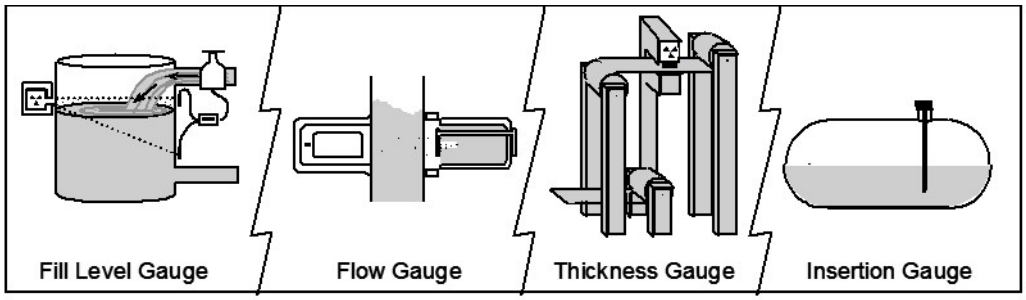


Figure 8-2. Examples of Sealed Sources or Devices Possessed, Used, or Serviced

Service providers who remove for disposal/transfer or dispose of *fixed gauges* at customer facilities may wish to perform this service for device models and sealed sources not specifically identified on their license. Specific authorization to provide these limited services for *fixed gauges* that are similar in design and activity to those listed on their license from other manufacturers will be included in the license.

The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated "Category 1 quantity of radioactive material" or "Category 2 quantity of radioactive material." These terms are defined in 10 CFR 37.5, and the radionuclides referenced in these 10 CFR 37.5 definitions are listed in Appendix A to 10 CFR Part 37. See Section 8.10.11, "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:

- Identify each radionuclide that will be possessed in each SSD, and specify the maximum activity per source. Also, specify the maximum number of sources or the total activity for each radionuclide.

- Identify the manufacturer or distributor and model number of each type of sealed source and device requested, or provide SSD registration certificate number.

- Identify any depleted uranium that is used as shielding material, if applicable. If depleted uranium is used, specify the total amount in kilograms.

- 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.

- Confirm that the activity per source and maximum activity per device will not exceed the maximum activity listed on the approved certificate of registration issued by the NRC or by an Agreement State.

- Identify the special circumstances under which sealed sources and devices that are not registered by the NRC or an Agreement State may be possessed, used, or serviced.

- If the applicant will not take possession of the sealed sources and devices, the applicant should make this statement in its application request.

Note: Licensees who are authorized to possess small quantities of material, below the Category 2 quantities described in Appendix A to 10 CFR Part 37 are not subject to access control and physical protection requirements described in 10 CFR Part 37. If applicants or licensees plan to service or acquire a Category 1 or Category 2 quantity, they should visit the NRC's public Web site (www.nrc.gov) for additional information regarding access control and security program requirements for Category 1 and Category 2 licensed material. Please contact the appropriate regional office for questions regarding the security of licensed material.

Reference: For more information about the SSD registration process, see the current version of NUREG–1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

8.5.2 Unsealed Radioactive Material

Regulations: 10 CFR 30.32(i), 10 CFR 30.33, 10 CFR 40.31, 10 CFR 70.22

Criteria: The applicant must provide the name of the radionuclide(s), chemical form, and maximum possession limit that the applicant will possess, use, and service.

Discussion: The applicant should list each requested radionuclide by its element name and its mass number [e.g., carbon-14(C-14)] in item 5. In certain situations, the applicant may request authorization to possess and use any form of byproduct material with atomic numbers from 1 through 83. The name of the specific chemical compound that contains the radionuclide is not required. For volatile radioactive material, applicants should specify whether the requested radionuclides will be acquired in free (volatile) or bound (nonvolatile) form because additional safety precautions may be necessary when handling and using free form volatile material. For example, when requesting authorization to use tritium (H-3) or iodine-125 (I-125), the applicant should specify whether the material will be acquired in free form or bound form. If a radionuclide will be acquired in both free and bound forms, then separate possession limits for each form should be specified.

Applicants requesting an authorization to use volatile radioactive material must provide appropriate facilities, engineering controls, and radiation safety procedures for handling of such material.

Note: Additional safety equipment and precautions may be necessary when handling and using unsealed free form volatile radioactive materials. Volatile means that a liquid, and in rare cases a solid, becomes a gas at a relatively low temperature when exposed to the environment.

Table 8-1. Types of Radioactive Materials		
Type of Material	**Covered by this NUREG**	**Examples**
Byproduct	Yes	H-3, C-14, Na-22, I-131, I-125, S-35, P-32, P-33, Ca-45, Ni-63, Cd-109, Cs-137, Co-57, Na-22, Cd-109, Tl-201, Ga-67
Source material	Yes	U, Th
Special nuclear material	Yes	Pu, U-233, uranium enriched in U-235 or U-233
Naturally occurring radioisotopes	Yes	Ra-226 (Discrete Sources)

Note: Authorization to possess byproduct materials with atomic numbers 84 through 96 does not include authorization to possess uranium, thorium, or plutonium. Even though these elements have atomic numbers within the range of 84 through 96, they are designated source or special nuclear material (SNM), not byproduct material, and should be requested individually. Quantities of SNM addressed in this guide are limited to small activities that cannot, under any circumstances, achieve critical mass configuration as defined in 10 CFR 150.11.

The NRC has jurisdiction over discrete sources of radium (Ra)-226, accelerator-produced radioactive materials, and other discrete sources of naturally occurring radioactive material. See Energy Policy Act of 2005.

The anticipated possession limit in megabequerels (MBq) [millicuries (mCi)] or gigabequerels (GBq) [millicuries (mCi) or curies (Ci)] for each radionuclide must 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 radionuclide with a half-life greater than 120 days. These requirements are discussed in the section on Financial Assurance and Decommissioning.

Response from Applicant: For each radionuclide, provide the element name with mass number, the chemical and physical form, and the maximum requested possession limit.

- For potentially volatile materials (e.g., I-125, I-131, H-3), specify whether the material will be free (volatile) or bound (nonvolatile) and the requested possession limit for each form.

- For unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities listed in 10 CFR 30.72 must include either of the following in accordance with 10 CFR 30.32(i),:

  — an evaluation showing that the maximum offsite dose caused by a release of radioactive materials would not exceed 0.01 sievert (Sv) [1 rem] effective dose equivalent or 0.05 Sv [5 rem] to the thyroid; or

— an emergency plan for responding to the release of radioactive material in accordance with the criteria listed in 10 CFR 30.32(i)(3)

- For source material, specify the number of kilograms and the activity of natural uranium, depleted uranium, and thorium requested.

- For SNM, specify the number of grams of material, the activity requested for each isotope, the percent enrichment, and specify whether the material will be free (volatile) or bound (nonvolatile).

- If the applicant will not take possession of the unsealed radioactive material, the applicant should make this statement in its application request.

8.5.3 Recordkeeping for Decommissioning

Regulations: 10 CFR 30.34, 10 CFR 30.35, 10 CFR 30.36, 10 CFR 30.51, 10 CFR 40.36(f), 10 CFR 40.46, 10 CFR 40.61, 10 CFR 70.25(g), 10 CFR 70.36, 10 CFR 70.51

Criteria: In accordance with 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), all licensees must maintain records of structures and equipment where licensed materials are used or stored at locations specifically listed in the license. Also pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.51(b), respectively, licensees must transfer records important to decommissioning to the new proposed licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and 10 CFR 70.36, respectively. Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and 10 CFR 70.51(a), prior to license termination, each licensee must forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g) to the appropriate NRC regional office.

Discussion: Decommissioning requirements are intended to ensure that decommissioning will be carried out minimizing the impact on the public, maximizing occupational health and safety, and maximizing protection of the environment.

In accordance with 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), all licensees must maintain records of structures and equipment where licensed materials are used or stored at locations specifically listed in the license until the site is released for unrestricted use. As-built drawings (not blueprints) with modifications of structures and equipment shown, as appropriate, fulfill this requirement. If drawings are not available, licensees may substitute appropriate records concerning the areas and locations where licensed materials are used. In addition, if licensees have experienced unusual occurrences (e.g., leaking sources or other incidents that involve the spread of contamination), they must maintain records about contamination that remains after cleanup or contamination that may have spread to inaccessible areas. Under NRC regulations when terminating the license, licensees must transfer records important to decommissioning to either of the following:

- the new licensee before licensed activities are transferred or assigned [10 CFR 30.35(g), 10 CFR 30.51(e), 10 CFR 40.36(f), 10 CFR 40.61(e), and 10 CFR 70.51(b)]

- the appropriate NRC regional office before the license is terminated [10 CFR 30.51(f), 10 CFR 40.61(f), and 10 CFR 70.51(a)]

Decommissioning records described above are not required for temporary jobsite locations.

In accordance with 10 CFR 30.36(d)(3), licensees must begin decommissioning if no principal activities under the license have been conducted for 24 months. Service provider licensees who store or possess radioactive material must comply with the "decommissioning timeliness rule" in 10 CFR 30.36(d). The intent of 10 CFR 30.36(d) is to prevent delays in decommissioning and site cleanup. Service provider licensees should request an alternate schedule for decommissioning if no radioactive materials are used or stored at the location of use for 24 months. This request will be evaluated on a case-by-case basis to determine the activities that have been conducted at the facility and the extent of decommissioning activities needed, if any. Refer to Sections 2.2 and 2.6 of NUREG–1757, Volume 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping and Timeliness," for guidance on what needs to be provided and the criteria the NRC will use to review a licensee's request for an alternate schedule.

Response from Applicant: State the following: "Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), and 10 CFR 70.51(b)(3), as appropriate, we will maintain drawings and records important to decommissioning and will transfer these records to an NRC or Agreement State licensee before licensed activities are transferred. Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and 10 CFR 70.51(a), as appropriate, prior to license termination, we will forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), as appropriate, to the appropriate NRC regional office or to assign the records to the appropriate NRC regional office before the license is terminated."

8.5.4 Financial Assurance

Regulations: 10 CFR 30.34(b), 10 CFR 30.35, 10 CFR 40.36, 10 CFR 40.46, 10 CFR 70.25, 10 CFR 70.36

Criteria: Financial assurance is not required for many service providers. A service provider who will be authorized to *possess* licensed material in excess of the limits specified in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25, "Financial assurance and recordkeeping for decommissioning," must provide evidence of financial assurance for decommissioning.

Discussion: The NRC's regulations are intended to ensure that decommissioning will be carried out so as to minimize the impact on the public, maximize occupational health and safety, and maximize protection of the environment. The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license.

NRC regulations requiring a certification of financial assurance (FA) or a decommissioning funding plan (DFP) are designed to provide reasonable assurance that the technical and environmental components of decommissioning are carried out and unrestricted use of the facilities is possible at the conclusion or termination of licensed activities. These requirements, if applicable, specify that a licensee must either set aside funds for decommissioning activities or provide a guarantee through a third party that funds will be available. Applicants are required to submit a certification of FA or a DFP when the possession of radioactive material with a half-life ($T_{1/2}$) greater than 120 days exceeds certain limits. Criteria for determining if an applicant is required to submit a DFP or has the option of submitting either a DFP or a certification of FA are stated in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25, all entitled, "Financial assurance and recordkeeping for decommissioning." A DFP contains a site-specific

cost estimate and a certification of FA. An FA certification includes a certification that the licensee has provided the required FA and an acceptable FA instrument.

NUREG–1757, Volume 3, Rev. 1, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," provides guidance acceptable to the NRC staff on the information to be provided for establishing FA for decommissioning and a standard format for presenting the information. Note that FA is required for four types of licensed materials: unsealed byproduct material (10 CFR 30.35); sealed byproduct material (10 CFR 30.35); dispersible source material (10 CFR 40.36); and unsealed special nuclear material (10 CFR 70.25). The total amount of FA required is the sum of the FA required for each of these types of materials. The regulations no longer allow escrow accounts or lines of credit. The regulations also require that any licensee that does not use the prepayment option as its financial assurance instrument must have a standby trust fund to receive any funds from the licensee for decommissioning because the NRC cannot receive funds directly.

For radiation waste broker service providers, 10 CFR 30.35(c)(5) requires that waste collectors and waste processors, as defined in 10 CFR Part 20, Appendix G, must provide financial assurance in an amount based on a decommissioning funding plan. The DFP must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license and the cost of disposal of the maximum quantity, by volume, of radioactive material that could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 10 CFR Part 20.

Response from Applicant:

Financial assurance is not required for most service provider applicants.

If the applicant is going to possess radioactive material but wants to keep the possession limits below the requirements for financial assurance, applicants should provide a statement that, "We shall restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 10 CFR 40.36(b), and 10 CFR 70.25(d), for establishing decommissioning financial assurance."

OR

If financial assurance is required, submit evidence of financial assurance following the guidance in NUREG–1757, Volume 3.

Reference: NUREG–1757, Volume 3, Rev. 1, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping and Timeliness."

8.5.5 Emergency Plan

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

Criteria: Applicants who will be authorized to possess radioactive material in excess of the quantities listed in 10 CFR 30.72, "Schedule C—Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release," must prepare for the potential release of radioactive material.

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

- an evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv [1 rem] effective dose equivalent or 0.05 Sv [5 rem] to the thyroid; or

- an emergency plan for responding to the release of radioactive materials in accordance with the criteria listed in 10 CFR 30.32(i)(3).

Response from Applicant:

If an emergency plan is required per 10 CFR 30.32(i), applicant must provide either:

An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv [1 rem] effective dose equivalent or 0.05 Sv [5 rem] to the thyroid;

OR

An emergency plan for responding to the release that contains the information specified in 10 CFR 30.32(i)(3).

Reference: Regulatory Guide 3.67, Revision 1, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities." (ADAMS Accession No. ML103360487)

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

Regulations: 10 CFR 30.32 (d); 10 CFR 30.33(a)(1), 10 CFR 40.31(d), 10 CFR 51.21, 10 CFR 70.22(a)(2); 10 CFR 70.23(a)(1).

Criteria: Applicants must provide a basis for confidence that radioactive materials will be used as specified on a license. The variety of uses described in Chapter 1," Purpose of Report," are delineated into low or high-risk activities. An application for a license will be approved if the proposed activity is authorized by the Atomic Energy Act of 1954, as amended, and devices will be used only for the purposes for which they were designed and according to the manufacturer's and distributor's recommendations and instructions for use, as specified in an approved SSD registration certificate, unless otherwise authorized in the license. Use of sealed sources and devices other than those listed in the SSD registration certificate require review and approval by the NRC or an Agreement State.

Discussion: In the interest of national security and the protection of the public health and safety, and in order to provide a basis for confidence that new applicants will use licensed material as specified in a license, the NRC has changed its policy for processing applications for new licenses. All new applicants for NRC licenses may now be subject to a pre-licensing site visit. The purpose of the visit is to verify the content of the application and that licensed material will be used as specified on the license.

Use of licensed materials in tracer studies: If the material will be used in tracer and field studies in which licensed material is deliberately released into the environment, an environmental assessment (EA) may be needed, according to 10 CFR 51.21, "Criteria for and

Identification of Licensing and Regulatory Actions Requiring Environmental Assessments." NUREG–1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," addresses procedures that staff should use in conducting environmental reviews, and is available on the NRC Web site under "Document Collections." Memoranda dated March 19, 2004 (ADAMS Accession No. ML040790751) and October 20, 2009 (ADAMS Accession No. ML092321078), provide further guidance. Applicants for tracer or field studies must provide the NRC with a description of the study for review and approval before performing such studies.

Applicants should note that authorization from the NRC to use licensed material in tracer studies does not relieve them of their responsibilities to comply with any other applicable Federal, State or local regulatory requirements.

If the licensed material will remain at the customer's facility (and the customer does not maintain an NRC license) and the material is an exempt concentration in accordance with 10 CFR 30.70, "Schedule A—Exempt concentration," the applicant should contact the NRC to determine if an Exempt-Distribution license would be required. Applicants can refer to the guidance in NUREG–1556, Volume 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses."

Response from Applicant: In accordance with 10 CFR 30.32(d), 10 CFR 40.31(d) and 10 CFR 70.22(a)(2), the service provider must specify the purpose for which each radioisotope or sealed source listed in Item 5 is to be used or possessed incident to providing a specific service. The service provider must also specify the specific services that will be provided. Refer to Appendix B, "Suggested Format for Providing Information Requested in Items 5-11 of NRC Form 313" of this NUREG for additional guidance.

AND

If the applicant wants to perform field studies in which licensed material is deliberately released to the environment, the following information should be provided:

- a complete application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material
- a copy of the applicant's operating and emergency procedures
- a description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment, if appropriate, and procedures for minimizing releases
- a description of the expected radiation dose to humans
- a sample agreement letter between the applicant and the applicant's customer acknowledging the use of radioactive materials at the customer's site
- a letter from the appropriate State health authorities indicating that they have reviewed the applicant's application and concur with the applicant's request

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

8.7.1 Radiation Safety Officer (RSO)

Regulations: 10 CFR 30.33(a)(3), 10 CFR 40.32(b), 10 CFR 70.22(a)(6)

Criteria: Radiation Safety Officers (RSOs) must be qualified by training and experience in radiation protection and be available for advice and assistance on radiological safety matters. The RSO's training and experience must be commensurate with the requested licensed material to be identified on the license. The RSO is typically the first responder for all radiological emergencies.

Discussion: The person responsible for the radiation protection program is the RSO. The RSO must also be responsible for compliance with the regulations for the use of radioactive material, which may include byproduct, source, and special nuclear material. The RSO must ensure that radiation safety activities are being performed safely according to approved policies and procedures and that all regulatory requirements are met. The RSO should have full access to all activities involving the use of licensed material and the authority to terminate any activity in which health and safety appear to be compromised without consulting with executive management.

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and the DOT regulations and the conditions of the license (see Appendix C of this NUREG).

The responsibilities of the RSO may not be transferred to other individuals. Many tasks and duties associated with managing the program may be assigned or delegated to other qualified individuals; however, the responsibility for these tasks and duties remains with the RSO. The NRC recognizes that a qualified individual will on occasion fill in for the RSO when the RSO is away for short periods of time (e.g., professional conferences, vacation, illness). Absences that have a major impact on licensed activities should not occur for extended or indefinite periods of time. Consideration should be given to how individuals temporarily delegated the duties and tasks of the absent RSO could contact the RSO in the event of an emergency.

When management selects an RSO, they should keep in mind the duties and responsibilities of the position, and select an individual who is qualified to serve as the RSO. The RSO will need a basic technical knowledge sufficient to understand, in general, the majority of the work being done with licensed materials under his or her responsibility. The individual selected as RSO must have sufficient training and experience to perform the duties required by his or her position. Executive management should ensure that the RSO has sufficient time allocated to carry out the responsibilities of the position. The NRC requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and that the named individual knows of his or her designation as RSO. Appendix C of this NUREG also provides a model Delegation of Authority, which should be used to further emphasize the agreement on duties and responsibilities of the RSO by management and the designated RSO.

Response from Applicant:

- Provide the name of the proposed RSO who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

AND

- Demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position and demonstrating day-to-day oversight of the radiation safety activities.

AND

- Confirm that the RSO will be available for emergencies and can be on-site within 24–48 hours, if applicable.

AND

- Provide the specific training and experience of the RSO, and include the specific dates of training in radiation safety.

OR

- Provide alternative information demonstrating that the proposed RSO is qualified by training and experience (e.g., Board Certification by the American Board of Health Physicists, completion of a bachelor's and/or master's degree in the sciences with at least 1 year of experience in the conduct of a radiation safety program of comparable size and scope).

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 CFR 19.13, 10 CFR 30.33(a)(3), 10 CFR 30.34(e), 10 CFR 40.32, 10 CFR 70.22

Criteria: Individuals 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)].

Discussion: Authorized users (AUs) and radiation workers must have adequate training and experience to use, possess, or provide services involving licensed materials. An individual named as an AU on an NRC license is responsible for ensuring that radioactive materials are handled and used safely and in accordance with NRC regulations and the terms and conditions of the NRC license.

Duration of training and experience should be commensurate with the expected hazards that service provider personnel may encounter during routine and emergency conditions. Successful completion of training as described in Appendix D of this NUREG is evidence of adequate training and experience. Experience requirements could consist of on-the-job training completed under the supervision of a qualified individual [AU, RSO, or manufacturer's representative that is authorized by the NRC or an Agreement State for the purpose(s) or activities that will be authorized in the license, when issued].

An AU is a person whose training and experience meet NRC criteria specified in Appendix D of this NUREG, who is named either explicitly or implicitly on the license, and who uses or directly supervises the use of licensed materials. An AU must ensure the proper use of licensed materials possessed under the license. AUs must have training to provide reasonable assurance that they will use, possess, or provide services involving licensed materials in a safe manner, maintain security, prevent unauthorized access, and respond appropriately to emergencies. AUs are responsible for the use of material by radiation workers. Applicants who want to provide radiation safety training involving the use of licensed material as a service to their customers should provide to the NRC for review a description of the training program that corresponds to the appropriate NUREG–1556 volume, to include radiation safety topics, frequency and duration of training, testing methodology, and qualification of course instructors. The NRC will review such requests to determine that the radiation safety aspect of the use of licensed material during hands-on training is adequate to protect occupational workers and members of the public.

Service providers should not assume that safety instruction has been adequately covered by previous radiation safety training. Particular attention should be given to individuals performing work or in the immediate vicinity or work being performed with radioactive materials that may require special procedures (e.g., sealed source exchange, service operations that create high radiation areas). 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 a service provider may encounter. The guidance in Appendix D 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:

Applicants provide either of the following:

- A statement that: "Before using licensed material, authorized users will receive the training described in Appendix D in NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.'"

OR

- A description of the training and experience for proposed AUs.

AND

- A description of the radiation safety training involving the use of licensed material that will be provided as a service to customers, if training is provided by the service provider.

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

Regulations: 10 CFR 19.11, 10 CFR 19.12, 10 CFR 19.13, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.9, 10 CFR 30.33(a)(3), 10 CFR 30.34(e), 10 CFR 40.9, 10 CFR 40.32(b), 10 CFR 40.41(e), 10 CFR 70.9, 10 CFR 70.23(a)(2), 10 CFR 70.32(b)

Criteria: Ancillary personnel may include clerical, housekeeping, security, any customers' personnel or licensee staff members working under the supervision and direction of the service provider's RSO or AU at the time licensed materials are possessed (incident to providing services) under the service provider's license, and other similar types of personnel whose duties may require them to work in the vicinity of radioactive material, whether they are escorted or not by AUs. These individuals should be informed about radiation hazards and the appropriate precautions they should take when working in the vicinity of licensed material. The licensee should assess each individual's involvement with licensed material and provide appropriate training.

Discussion: Ancillary personnel must receive radiation safety training commensurate with their duties. Each individual should also receive periodic refresher training.

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).

Response from Applicant:

Provide either of the following:

- A statement that: "Before working in the vicinity of licensed materials, personnel will have successfully completed training commensurate with assigned duties."

OR

- 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 refresher training.

8.9 Item 9: Facilities and Equipment

Regulations: 10 CFR 20.1101(b), 10 CFR 20.1406, 10 CFR 30.33, 10 CFR 30.33(a)(2 and 5), 10 CFR 30.35(g), 10 CFR Part 37, 10 CFR 40.32(c), 10 CFR 51.20, 10 CFR 51.21, 10 CFR 70.23(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 materials, as defined in 10 CFR 37.5. Additionally, they must minimize the possibility of contamination, and keep exposure to occupationally exposed workers and the public ALARA.

Discussion: Applicants who will never take possession of licensed material, but require a license to perform work with the licensed material at their client's facilities, will not need to provide detailed information regarding their facilities, but should confirm that they will not take possession of radioactive materials.

Applicants who will possess licensed material at their facilities must demonstrate that proposed facilities and equipment provide adequate storage capabilities, appropriate shielding, maintain radiation exposures ALARA, and minimize the possibility of contamination or release of licensed materials, as a result of normal and emergency conditions, including fire, floods, earthquakes, and wind damage. Licensed materials located in an unrestricted area and not in storage must be under the constant surveillance and immediate control of the licensee. Licensed materials should be accessible only by authorized persons and secured or locked when an authorized person is not physically present. If accessible by unescorted, unauthorized persons, use or storage areas cannot be considered restricted areas for purposes of radiation safety.

Applicants may elect to delay completing permanent facilities that will be specifically listed on its license and acquiring equipment described in the application until the technical review of the application is completed by the licensing staff and the license is issued. Delaying the acquisition of certain equipment or modifications to the permanent facility allows for changes identified as a result of the technical review of the application to be implemented.

In all cases, the applicant cannot possess or use licensed 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.

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:

For guidance on which activities are considered low-risk and which are high risk, please refer to Chapter 1, "Purpose of the Report."

Service providers listed in the **low-risk group** (e.g., leak test, environmental sample analysis) only need to provide the location where these services will be performed. Indicate if services will be performed at temporary jobsites. No facility description is required. These applicants do not need to provide the additional information required of high-risk service providers listed below.

For those services listed in the **high-risk group** who will have permanent facilities specifically identified on the license, provide the following information, as applicable to the service the applicant intends to perform:

- Submit a drawing or sketch of the proposed permanent facility that fulfills the following requirements:

    — Identify area(s) assigned for the receipt, storage, security, preparation, handling, waste storage, and measurement of radioactive materials, including sealed sources and devices.

- Show the relationship and distance between restricted areas and adjacent unrestricted areas.

- Indicate the scale, or include dimensions on each drawing or sketch. The same scale should be used for all sketches and drawings. The recommended scale is 1/4 inch = 1 foot. Drawings to this scale that do not fit on 8-1/2 × 11-inch paper may be provided as sectional drawings. Please also include a compass directional arrow to indicate "North."

- Specify shielding materials (e.g., concrete, lead) and means for securing radioactive materials from unauthorized removal.

- Illustrate area(s) where explosive, flammable, or other hazardous materials may be stored.

- Identify area(s) where radioactive materials may become airborne. The diagram should contain descriptions of the ventilation systems, with pertinent airflow rates, filtration equipment, sample collection points, and monitoring systems.

- Identify specialized handling tools, facility safety interlocks designed to prevent operation of radiological safety systems in the event that operation of a system could result in accidental exposure or release of material [e.g., high efficiency particulate air (HEPA) filters, ventilation system, safety door interlocks, etc.] or equipment.

- Identify radioactive waste handling equipment that includes, for example, incinerators, compactors, solidification equipment, hold-up tanks, and sample collection points.

- In addition, describe:

  - Engineered safety systems (e.g., area monitors, interlocks, alarms).

  - Protective clothing (i.e., latex or rubber gloves, lab coats or coveralls, respirators, booties, and face shields), auxiliary shielding, absorbent materials, secondary containers for waste water storage for decontamination purposes, plastic bags for storing contaminated items, etc., that will be available for use when handling unsealed or uncontained radioactive materials.

  - The general location of each proposed permanent facility (e.g., an industrial park, an office complex) and its current use. If any proposed permanent facility is a private residence, provide diagrams of the installation that include the building, the proposed restricted area or areas, and adjacent areas, including above and below the restricted areas; provide commitments that restricted areas do not include residential quarters, and explain how radiation levels in unrestricted areas will be maintained at less than 1 mSv [100 mrem] per year.

  - The proposed nuclear laundry facilities, if applicable, used for contaminated protective equipment and clothing. Specify how the contaminated waste water from the laundry machines or sinks is disposed. Operating and emergency procedures should address decontamination of the laundry area and equipment.

Note: Mark drawings and diagrams that provide the exact location of materials, or depict specific locations of safety or security equipment as "Security-Related Information—Withhold under 10 CFR 2.390."

For temporary jobsites:

- No facility description is required. (NOTE: equipment used at temporary jobsites will be discussed in Section 8.10.1 "Operating and Emergency Procedures")

8.10 Item 10: Radiation Safety Program

Regulations: 10 CFR 20.1101, 10 CFR 30.33, 10 CFR 40.32, 10 CFR 70.23

Criteria: A radiation safety program must be established and submitted to the NRC as part of the application. The program must be commensurate with the scope and extent of activities for the use of licensed materials in service operations.

Each applicant must develop, document, and implement a radiation protection program that is specific to its types of operations. Radiation safety programs should address the following elements:

- development, implementation, and maintenance of written operating and emergency procedures to address all likely situations
- development and implementation of an access authorization program, if required
- development and implementation of an ALARA program
- description of equipment and facilities adequate to protect personnel, the public, and the environment
- confirmation that licensed activities are conducted only by individuals qualified by training and experience
- description of organization structure and individuals responsible for ensuring day-to-day oversight of the radiation safety program
- establishment and management of a radiation safety and decommissioning records system
- implementation of an audit program to ensure that, at least annually, the radiation safety program is reviewed
- development of a sample agreement letter between the applicant and the applicant's customer acknowledging the use of radioactive materials at the customer's site
- development and implementation of a program to ensure the security and control of licensed material

Discussion: The required components of the applicant's radiation safety program are detailed in the following topics found in this NUREG. Some topics will not require the applicant to

submit information as part of an application, but simply provide the applicant with guidance to comply with a specific NRC requirement.

8.10.1 Operating and Emergency Procedures

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1902-1905, 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 30.32(i), 10 CFR 30.34(e), 10 CFR 30.50, 10 CFR 30.72, 10 CFR 37.41, 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.81, 10 CFR 40.41(e), 10 CFR 40.60, 10 CFR 70.32(b), 10 CFR 70.50

Criteria: As part of the application package, the licensee must develop, implement, and maintain operating and emergency procedures. Operating procedures for high-risk licensed activities (described in Chapter 1, "Purpose of the Report") should be submitted with the application. Low-risk licensed activities do not require the submission of operating procedures. Emergency procedures should be submitted with all license applications and should address the important radiation safety aspects for the proposed activities and address all likely scenarios that may be encountered.

Discussion: The purpose of operating and emergency procedures is to provide personnel specific guidance for all operations they will perform. The operating and emergency procedures should include each topic important to safe operation considered applicable to the materials and uses proposed in the application.

Each licensee must develop, implement, and maintain operating and emergency procedures for all likely scenarios that might be encountered. Emergency scenarios may include high dose rate alarm; leaking source; stuck source; radioactive spill; natural phenomena, such as fire, earthquake, and tornados; medical emergency; contaminated or injured individual; inhalation or ingestion due to aerosolized contamination; radiation overexposure; unshielded source; device malfunction; device toppled over or damaged; activation of a safety or security alarm; lost or missing radioactive material, and transportation accident involving the transport of licensed material. The operating and emergency procedures should include the items outlined below:

- Procedure for obtaining an agreement with customers outlining the responsibilities of both the customer and service provider, when performing service operations at a customer's facility. The written agreement should include:
    - — description of roles and responsibilities of the service provider and the customer
    - — notice to the customer if the service provider will bring radioactive material into the customer's facility
    - — discussion on who will maintain security of the radioactive material (example: during comingling of multiple sources from multiple customers)
    - — discussion of who will take the lead for any emergency situations that might arise from this service call (e.g., spill, injured worker, overexposure, stuck source, leaking source, decontamination activities)

- — indication if any aftermarket sources or parts will be used BEFORE servicing
- — description of the authorized use of the customer's calibrated radiation survey meter, if the need arises

- Instructions for handling and using licensed materials.
- Instructions for maintaining security during storage and transportation.
- Instructions to keep licensed material under control and immediate surveillance during use.
- Instructions for posting areas and labeling containers.
- Steps to take to keep radiation exposures ALARA.
- Steps to maintain accountability during use.
- Steps to control access to work sites.
- Steps to take and whom to contact when an emergency occurs.
- Instructions for using remote handling tools when handling sealed sources, except low-activity calibration sources.
- Methods and occasions for conducting radiation surveys, including surveys for detecting contamination.
- Procedures to minimize personnel exposure during routine use and in the event of an incident, including exposures from inhalation and ingestion of licensed unsealed materials.
- Methods and occasions for locking and securing stored licensed materials.
- Procedures for personnel monitoring, including bioassays, and the use of personnel monitoring equipment.
- Procedures for transporting licensed materials to temporary jobsites, packaging of licensed materials for transport in vehicles (private or common carrier), placarding of vehicles when needed, and physically securing licensed materials in transport vehicles during transportation, to prevent accidental loss, tampering, or unauthorized removal.
- Procedures for picking up, receiving, and opening packages containing licensed materials, in accordance with 10 CFR 20.1906, "Procedures for receiving and opening packages."
- Instructions for maintaining records, in accordance with the regulations and the license conditions.
- Procedures for identifying and reporting to the NRC defects and noncompliance, as required by 10 CFR 21.21(a).

- Procedures and actions to be taken in an emergency situation that will cover all likely scenarios, including actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments.

- Instructions for the proper storage and disposal of radioactive waste.

- Procedures to be followed in the event of uncontrolled release of radioactive unsealed licensed material to the environment, including notification of the RSO, NRC, and other Federal and State agencies.

- Procedures for identifying and reporting to the NRC incident notifications (see Table 8-2 for a description of the typical incident notifications required by NRC regulations).

- Procedures for the implementation and adherence to good health physics practices while performing service operations, such as:

    — minimization of distance to areas, to the extent practicable, where licensed materials are used and stored

    — maximization of survey frequency, within reason, to enhance detection of contamination

    — segregation of radioactive material in waste storage areas

    — segregation of sealed sources and tracer materials to prevent cross-contamination

    — separation of radioactive material from explosives

    — separation of potentially contaminated areas from clean areas by barriers or other controls

- Method for reviewing the entire radiation safety program at least annually.

Written documentation of the procedures written above should be retained for review during inspection.

***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.

Table 8-2. Regulatory Required Notifications			
Typical NRC Notifications Required for Service Providers			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Package received with removable radioactive surface contamination exceeding the limits of 10 CFR 71.87(i) or external radiation levels exceeding the limits of 10 CFR 71.47	Immediate (NRC and final delivery carrier must be notified.)	None	10 CFR 20.1906(d)
Theft or loss of material	Immediate	Within 30 days	10 CFR 20.2201(a)(1)(i) & (b)(1)
Whole body dose greater than 0.25 Sv [25 rem] per event	Immediate	Within 30 days	10 CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Gy [250 rad]	Immediate	Within 30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rem] in 24 hours	Within 24 hours	Within 30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 0.5 Sv [50 rem] in 24 hours	Within 24 hours	Within 30 days	10 CFR 20.2202(b)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rem] in a year	None	Within 30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv [100 mrems] in a year	None	Within 30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	Within 2 days	Within 30 days	10 CFR 21.21(d)(3)(i) & (ii)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	Within 30 days	10 CFR 30.50(a)&(c)(2)

Table 8-2. Regulatory Required Notifications (Continued)			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Unplanned contamination event that requires restricted access for more than 24 hours and involves a quantity of material greater than five times the lowest annual limit on intake for the material as specified in Appendix B of 10 CFR Part 20 and requires the area to be restricted for a reason other than to allow radionuclides with half-lives less than 24 hours to decay	24 hours	30 days	10 CFR 30.50(b)(1) & (c)(2); 40.60(b)(1) & (c)(2); and 70.50(b)(1) & (c)(2)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	Within 24 hours	Within 30 days	10 CFR 30.50(b)(2) & (c)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	Within 24 hours	Within 30 days	10 CFR 30.50(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)

Table 8-2. Regulatory Required Notifications (Continued)			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Coordination with local law enforcement agency (LLEA) has failed, either because the LLEA has not responded or because the LLEA does not plan to participate	3 business days	Submittal of a written report concerning failures of coordination with LLEA as described in 10 CFR 37.45(b) is not required; however, licensees must document their efforts to coordinate with the LLEA and keep this documentation for 3 years	10 CFR 37.45(b)&(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)

Table 8-2. Regulatory Required Notifications (Continued)			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
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)

Table 8-2. Regulatory Required Notifications (Continued)			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
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 301-951-0550, except as noted. The Center is staffed 24 hours a day and accepts collect calls.

Response from Applicant: Applicants who perform low-risk licensed activities are not required to submit operating procedures but should provide emergency procedures for all likely scenarios.

Applicants who perform high-risk licensed activities should submit their operating and emergency procedures for radiological conditions that might be encountered as part of their license application. **Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.**

Note: Service providers who perform specific operations involving sealed sources, such as inspection and maintenance of devices, removal and replacement of sealed sources (source exchange), and operations that involve access to the sealed source(s) and safety systems, should include appropriate procedures and instructions for these operations in the applicant's operating and emergency procedures.

OR

Service providers should include operating and emergency procedures that are in accordance with the manufacturer's and distributor's procedures as well as the corresponding SSD registration certificate for the devices that are being serviced or maintained.

8.10.2 Material Receipt and Accountability

Regulations: 10 CFR 20.1501(a), 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 20.2001, 10 CFR 20.2108, 10 CFR 20.2201, 10 CFR 20.2207, 10 CFR 30.34(e), 10 CFR 30.35(g), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 31.11, 10 CFR 37.49, 10 CFR 37.71, 10 CFR 37.75, 10 CFR 37.77, 10 CFR 40.36(f), 10 CFR 40.41(e), 10 CFR 40.51, 10 CFR 40.61, 10 CFR 40.64, 10 CFR 70.25(g), 10 CFR 70.32(b), 10 CFR 70.42, 10 CFR 70.51,10 CFR 71.5, 10 CFR 71.47, 10 CFR 71.87

Criteria: Service provider licensees who will obtain and possess licensed material must do the following:

- Establish, maintain, and retain written procedures for safely opening packages (10 CFR 20.1906).

- Secure and maintain accountability of licensed material (10 CFR 20.1801, 10 CFR 20.1802, 10 CFR Part 37).

- Maintain records of receipt, transfer, and disposal of licensed material (10 CFR 20.2108, 10 CFR 30.51(a), 10 CFR 40.61(a), 10 CFR 70.51, 10 CFR Part 74).

- 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.

- Conduct physical inventories at intervals not to exceed 6 months (or some other interval justified by the applicant and approved by the NRC) to account for all sealed sources in accordance with license condition.

Discussion: Licensed radioactive material should only be ordered if it is authorized on the license. The radionuclide and chemical form should be commensurate with that listed on the license, and the activity should be within the prescribed license possession limit. Service Provider licensees who will obtain and possess licensed material are required to develop, implement, and maintain written procedures for safely receiving and opening packages, in accordance with 10 CFR 20.1906, "Procedure for receiving and opening packages." Some packages containing licensed material may require special opening procedures, based on the types, quantities, or half-lives of the nuclide being delivered. Arrangements should be made to receive radioactive packages expeditiously when they are delivered to the permanent facility or at temporary jobsites at a customer's facility that will receive packages. Alternatively, arrangements may be made for the applicant to be notified when radioactive packages arrive at the carrier's terminal. 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). A model procedure for safely opening packages containing licensed materials is included in Appendix E of this NUREG. 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.

Licensed material becomes part of the licensee's inventory at the time the licensee received the material, 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 should 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 package expeditiously. Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with 10 CFR 20.1906. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

Individuals that will receive packages containing licensed material should be trained to do the following:

- Identify the package as radioactive 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 his or her staff should retrieve the package and follow the safe opening procedures. If the radioactive material is needed at a customer's location and the package will be transported over public roads by the licensee, it must be repackaged and transported in accordance with DOT regulations (see Appendix J of this NUREG) .

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 8-3, below.

Table 8-3. 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 or Special Form Greater Than Type A†	Radiation Level [20.1906(b)(2)] and Radioactive Contamination [20.1906(b)(1)]	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater Than Type A	Radiation Level [20.1906(b)(2)]	As soon as practicable, but not later than 3 hours after receipt of package

Table 8-3. Package Monitoring Requirements (10 CFR 20.1906)			
Package	**Contents**	**Survey Type**	**Survey Time***
Labeled (White I, Yellow II, Yellow III)	Not Gas or Special Form Less Than 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 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)].

†Type A Quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2, for normal form radioactive material, where A_1 and A_2 are given in Table A–1 of 10 CFR Part 71, or may be determined by procedures described in Appendix A of 10 CFR Part 71.

‡Excepted Packages and limited quantity packages received by many laboratories are required to have the appropriate identification number from the Hazardous Materials Table in 49 CFR 172.101 (i.e., the "UN number") on the outside of the box, identifying it as containing radioactive materials. It is good health physics practices to perform an incoming survey on these packages, even though transportation regulations do not require it.

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 external radiation levels exceed the limits of 10 CFR 71.47, "External radiation standards for all packages" or removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i). The limits are (i) radiation levels exceeding 2 mSv/h [200 mrem/h] at any point on the external surface of the package; and (ii) removable radioactive surface contamination for beta/gamma emitters and low toxicity alpha emitters exceeding 4 Bq/cm^2 [240 disintegrations per minute per centimeter squared (dpm per cm^2)], or for all other alpha emitters 0.4 Bq/cm^2 [24 dpm/cm^2] on the external surfaces of the package.

As illustrated in Figure 8-3, 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 ensure that the possession limits listed on the license are not exceeded.

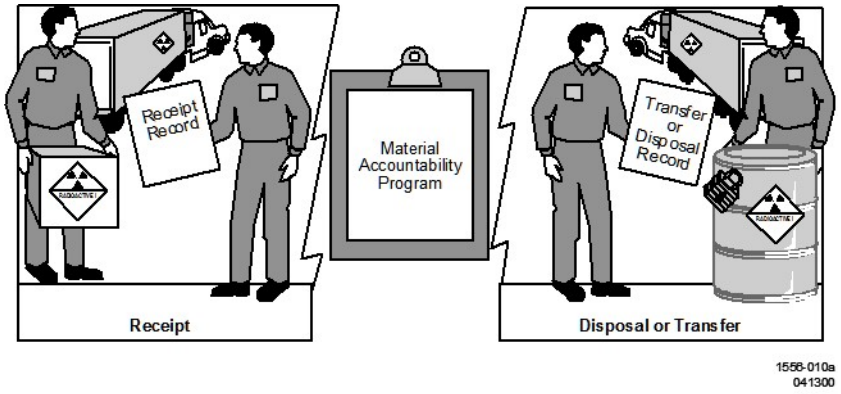


Figure 8-3. Material Receipt and Accountability. *Licensees must maintain records of receipt, transfer, and disposal of licensed material*.

Regulations in 10 CFR 20.1801, "Security of stored material," and 10 CFR 20.1802, "Control of material not in storage," require licensees 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 not in storage. Applicants should establish policies and procedures for ensuring accountability of licensed materials.

Licensed material possessed at customer's facilities may be received by the customer in advance of the service provider licensee performing services. In most circumstances, this material is received and possessed by the customer under the auspices of the customer's license. Service provider licensees must have in place an accountability and control system for promptly detecting missing licensed material at permanent facilities, customer's facilities, temporary jobsites, or any other locations where loss, theft, or misplacement of licensed material can occur. Operating and emergency procedures should address how the applicant will maintain control and accountability of licensed material possessed incident to performing commercial services at customers' facilities.

Licensees who possess Radioactive Material Subject to National Source Tracking System Requirements

Regulations in 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources," require that each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source must complete an National Source Tracking Transaction Report (NSTTR), in order to track high-risk radioactive sources from the time they are manufactured or imported, through the time of their disposal or export, or until they decay enough to no longer be of concern.

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

Inventory and Accountability of Radioactive Materials

Licensees who use or possess sealed sources are required by license condition to perform inventories of sealed sources every 6 months. 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 removed from storage at least every 6 months. Licensees are also required by license condition to conduct leak tests of sealed sources at 6-month intervals (or at longer intervals, as specified in the SSD Registration Certificate). Because the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program.

With regard to unsealed licensed material, licensees may use various methods (e.g., computer programs, manual ledgers, logbooks) to account for the inventory of unsealed materials from the time of receipt, through the use and storage of the unsealed materials, to removal from inventory through transfer, disposal, and radioactive decay. The chosen methods should

ensure that possession limits are not exceeded. Licensees should be able to account for all materials in their possession, regardless of its form (solid, liquid, or gas), its container (stock vial, dispersed in samples, etc.), or its placement into waste in the licensee's laboratory. The licensee should be able to account for the location of all materials possessed, whether the material is located in a secured laboratory cabinet, a locked sample container in a refrigerator or freezer, or in appropriate waste containers awaiting disposal. The RSO should periodically update the total inventory of all unsealed materials possessed under the license. Depending on the how often unsealed materials are received and used, the periodic update may be weekly, monthly, quarterly or at less frequent intervals.

NRC regulations applicable to transfers are provided in 10 CFR 30.41, "Transfer of byproduct material." Sample policy transfer statements are included in Appendix E of this NUREG. 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.

Licensees must maintain records of receipt, transfer, and disposal (as waste) of all licensed material, in accordance with 10 CFR 30.51(a); 10 CFR 40.61(a); and 10 CFR 70.51. Table 8-4 below lists each type of record and how long the record must be maintained. Records for the transfer of licensed material should include verification that the receiver is authorized to possess the licensed material being transferred in accordance with 10 CFR 30.41(c). 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.

Lost Source Policy is the NRC's policy that a civil penalty may be issued for violations resulting in regulated material being out of the control of the licensee, regardless of the use, license type, quantity, or type of regulated material (e.g., loss, abandonment, improper transfer, or improper disposal of regulated material).

Table 8-4. 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 5 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

*See Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning," for more details.

Receipt, transfer, and disposal records must be maintained for the times specified in Table 8-4. Typically, these records contain the following types of information:

- radionuclide and activity (in units of becquerels or curies) of byproduct material in each sealed source
- manufacturer's or distibutor's name, model number, and serial number (if appropriate) of each device containing byproduct material
- location of each sealed source and device
- for inventories, the date of the inventory and name and signature of the individual performing the inventory
- for materials transferred or disposed of, the date of the transfer or disposal, the name and license number of the recipient, and description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number)

Licensed material possessed incident to performing services at customers' facilities is not normally transferred to the service provider during the time service is being performed. One notable exception is when the service provider is preparing the shipment to be shipped and is designated as the shipper of record (i.e., signing the shipper's certification on the shipping paper).

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

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

Response from Applicant:

Provide the following:

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

AND

- If applicable, provided the following statement: "We will comply with the National Source Tracking System (NSTS) reporting requirements 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 inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory."

OR

  — A description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced.

Note:

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

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

References:

- NUREG–1516, "Management of Radioactive Material Safety Programs at Medical Facilities" (1997)

- National Council on Radiation Protection and Measurements (NCRP) Report No. 114, "Maintaining Radiation Protection Records," (1992)[1]

- NCRP Report No. 105, "Radiation Protection For Medical and Allied Health Personnel," (1989)

- NCRP Report No. 127, "Operational Radiation Safety Program," (1998)

- NCRP Report No. 157, "Radiation Protection in Educational Institutions," (2007)

[1]Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Ave., Suite 400, Bethesda, MD 20814-3095, or ordered electronically at http://www.ncrponline.org.

8.10.3 Radiation Monitoring Instruments

Regulations: 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2), 10 CFR 40.32(c), 10 CFR 70.23(a)

Criteria: Licensees must possess and periodically calibrate 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 ensure that an adequate number of calibrated radiation detection and measurement instruments are available to make radiation measurements. Licensees should ensure that when performing work at temporary jobsites, a backup calibrated instrument is readily available if the primary instrument becomes inoperable. Instruments should be calibrated periodically for the types of radiation being measured. In this document, survey instruments are defined as any device used to measure radiological conditions. Figure 8-4 illustrates some common survey instruments used for making contamination surveys and for taking direct radiation measurements.

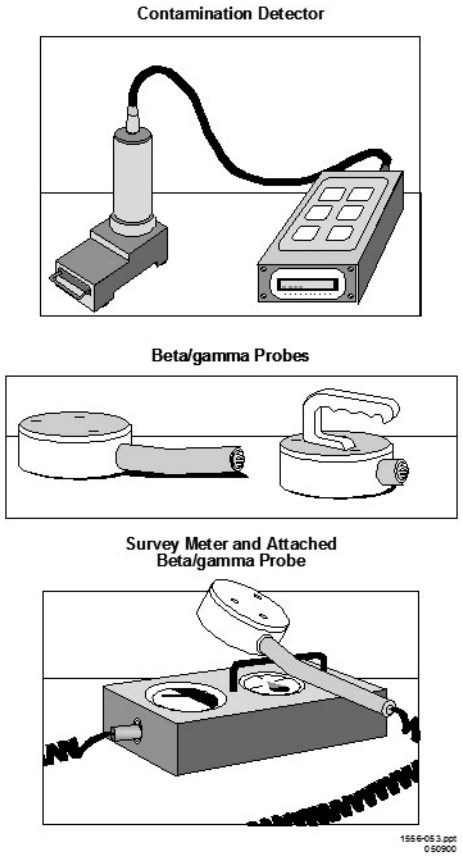


Figure 8-4. Examples of Portable Instruments

Service provider applications should include the following with regard to radiation monitoring instruments:

- criteria used in determining what radiation detection and monitoring equipment will be required for the type of measurement to be taken (e.g., count rate, dose rate)

- type of use

- number and availability of a sufficient quantity of calibrated radiation detection and measurement instruments, such as

    — ion-chambers
    — Geiger-Mueller detectors
    — liquid scintillation counters
    — pocket ionization chambers (PIC)
    — alarming ratemeters
    — area monitors
    — air samplers

NRC regulations require that radiation monitoring devices used to determine compliance with regulatory requirements be calibrated periodically by the licensee. Radiation monitoring devices and personnel dosimetry devices (e.g., PIC, alarming ratemeters) should be calibrated at least annually (every 12 months), unless otherwise specified by regulation or license condition. Applicants or licensees seeking authorization to perform radiation monitoring instrument calibrations should submit procedures for review or commit to implementing the procedure in Appendix F of this NUREG. The licensee may wish to review available industry standards for calibration of instruments such as American National Standards Institute (ANSI) N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts an authorized firm to perform calibrations, the licensee must retain records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made in accordance with 10 CFR 20.2103(a).

Response from Applicant:

Provide one of the following:

- A description of the instrumentation (as outlined above) that will be used to perform required radiological surveys and a statement that, "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F of NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses." We reserve the right to upgrade our survey instruments as necessary."

OR

- A description of the instrumentation (as outlined above) that will be used to perform required radiological surveys and a statement that, "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F of NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials

Licenses: Program-Specific Guidance About Service Provider Licenses." Additionally, we will implement the model radiation survey meter calibration program published in Appendix F of NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider 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. Include a statement that, "We reserve the right to upgrade our survey instruments as necessary."

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

8.10.4 Surveys

Regulations: 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1406, 10 CFR 20.1501, 10 CFR 20.2103, 10 CFR 20.2203, 10 CFR 30.53, 10 CFR 40.63, 10 CFR 70.56

Criteria: 10 CFR 20.1501 and 10 CFR 20.2103 contain general survey and survey recordkeeping requirements. When designing facilities and developing procedures for the safe use of these facilities, licensees should consider how to minimize radioactive contamination during operation, decontamination and decommissioning efforts, and radioactive waste generation. Procedures should address contamination of subsurface soil, drains/piping, and other potentially contaminated, inaccessible areas. Records of surveys and leak-test results must be maintained.

Discussion: Surveys are defined as evaluations of 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 8-5). These evaluations may be measurements (e.g., radiation levels measured with a survey instrument or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. Licensees should also use surveys to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public. In certain cases, environmental monitoring may be required to demonstrate compliance with 10 CFR Part 20. In order to meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, or gamma) and compared to the appropriate regulatory limits.

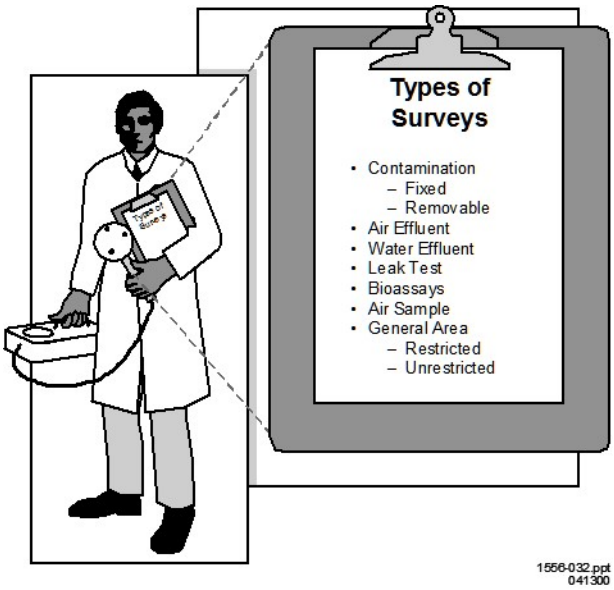


Figure 8-5. Types of Surveys

8.10.4.1 Types of Surveys

Radiation surveys are used to detect and evaluate contamination of

- facilities
- equipment
- personnel (during use, transfer, or disposal of licensed material) (See Figure 8-6)
- restricted and unrestricted areas

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 the following:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment.

- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form and where operations could expose workers to the inhalation or ingestion of radioactive material or where licensed material is or could be released to unrestricted areas.

- Measurements of radioactive material concentrations in water that is allowed by regulation to be 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.

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. Refer to Appendix F of this NUREG for a listing of the types of radiation survey instruments available.

Ambient survey and routine contamination survey frequencies depend 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. NRC regulations do not provide specific limits for surface contamination in restricted areas, only that ALARA considerations must prevail. Each applicant should propose and justify fixed and removable surface contamination limits allowable in a work area before decontamination is required.

8.10.4.2 Contamination Survey Frequency

Personnel working with, in, or around unsealed forms of radioactive material should survey for contamination. Contamination surveys should be conducted at a frequency appropriate to the types and quantities of radioactive materials in use. If the activity used is greater than or equal to the smallest annual limit of intake (ALI) (for either inhalation or ingestion), as identified in

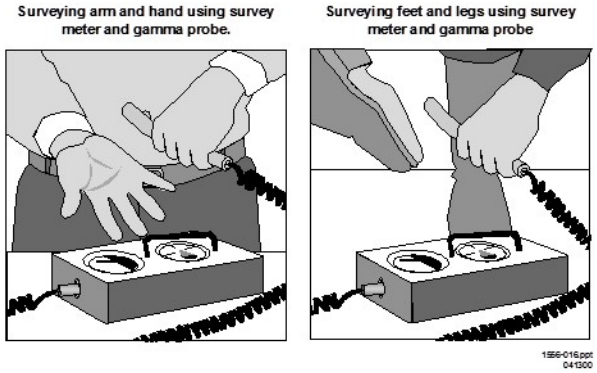


Figure 8-6. Personnel Surveys. *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the laboratory or any area with potential contamination.*

10 CFR Part 20, Appendix B, then documented surveys should be performed at least daily and records retained in accordance with 10 CFR 20.2103, "Records of surveys." Table 8-5 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 8-5. Suggested Contamination Survey Frequency

	< 0.1 ALI	0.1 ALI to < 1.0 ALI	≥ 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months	Every 6 Months	Every 6 Months

8.10.4.3 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 levels specified in NUREG–1757, 'Consolidated Decommissioning Guidance,' Volume 1 'Decommissioning Process for Materials Licensees' and Volume 2 'Characterization, Survey, and Determination of Radiological Criteria' and NUREG–1575 'Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)', including Supplement 1, 'Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)' for unrestricted use. When equipment or facilities that are potentially contaminated are to be released for unrestricted use, surveys should be completed to ensure that the dose rates are in compliance with current decommissioning guidance. Surface contamination surveys should be conducted for both removable and fixed contamination before equipment and facilities are released from restricted to unrestricted use in order to ensure that they meet current decommissioning limits. The following NRC documents provide guidance on unrestricted use release criteria:

NUREG–1757, "Consolidated Decommissioning Guidance," has three volumes that address the following topics:

Volume 1: "Decommissioning Process for Materials Licensees," Revision 2, (ADAMS Accession No. ML063000243)

Volume 2: "Characterization, Survey, and Determination of Radiological Criteria," Revision 1, (ADAMS Accession No. ML06300252)

Volume 3: "Financial Assurance, Recordkeeping, and Timeliness, Revision 1, (ADAMS Accession No. ML12048A683)

Volume 2 of NUREG–1757 provides guidance on compliance with the radiological criteria for license termination in 10 CFR Part 20, Subpart E, using a screening approach dose analysis. Volume 2 contains acceptable license termination screening values of common radionuclides for building-surface contamination, as well as screening values for soil contaminated with radionuclides.

NUREG–1575, Revision 1, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," provides detailed guidance for planning, implementing, and evaluating environmental and facility radiological surveys conducted to demonstrate compliance with a dose- or risk-based regulation. The MARSSIM guidance focuses on the demonstration of compliance during the final status survey following scoping, characterization, and any necessary remedial actions. NUREG 1575 can be found under ADAMS Accession No. ML082470583.

NUREG–1575, Supplement 1, "Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)," is a supplement to MARSSIM. MARSAME provides technical information on approaches for planning, implementing, assessing, and documenting surveys to determine proper disposition of materials and equipment. NUREG–1575, Supplement 1, can be found under ADAMS Accession No. ML090260577.

8.10.4.4 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 test was performed
- background radiation levels with appropriate units
- contamination levels with appropriate units
- make and model number of instruments used, including calibration dates
- name of the person making the evaluation and recording the results and date

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

8.10.4.5 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.

Note: 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 (RG) 8.25, Rev. 1, "Air Sampling in the Workplace," (ADAMS Accession No. ML003739616) for further guidance on air sampling.

8.10.4.6 Airborne Effluent Release Monitoring

Applicants must use procedures and engineering controls to achieve occupational doses and doses to members of the public that are ALARA. To implement ALARA in accordance with 10 CFR 20.1101(d), the applicant must establish a constraint on air emissions of radioactive material, excluding Radon-222 and its daughters, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 millirem per year [0.1 millisievert per year] from these emissions. If this dose constraint is exceeded, the applicant must report the exceedance in accordance with 10 CFR 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive

material exceeding the constraints or limits," and promptly take appropriate corrective action to ensure against recurrence.

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.

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

RG 8.37, "ALARA Levels for Effluents from Materials Facilities," 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 or 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 International Organization for Standardization (ISO) 2889:2010, "Sampling Airborne Radioactive Materials 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".

ISO 2889:2010 sets forth performance-based criteria and recommendations for the design and use of systems for sampling of airborne radioactive materials in the effluent air from the ducts and stacks of nuclear facilities.

ANSI N42.18-2004 provides recommendations for the selection of instrumentation specific to the continuous monitoring and quantification of radioactivity in effluents released to the environment. The effluent streams considered may contain radioactive gases, liquids, particulates, or dissolved solids singly or in combination. This standard specifies detection capabilities, physical and operating limits, reliability, and calibration requirements and sets forth minimum performance requirements for effluent monitoring instrumentation.

8.10.4.7 Liquid Effluent Release Monitoring

The licensee must evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. These releases must meet the limits in 10 CFR 20.1301, "Dose limits for individual members of the public," and 10 CFR 20.2003, "Disposal by release into sanitary sewerage," respectively.

The topic of sanitary sewerage releases is more fully discussed in Appendix M of this NUREG.

Response from Applicant:

Choose one of the following:

- Provide a statement that: "We will conduct surveys and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Section 8.10.4 of NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

OR

- Submit description of alternative survey method and frequency for demonstrating how to evaluate a radiological hazard.

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

References:

- Regulatory Guide 8.20, Revision 2, "Applications of Bioassay for Radioiodine," September 2014 (ADAMS Accession No. ML14064A060);

- Regulatory Guide 8.21, Revision 1, "Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants," October 1979 (reviewed October 2012); (ADAMS Accession No. ML003739577)

- Regulatory Guide 8.32, "Criteria for Establishing a Tritium Bioassay Program" dated July 1988 (reviewed October 2011). (ADAMS Accession No. ML003739479)

- *Federal Register* (76 FR 35564) dated July 17, 2011, a final rule amending Subpart E, "Radiological Criteria for License Termination," and Subpart F, "Surveys and Monitoring," Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection against Radiation."

8.10.5 Leak Tests

Regulations: 10 CFR 30.53, 10 CFR 35.67, 10 CFR 35.2067(a), 10 CFR 39.35, 10 CFR 40.63, CFR 70.56

Criteria: The NRC requires testing of sealed sources containing greater than 3.7 MBq [100 microcuries] of beta/gamma or 0.37 MBq [10 microcuries] of alpha radioactive material, in order to determine whether there is any radioactive leakage from sealed sources. Requirements for leak tests are based on the type of radiation escaping from the inner capsule. Records of test results must be maintained in accordance with license conditions or, if applicable, NRC regulations.

Discussion: Sealed sources and devices that are approved by NRC or an Agreement State and used according to the respective SSD registration certificate usually pose little risk of contamination. Leak tests performed at the frequency specified in the SSD registration

certificate should identify leaking sources. Leaking sources must be withdrawn immediately from use and decontaminated, repaired, or disposed in accordance with the disposal requirements in Subpart K of 10 CFR Part 20. NRC licenses will require the performance of leak tests on sealed sources at intervals approved by NRC or an Agreement State and specified in the SSD Registration Sheet. 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 [0.005 microcuries] of radioactivity.

Manufacturers, distributors, consultants, and other organizations may be authorized by the NRC or an Agreement State to either perform the entire leak test sequence on behalf of licensees or provide leak test kits to licensees. In the latter case, the licensee takes the leak test sample according to the manufacturer's or the kit supplier's instructions and returns it 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. The NRC or an Agreement State may, in a license condition, specifically authorize licensees to conduct the entire leak test sequence themselves. A model leak test procedure can be found in Appendix G of this NUREG.

If the applicant will be providing leak tests as a service to others, the applicant may wish to distribute commercial leak test kits.

Leak test kits should contain the following:

- swabs, wipes, absorbent-tipped sticks that are to be used to make the wipes on the specified sources or devices
- envelopes and vials, where wipe sample will be placed after sample has been taken
- step-by-step instructions for safe use of the particular kit (these instructions will be specific to the types of devices/sealed sources for which the kit is designed)
- procedures for returning the wipes for analysis
- label for the customer to fill out that identifies
    - — customer's name
    - — license number
    - — source or device (by manufacturer, model number, nuclide and activity) wiped
    - — the name of the individual who made the wipes

Response from Applicant:

Provide one of the following:

- A statement that: "Leak tests sample collection and analysis 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."

OR

- A statement that: "Leak testing and analysis will be done by the applicant." Provide the information in Appendix G of this NUREG supporting a request to perform leak testing and sample analysis and either (1) state that the applicant will follow the model procedures in Appendix G of NUREG–1556, Volume 18, Revision 1 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," or (2) submit alternative procedures.

Note: Requests for authorization to perform leak testing and sample analysis will be reviewed on a case-by-case basis and, if approved, the NRC staff will authorize these activities via a license condition.

8.10.6 Occupational Dose

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

Criteria: Each licensee must evaluate the potential exposures of all workers and monitor occupational exposure to radiation when required, and control the occupational dose to individual adults to comply with the dose limits set forth in 10 CFR 20.1201, "Occupational dose limits for adults." If monitoring of occupational doses is required in accordance with 10 CFR 20.1502, then the licensee must determine the occupational radiation dose received during the current year, in accordance with 10 CFR 20.2104, and maintain records of the monitoring, regardless of the actual dose received, in accordance with 10 CFR 20.2106.

Discussion: "Occupational Dose" is defined in 10 CFR 20.1003, "Definitions," as "the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under §35.75, from voluntary participation in medical research programs, or as a member of the public."

The licensee should perform an evaluation of the dose the occupationally exposed individual is likely to receive prior to allowing the individual to receive the dose (prospective evaluation). When performing the prospective evaluation, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. 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. This evaluation need not be made for every individual. Evaluations can be made for employees with similar job functions or work areas. If the prospective evaluation shows that an individual's dose is not likely to exceed 10 percent of any applicable regulatory limit, the individual is not required to be monitored for radiation exposure, and there are no recordkeeping or reporting requirements for doses received by that individual. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. If it was determined that monitoring was not required and a subsequent evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when monitoring was not provided should be

estimated, recorded, and reported. If the prospective dose evaluation shows that the individual is likely to exceed 10 percent of an applicable limit appropriate for the individual (i.e., adult, minor, declared pregnant woman), monitoring is required pursuant to 10 CFR 20.1502. See Appendix I of this NUREG for additional information on providing a prospective dose evaluation for individual members of the public.

Licensees must monitor worker occupational exposures. 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

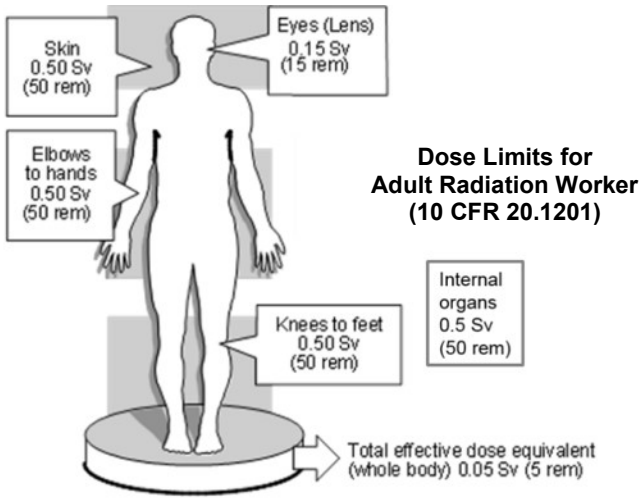
- minors (individuals less than 18 years of age have annual occupational dose limits that are 10 percent of the annual dose limits specified for adults) who are likely to receive an annual dose from sources external to the body in excess of any of the following (each evaluated separately):

  — 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

As defined in 10 CFR 20.1003, a declared pregnant woman is a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The licensee must ensure that the dose to the embryo/fetus of a declared pregnant woman, during the entire pregnancy, does not exceed 5 mSv [0.5 rem]. Licensees are required to monitor declared pregnant women who are likely to receive during the entire pregnancy, from radiation sources external to the body, a deep-dose equivalent in excess of 1.0 mSv [0.1 rem]. All of the occupational dose limits continue to be applicable to the declared pregnant woman as long as the dose to the embryo/fetus is not exceeded.



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

Figure 8-7. Annual Dose Limits for Adult Radiation Workers

To assess and determine external radiation dose, most licensees use either thermoluminescent dosimeters (TLDs) or optically stimulated luminescence dosimeters. In accordance with 10 CFR 20.1501(d)(1), these dosimeters must be processed and evaluated by a laboratory that holds current accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) and is approved to process and evaluate the type(s) of radiation being monitored. The exchange frequency for whole body and extremity dosimeters is generally monthly or quarterly, depending on the scope and extent of services.

Licensees using personnel dosimeters that require processing to determine the radiation dose to comply with the individual monitoring requirement for external doses in 10 CFR 20.1502(a), must use dosimeters supplied by a NVLAP-approved processor. Licensees should verify that the processor is NVLAP accredited and may consult with the processor for its recommendations for exchange frequency and proper use.

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. Licensees must provide individual radiation exposure data to each worker as required by 10 CFR 19.13.

Note: Personnel should be familiar with the survey instruments operation and capabilities before using the instrument at a jobsite.

Internal Radiation Dose:

Internal exposure monitoring is required, pursuant to 10 CFR 1502(b), for:

- adults likely to receive in 1 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 1 year, a committed effective dose equivalent (CEDE) in excess of 1.0 mSv [0.1 rem]

- declared pregnant women likely to receive, during the entire pregnancy, a CEDE in excess of 1.0 mSv [0.1 rem]

Bioassays are required when individuals work with airborne radioactive material in the quantities, chemical and physical forms, and activities that make it likely that the radionuclide will be ingested, inhaled, or absorbed, resulting in an intake in excess of 10 percent of the ALIs in Table 1, Columns 1 and 2, of Appendix B to 10 CFR Part 20.

For guidance on developing bioassay programs and determining internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," and Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses."

Response from Applicant:

Provide one 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 criteria in Section 8.10.6, 'Radiation Safety Program-Occupational Dose' in NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

OR, IN LIEU OF THESE STATEMENTS

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

References:

- The National Institute of Standards and Technology maintains the National Voluntary Laboratory Accreditation Program Directory of Accredited Laboratories at https://ts.nist.gov/standards/scopes/dosim.htm.

- Regulatory Guide 8.7, Revision 2, "Instructions for Recording and Reporting Occupational Radiation Dose Data," November 2005 (ADAMS Accession No. ML052970092).

- Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program," July 1993 (ADAMS Accession No. ML003739554).

- Regulatory Guide 8.20, Revision 2, "Applications of Bioassay for Radioiodine," September 2014 (ADAMS Accession No. ML14064A060)

- Regulatory Guide 8.34, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses,” July 1992 (ADAMS Accession No. ML090770221).

- Regulatory Guide 8.13, Revision 3, “Instruction Concerning Prenatal Radiation Exposure,” June 1999 (ADAMS Accession No. ML003739505).

- IN 2003-12, “Problems Involved in Monitoring Dose to the Hands Resulting from the Handling of Radiopharmaceuticals,” August 22, 2003 (ADAMS Accession No. ML032320470).

- IN 2000-10, “Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits,” July 18, 2000 (ADAMS Accession No. ML003732340).

- IN 2000-16, “Potential Hazards due to Volatilization of Radionuclides,” October 5, 2000 (ADAMS Accession No. ML003753003).

8.10.7 Public Dose

Regulations: 10 CFR 20.1003, 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2107

Criteria: Licensees must do the following to prevent or minimize dose to members of the public:

- 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 one year, and the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour, from licensed operations.

- Ensure 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] in a year from those emissions.

- Control/maintain constant surveillance of licensed material when in use and not in storage.

- Secure stored licensed material from unauthorized access or removal.

Discussion: “Public dose” is defined in 10 CFR 20.1003 as “the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee.” Public dose excludes occupational dose or doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual’s assigned duties and not on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

For guidance about accepted methodologies for determining dose to members of public, please refer to Appendix I of this NUREG.

Members of the public include persons who work in or may occupy locations where licensed material is used or stored. Employees whose assigned duties do not include the use of

licensed material and work in the vicinity where it is used or stored are also included as members of the public. Public dose is controlled, in part, by ensuring that licensed material is secured (e.g., located in a locked area) to prevent unauthorized access or use. Sealed and unsealed materials are usually restricted by controlling access to the keys needed to gain access to storage locations, including storage bunkers. Only the RSO or authorized user should have access to the keys.

Public dose is also affected by the choice of storage and use locations at temporary jobsites. Licensed material must be located so that the resulting public dose in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv [100 mrem] in a year or 0.02 mSv [2 mrem] in any one hour. Applicants should use the concepts of controlling time, distance, and shielding when choosing storage and use locations. Decreasing the time that an individual is exposed, increasing the distance from the radioactive material, and adding shielding that is appropriate for the specific type of radiation (e.g., steel, concrete, lead, hydrogenous materials) will reduce the radiation exposure.

Information provided on anticipated radiation levels of sealed sources and unsealed materials, both inside their respective transport containers and outside the transport container at given distances, is the type of information needed to make public dose calculations. Licensees may assess radiation levels located in adjacent areas to radioactive material either by making calculations or by using a combination of direct measurements and calculations. After obtaining anticipated radiation levels or by making direct radiation measurements using an appropriate survey instrument, an applicant can use the “inverse square” law for point sources to evaluate the effect on the public, and use this information to determine operating and emergency procedures for using radioactive materials. See Appendix I of this NUREG for an example demonstrating that individual members of the public will not receive doses exceeding the allowable public limits.

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

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

(i) inhaled radioactive material
(ii) ingested radioactive material
(iii) external radioactive exposure

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

If, after making an initial public dose evaluation, a licensee changes the conditions used for the evaluation (e.g., relocates radioactive material within a designated storage area, increases the amount of radioactive materials in storage, changes the frequency radioactive material is in use, or changes the occupancy of adjacent areas), the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, if required.

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 specific needs.

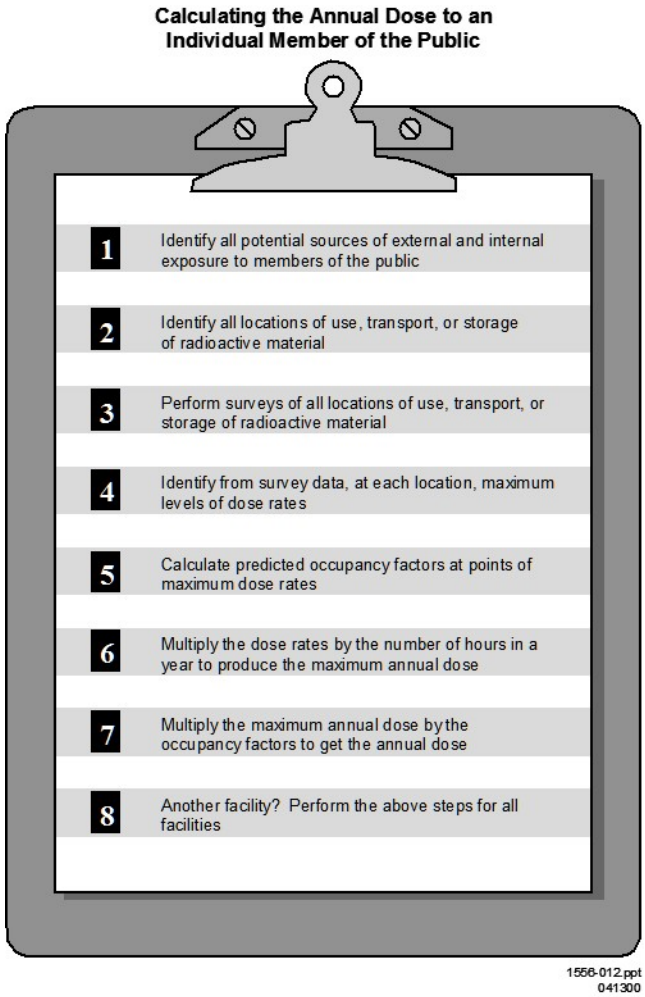


Figure 8-8. Calculating Public Dose. *Steps to calculate the annual dose to an individual member of the public (see Appendix I of this NUREG for more information about occupancy factors).*

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.

During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement, calculation, or a combination of both, that the total effective dose equivalent to any individual member of the public that is likely to receive the highest dose from licensed operations is less than 1 mSv [100 mrem] in 1 year, and any unrestricted area does not exceed 0.02 mSv [2 mrem] in any 1 hour. See Appendix I of this NUREG for examples of methods to demonstrate compliance.

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

8.10.8 Transportation

Regulations: 10 CFR Part 20, 10 CFR 30.41, 10 CFR 30.51, 10 CFR Part 37 (Subpart D), 10 CFR 40.51, 10 CFR 40.61, 10 CFR 70.42, 10 CFR 70.51, 10 CFR 71.5, 10 CFR 71.13, 10 CFR 71.14, 10 CFR 71.17, 10 CFR 71.37, 10 CFR 71.38, 10 CFR 71.47, Subpart H of 10 CFR Part 71, 10 CFR Part 110, 49 CFR Parts 171-178

Criteria: Applicants that will be packaging and transporting licensed material 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: In 10 CFR 71.5, "Transportation of licensed material," the NRC regulations require all licensees who transport radioactive materials outside the site of usage or where transport is on public highways to comply with DOT regulations. Licensees should consider the safety of all individuals who may handle or may come into contact with the transport containers or packages containing licensed material. The primary consideration in packaging licensed material should be to ensure that the package integrity is not compromised during transport, and that the radiation levels or removable contamination levels at the package surfaces meet the regulatory requirements of 10 CFR 71.47, "External radiation standards for all packages." In all cases, ALARA concerns are addressed prior to, during, and after transporting any radioactive material.

Service provider personnel are authorized to prepare packages for shipment at customer facilities. The person signing the Shipper's Certification on the shipping papers is responsible for proper package preparation. If licensed material is transferred from the customer to the service provider's license at the customer's facility, the service provider licensee becomes responsible for subsequent shipment of that material. Under 49 CFR 172.704—"Training requirements," each person (shipper or carrier) involved in the transportation of radioactive materials must receive appropriate training for the jobs the employee performs related to transportation, every 3 years. These jobs include activities such as packaging radioactive materials, loading and securing the package on a vehicle, or preparation of paperwork for shipping the material.

Transporting licensed materials originating at certain facilities (e.g., irradiators) may involve quantities of radioactive material that require a Type B package that involves special requirements. In many cases, this material will be transferred to the service provider's license and the service provider will then be responsible for its shipment. In these cases, the service provider must ensure that the applicant:

- is authorized to possess the licensed material at temporary jobsites (i.e., at the facility in question)
- takes possession of the licensed material that is transferred
- uses an approved Type B package authorized for the material to be transported

- is registered with NRC as a user of the Type B package
- has an NRC-approved quality assurance (QA) plan

The general license requirements of 10 CFR 71.101, "Quality assurance requirements," apply to all NRC licensees that transport, or deliver to a carrier for transport, licensed material in an NRC-approved transport package. For information about QA plans, see RG 7.10, Rev.3, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material." NRC licensees using NRC-approved transport packages are responsible for ensuring that all of these requirements have been met and that they are using currently authorized packages (see list of approved packages in NUREG–0383, "Directory of Certificates of Compliance for Radioactive Materials Packages").

Renewal of these certificates of compliance must be submitted in accordance with 10 CFR 71.38, "Renewal of a certificate of compliance or quality assurance program approval."

Note: Licensees shipping radioactive waste for disposal must prepare the shipment and its shipping manifest, as required by 10 CFR Part 20. Service providers that would like to use one transport package for multiple customers with multiple sources during one transportation trip should discuss this process with the appropriate NRC Region or Agreement State staff.

During an inspection, NRC uses the provisions of 10 CFR 71.5 and a "Memorandum of Understanding with DOT on the Transportation of Radioactive Material" (signed June 6, 1979) to examine and enforce various DOT requirements. See Appendix J of this NUREG for a list of DOT regulations that may be applicable to service provider licensees.

Service providers who may transport licensed material by air outside of the United States may need to comply with the International Air Transport Association regulations (www.iata.org). Service providers may also need to obtain an additional license from the NRC for import and export of licensed material, in accordance with 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material." Service providers should be aware of countries that are listed as embargoed destinations in 10 CFR 110.28, "Embargoed destinations" and as restricted destinations in 10 CFR 110.29, "Restricted destinations."

Note: Service providers must comply with import and export requirements, as specified in 10 CFR Part 110, and obtain the necessary authorizations.

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

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

Response from Applicant: No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials in Type B packages, a

licensee must have registered with the NRC as a user of the package and obtained NRC's approval of its QA program. Transportation issues will be reviewed during inspection.

References: "Radioactive Materials Regulations Review" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at 202-366-2301. The current version of RG 7.10, Rev.3, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material," (ADAMS Accession No. ML14064A505).

8.10.9 Maintenance

Regulations: 10 CFR 20.1101, 10 CFR 21

Criteria: Service providers who perform maintenance as a commercial service to other licensees must maintain devices (e.g., survey instrument calibrators and self-shielded irradiators) according to the manufacturer's written recommendations and instructions and SSD registry, if applicable.

"Routine maintenance" of the device includes, but is not limited to, cleaning; lubrication; and changing batteries, relays, or fuses. "Nonroutine maintenance" is the repair, removal, replacement, or alteration involving activities during which personnel could receive radiation doses exceeding NRC limits. These activities could include maintenance on electrical and mechanical systems that directly control source or shielding movement, the device's shielding or sealed source (e.g., removal), safety interlocks, any component that may affect safe operation of the device, or any other nonroutine maintenance that must be performed by the device manufacturer (or distributor) or a person specifically licensed by the NRC or an Agreement State.

Note: Only a person specifically licensed by the NRC or an agreement state (see comment below) shall install, maintain, adjust, or repair a device that involves work on the sealed source(s) shielding, the source(s) driving unit, or other electrical or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s).

Discussion: Before any maintenance or repair work is performed on licensed devices, the service provider licensee should ensure that:

- The service to be performed is authorized on the service provider's license.
- The manufacturer's and distributor's procedures will be used and followed; otherwise, provide an equivalent procedure that will be used to perform this particular service activity.
- Radiation safety procedures, including the possible need for compensatory measures, are considered.
- ALARA considerations are factored into the activity(ies).
- Only trained and qualified individuals will perform the activity.
- Only approved parts and components will be used.

- All necessary specialized equipment will be available to perform these activities.

- The device will be tested for full operation before it is returned to routine use.

The license will require that nonroutine maintenance be performed by the manufacturer (or distributor) or other persons specifically licensed by the NRC or an Agreement State to perform such services. Applicants seeking authorization to perform nonroutine maintenance should develop and submit specific procedures for review, if they do not have access to the manufacturer's or distributor's procedures. See Appendix K of this NUREG for more information.

Use of replacement parts (nonsafety related):

If an identical original equipment manufacturer (OEM) replacement part cannot be obtained and the maintenance activity does NOT involve work:

- on the sealed source(s) shielding
- on the source(s) driving unit
- on other electrical or mechanical component that could expose the source, or
- that would reduce the shielding around the source(s)
- that could compromise the radiation safety of the device or the source(s)

The service provider may substitute a non-OEM part, provided that it has the same form, fit, and function, and this new part does not invalidate the SSD registration certificate.

EXAMPLE: Replacement Parts NOT critical to safe operations.

A light bulb on the device is not working. The service provider should replace the bulb but does not obtain an OEM bulb. Instead, the service provider obtains a bulb from a local vendor retail store. The bulb is the same wattage and similar in size. The bulb can fit into the socket. When installed, the bulb is operational. The service provider ensures that the bulb met the form, fit and function test. If the bulb was needed to illuminate red as an indicator warning light on the device, the service provider should make sure that the bulb met that function, because the instruction user manual may have pictures or diagrams indicating what to do if a red light is illuminated. Again, the service provider should perform a form, fit, and function test to ensure that the device functioned accordingly.

Use of replacement parts (safety related):

If an identical OEM replacement part cannot be obtained and the maintenance does involve work:

- on the sealed source(s) shielding
- on the source(s) driving unit
- on other electrical or mechanical component that could expose the source, or
- that would reduce the shielding around the source(s)
- that could compromise the radiation safety of the device or the source(s)

The service provider may obtain a part from another vendor or fabricate the part. The service provider should verify that the replacement part will have the commensurate form, fit, and function as the original component and provide this technical information to its customer. The

service provider should instruct its customer to provide the technical information to the NRC or Agreement State for a safety review of the information submitted by the customer, before maintenance activities occur. The service provider must have its customer obtain NRC or Agreement State approval, in accordance with 10 CFR 32.210, to ensure compliance with radiation safety measures of the original equipment BEFORE beginning this service activity.

The NRC approval for the use of non-OEM parts that could affect the safety of the device may be granted through one of two pathways. The service provider's customer may request either (1) a custom SSD registration in accordance with 10 CFR 30.32(g)(1) and 10 CFR 32.210, or (2) an amendment to the license in accordance with 10 CFR 30.32(g)(2).

The custom registration process involves a submission, by the customer, of information similar to that submitted for a new device registration, a full safety evaluation by the SSD registration staff, and the payment of an application fee and annual fees by the customer. The safety review for the license amendment is limited in scope, depending on the replacement parts involved, and is conducted by the technical staff, based on the existing SSD registration certificate. In either case, the service provider will need to assist its customer with the submission by providing details (e.g., description of the part(s), drawings, technical specifications, and the form, fit, and function).

EXAMPLE: Replacement Parts CRITICAL to safe operation

A service provider is replacing a manually operated self-shielded irradiator with a pneumatic tower assembly. The tower was fabricated by another service provider (here referred to as the subcontractor). The subcontractor fabricates and sells a pneumatic tower to the service provider. The service provider should ensure that the subcontractor also provides essential technical specifications, drawings, and other relevant information to the service provider. All of the technical information, including a form, fit, and function assessment, should be provided to the customer by the service provider. The service provider should instruct the customer to send this information to the regulator for a safety review. Once the safety review is complete and the customer receives authorization to change the tower from manual to pneumatic operation, the service provider may proceed with the replacement.

Equipment defects that could create a substantial safety hazard or equipment failures involving NRC-regulated activities must be reported to the NRC in accordance with 10 CFR 21.21 and 10 CFR 30.50. For example, a safety interlock failure for an irradiator/calibrator and a failure of a source retraction mechanism in a high-dose rate (HDR) afterloader are defects that must be reported to the NRC. IN 91-39, "Compliance with 10 CFR Part 21, Reporting of Defects and Noncompliance," dated June 17, 1991, provides additional guidance on determining whether a safety hazard exists and sample procedures for identifying and reporting defects. The Information Notice can be found on the NRC's Generic Communications Web page under Information Notices at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

Response from Applicant:

For performance of routine maintenance, applicants submit either of the following:

- A statement that "We will implement and maintain procedures for conducting routine maintenance of devices according to each manufacturer's (or distributor's) written recommendations and instructions."

OR

- Alternative routine maintenance procedures for the NRC's review.

For performance of nonroutine maintenance, submit the following:

- Before service begins, obtain NRC approval if OEM replacement parts cannot be used for sealed source shielding, the source driving unit, or other electrical or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the device or the source.

AND

- A statement that "We will have the device manufacturer (or distributor) or other person authorized by NRC or an Agreement State perform nonroutine maintenance."

OR

- Provide alternative procedures for the NRC's review addressing the information listed in Appendix K of NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

Note: Alternative procedures submitted by the applicant for performing routine maintenance will be reviewed using the criteria in Appendix K of this NUREG. Information requested in Appendix K will be reviewed on a case-by-case basis. If approved, the license will contain a specific condition authorizing the licensee to perform nonroutine maintenance.

References: IN 91-39, "Compliance with 10 CFR Part 21, Reporting of defects and noncompliance," dated June 17, 1991, can be found on the NRC's Generic Communications Web page under Information Notices at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/ RIS 2013-01 "Use of Aftermarket Sealed Sources Registered under 10 CFR 32.210," issued March 12, 2013 (ADAMS Accession No. ML12313A147)

8.10.10 Audit and Review of Program

Regulations: 10 CFR 20.1101, 10 CFR 20.2102 – 20.2110, 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 that the program:

- is commensurate with the scope and extent of licensed activities
- is compliant with NRC and DOT regulations (as applicable)
- is compliant with the terms and conditions of the license
- maintains occupational doses and doses to members of the public ALARA
- is documented and that appropriate records are maintained for the required duration

Licensees that are subject to the requirements in 10 CFR Part 37 must annually review their access authorization program and security program.

Discussion: Appendix L of this NUREG contains a suggested annual audit checklist that is acceptable to the NRC and is specific to Service Provider licensees who perform activities within the scope of this NUREG. Because all areas indicated in Appendix L 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. For example, licensees do not need to address activities that have not occurred since the last audit.

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 licensees' audit program, licensees should consider including unannounced audits to determine if, for example, Operating and Emergency Procedures are available and are being followed.

It is essential that once problems are identified, comprehensive corrective actions are taken in a timely manner. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," 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 after the record is made, 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: No response required. The licensee's program for auditing its radiation safety program may be reviewed during inspection.

References:

- Inspection Procedure 87126, "Industrial/Academic/Research Programs," September 2005 (ADAMS Accession No. ML052730315)

- IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, (ADAMS Accession ML031060071)

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

8.10.11 Security Program for Category 1 and Category 2 Materials

Regulations: 10 CFR Part 37

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

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

Discussion:

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

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

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

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

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

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

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

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

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

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

Reference:

Regulatory Issue Summary (RIS) 2017-02, "Applicability of Title 10 of the *Code of Federal Regulations* Part 37 to Non-Manufacturing and Distribution Service Provider Licensees," dated February 2017.

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1301, 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 20.2008, 10 CFR 20.2108, 10 CFR Part 20, Appendices B and G, 10 CFR 30.51, 10 CFR 40.61, 10 CFR 61, 10 CFR 70.51

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

Discussion: This section applies to service providers who generate radioactive waste as a result of services operations or provide waste management services to customers. Waste management service may include, but is not limited to, commercial incineration; compaction; solidification/vitrification; and packaging, repackaging, and transportation of radioactive waste. Service providers who perform these activities as a service to other licensees should also refer to Section 8.10.1, "Operating and Emergency Procedures" of this NUREG.

Radioactive waste generated or handled when conducting licensed activities may include contaminated samples, sealed sources, and unusable items contaminated with radioactive material (e.g., absorbent paper, gloves, filters, tools). The applicant may also be called upon to package radioactive waste at customer facilities for disposal. For different types of radioactive waste, consult with radioactive waste brokers to ensure that any waste that was generated will be accepted at a low-level waste disposal facility.

Service providers may not receive radioactive waste from other licensees for processing, storage, or disposal, unless specifically authorized to do so by the NRC. If customers wish to dispose of radioactive waste, including sealed sources, service provider licensees may assist them only by transferring licensed material to any person authorized to possess these materials. Individuals authorized to possess materials include:

- the original manufacturer
- the distributor
- commercial firms licensed by the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material

All radioactive waste must be stored in appropriately labeled containers until it is disposed. During the period between storage and disposal, container integrity must be assured. All radioactive waste must be secured against access or removal by unauthorized personnel.

Licensees may implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay-in-storage (DIS). 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.

In accordance with 10 CFR 20.2001-20.2007, all licensees must dispose of radioactive waste through one of the following methods:

- decay-in-storage
- release into sanitary sewerage
- release in effluents to unrestricted areas, other than into sanitary sewerage
- transfer to an authorized recipient
- disposal of waste as if it were not radioactive (specific wastes)
- extended interim storage
- obtaining prior approval from the NRC of an alternate method

With service provider licensees, the NRC's experience is that most dispose of radioactive waste by transfer to an authorized recipient(s). Applicants requesting authorization to dispose of radioactive waste by incineration should refer to Policy and Guidance Directive PG 8-10, "Disposal of Incineration Ash as Ordinary Waste," dated January 1997.

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 radioactive waste management program. This program should include procedures for handling and storing, characterization and 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 issued guidance for development of a comprehensive program to reduce hazardous waste, including 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.

Disposal by Decay-in-Storage

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

Procedures for management of waste being held for DIS should include methods of segregation according to half-life, surveys prior to disposal, and maintenance of records of disposal. Records should include the date when the waste was put in storage for decay, date of disposal, and results of final survey before disposal as ordinary trash. Appendix M of this NUREG provides a model procedure for disposal of radioactive waste by DIS that incorporates the above guidelines.

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 easily dispersible biological material) in water.

- Quantity of licensed material or other radioactive material that the licensee releases into the sewer each 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 radionuclide 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 and other radioactive material released into the sanitary sewerage system in a year does not exceed 185 gigabecquerel (GBq) [5 Ci] of H-3, 37 GBq [1 Ci] of C-14, and 37 GBq [1 Ci] of all other radionuclides combined.

Licensees are responsible for demonstrating that licensed materials discharged into the public sewerage system are indeed readily soluble in water. NRC IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20," dated January 1994, provides 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." Careful consideration should be given to the possibility of re-concentration of radionuclides that are released into the sewer. The NRC alerted licensees to the potentially significant problem of re-concentration of radionuclides released to sanitary sewage systems in IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted under 10 CFR 20.303 (now 10 CFR 20.2003)," dated December 1984.

The regulations in 10 CFR 20.2003 are not applicable for 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 subject to 10 CFR 20.1301, "Dose limits for individual members of the public." However, if licensed material is released to a private sewage treatment system, septic system, or leach field, the sludge or other solids from these 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 M of this NUREG.

Incineration

Applicants that wish to treat or dispose of licensed material by incineration must comply with the requirements of 10 CFR 20.2004, "Treatment or disposal by incineration." Policy and Guidance Directive PG 8-10, "Disposal of Incineration Ash as Ordinary Waste," dated January 1997, provides guidance on the disposal of ash.

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

After the applicant reviews the program and confirms that the applicant has waste that requires specific NRC approval for incineration, a description of the procedures used to incinerate waste should be provided. A model program for disposal of radioactive waste by incineration is described in Appendix M of this NUREG.

Note: Incinerators must also be authorized by other Federal, State, and local authorities to operate.

Compaction

Licensees may implement procedures to reduce the volume of radioactive waste for final disposal in an authorized LLW disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity or increased radiation levels) to workers, members of the public, and the environment. Safety procedures to address these concerns should be implemented. A model program for disposal of radioactive waste by compaction is described in Appendix M of this NUREG.

Transfer to an Authorized Recipient

When transferring radioactive waste, 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 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. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Disposal of Specific Waste as if It Were Not Radioactive

In accordance with 10 CFR 20.2005, the following radioactive wastes may be disposed of as nonradioactive waste:

- liquid scintillation media (including vials and other items contaminated with liquid scintillation media) containing no more than 1.85 kBq [0.05 mCi] of H-3 or C-14 per gram of the medium

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

Applicants must have procedures that will ensure that the above limits are not exceeded and that the disposal of animal tissue or carcasses containing licensed material is in a manner that will not permit their use either as food for humans or animals. Applicants must maintain accurate records of these disposals, in accordance with 10 CFR 20.2108.

Extended Interim Storage

The NRC does not consider interim or long-term storage as a substitute for final disposal of LLW. 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. Other than DIS, 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 5, 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW. Regulatory Issue Summary 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated May 9, 2008, updates information provided in IN 90-09. In addition, the NRC issued Regulatory Issue Summary 2011-09, "Available Resources Associated with Extended Storage

of Low-Level Radioactive Waste," dated August 16, 2011, which refers to other helpful guidance documents.

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.

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

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

Response from Applicant:

Provide the following:

- A statement that "We will use the model waste procedures published in Appendix M of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.'"

OR

- If the applicant wishes to use only selected model procedures, provide a statement that "We will use the model waste procedures that are published in Appendix M of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.'" (Specify (i) DIS, (ii) disposal of liquids into sanitary sewerage, (iii) incineration, or (iv) compaction.)

AND

- If the applicant wishes to compact or incinerate radioactive waste, provide the requested information concerning these activities in Appendix M of this NUREG.

OR

- Provide procedures for waste management by any of the methods described in Section 8.11, "Waste Management," of this NUREG. Applicants should contact appropriate regional office of the NRC for guidance as to how to obtain approval of any method(s) of waste disposal other than those discussed in this section.

OR

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

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

References:

- Policy and Guidance Directive (PG) 8-10, "Disposal of Incineration Ash as Ordinary Waste," dated January 1997 (ADAMS Accession Nos. ML003744979 and ML 003752866 and Addendum, ADAMS Accession Nos. ML003744984 and ML003744988).

- Information Notice (IN) 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program," dated March 1994.

- IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," dated January 1994.

- IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted under 10 CFR 20.303 [now 10 CFR 20.2003]," dated December 1984.

- IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990.

- Regulatory Issue Summary (RIS) 2008-12, "Considerations For Extended Interim Storage Of Low-Level Radioactive Waste By Fuel Cycle And Materials Licensees," dated May 2008.

- RIS 2011-09, "Available Resources Associated With Extended Storage Of Low-Level Radioactive Waste," dated August 2011.

- RIS 2004-17, Revision 1, "Revised Decay-In-Storage Provisions For The Storage Of Radioactive Waste Containing Byproduct Material," dated September 2005.

- All Agreement State Letter SP-97-056, dated August 1997, "Technical, Solubility Criteria."

- State and Tribal Communication Letter FSME 12-025 dated March 13, 2012 "Clarification of the Authorization for Alternative Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR" (ADAMS Accession No. ML12065A038).

- Division of Waste Management and Environmental Protection, Environmental and Performance Assessment Directorate, Operating Procedures, EPPAD 3.5 (Draft for Interim Use), "Review, Approval, and Documentation of Low-Activity Waste Disposals in Accordance with 10 CFR 20.2002 and 10 CFR 40.13(a)," dated August 2009.

- Regulatory Issue Summary 2016-11, "Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002," November 13, 2016

8.12 Item 12: License Fees

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

Direct all questions about the NRC's fees or completion of Item 12 on 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.

Note: Applicants who wish to perform service operations (e.g., licensees that will repackage radioactive wastes) that require an environmental assessment should review 10 CFR Part 51 (particularly 10 CFR 51.30, 51.60, and 51.66) for further information concerning the environmental information needed by NRC to prepare an environmental assessment. Environmental assessments are full-cost recovery items under 10 CFR Part 170. Full cost will be determined based on the professional staff time and appropriate staff time expended, as described in footnote 3 to 10 CFR 170.31.

Note: 10 CFR 51.22(c)(14)(xii) grants a categorical exclusion for the acceptance of packaged radioactive wastes from others for transfer to licensed land burial facilities, provided the interim storage period for any package does not exceed 180 days and the total possession limit for all packages held in interim storage at the same time does not exceed 50 Curies.

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 regulatory requirements.

9 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date Title 10 of the *Code of Federal Regulations* [10 CFR 2.109(a), 10 CFR 30.36(a), 10 CFR 40.42(a), 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 30.34(b), 10 CFR 40.41, 10 CFR 70.31

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 Title 10 of the *Code of Federal Regulations* (10 CFR) 30.34(b) 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

- the transferee has the financial resources to decommission the license, if necessary
- Public health and safety are not compromised by the use of such materials.

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 (RIS) 2014-08, Rev. 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licensees," dated May 5, 2016 (ADAMS Accession No. ML15181A223). This RIS can also be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

10 APPLICATIONS FOR EXEMPTIONS

Regulations: Title 10 of the *Code of Federal Regulations* (10 CFR) 19.31, 10 CFR 20.2301, 10 CFR 30.11, 10 CFR 40.14, 10 CFR 70.17

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 30.11, "Specific exemptions"; 10 CFR 40.14, "Specific exemptions"; and 10 CFR 70.17, "Specific exemptions"). These regulations state that the NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

Exemptions are not intended to revise regulations or 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) 20.1401, 10 CFR 20.1402, 10 CFR 20.1403, 10 CFR 20.1404, 10 CFR 20.1405, 10 CFR 20.1406, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36, 10 CFR 30.51, 10 CFR 40.36(f), 10 CFR 40.42, 10 CFR 40.61, 10 CFR 70.25(g), 10 CFR 70.38, 10 CFR 70.51

Criteria: The licensee must do the following:

- Notify the U.S. Nuclear Regulatory Commission (NRC), in writing, within 60 days of the occurrence of any of the following:
  - — expiration of its license
  - — a decision to permanently cease principal activities[1] at the entire site
  - — for licensees subject to 10 CFR 30.36, a decision to permanently cease principal activities in any separate building or outdoor area that contains residual radioactivity, such that the building or area is unsuitable for release according to NRC requirements
  - — for licensees subject to 10 CFR 40.42 or 10 CFR 70.38, a decision to permanently cease principal activities in any separate building or outdoor area
  - — no principal activities under the license conducted for a period of 24 months
  - — no principal activities having been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements.
- Submit a decommissioning plan, if required by 10 CFR 30.36(g), 10 CFR 40.42(g), and/or 10 CFR 70.38(g).
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j), 10 CFR 40.42(h) and (j), and/or 10 CFR 70.38(h) and (j).
- Submit to the appropriate NRC regional office a completed NRC Form 314, “Certificate of Disposition of Materials” (or equivalent information), and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final surveys and results of leak tests of sealed sources).

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[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.

- Before a license is terminated, send records important to decommissioning that are required by 10 CFR 30.35(g), 10 CFR 40.36(f) and/or 10 CFR 70.25(g) to the appropriate NRC regional office in accordance with 10 CFR 30.51(f), 10 CFR 40.61(f), and/or 10 CFR 70.51(a)(3), respectively.

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

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

The permanent cessation of principal activities[6] 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.

For information about requirements that apply to the timeliness of decommissioning, see Regulatory Issue Summary (RIS) 2015-19, Rev. 1, "Decommissioning Timeliness Rule Implementation and Associated Regulatory Relief," dated September 27, 2016 (ADAMS Accession No. ML16008A242), which can also be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": https://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2015/.

For guidance on the disposition of licensed material, see Section 8.11, "Waste Management." For guidance on decommissioning records, see Section 8.5.3, "Recordkeeping for Decommissioning."

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

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

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

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

Reference: NRC Form 314 is available at 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 (06-2016) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40 — **U.S. NUCLEAR REGULATORY COMMISSION**

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **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 FOIA, Privacy, and Information Collections Branch (T-5 F53), 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

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 MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

BUSINESS TELEPHONE NUMBER | BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL 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 $ ____

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 CONTANED 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 (06-2016)

APPENDIX B

SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN ITEMS 5 THROUGH 11 OF NRC FORM 313

Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313

Appendix B is designed to be used for all types of applicants requesting a service provider license. All applicants should complete Tables B–1 through B–4, as applicable.

After selecting the applicable items that need to be addressed, refer to the corresponding sections in the NUREG. It is necessary for applicants to provide the level of detail required for the individual types of service(s) requested in the application. Note that providing information for very limited licenses (e.g., leak-test service provider) requires less information than would be required for a commercial nuclear laundry or a waste management license. Applicants for service provider licenses requiring authorization for types and quantities of material specific for broad scope licenses should refer to NUREG–1556, Vol. 11, "Consolidated Guidance About Material Licenses: Program-Specific Guidance About Licenses of Broad Scope." Applicants for service provider licenses requiring authorization for research and development should refer to NUREG–1556, Vol. 7, "Consolidated Guidance About Material Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers."

Table B–1. Items 5 & 6: Unsealed Radioactive Materials To Be Possessed and Proposed Uses						
Unsealed Radionuclide	**Chemical or Physical Form**				**Total Activity Requested**	**Use Code***
	❒ Gas	❒ Liquid	❒Solid	❒ Other: Specify		
	❒Gas	❒ Liquid	❒Solid	❒ Other: Specify		
	❒Gas	❒ Liquid	❒Solid	❒ Other: Specify		
	❒Gas	❒ Liquid	❒Solid	❒ Other: Specify		

Is the applicant going to possess, or take possession from its clients of, unsealed radionuclides? Provide a response and explain.

❒ Yes ❒ No Explain:

Table B–2. Items 5 & 6: Sealed Radioactive Materials To Be Possessed and Proposed Uses					
Radionuclide (Sealed Source)	**Device Manufacturer and Model No.**	**Sealed Source Device Registration No.**	**Maximum Activity per Source**	**Total Source Activity**	**Use Code**

Is the applicant going to possess, or take possession from its clients of, sealed radionuclides and/or devices? Provide a response and explain.

❒ Yes ❒ No Explain:

Table B–3. Items 5 & 6: Source and Special Nuclear Materials To Be Possessed and Proposed Uses				
Source Material				
	Material	Mass	Activity	Use Code*
❒	Depleted Uranium	Kilograms	MBq (mCi)	
❒	Uranium-238	Grams	MBq (mCi)	
❒	Thorium-232	Grams	MBq (mCi)	
❒	Other: Specify	Grams	MBq (mCi)	
Special Nuclear Material				
❒	Uranium-234	Grams	MBq (mCi)	
Special Nuclear Material				
	Material	Mass	Activity	Use Code*
❒	Uranium-235	Grams	MBq (mCi)	
❒	Plutonium-238	Grams	MBq (mCi)	
❒	Plutonium-239	Grams	MBq (mCi)	
*Use code represents the purpose for which licensed material will be possessed or used. Use codes are provided below				

Use Code* Low-Risk Activities:

A. analysis of Leak-Test Samples (no collection)

B. analysis of Environmental Samples (no collection)

C. sample Collection and Analysis of Leak Tests

D. sample Collection and Analysis of Environmental Samples

E. calibration of instrument/dosimeter using low-activity sources

F. service/repair of gas chromatographs, X-ray fluorescence analyzers, and/or similar devices

G. training/instruction to individuals on radiation safety-related topics

H. other low-risk services not identified above, where radioactive material is used for commercial service activities

Use Code* High-Risk Activities:

I. service and/or repair of portable nuclear gauges (including removal of source rod)

J. service and/or repair of fixed gauges

K. service and/or repair of fixed gauges mounted on a mobile object, like a truck or railcar

L. storage of radioactive material for other entities

M. use of unsealed material in tracer studies (e.g., use inside pipes in a refinery)

N. use of remote activated robotics in radioactive contaminated areas

O. calibration of survey instruments and personnel dosimetry equipment as a service for others.

P. installation, radiation surveys, routine and preventive maintenance, adjustment or repair of high-dose rate (HDR) remote afterloaders, teletherapy, or gamma stereotactic radiosurgery units that require access to the sealed source(s), driving units, or other electronic components that could expose the sealed source, reduce the shielding, or compromise the radiation safety of the device or safety systems

Q. installation, relocation, removal from service, disposal, radiation surveys, routine or preventive maintenance, adjustment, training, or repair of

(1) self-shielded irradiators [American National Standards Institute (ANSI) Category I irradiators].

(2) Title 10 of the *Code of Federal Regulations* (10 CFR) Part 36 irradiators (ANSI Categories II, III, and IV irradiators)

R. nuclear laundry services

S. retrieval of industrial radiography sealed sources

T. decontamination and decommissioning services (NUREG–1757, Volume 1)

U. waste management services, including, packaging and repackaging of radioactive waste for transportation, commercial incineration, compaction, super compaction, solidification, or vitrification

V. other high-risk services not identified above, excluding activities involving critical mass quantities of special nuclear material

If the applicant desires to perform tracer/field studies in which licensed material is deliberately released to the environment, please provide the following information:

- a complete application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material
- a copy of the applicant's operating and emergency procedures
- a description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment, if appropriate, and procedures for minimizing releases
- a description of the expected radiation dose to humans
- a sample agreement letter between the applicant and the applicant's customer acknowledging the use of radioactive materials at the customer's site.
- a letter from the appropriate state health authorities, indicating that they have reviewed the applicant's application and concur with the applicant's request

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
	RADIOACTIVE MATERIAL				
5.3	**Recordkeeping For Decommissioning** Provide the following statement: Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), and 10 CFR 70.51(b)(3), as appropriate, we will maintain drawings and records important to decommissioning and will transfer these records to an NRC or Agreement State licensee before licensed activities are transferred. Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and 10 CFR 70.51(a), as appropriate, prior to license termination, we will forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), as appropriate, to the appropriate NRC regional office or to assign the records to the appropriate NRC regional office before the license is terminated."	❒			
5.4	**Financial Assurance** Financial assurance is not required for most service provider applicants. If the applicant is going to possess radioactive material but wants to keep the possession limits below the requirements for financial assurance, commit to the following statement: "We shall restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 10 CFR 40.36(b), and/or 10 CFR 70.25(d) for establishing decommissioning financial assurance." **OR** If financial assurance is required, submit evidence of financial assurance following the guidance in NUREG–1757, Volume 3.	❒		❒ ❒	❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
5.5	**Emergency Plans** **Low Risk Activities**: The applicant is not required to submit a response to emergency plans during the licensing process. If an emergency plan is required as described in 10 CFR 30.32(i), provide either: An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv [1 rem] effective dose equivalent or 0.05 Sv [5 rem] to the thyroid; **OR** An emergency plan for responding to the release that contains the information specified in 10 CFR 30.32(i)(3).			❒ ❒ ❒	 ❒ ❒
7	**Individual(s) Responsible For Radiation Safety Program And Their Training Experience**				
7.1	**Radiation Safety Officer** Provide the name of the proposed RSO who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures. **AND** Demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position and demonstrating day-to-day oversight of the radiation safety activities. **AND** Confirm that the RSO will be available for emergencies and can be on-site within 24-48 hours, if applicable. **AND**				❒ ❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
7.1	**Radiation Safety Officer** Provide the specific training and experience of the RSO, and include the specific dates of training in radiation safety. Provide alternative information demonstrating that the proposed RSO is qualified by training and experience (e.g., Board Certification by the American Board of Health Physicists, completion of a bachelor's and/or master's degree in the sciences with at least one year of experience in the conduct of a radiation safety program of comparable size and scope). **OR**				❒ ❒
7.2	**Authorized Users And Radiation Workers** Provide either of the following: A statement that: "Before using licensed material, authorized users will receive the training described in Appendix D of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.'" **OR** A description of the training and experience for proposed authorized users. **AND** A description of the radiation safety training involving the use of licensed material that will be provided as a service to customers, if training is provided by the service provider.	❒	❒		 ❒ ❒
8	**Training For Individuals Working In Or Frequenting Restricted Areas** Provide either of the following: A statement that: "Before working in the vicinity of licensed materials, personnel will have successfully completed training commensurate with assigned duties." **OR**	❒	❒		

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
8	**Training For Individuals Working In Or Frequenting Restricted Areas** 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 refresher training.				❒
9	**Facilities And Equipment** **Low Risk Activities**: For service providers performing low-risk activities, no facility description is required. Provide the location where these services will be performed. **AND** Indicate if services will be performed at temporary jobsites. No facility description is required. **High Risk Activities**: For service providers performing the high-risk activities that will not take possession of radioactive material, provide the location where these services will be performed. Also indicate if services will be performed at temporary jobsites. **OR**				❒ ❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
9	**Facilities And Equipment** For those services listed in the **high-risk group** where permanent facilities are specifically identified on the license, provide the following information, as applicable to the service the applicant intends to perform: Submit a drawing or sketch of the proposed permanent facility that fulfills the following requirements: 1. Identify area(s) assigned for the receipt, storage, security, preparation, handling, waste storage, and measurement of radioactive materials, including sealed sources and devices. 2. Show the relationship and distance between restricted areas and adjacent unrestricted areas. 3. Indicate the scale, or include dimensions on each drawing or sketch. The same scale should be used for all sketches and drawings. The recommended scale is 1/4 inch = 1 foot. Drawings to this scale that do not fit on 8-1/2 x 11-inch paper may be provided as sectional drawings. Please also include a compass directional arrow to indicate “North.” 4. Specify shielding materials (e.g., concrete, lead) and means for securing radioactive materials from unauthorized removal. 5. Illustrate area(s) where explosive, flammable, or other hazardous materials may be stored; 6. Identify area(s) where radioactive materials may become airborne. The diagram should contain descriptions of the ventilation systems, with pertinent airflow rates, filtration equipment, sample collection points, and monitoring systems;				❒ ❒ ❒ ❒ ❒ ❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
9	**Facilities and Equipment** 7. Identify specialized handling tools, facility safety interlocks designed to prevent operation of radiological safety systems, in the event that operation of a system could result in accidental exposure or release of material [e.g., high efficiency particulate air (HEPA) filters, ventilation system, safety door interlocks, etc.] or equipment; 8. Identify radioactive waste handling equipment that includes, for example, incinerators, compactors, solidification equipment, hold-up tanks, and sample collection points; In addition, describe: 1. Engineered safety systems (e.g., area monitors, interlocks, alarms); 2. Protective clothing (such as latex or rubber gloves, lab coats or coveralls, respirators, booties, and face shields), auxiliary shielding, absorbent materials, secondary containers for wastewater storage for decontamination purposes, plastic bags for storing such items as contaminated items, etc., that will be available for use when handling unsealed or uncontained radioactive materials; 3. The general location of each proposed permanent facility (e.g., an industrial park, an office complex) and its current use. If any proposed permanent facility is a private residence, provide diagrams of the installation that include the building, the proposed restricted area or areas, and adjacent areas, including above and below the restricted areas; provide commitments that restricted areas do not include residential quarters, and explain how radiation levels in unrestricted areas will be maintained at less than 1 mSv [100 mrem] per year.				❒ ❒ ❒ ❒ ❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
9	**Facilities and Equipment** 4. The proposed nuclear laundry facilities, if applicable, used for contaminated protective equipment and clothing. Specify how the contaminated waste water from the laundry machines or sinks is disposed. Operating and emergency procedures should address decontamination of the laundry area and equipment.				❒
10	**Radiation Safety Program**				
10.1	**Operating and Emergency Procedures** **Low Risk Activities**: Applicants who perform low-risk licensed activities are not required to submit operating procedures but should provide emergency procedures for all likely scenarios. **High Risk Activities**: Applicants who perform high-risk licensed activities should submit their operating and emergency procedures for radiological conditions that might be encountered as part of their license application.				❒ ❒
10.2	**Material Receipt and Accountability** Provide the following statement: "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times." **AND** Provide the following statement, if applicable: "We will comply with the National Source Tracking System (NSTS) reporting requirements, as described in 10 CFR 20.2207." **AND**	❒ ❒		❒	

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
10.2	**Material Receipt and Accountability** 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 inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory." **OR** A description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced.	❒	❒		❒
10.3	**Radiation Monitoring Instruments** **Provide one of the following:** Describe the instrumentation that will be used to perform the required radiological surveys and state that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.' We reserve the right to upgrade our survey instruments as necessary." **OR** Describe the instrumentation that will be used to perform the required radiological surveys and state, "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.' Additionally, we will implement the model radiation survey meter calibration program published in Appendix F of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.' We reserve the right to upgrade our survey instruments as necessary."	❒ ❒	❒ ❒	❒	❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
	OR				
10.3	**Radiation Monitoring Instruments** Describe alternative equipment and/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. Include a statement that: "We reserve the right to upgrade our survey instruments as necessary."	❒	❒		❒
10.4	**Surveys** Choose one of the following: Provide the following statement: "We will conduct surveys and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Section 8.10.4 of NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."" **OR** Submit a description of an alternative survey method and frequency for demonstrating how to evaluate a radiological hazard.	❒		❒	❒
10.5	**Leak Tests** Provide one of the following: A statement that: "Leak tests sample collection and analysis 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 tesing services." **OR**	❒	❒		

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
10.5	**Leak Tests** A statement that: "Leak testing and analysis will be done by the applicant." Provide the information in Appendix G of this NUREG supporting a request to perform leak testing and sample analysis, and either (1) state that the applicant will follow the model procedures in Appendix G of NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses, or (2) submit alternative procedures.	❒	❒		❒
10.6	**Occupational Dose** Provide one 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 criteria in the Section 8.10.6, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."" **OR,** **IN LIEU OF THESE STATEMENTS** Provide a description of an alternative method for demonstrating compliance with the referenced regulations.	❒ ❒	❒ ❒		 ❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
10.7	**Public Dose** No response is required from the applicant in a license application, but compliance will be evaluated during inspection.				
10.8	**Transportation** No response is needed from applicants during the licensing phase. Transportation issues will be reviewed during inspection.				
10.9	**Routine Maintenance** Provide either of the following: A statement that: "We will implement and maintain procedures for conducting routine maintenance of devices according to each manufacturer's (or distributor's) written recommendations and instructions." **OR** Provide alternative routine maintenance procedures for NRC's review.	❒		❒	❒
10.9	**Nonroutine Maintenance** Provide the following: Obtain prior NRC approval, if OEM replacement parts cannot be used, for sealed source shielding, the source driving unit, or other electrical or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the device or the source **AND**	❒		❒	

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
10.9	**Nonroutine Maintenance** A statement that: "We will have the device manufacturer (or distributor) or other person authorized by NRC or an Agreement State to perform nonroutine maintenance of devices." **OR** Provide alternative procedures for the NRC's review addressing the information listed in Appendix K of NUREG–1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."	❒			❒
10.10	**Audit and Review of Program** No response is needed from applicants during the licensing phase. The licensee's program for auditing its radiation safety program may be reviewed during inspection.				
10.11	**Security Program for Risk Significant Radioactive Material** Licensees must ensure the security and control of licensed material. In addition, 10 CFR Part 37 describes increased security measures for certain types and amounts of radioactive material. No response is required from the applicant or licensee. Compliance with access authorization and security program requirements may be reviewed during NRC inspections.				

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
11	**Waste Management** Provide the following: A statement that: "We will use the model waste procedures published in Appendix M of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.'" **OR** If the applicant wishes to use only selected model procedures, provide a statement that: "We will use the model waste procedures that are published in Appendix M of NUREG–1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses'" (specify below); (1) Decay-In-Storage (2) Disposal of Liquids Into Sanitary Sewerage (3) Incineration (4) Compaction **AND** If the applicant wishes to compact or incinerate radioactive waste, provide the requested information concerning these activities in Appendix M of this NUREG. **OR** Provide procedures for waste management by any of the methods described in Section 8.11, "Waste Management" of this NUREG. Applicants should contact the appropriate regional office of the NRC for guidance as to how to obtain approval of any method(s) of waste disposal other than those discussed in this section.	❒ ❒ ❒ ❒ ❒ ❒	❒ ❒ ❒ ❒ ❒ ❒		 ❒ ❒

Table B–4. Items 5.3 through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)					
Item Nos.	**Title and Criteria**	**Yes**	**No**	**N/A**	**Description Attached**
11	**Waste Management** **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.	❒	❒		❒

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 and compliance with the U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Transportation (DOT) regulations and the conditions of the license. Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the radiation safety officer (RSO) considers unsafe are stopped.
- Radiation exposures are kept as low as is reasonably achievable (ALARA).
- Up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed.
- All activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used are overseen.
- 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 U.S. Nuclear Regulatory Commission (NRC) or an Agreement State.
- Any incidents are investigated and any emergencies are responded to.
- Availability to serve as a point of contact for the NRC's, Agreement State's, and licensee's management during routine operations, emergencies, or incidents.
- Proper authorities of incidents, such as damage to sealed sources/devices, loss of licensed material, fire, theft, etc are notified.
- Investigation of unusual occurrences, identify cause(s) and appropriate corrective action(s), and take timely corrective action(s) to prevent recurrence.
- Properly secure licensed radioactive materials.
- 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.
- 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.
- Identification of 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.

- 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."

- Licensed material is transported in accordance with all applicable NRC and DOT requirements.

- Understanding of and maintenance of 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.

- Amendment and renewal requests are submitted in a timely manner.

- All areas in which radioactive material is used are monitored and surveyed.

- The inventory and leak testing of sealed sources is performed/overseen.

- The inventory and calibration of radiation survey instruments is performed/overseen.

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

- 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 are overseen.

- Individuals involved with using radioactive materials are properly trained and evaluated.

- The radioactive waste disposal program, including effluent monitoring and record-keeping on waste storage and disposal records is supervised and coordinated.

- Licensed material is disposed of properly.

- The storage of radioactive material not in current use, including waste, is overseen.

- An inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license is maintained.

- Decontamination and recovery activities are overseen.

- Periodic audits are performed, 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.

- 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.

- 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.

- 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.

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

- 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 notice is posted indicating where these documents can be examined.

Model Delegation of Authority

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

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

_____ _____
Signature of Management Representative Date

I accept the above responsibilities,

_____ _____
Signature of Radiation Safety Officer Date

cc: Affected department heads

APPENDIX D

CRITERIA FOR ACCEPTABLE TRAINING AND EXPERIENCE FOR AUTHORIZED USERS

Criteria for Acceptable Training and Experience for Authorized Users

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) 30.51(b) and be available for inspection.

Frequency of Training

Training should be completed:

- 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)
  - — As low as is reasonably achievable (ALARA) concept
- Radiation Detection Instruments:
  - — Operation
  - — Calibration
  - — Limitations of radiation survey 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
- U.S. Nuclear Regulatory Commission (NRC) regulations (10 CFR Parts 19 and 20)
- NRC regulations (10 CFR Parts 21, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, and 71) 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 is 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 and/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 E

MATERIAL ORDERING AND PACKAGE RECEIPT AND OPENING

Material Ordering and Package Receipt and Opening

The radiation safety officer (RSO) will approve or place all orders for radioactive material and will ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded. The RSO should be aware of how much licensed material is actually possessed, as opposed to the licensed possession limits. The licensed inventory includes all radioactive materials in use, in storage, and in waste. The regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 30.51, 40.61, 70.51 and 10 CFR Part 74 require the licensee to maintain records of receipt, transfer, and disposal of all licensed materials.

Sample Model Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.

- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the Radiation Safety Office (or designated receiving area).

- If radioactive material will be held at an alternate location (for example, a carrier's holding facility) or shipped directly to the service provider's customer's location, the RSO will ensure that the package is received properly.

- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

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

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

Radiation Safety Officer (RSO): _____
Office Phone: _____
Business Cell Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package remain until the RSO responds to monitor the package to determine if additional surveys are required of the vehicle or personnel.

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

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

Name _____

Phone _____

For additional information on worker training, see Section 8.8, “Training for Individuals Working In or Frequenting Restricted Areas.”

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

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

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

Sample Procedure for Safely Opening Packages Containing Licensed Materials

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

- Wear gloves to prevent hand contamination.

- Visually inspect the package for any sign of damage (e.g., crushed, punctured). If damage is noted, stop and notify the RSO.

- Monitor the external surfaces of a labeled package, according to specifications in Table 8-3, "Package Monitoring Requirements," Section 8.10.2 of this NUREG.

- Check U.S. Department of Transportation (DOT) White I, Yellow II, or Yellow III label or packing slip for activity of contents, to ensure that the shipment does not exceed license possession limits.

- Open the outer package (following supplier's directions, if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on the bottle or other container). Check integrity of the final source container (e.g., inspect for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). If anything is found other than what was expected, stop and notify the RSO.

- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash.

- Maintain records of receipt, package survey, and wipe test results.

- Notify the final delivery carrier and, the NRC Operations Center at 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."

Sample Transfer Policy Statement

Internal Transfers

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

External Transfers

Licensed material should not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers and shipments must be packaged and labeled in accordance with DOT, NRC, or U.S. Postal Service Regulations, whichever is applicable. If licensed material is possessed at a customer's facility incident to performing services, this material will not be transferred to the service provider unless the service provider will be preparing it to be shipped AND will be the shipper of record (i.e., signing the Shipper's Certification on the shipping paper.) Prior to any transfer from the license, the licensee must

verify that the recipient is authorized to receive the licensed material, as required by 10 CFR 30.41, 40.51 and 70.42.

Donations

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

APPENDIX F

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

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

The specifications in Table F–1[1] will help applicants and licensees choose the proper radiation-detection equipment for monitoring the radiological conditions at their facilities or jobsites. 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[2]

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-Ray	micro-Roentgen to Roentgen	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 percent
Sodium Iodide (NaI) Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
BF_3 Proportional Tube*	Neutron	Thermal Neutron	High
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
Liquid Scintillation Counter*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High

[1]Table from "The Health Physics and Radiological Health Handbook, Revised Edition," edited by Thomas E. Johnson and Brian K. Birky, 2012 (except for * items).

[2]Instruments used to measure radiological conditions at licensed facilities or jobsites.

Table F–1. Typical Survey Instruments[2]			
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
	Gamma	All energies	< 1 percent

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 to make measurements at the required level. This is particularly important for measurements such as leak-test samples and bioassay measurement, and for decommissioning of facilities or equipment. The "minimum detectable activity" (MDA) for the applicant's instrument should be a fraction (10 to 50 percent) of the criteria the applicant must meet.

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

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

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

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

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

This simplified equation is:

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

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

Example:

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

background count rate (bkg) = 300 cpm
sample counting time (t) = 1 min
background counting time (t) = 1 min
efficiency (E) = 0.15 c/d

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

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

For example, suppose the above measurement was made with a radiation survey meter probe with a surface area of 15 square centimeters (cm^2); then the MDC would be calculated as follows:

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

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

Model Radiation Survey Instrument Calibration Program

Training

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

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and the use of radiation detection instruments
- mathematics related to the use and measurement of radioactivity
- biological effects of radiation

- On-the-job training will consist of the following:
  - observing authorized personnel performing radiation survey instrument calibration
  - conducting radiation survey meter calibrations under the supervision and in the physical presence of an individual 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. Posting as a radiation area also may be required by Subpart J of 10 CFR Part 20.
- Depending on the type of calibrator or irradiator source used for calibration, the device and facilities may fall under the regulations on 10 CFR Part 36, “Licenses and Radiation Safety Requirements for Irradiators,” and require interlocks and alarms. Review NUREG–1556, Vol. 5, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses” and Vol. 6, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses,” for additional guidance.

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 radiation 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 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.

Calibration of Surface Contamination Measurement Instruments

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

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

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

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

Analytical instruments used to determine radioactivity in a sample may be specialized equipment according to the type of samples to be analyzed and the types and quantities of radioactivity to be measured. Typically, the sample sizes and activities are very small, and can be difficult to measure. Sample collection and preparation may differ for the various analytical instruments, so manufacturer procedures and industry standard practices should be followed. Such analytical instruments should be calibrated in accordance with the manufacturer's

instructions. Analytical instruments typically require routine maintenance and verification procedures to ensure that they are operating properly when used.

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

Calibration Records

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

- the owner or user of the radiation survey instrument
- a description of the radiation survey instrument, 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 as to 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

Service providers who will perform calibrations as a commercial service will also include their company name and radioactive materials license number on the calibration certificate.

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 (Regulatory Guide 8.25, Rev. 1, “Air Sampling in the Workplace”).

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

- Routine instrument maintenance should be performed as recommended by the manufacturer.

- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit for Measurement of Air Sample Volume

Most methods of calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has been calibrated against a primary standard.

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

E_C: The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)[3]

E_S: Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading.)

E_t: The percentage error in measurement of sampling time that should be kept within 1 percent.

E_V: The most probable value of the cumulative percentage error in the determination of the total air volume sampled. E_V can be calculated from the following equation, provided there are no additional significant sources of errors:

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

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

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

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

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

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

where V_s = volume at standard pressure and temperature (760 mm Hg and 273° K)
V_1 = volume measured at conditions P_1 and T_1
T_1 = temperature of V_1 in K
P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

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

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[3]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, licensees should include an additional error term in the calculation above.

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 and Radiological Health Handbook, 4th Edition.
  Edited by Thomas E. Johnson and Brian K. Birky, dated 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

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 for beta-emitters, gas-flow proportional counters for alpha-emitters].

- If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) will be determined. 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

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

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

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

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

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

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

Frequency for Conducting Leak Tests of Sealed Sources

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

Leak Testing Kits

Leak-test kits will contain

- for example, swabs, wipes, absorbent-tipped sticks, that are to be used to make the wipes on the specified sources or devices
- for example, envelopes, vials, where the leak-test sample will be placed after the sample has been taken
- step-by-step instructions for safe use of the particular kit (these instructions will be specific to the types of devices/sealed sources that the kit is designed)
- procedures for shipping the sample for analysis
- a label that contains the following information:
  - — customer's (or Company) name
  - — license number
  - — date leak test was taken

— source or device (by manufacturer, model number, nuclide and activity)
— the name of the individual who performed the leak test

Procedure for Performing Leak Testing and Analysis

- Either use a leak test kit or, for each sealed source to be tested, list identifying information such as the manufacturer's name, model number, sealed source serial number, radionuclides, and activity of the sealed source.

- 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 Bq [0.005 microcuries] 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 efficiency.

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

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

- Count each wipe sample; determine net count rate.

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

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

- Sign and date the list of sources, data, and calculations. Retain records for 3 years [under Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2103(a)].

- If the wipe test activity is 185 Bq [0.005 microcurie] or greater, notify the radiation safety officer (RSO) so that the source can be withdrawn from use and disposed of properly. Also, notify the U.S. Nuclear Regulatory Commission (NRC) in accordance with the conditions of the license.

Example Notification for a Leaking Source:

Name and mailing address of customer

NRC Regional Office address

Re.: Notice of Leak Test Exceeding 0.005 microcuries [185 becquerels]

Dear Sir or Madam:

Per the requirements of our NRC materials license <insert license number>**,** I am notifying your office of a sealed source that has exhibited a wipe in excess of 0.005 microcuries [185 becquerels]. The wipe was detected during a scheduled 6-month wipe of our sealed sources used in the laboratories/room at the address below. The instrument housing the sealed source was removed from service.

Following is information provided in accordance with the requirements outlined in 10 CFR 30.50 (c)(2).

A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned.

The high wipe was determined during a routine 6-month wipe of sealed sources. The initial wipe result was <insert activity> microcuries on the <insert location wipe tested>. The high wipe was reported to the RSO by our service provider.

Possible cause of the high wipe is attributed to _____**.**

Manufacturer:<insert manufacturer>

Model Number: <insert model number>

The exact location of the event:

- Lab/Room <insert bldg., lab or room number>

The isotopes, quantities, and chemical and physical form of the licensed material involved:

- Isotope: <insert isotope>

- Quantity: <insert activity of source>

- Chemical and physical form: <insert sealed or plated, form>

Date and time of the event:

Date and Time: <insert date and time of event>

Corrective actions taken or planned and the results of any evaluations or assessments <insert actions here>

The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

No exposure expected. The sealed source was housed in an enclosed instrument.

Please contact me if you have any questions.

Sincerely,

RSO

APPENDIX H

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, "Occupational dose limits for adults." 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 and/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:

A radiation measurement of the work area indicates a dose rate of 0.015 mSv/h [1.5 mrem/h]. Service provider personnel are not expected to spend more than a total of 6 hours per week at the location of the measurement. Based on this measured dose rate, the annual dose is expected to be less than 4.68 mSv [468 mrem]. Specifically, 6 h/wk × 1.5 mrem/h × 52 wk/yr = 468 mrem. Based on the above, if any service personnel work in the area less than 6 hours per week, no dosimetry is required. If the service personnel work in the area for greater than 6 hours per week, then dosimetry is required. The threshold for monitoring is 10 percent [500 millirems] of the applicable limit (for personnel with an annual dose limit of 5,000 millirems).

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 individual licensee situations. In their evaluations, licensees will use information appropriate to the type of work being conducted.

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

For guidance on determining internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," and Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses."

Licensees should review evaluations periodically and revise them, as needed. They need to check assumptions used in their evaluations to ensure that the assumptions are up-to-date and accurate, especially when there is an increase in the possession of radioactive material.

Table H–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 I

GUIDANCE FOR DEMONSTRATING THAT INDIVIDUAL MEMBERS OF THE PUBLIC WILL NOT RECEIVE DOSES EXCEEDING THE ALLOWABLE LIMITS

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

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

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv [100 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 1 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.

Table I–1. Doses to Members of the Public

Doses to Members of the Public	
INCLUDES doses from:	DOES NOT INCLUDE doses from:
• radiation or radioactive material released by a licensee • sources of radiation under the control of a licensee • air 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 non-radioactive materials, and other facilities and laboratories where licensed materials are not normally used or stored.

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

- demonstrating by measurement or calculation that the total effective dose equivalent (TEDE) to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv [100 mrem] in a year

- demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in Table 2, "Effluent Concentrations," of Appendix B to 10 CFR Part 20; and if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv [2 mrem] in 1 hour and 0.5 mSv [0.05 rem] in 1 year

- demonstrating that air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1 mSv [10 mrem] TEDE

- demonstrating by measurement or calculation that the TEDE to an individual will not exceed 0.02 mSv [2 mrem] in any one hour at an established boundary for temporary jobsites

To perform a dose assessment, licensees 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 their facilities. Licensees 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 to demonstrate that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv [100 mrem] in a year. These measurements may include:

- dose rate surveys for radiation exposures from external radiation sources

- measurements of radionuclides in air and water effluent

The method used to measure dose will depend upon 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 waste compactions or incinerations, but the discharge itself is usually not continuous because volatile materials are often used periodically rather than continuously. Liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

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

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. 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 I–2 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present. The occupancy factors in Table I–2 are general guidance values and may be used if more detailed information is not available.

Table I–2. 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 used for patient examinations and treatments and similar areas where individuals are present for a major part of the day
1/5	Corridors, employee lounges, staff rest rooms, patient rooms, and classrooms
1/20	Unattended waiting rooms, public rest rooms, unattended vending rooms, storage areas, janitor's closets, attics, outdoor areas with seating, patient holding areas, 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 will identify the instruments used in the survey, the name of the surveyor, the date of the survey, the location of the survey(s), including a description or drawing of the area surveyed, survey results, and if applicable, the occupancy factors used and justification for their use. In addition, records demonstrating the dose to an individual member of the public that involve effluent sampling analysis should include information on concentrations of specific radionuclides, minimum detectable activity of the system, and the estimated uncertainty of measurements.

Service provider licensees who perform tracer flow studies at temporary jobsites must maintain records in accordance with 10 CFR 32.12, "Same: Records and material transfer reports," and 10 CFR 32.52, "Same: Material transfer reports and records."

The following is a simple example to demonstrate the above concepts for calculating direct measurement with sensitive instrumentation and combination of calculating and measurement.

[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.

Recordkeeping

Regulations in 10 CFR 20.2107 “Records of dose to individual members of the public,” require licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Calculation Method[2]

These measurements must be made with calibrated radiation survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making these measurements, and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv [100 mrem] received by an individual over a period of 2080 hours (i.e., a “work year” of 40 h/wk for 52 wk/yr) is equal to less than 0.5 microsievert [0.05 mrem] per hour.

This rate is well below the minimum sensitivity of most commonly available Geiger-Mueller survey instruments.

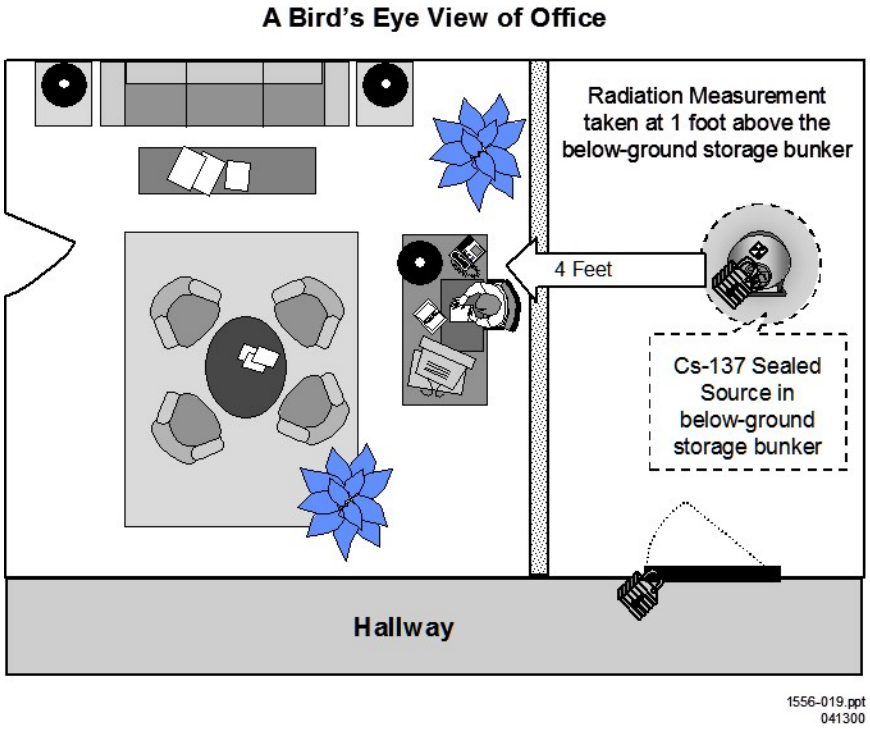


Figure I–1. Bird’s-Eye View of Office with Stored Calibration Source

[2]For ease of use, the examples in this Appendix use conventional units. The conversions to International System of Units units are as follows: 1 foot (ft) = 0.305 meter; 1 mrem = 0.01 mSv.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector [e.g., NaI(Tl)] or a micro-Roentgen meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental thermoluminescent dosimeters (TLDs) in unrestricted areas next to the down-hole source storage area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr [100 mrem/yr] limit.

TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for environmental monitoring. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv [120 mrem], a value in excess of the 1 mSv/yr [100 mrem/yr] limit. If licensees use TLDs to evaluate compliance with the public dose limits, they may need to consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF_2 that are used for environmental monitoring.

The combined measurement-calculation method may be used to estimate the maximum dose to a member of the public. The combined measurement-calculation method takes a tiered approach, going through a two-part process, starting with a worst-case situation and moving toward more realistic situations. It makes the following simplifications: (i) each cesium-137 source is considered a point source; (ii) typical radiation levels are encountered when the source is in the unshielded position; and (iii) no credit is taken for any shielding found between the source storage area and the unrestricted areas. The method is only valid for the source activity at the time of measurement and must be repeated if the source strength or shielding is changed.

Part 1 of the combined measurement-calculation method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the down-hole storage area and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but they provide a method for estimating conservative doses that could be received.

Example

To better understand the combined measurement-calculation method, we will examine DISPOZ, Inc., a waste management broker. Yesterday, the company's president noted that the top shield of the down-hole storage area is close to an area used by workers whose assigned duties do not include the use of licensed materials, and he asked Jenny, the radiation safety officer (RSO), to determine if the company is complying with U.S. Nuclear Regulatory Commission (NRC) regulations.

The area in question is near the floor under the workers' desks, which constitutes the primary shield of the down-hole storage area. Jenny measures the distance from the shield to the

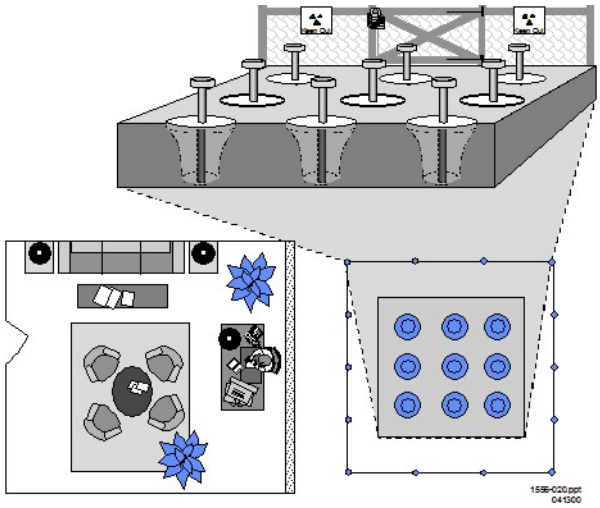


Figure I–2. Down-Hole Storage Array in Waste Broker Facility

center of the area in question and, using a calibrated survey instrument, measures the highest dose rate at 1 foot from the shield to be 2 mrem per hour.

Table I–3 summarizes the information Jenny has on the down-hole storage area.

Table I–3. Information Known about Dose at the Shield of the Cs-137 Source

Description of Known Information	Cesium-137 Logging Source
Dose rate encountered at 1 foot from the top of the shield, in mrem/h	2 mrem/h
Distance from the face of the shield to the nearest occupied work area, in ft.	4 ft

Example: Part 1

Jenny's first thought is that the distance between the down-hole storage area shield and the area in question may be sufficient to show compliance with the regulation in 10 CFR 20.1301, "Dose limits for individual members of the public." So, taking a worst-case approach, she assumes: (i) the cesium-137 is constantly located in down-hole storage area (i.e., 24 h/day); and (ii) the workers are constantly in the unrestricted work area (i.e., 24 h/day). Jenny proceeds to calculate the dose the workers might receive hourly and yearly from the source, as shown in Table I–4 below.

Table I–4. Calculation Method, Part 1: Hourly and Annual Doses Received From a Source Stored Above Ground			
Step No.	**Description**	**Input Data**	**Results**
1	Multiply the measured dose rate measured at 1.0 ft from the face of the shield floor in mrem/h by the square of the distance (ft) at which the measurement was made (e.g., 1 ft from the face of the shield).	$2 \times (1)^2$	2
2	Square of the distance (ft) from the face of the shield to the nearest unrestricted area, in ft^2	$(4)^2$	16
3	Divide the result of Step 1 by the result of Step 2 to calculate the dose received by an individual in the area near the shield. HOURLY DOSE RECEIVED FROM SOURCE, in mrem in an hour.	2/16	0.125
4	Multiply the result of Step 3 by 40 h/work week× 52 weeks/year = MAXIMUM ANNUAL DOSE RECEIVED FROM Cs-137 Source, in mrem in a year.	0.125 × 40 × 52	260

Note: The result in Step 3 demonstrates compliance with the 2 mrem in any 1-hour limit. Reevaluate if assumptions change. If the result in Step 4 exceeds 100 mrem/yr, proceed to Part 2 of the calculation method.

At this point, Jenny is pleased to see that the total dose that an individual could receive in any 1 hour is only 0.125 mrem in 1 hour, less than the 2 mrem in any 1 hour limit but notes that an individual could receive a dose of 260 mrem in 1 year, higher than the 100 mrem limit.

Example: Part 2

Jenny reviews the assumptions and recognizes that the workers are not in the area all of the time. A realistic estimate of the number of hours the workers spend in the area is made, keeping the other assumptions constant [i.e., the source is constantly in the down-hole storage area (i.e., 24 h/day)]. The annual dose received is then recalculated.

Table I–5. Calculation Method, Part 2: Annual Dose Received From a Source Stored Above Ground		
Step No.	**Description**	**Results**
7	A. Average number of hours per day an individual spends in area of concern (e.g., a nonradiation worker spends 1.5 h/day in the area near the shield); the remainder of the day the workers are away from the area assigned to jobs unrelated to radiation (e.g., painting, grounds keeping, desk jobs) B. Average number of days per week in area C. Average number of weeks per year in area (e.g., full-time workers)	1.5 5 52
8	Multiply the results of Step 7.A. by the results of Step 7.B. by the results of Step 7.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR.	1.5 × 5 × 52 = 390
9	Multiply the results in Step 3 by the results of Step 8 = ANNUAL DOSE RECEIVED FROM CESIUM-137 LOGGING SOURCE CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN, in mrem in a year.	0.125 × 390 = 49

Jenny is pleased to note that the calculated annual dose received is significantly lower and does not exceed the 100 mrem in 1 year limit.

Jenny is glad to see that the results in Step 9 show compliance with the 100 mrem in 1 year limit. Had the result in Step 9 been higher than 100 mrem in 1 year, then Jenny could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions.
- Calculate the effect of any shielding located between the storage area and the floor of the public area—such calculation is beyond the scope of this Appendix.
- Take corrective action (e.g., change work patterns to reduce the time spent in the area near the shield) and perform new calculations to demonstrate compliance.
- Designate the area inside the use area as a restricted area and the workers as occupationally exposed individuals. This would require controlling access to the area for purposes of radiation protection and training the workers as required by 10 CFR 19.12, “Instruction to workers.”

Note that in the example Jenny evaluated the unrestricted area outside only one wall of the down-hole storage area. Licensees also need to make similar evaluations for other unrestricted

areas and to keep in mind the as low as is reasonably achievable (ALARA) principle, taking reasonable steps to keep radiation dose received below regulatory requirements.

In addition, licensees should be alert to changes in situations (e.g., adding sources to the storage area, changing the work habits of the workers, or otherwise changing the estimate of the portion of time spent in the area in question) and will perform additional evaluations, as needed.

Reference:

National Council on Radiation Protection and Measurements (NCRP) Report No. 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities (2005)."

APPENDIX J

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 non-bulk packagings
  - 49 CFR 172.304—Marking requirements
  - 49 CFR 172.310—Class 7 (radioactive) materials
  - 49 CFR 172.324—Hazardous substances in non-bulk packagings [designation of "reportable quantities" with the letters "RQ"]
- Labeling—49 CFR 172, Subpart E
  - 49 CFR 172.400—General labeling requirements
  - 49 CFR 172.400a—Exceptions from labeling
  - 49 CFR 172.401—Prohibited labeling
  - 49 CFR 172.403—Class 7 (radioactive) material
  - 49 CFR 172.406—Placement of labels
  - 49 CFR 172.436—RADIOACTIVE WHITE-I label
  - 49 CFR 172.438—RADIOACTIVE YELLOW-II label
  - 49 CFR 172.440—RADIOACTIVE YELLOW-III label

- Placarding—49 CFR 172, Subpart F

  — 49 CFR 172.500—Applicability of placarding requirements
  — 49 CFR 172.504—General placarding requirements
  — 49 CFR 172.516—Visibility and display of placards
  — 49 CFR 172.556—RADIOACTIVE placard

- Emergency Response Information—49 CFR 172, Subpart G

  — 49 CFR 172.600—Applicability and general requirements
  — 49 CFR 172.602—Emergency response information
  — 49 CFR 172.604—Emergency response telephone number

- Training—49 CFR 172, Subpart H

  — 49 CFR 172.702—Applicability and responsibility for training and testing
  — 49 CFR 172.704—Training requirements

- Safety and Security Plans—49 CFR 172, Subpart I

  — 49 CFR 172.800—Purpose and applicability
  — 49 CFR 172.802—Components of a security plan

- Shippers—General Requirements for Shipments and Packagings—49 CFR Part 173

  — 9 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).

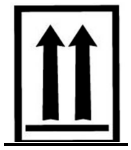
[2] For mixtures of radionuclides, the radionuclides to be shown must be determined in accordance with § 173.433(g), which is commonly known as the 95% rule; abbreviations (symbols) are authorized.

[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]	Additional Markings Sometimes Required	Optional Markings
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]	**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	• 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

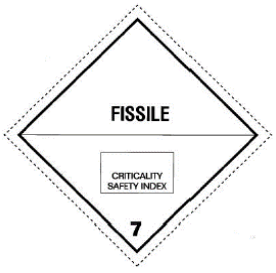
Maximum Radiation Surface Level (RSL)

	White-I	Yellow-II	Yellow-III
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]

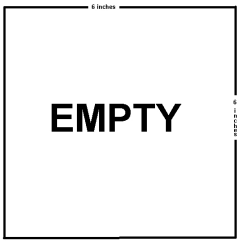
White-I	Yellow-II	Yellow-III
TI = 0	0 < **TI** ≤ 1	1 < **TI** ≤ 10[5]

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 K

INFORMATION NEEDED TO SUPPORT APPLICANT'S REQUEST TO PERFORM NONROUTINE MAINTENANCE CHECKLIST

Information Needed to Support Applicant's Request to Perform Nonroutine Maintenance Checklist

Applicants should review the section in this document on "Maintenance," which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Routine maintenance is maintenance that the manufacturer or distributor allows their customers to perform in accordance with instructions in the user manual. Nonroutine maintenance is maintenance that requires specialized training and experience. Nonroutine operations include installation of the sealed source/device, repair or maintenance involving or potentially affecting components, including electronics, related to the radiological safety (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding), relocation, replacement, and disposal of sealed sources, alignment, removal of a sealed source/device from service, and any other activities during which personnel could receive radiation doses exceeding U.S. Nuclear Regulatory Commission (NRC) limits.

The service provider may obtain replacement parts from the manufacturer/distributor or have its customer order the parts from the manufacturer/distributor. If neither the service provider nor the customer can obtain a replacement part from the manufacturer or distributor, the service provider may purchase a part from another vendor or fabricate the part.

It is preferable to use the original equipment manufacturer or distributor (OEM) supplied components or parts. Any non-OEM replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor will need to be evaluated to ensure that they do not degrade the results of the engineering safety analysis performed and accepted as part of the device sealed source and device (SSD) registration. If the service provider uses a part integral to the safe operation of the device that has not been provided by the manufacturer, the service provider will verify that the part will have the commensurate form, fit, and function as the original component. In addition, the service provider will provide the information related to the form, fit, and function of a non-OEM part (as specified in Section 8.10.9 "Maintenance") to the customer, and the customer will provide the technical information to the NRC for a safety review. The use of replacement parts may result in the device being a custom device in accordance with NUREG–1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration." The service provider will not install this part until verifying that its customer has retained the appropriate authorization to proceed. Licensees will also ensure that, after maintenance or repair is completed, the sealed source/device is tested and functions as designed, before the unit is returned to routine use.

For guidance on the use of sources that have not been supplied by the manufacturer and/or distributor, see Regulatory Issue Summary 2013-01, March 12, 2013 (ADAMS Accession No. ML12313A147).

If nonroutine operations are not performed properly with attention to good radiation safety principles, the sealed source/device may not operate as designed and personnel performing these tasks could receive radiation doses exceeding NRC limits.

Thus, applicants wishing to perform nonroutine operations must use personnel with special training and follow appropriate procedures consistent with the manufacturer's or distributor's instructions and recommendations that address radiation safety concerns (e.g., use of radiation

survey meter, shielded container for the source, and personnel dosimetry (if required)). Accordingly, provide the following information.

Describe the types of work, maintenance, cleaning, or repair that involve:

- installation, relocation, or alignment of the sealed source/device
- components, including electronics, related to the radiological safety of the device (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)
- replacement and disposal of sealed sources
- removal of a sealed source/device from service
- a potential for any portion of the body to come into contact with the primary radiation beam
- any other activity during which personnel could receive radiation doses exceeding NRC limits

The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.

- Identify who will perform nonroutine operations and their training and experience. Acceptable training would include manufacturer's or distributor's courses for nonroutine operations or equivalent.
- Verify that the maintenance activities are authorized on the license.
- Submit operating and emergency procedures for nonroutine operations. These procedures will ensure the following:
    - — Doses to personnel and members of the public are within regulatory limits and as low as is reasonably achievable (ALARA) (e.g., use of shielded containers or shielding).
    - — The source is secured against unauthorized removal or access or under constant surveillance.
    - — Appropriate labels and signs are used.
    - — Manufacturer's or distributor's instructions and recommendations are followed.
    - — Any nonmanufacturer/nondistributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration.

— Before being returned to routine use, the sealed source/device is tested to verify that it functions as designed and source integrity is not compromised.

- Ensure emergency procedures will be developed and reviewed for all likely accident scenarios.

- Confirm that individuals performing nonroutine operations will wear both whole body and extremity monitoring devices or perform a prospective evaluation demonstrating that unmonitored individuals performing nonroutine operations are not likely to receive, in a year, a radiation dose in excess of 10 percent of the allowable limits.

- Verify possession of at least one survey instrument that meets the criteria in Appendix F of this document.

- Describe steps to be taken to ensure that radiation levels in areas where nonroutine operations will take place do not exceed the limits in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1301, "Dose limits for individual members of the public." For example, applicants can do the following:

  — Commit to performing surveys with a survey instrument (as described above).

  — Specify where and when surveys will be conducted during nonroutine operations.

  — Commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by 10 CFR 20.2103.

- Commit to providing the customer a service report describing the work that was completed, especially replacement parts and/or sources.

APPENDIX L

SUGGESTED SERVICE PROVIDER AUDIT CHECKLIST

Suggested Service Provider 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, "Radiation protection programs," for a periodic review, at least annually, 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) or Agreement State inspection identifies the weaknesses]. During an audit, the auditor [e.g., radiation safety officer (RSO)], management representative, and consultant should 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.

Licensee management should conduct performance-based reviews by observing work in progress, interviewing staff, and spot-checking required records. As a part of applicants' audit program, applicants should consider performing unannounced audits to determine if, for example, Safe Use and Emergency Procedures are available and are being followed.

The form in this Appendix can be used to document the 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), and timeframe for completion.

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

Section 2, Organization and Scope of Program. Give a brief description of the organizational structure. Note any changes in personnel, operating and emergency procedures, or amendments to the license. Describe the scope of licensed activities at the audited location. Check whether the RSO is the person identified in the license and fulfills the duties specified in the license. Notify the NRC promptly, and in writing, when no principal activities under the license have been conducted for a period of 24 months, in accordance with 10 CFR 30.36(d), 10 CFR 40.42(d), or 10 CFR 70.38(d), and complete an audit.

Section 3, Training, Retraining, and Instructions to Workers. Ensure that workers have received the training required by 10 CFR 19.12, "Instruction to workers." 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. Ensure that each worker has a copy of the licensee's procedures, and by interview and/or observation of selected workers, that the individual can implement them. Records will be maintained.

Section 4, Internal Audits, Reviews, or Inspections. Verify that audits fulfill the requirements of 10 CFR 20.1101, are conducted in accordance with licensee commitments, and are properly documented.

Section 5, Facilities. Verify that the licensee's facilities are as described in its licensing documents.

Section 6, Materials. Verify that the license authorizes the quantities and types of byproduct, source, and/or special nuclear material that the licensee possesses. Verify whether financial assurance is or is not needed, based on possession limits on the license and whether financial instruments are still valid or need revision.

Section 7, Leak Tests. Verify that all sealed/plated foil sources are tested for leakage at the prescribed frequency described in the Sealed Source and Device registration certificate, and in accordance with licensee commitments. Records of results will be maintained.

Section 8, Inventories. Verify that physical inventories are conducted at least once every 6 months to account for all sources; inventory records will be maintained. In addition, licensees in possession of nationally tracked sources must complete an annual reconciliation inventory in accordance with 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources."

Section 9, Radiation Surveys. Verify that the licensee has appropriate, operable, and calibrated survey instruments available, that the instruments are calibrated periodically in accordance with 10 CFR 20.1501, "General," and in accordance with license conditions. Calibration records must be retained for 3 years after the record is made, in accordance with 10 CFR 20.2103, "Records of surveys." Check that radiation levels in areas adjacent to use are within regulatory limits. Verify compliance with 10 CFR 20.1301, "Dose limits for individual members of the public." Records of surveys must be retained for 3 years after the record is made.

Section 10, 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, "Procedures for receiving and opening packages." Ensure that transfers are performed in accordance with 10 CFR 30.41, "Transfer of byproduct material." Records of surveys, receipt, and transfer must be maintained in accordance with 10 CFR 20.2103 and 10 CFR 30.51, 10 CFR 40.61, or 10 CFR 70.51, as applicable.

Section 11, Transportation. 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 177.817(e)]. Verify that any import and/or export of licensed material is conducted in accordance with the requirements set forth 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material."

Section 12, Personnel Radiation Protection. Evaluate the licensee's assessment that unmonitored occupational workers are not likely to receive more than 10 percent of the allowable limits (i.e., 500 millirem in a year). 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 voluntarily declares her pregnancy in writing, evaluate the licensee's compliance with 10 CFR 20.1208, "Dose equivalent to an embryo/fetus." Check whether records are maintained, as required by 10 CFR 20.2101, 2102, 2103, 2104, and 2106.

Section 13, Security Program for Category 1 and Category 2 Materials. Conduct a hands-on and record-review of the licensee's physical protection program, to verify the licensee's compliance with 10 CFR Part 37, "Physical Protection of Category 1 and Category 2

Quantities of Radioactive Material. NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,"" contains useful information. Licensees may propose alternative ways for demonstrating compliance with these requirements.

Section 14, Auditor's Independent Measurements (If Made). 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 to determine the licensee's compliance with the notification and reporting requirements in 10 CFR Parts 19, 20, 21, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70, and 71. Ensure that the licensee is aware of the telephone number for NRC's Emergency Operations Center; 301–816-5100.

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

Section 18, Recordkeeping for Decommissioning. Check to determine compliance with 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), as appropriate. The Decommissioning Planning Rule [76 FR 35512 (June 17, 2011,)] requires licensees to minimize contamination released into the site, and to identify the location and amount of significant residual radioactivity throughout the facility and site, including in the subsurface. The results of these surveys must be documented in records important to decommissioning if the identified contamination will require remediation to meet the unrestricted use criteria of 10 CFR 20.1402, "Radiological criteria for unrestricted use."

Section 19, NRC Correspondence. Check to determine if the licensee is receiving such documents as regulatory issue summaries, bulletins, information notices, and Office of Nuclear Material Safety and Safeguards (NMSS) Newsletters, from the NRC. Check whether the licensee took appropriate action in response to NRC mailings.

Section 20, License Conditions or Issues. Verify compliance with conditions on the service provider's license. Review the last license condition to determine if all documents listed should remain on the license or be revised.

Section 21, 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, Safe Use and Emergency Procedures are available and are being followed. The NRC conducts performance-based observations during inspections and encourages licensees to also observe licensed activities in process as part of the audit review.

Section 22, Problems or Deficiencies Noted and Recommendations. Note any deficiencies that were identified and the corrective actions taken (or to be taken) and timeframe for completion.

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.

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 Audit Checklist

Audit Report No._____ License No._____

Licensee's name and mailing address:

_____

_____

_____

_____

Audit of licensed activities at [Address(es)]:

_____

_____

_____

Contact at Audit Location _____ Telephone No._____

Date of this Audit _

Summary of Findings and Action:

❒ No deficiencies

❒ Deficiencies

❒

Indicate if corrective actions taken to prevent recurrence from the previous audit were comprehensive and effective recommendations:

Auditor:_____ Date: _____

(Signature)

Note: Except where noted, references 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 on: _____

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

   c. Open problems/deficiencies from the previous audits:

Status Requirement	Problem/Deficiency	Corrective Action Taken (Y/N)	Open/Closed

   d. Any previous problem/deficiency not corrected or repeated..... ❒ Y ❒ N ❒ N/A

      Explain:

2. ORGANIZATION AND SCOPE OF PROGRAM

   a. Briefly describe organizational structure

   b. Structure is as described in license documents ..... ❒ Y ❒ N

   c. Operating and Emergency Procedures are up to date and have been submitted to the NRC ..... ❒ Y ❒ N ❒ N/A

   d. Multiple authorized locations of use listed ..... ❒ Y ❒ N

      Provide address(es) of those locations reviewed as part of this audit:

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

   f. Radiation Safety Officer:

      Authorized on license ..... ❒ Y ❒ N

      Fulfills duties as RSO ..... ❒ Y ❒ N

g. Use of licensed material only by authorized individuals ..... ❒ Y ❒ N

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

a. Instructions to workers per [10 CFR 19.12]..... ❒ Y ❒ N

b. Training program implemented as required [L/C[1]] ..... ❒ Y ❒ N

c. Training records maintained [L/C]..... ❒ Y ❒ N

d. Evaluation of individuals' understanding of procedures and requirements based on interviews, observation of selected workers was performed..... ❒ Y ❒ N

If so:

Each has an up-to-date copy of the licensee's operating use and emergency procedures ..... ❒ Y ❒ N

Adequate understanding of:

Operating procedures..... ❒ Y ❒ N

Emergency procedures..... ❒ Y ❒ N

e. 10 CFR Part 20

Workers cognizant of requirements for:

Radiation Protection Program [20.1101] ..... ❒ Y ❒ N

Annual dose limits [20.1301, 20.1302] ..... ❒ Y ❒ N

NRC Forms 4 and 5..... ❒ Y ❒ N

10 percent monitoring threshold [20.1502]..... ❒ Y ❒ N

Dose limits to embryo/fetus and declared pregnant women [20.1208] ..... ❒ Y ❒ N

Procedures for opening packages [20.1906]..... ❒ Y ❒ N

f. 10 CFR Parts 19, 20, 21, 30, 37, 40, 70 and 71 reviewed as applicable..... ❒ Y ❒ N

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[1] L/C refers to license condition.

Remarks:

4. INTERNAL AUDITS, REVIEWS OR INSPECTIONS

   a. Audits are conducted ❒ Y ❒ N

      1. Audits conducted by_____

      2. Frequency_____

   b. Content and implementation of the radiation protection program reviewed at least annually [20.1101(c)] ..... ❒ Y ❒ N

   c. Records maintained [20.2102] ..... ❒ Y ❒ N

   Remarks:

5. FACILITIES

   a. Facilities as described in license documents ..... ❒ Y ❒ N

   b. Access to restricted area/licensed material in accordance with 20.1801, 20.1802 ..... ❒ Y ❒ N

   Remarks:

6. MATERIALS

   a. Isotopes, quantities, model numbers, and use as authorized on license..... ❒ Y ❒ N

   b. Using NUREG–1757 Volume 3: Financial Assurance is current ..... ❒ Y ❒ N ❒N/A [10 CFR 30.35, 10 CFR 40.36, 10 CFR 70.25]

   Remarks:

7 LEAK TESTS

   a. Leak test performed as described in correspondence with NRC (leak-test kit; service provider licensee performed and/or analyzed)..... ❒ Y ❒ N

   b. Frequency: every 6 months or other interval, as approved by NRC or Agreement State ..... ❒ Y ❒ N

   c. Records with appropriate information maintained ..... ❒ Y ❒ N

   Remarks:

8. INVENTORIES

a. Conducted at 6-month intervals [L/C] ..... ❒ Y ❒ N

b. Visual verification confirmed or security seal still in place ..... ❒ Y ❒ N

c. Transactions entered into the National Source Tracking System,

including annual reconciliation [10 CFR 20.2207] ..... ❒ Y ❒ N ❒ N/A

d. Records with appropriate information maintained ..... ❒ Y ❒ N

Remarks:

9. RADIATION SURVEYS

a. Instruments and Equipment:

Appropriate operable survey instrumentation possessed or readily

available [L/C]..... ❒ Y ❒N

Calibrated as required [20.1501]..... ❒ Y ❒ N

Calibration records maintained [20.2103(a)] ..... ❒ Y ❒ N

b. Briefly describe survey requirements [20.1501]:

c. Performed as required [20.1501(a)]..... ❒ Y ❒ N

Radiation levels within regulatory limits ..... ❒ Y ❒ N

Corrective action taken and documented..... ❒ Y ❒ N ❒N/A

d. Records maintained [20.2103]..... ❒ Y ❒ N

e. Protection of members of the public:

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), 20.1302(b)] ..... ❒ Y ❒ N

Unrestricted area radiation levels do not exceed 2 mrem in any one hour

[20.1301(a)(2)]..... ❒ Y ❒ N

Records maintained [20.2103, 20.2107] ..... ❒ Y ❒ N

Remarks:

10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

a. Describe how packages are received and by whom:

b. Written package opening procedures established and followed

[20.1906(e)] ❒ Y ❒ N

c. If package shows evidence of degradation, monitor

for contamination and radiation levels ❒ Y ❒ N ❒ N/A

d. Monitoring of degraded packages performed within time specified [20.1906(c)] ❒ Y ❒ N ❒ N/A

e. Transfer(s) between licensees performed in compliance with 30.41, 40.51, or 70.42, as applicable ❒ Y ❒ N ❒ N/A

f. Records of receipt/transfer maintained [30.51, 40.61, or 70.51] ❒ Y ❒ N

g. Transfers within licensee's authorized users or locations performed

as required [L/C] ❒ Y ❒ N ❒ N/A

h. Package receipt/distribution activities evaluated for compliance with

20.1301 [20.1302] ❒ Y ❒ N ❒ N/A

Remarks:

11. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 170-189) ❒ N/A

a. Licensee shipments are:

Delivered to common carriers ❒ Y ❒ N ❒ N/A

Transported in licensee's own private vehicle ❒ Y ❒ N ❒ N/A

No shipments since last audit ❒ Y ❒ N

b. Hazmat Training

Applicability and responsibility for training and

testing [49 CFR 172.702] ❒ Y ❒ N ❒ N/A

Training requirements [49 CFR 172.704] ❒ Y ❒ N ❒ N/A

c. Packages ❒ N/A

Authorized packages used [49 CFR 173.415, 416] ❒ Y ❒ N ❒ N/A

Closed and sealed during transport [49 CFR 173.475(f)] ..... ❒ Y ❒ N

Properly labeled and marked [49 CFR 172.403, 172.441, 173.471] ..... ❒ Y ❒ N

d. Shipping Papers ..... ❒ N/A

Prepared and used [49 CFR 172.200(a)] ..... ❒ Y ❒ N

Proper {Shipping Name, Hazard Class, UN Number[2], Quantity, Package

Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form,

Activity, Category of Label, Transport Index, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Cargo Aircraft Only" (if applicable)}

[49 CFR 172.200-204] ..... ❒ Y ❒ N

Readily accessible during transport [49 CFR 177.817(e)] ..... ❒ Y ❒ N

e. Vehicles ..... ❒ N/A

Cargo blocked and braced [49 CFR 177.842(d)] ..... ❒ Y ❒ N

Placarded, if needed [49 CFR 172.504] ..... ❒ Y ❒ N

Proper overpacks, if used (shipping name, UN Number, labeled,

statement indicating that inner package complies with specification

package) [49 CFR 173.25] ..... ❒ Y ❒ N ❒ N/A

f. Security Plans ..... ☐ N/A

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

g. Any incidents reported to DOT [49 CFR 171.15, 171.16] ..... ❒ Y ❒ N

Remarks:

12. PERSONNEL RADIATION PROTECTION

a. ALARA considerations are incorporated into the Radiation Protection

Program [20.1101(b)] ..... ❒ Y ❒ N

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[2] The UN number identifies the hazardous substance. The UN number is universally recognized and assigned by the United Nations.

b. Adequate documentation of determination that unmonitored individuals are not likely to receive >10 percent of allowable limit [20.1502(a)] ..... ❒ Y ❒ N ❒ N/A

OR

c. External dosimetry required and used ..... ❒ Y ❒ N ❒ N/A

Supplier: _____ Frequency: _____

Supplier is NVLAP-approved [20.1501(d)(1))]..... ❒ Y ❒N

Dosimeters exchanged at required frequency [L/C] ..... ❒ Y ❒ N

d. Occupational intake monitored and assessed [20.1502(b)]..... ❒ Y ❒ N ❒ N/A

e. Reports:..... ❒ N/A

Reviewed by: _____ Frequency: _____

Auditor reviewed personnel monitoring records for period _____ to _____

Prior dose determined for individuals likely to receive doses [20.2104]..... ❒ Y ❒ N

Maximum exposures TEDE: _____ Other: _____

f. NRC Forms or equivalent [20.2104(d), 20.2106(c)]:

NRC-4 “Cumulative Occupational Exposure History” Complete:..... ❒ Y ❒ N

NRC-5 “Occupational Exposure Record for a Monitoring Period” Complete: .... ❒ Y ❒ N

g. Worker declared her pregnancy <u>in writing</u> during audit period

(review records)..... ❒ Y ❒ N ❒ N/A

If yes, determine compliance with 20.1208 ..... ❒Y ❒ N

and check for records per 20.2106(e)..... ❒ Y ❒ N

h. Records of exposures, surveys, monitoring, and evaluations maintained

[20.2102, 20.2103, 20.2106, L/C] ..... ❒ Y ❒ N

i. Pocket dosimeters and/or alarming rate meters [L/C]: ..... ❒ N/A

Possessed and used as required..... ❒ Y ❒ N

Operable and calibrated/checked at required frequency..... ❒ Y ❒ N

Records maintained..... ❒ Y ❒ N ❒ N/A

Remarks:

13. SECURITY PROGRAM FOR CATEGORY 1 AND CATEGORY 2 MATERIALS

[10 CFR Part 37]

a. Commensurate security program implemented ……....❒ Y ❒ N ❒ N/A

b. Trustworthiness and Reliability Determinations Made..... ❒ Y ❒ N

c. Access Control to information and Category 1 or Category 2 radioactive material ❒ Y ❒ N

d. Monitoring/Detection/Assessment/Response Operational 24/7 ….…....❒ Y ❒ N ❒ N/A

e. Valid test of security system to ensure operability ……...❒ Y ❒ N ❒ N/A

f. Local Law Enforcement Agency Coordination and Written Plan ……...❒ Y ❒ N ❒ N/A

g. Package tracking for transport of Category 1 or Category 2 radioactive material ...❒ Y ❒ N ❒ N/A

h. Mobile devices secured ..... ❒ Y ❒ N ❒ N/A

i. Sensitive information secured and only available to personnel

who have been deemed trustworthy and reliable..... ❒ Y ❒ N

j. Reports made (loss, theft, or sabotage of Category 1 or Category 2 radioactive material, or if results of fingerprints are

positive for the FBI Terrorist Screening Data, etc.) ..... ❒ Y ❒ N

k. Records maintained..... ❒ Y ❒ N

Remarks:

14. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)

Survey instrument	Serial No.	Last calibration
_____	_____	_____

Auditor's measurements compared to licensee's..... ❒ Y ❒ N

Describe the type, location, and results of measurements; attach a diagram/survey sheet and refer to this section:

15. RADIOACTIVE EFFLUENTS, WASTE MANAGEMENT, AND DISPOSAL

a. Waste disposed of by decay-in-storage (DIS): ..... ❒ N/A

Procedure for DIS disposal approved by license condition ..... ❒ Y ❒ N

Disposal by DIS in accordance with L/C ..... ❒ Y ❒ N

Licensee in compliance with 20.1501 and 20.1904(b) ..... ❒ Y ❒ N

Records maintained [20.2103(a), L/C] ..... ❒ Y ❒ N

Remarks:

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

Material is readily soluble (or is readily dispersible biological material) in water [20.2003(a)(1)] ..... ❒ Y ❒ N

Monthly average release concentrations do not exceed Appendix B values [20.2003(a)(2,3)] ..... ❒ Y ❒ N

No more than 5 curies of hydrogen-3,1 curie of carbon-14 and 1 curie of all other radionuclides combined were released in a year [20.2003(a)(4)] ..... ❒ Y ❒ N

Procedures for ensuring adequate sample representativeness and analysis properly implemented [20.1501, L/C] ..... ❒ Y ❒ N

Records maintained [20.2108] ..... ❒ Y ❒ N

Remarks:

c. Waste disposed of by incineration: ..... ❒ N/A

License authorizes incineration [20.2004(a)(3)] ..... ❒ Y ❒ N

If licensee directly monitors incinerator exhaust, the monitor sample is representative and the monitoring instrumentation is operational and properly calibrated [20.1501] ..... ❒ Y ❒ N ❒ N/A

If licensee calculates exhaust concentrations, incinerator airflow and activities incinerated are accurately known, and the calculations are correct [20.1501] ..... ❒ Y ❒ N ❒ N/A

Management of effluents and ashes in accordance with 20.1301,

20.1201, 20.1501, 20.2001 and L/C ..... ❒ Y ❒ N

Records maintained [20.2108] ..... ❒ Y ❒ N

Remarks:

d. Disposal of liquid scintillation (LS) media and/or animal carcasses: ..... ❒ N/A

Licensee disposes of LS media and carcasses contaminated with only H-3 or

C-14, and at a concentration not exceeding 0.05 µCi/g per gram of media used for LS counting or per gram of animal tissue per 20.2005 ..... ❒ Y ❒ N

Records maintained [20.2108] ..... ❒ Y ❒ N

Remarks:

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

Waste transferred to person specifically licensed to receive waste [30.41, 40.51, 70.42, as applicable, 20.2001(b)] ..... ❒ Y ❒ N

Each shipment accompanied by a shipment manifest prepared as specified

in Section I of Appendix G to 10 CFR Part 20 [10 CFR 20.2006(b)

and Section III.A.4 of Appendix G to 10 CFR Part 20] ..... ❒ Y ❒ N

Shipment manifests certified as specified in Section II of Appendix G to

10 CFR Part 20 [10 CFR 20.2006(c)] ..... ❒ Y ❒ N

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

Note: The licensee's waste is likely to be Class A waste not packaged for

disposal in cardboard or fiberboard boxes [61.56(a)]

Liquid wastes solidified [61.56(a)] ..... ❒ Y ❒ N

Volume of solid wastes contain less than 1 percent freestanding liquid

[61.56(a)(3)] ..... ❒ Y ❒ N

Waste does not generate harmful vapors [61.56(a)] ..... ❒ Y ❒ N

Waste structurally stable, i.e., will maintain its physical dimensions and

form under expected disposal conditions [61.56(b)] ..... ❒ Y ❒ N

Void spaces within the waste and between the waste and its package minimized [61.56(b)] ..... ❒ Y ❒ N

Waste packages labeled to identify their proper class [Section III.A.2 of Appendix G to 10 CFR Part 20] ..... ❒ Y ❒ N

Licensee conducts a QA program to ensure compliance with 61.55 and 61.56, and which includes management evaluation of audits [Section III.A.3 of Appendix G to 10 CFR Part 20] ..... ❒ Y ❒ N

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] ..... ❒ Y ❒ N ❒ N/A

Records maintained [20.2108] ..... ❒ Y ❒ N

Remarks:

f. Special disposal procedures and other effluents (e.g., hood exhausts, special dilutions): ..... ❒ N/A

Performed in accordance with L/C ..... ❒ Y ❒ N

Appropriate surveys conducted [20.1501, L/C] ..... ❒ Y ❒ N

Operations comply with 20.1201 and 20.1301 ..... ❒ Y ❒ N

Special disposals per 20.2001 and 20.2002, i.e., no improper/unauthorized disposals were noted ..... ❒ Y ❒ N

Use of dose constraint/ALARA [20.1101(d)] ..... ❒ Y ❒ N

Records maintained [20.2108] ..... ❒ Y ❒ N

Remarks:

g. Waste compaction operations: ..... ❒ N/A

Airborne releases evaluated and controlled [20.1501, 20.1701, L/C] ..... ❒ Y ❒ N

Internal exposures evaluated and controlled [20.1501, 20.1204, 20.1702, 20.1703, 20.1201] ..... ❒ Y ❒ N

Compliance with 20.1301 evaluated [20.1302] ..... ❒ Y ❒ N

Remarks:

h. Waste storage areas: ..... ❒ N/A

Adequate protection from the elements (floods, tornadoes, hurricanes, etc.)

and fire [L/C]..... ❒ Y ❒ N

Adequate control of waste in storage [20.1801]..... ❒ Y ❒ N

Containers properly labeled and area properly posted [20.1902, 20.1904] ..... ❒ Y ❒ N

Package integrity adequately maintained [L/C]..... ❒ Y ❒ N

Adequate records of surveys and material accountability are maintained

[20.2103, 20.2108] ..... ❒ Y ❒ N

16. NOTIFICATION AND REPORTS ..... ❒ N/A

a. Licensee in compliance with 19.13 (reports to individuals,

public and occupational, monitored to show compliance with Part 20).. ❒ Y ❒ N ❒ N/A

b. Licensee in compliance with 20.2201 (theft or loss)..... ❒ Y ❒ N ❒ None

c. Licensee in compliance with 20.2202, 30.50, 40.60, 70.50
(incidents)..... ❒ Y ❒ N ❒ None

d. Licensee in compliance with 20.2203, 30.50, 40.60, 70.50

(overexposures and high radiation levels) ..... ❒ Y ❒ N ❒ None

e. Licensee in compliance with 21.21 (device defect)……..... ❒ Y ❒ N ❒ None

f. Annual reports furnished to the NRC in compliance

with 20.2206 (b), (c) (individual monitoring)..... ☐ Yes ☐ No ☐ N/A

g. Licensee aware of telephone number for NRC Emergency Operations

Center [301-816-5100] ..... ❒ Y ❒ N

17. POSTING AND LABELING

a. NRC Form 3 “Notice to Workers” is posted [19.11]..... ❒ Y ❒ N

b. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures

adopted pursuant to Part 21, and license documents are posted, or a notice

indicating where documents can be examined is posted [19.11, 21.6]..... ❒ Y ❒ N

c. Other posting and labeling per [20.1902, 1904] and the licensee is not exempted by 20.1903, 20.1905 ..... ❒ Y ❒ N

Remarks:

18. RECORDKEEPING FOR DECOMMISSIONING ..... ❒ N/A

a. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination..... ❒ Y ❒ N

b. Records include all information outlined in 30.35(g), 40.36(f), 70.25(g) ..... ❒ Y ❒ N

Remarks:

19. NRC CORRESPONDENCE

a. Review of such documents as NRC Regulatory Issue Summaries, Bulletins, Information Notices, NMSS Newsletters..... ❒ Y ❒ N

b. Appropriate action taken in response to NRC correspondence..... ❒ Y ❒ N

Remarks:

20. LICENSE CONDITIONS OR ISSUES ..... ❒ N/A

a. Review license conditions; NRC/Agreement State violations, Orders, Confirmatory Action Letters; site-specific procedures and 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. 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 measures.

Note: Performance-based reviews may include observation of licensed activities, review of records, and interviews with key personnel.

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

Note: Briefly state (1) the requirement and (2) how and when violated. Provide corrective actions 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/or RSO oversight..... ❒ Y ❒ N

b. RSO has sufficient time to perform his or her radiation safety duties and is not too busy with other assignments..... ❒ Y ❒ N

c. Licensee has sufficient staff..... ❒ Y ❒ N

Remarks:

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit _____ Date of Last Audit _____

Next Audit Date _____

Auditor _____ Date _____

(Signature)

Management Review _____ Date _____

(Signature)

APPENDIX M

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 by Decay-in-storage (DIS)

Applicants should ensure that adequate space and facilities are available for the storage of waste for DIS. Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.

- Short-lived waste should be segregated from long-lived waste.

- Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.

- Liquid and solid wastes should be stored separately.

- When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.

- The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, total activity, date when the longest-lived radioisotope cannot be distinguished from the background radiation level, and the name of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after many half-lives and persons performing surveys should be aware of the potential for measurable radiation.

- The contents of the container should be allowed to decay for a period of time after which it is expected that the radiation levels would not be distinguishable from background. The period of time depends on both the half-life of the radionuclide(s) and the original amount present.

- Prior to disposal as ordinary trash, each container should be monitored with an appropriate radiation detection instrument, on the lowest setting, as follows:

    — Check the radiation survey meter for proper operation.

    — Survey the contents of each container in a low-background area.

    — Remove any shielding from around the container.

    — Monitor all surfaces of the container.

    — Discard the contents as ordinary trash, only if the surveys of the contents indicate no residual radioactivity (i.e., surface readings are indistinguishable from background).

    — If the surveys indicate residual radioactivity, return the container to the DIS area and contact the radiation safety officer (RSO) for further instructions.

    — If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (e.g., used or unused material, gloves), survey instrument used, and the name of the individual performing surveys and disposing of the waste.

In accordance with 10 CFR 20.1904(b), all radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed, provided that the following is done: waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility; labels are removed from the waste barrels/containers; waste is incinerated, not placed in a landfill; and the waste disposal firm is cautioned not to open the container prior to incineration.

Model Procedure for Disposal of Liquids into Sanitary Sewerage

- Confirm that the sewer system is a public system, not a private sanitary sewer, septic system, or leach field.

- Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.

- Calculate the amount of each radionuclide that can be discharged by using the information from prior, similar discharges and the information in 10 CFR Part 20, Appendix B.

- Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR Part 20, Appendix B, Table 3.

- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 must not exceed unity.

- Confirm that the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq [5 Ci] of H-3 (tritium), 37 GBq [1 Ci] of 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 Disposal by Incineration

These guidelines apply to non-commercial waste disposal, i.e., incineration of a licensee's own waste. An applicant or licensee does not need specific U.S. Nuclear Regulatory Commission (NRC) approval to incinerate certain categories of radioactive waste. For example, 10 CFR 20.2005 provides that tritium and carbon-14 in low level concentrations in liquid scintillation media and animal tissue may be disposed of without regard to radioactivity. After the applicant or licensee reviews its program and confirms that they have waste that requires specific NRC approval for incineration, please provide the following information:

- Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.

- Describe the waste that is proposed to be incinerated, to include: the chemical and physical form of the waste containing licensed material and a description of how the waste is segregated, packaged, and labeled for transfer from the generation site to the incinerator; the name of the radionuclide; concentration of radioactivity averaged over the weight of the material to be incinerated (microcuries per gram of waste medium) for each isotope to be incinerated; and the total radioactivity of each isotope per burn and the total number of burns per year. Describe procedures for ensuring that these frequencies and activities will not be exceeded.

- Describe the procedures for packaging, handling, securing, and monitoring of waste to prevent contamination or unnecessary exposure to personnel or property during the waste life cycle.

- Describe the method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe the procedures for collection, handling, and disposal of the ash residue.

- Describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incinerations, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records must be maintained in the same units as applicable regulations.

- Describe the characteristics of the site location and incinerator, including: height of the stack, rated air flow (cubic feet per hour or similar units), proximity of the stack or other discharge to occupied areas (e.g., residences, schools, hospitals), and distance to the nearest air intake ducts of adjacent buildings. Describe any scrubbers, filters, or air-cleaning equipment that is present.

- State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined. Describe any stack monitoring that is planned.

- Provide a copy of the written safety analysis that demonstrates the applicant or licensee will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in 10 CFR Part 20.

- Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations and for monitoring all effluent generated by the incineration process. The procedures must ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant should describe the disposal method for any ash generated that exceeds regulatory limits.

- Provide a written commitment that the applicant or licensee has coordinated with appropriate State and local authorities and that such permits and other authorizations as may be necessary have been obtained.

Model Procedure for Compaction

The following information should be provided by licensees that propose to compact waste:

- Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations. Provide manufacturer's specifications, annotated sketches or photographs, and other information about the compactor design.

- Describe the type, quantities, and concentrations of waste to be compacted.

- Provide an analysis of the potential for airborne release of radioactive material during compaction activities.

- Provide the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtration systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange.

- Discuss the methods used to monitor worker breathing zones and/or exhaust systems.

- Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.

- Discuss the instruction provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and method of examining containers for defects.

Nuclear Laundry

Based on 10 CFR 20.2003, "Disposal by release into sanitary sewerage," a nuclear laundry licensee is authorized to dispose of radioactive waste by release into the sanitary sewer. Generally, a nuclear laundry licensee is not authorized to possess or transfer for disposal radioactive waste, except that generated as a result of laundering activities, such as solid residue waste from the water treatment or air exhaust systems. The solid residue resulting from laundry activities must be disposed of in accordance with license requirements and 10 CFR 20.2001, "General requirements," which usually results in transfer to a licensed radioactive waste disposal facility.

Solid residue waste, such as sludge and lint from the water treatment or air exhaust systems, and process liquids, are considered to be part of the waste generated as a result of the nuclear

laundry operation. Rejected laundry items, such as coveralls and rubber shoe covers, which are unusable or contaminated with residual radioactivity exceeding the preset radiation limits for reuse, are returned to the customers for treatment and disposal, in accordance with the customers' waste management program. In some cases, it might be acceptable to conclude that zippers, in the case of dissolved disposable protective clothing, are more like residue from the laundry process and, therefore, to allow licensed nuclear laundry facilities to send them directly for disposal as radioactive waste. The U.S. Nuclear Regulatory Commission (NRC) finds this approach acceptable. NRC would also find acceptable an approach whereby the zippers would be treated like unusable material similar to rejected laundry items, noted above, that are returned to the customers for treatment and disposal. Thus, in either case, the NRC does not consider a nuclear laundry facility, including one engaged in laundering and dissolving of disposable protective clothing, to constitute a waste receipt or processing facility.

APPENDIX N

SAFETY CULTURE STATEMENT OF POLICY

Safety Culture Statement of Policy

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) Agencywide Document and Access 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.

(9) *Questioning Attitude*—Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

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

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

APPENDIX 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 nonproprietary portions intact. This copy should **not** be marked as proprietary.
☐	An affidavit that:
☐	• Is signed under oath and affirmation (notarization may suffice).
☐	• Clearly identifies (such as by name or title and date) the document to be withheld.
☐	• Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information the organization is seeking to withhold and is authorized to apply for withholding on behalf of the organization.
☐	• States that the organization submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
☐	• Provides a rational basis for holding the information in confidence.
☐	Fully addresses the following issues:
☐	• Is the information submitted to, and received by, the NRC in confidence? Provide details.
☐	• To the best of the applicant's knowledge, is the information currently available 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.

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This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses for service providers. 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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