

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About
Possession Licenses for Manufacturing
and Distribution

Final Report

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Possession Licenses for Manufacturing
and Distribution

Final Report

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ABSTRACT

This technical report contains information intended to provide program-specific guidance and to assist applicants and licensees in preparing applications for manufacturing and distribution licenses. 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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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 3150-0001, 3150-0008, 3150-0009, 3150-0010, 3150-0014, 3150-0016, 3150-0017, 3150-0020, 3150-0035, 3150-0044, 3150-0120, 3150-0158, and 3150-0214. Send comments regarding this information collection to the Information Services Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0001, 3150-0008, 3150-0009, 3150-0010, 3150-0014, 3150-0016, 3150-0017, 3150-0020, 3150-0035, 3150-0044, 3150-0120, 3150-0158, and 3150-0214) Office of Management and Budget, Washington, DC 20503.

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FOREWORD

The U.S. Nuclear Regulatory Commission (NRC) 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 12, Revision 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution,” 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 12, issued December 2000.

This report takes a risk-informed, performance-based approach to licensing the possession and use of radioactive material for manufacturing and distribution. 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 licenses authorizing possession for manufacturing and distribution.

NUREG–1556, Volume 12, 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 the different methods include a basis for the staff to make the determinations needed to issue or renew a license.

The comments received during the public comment period for NUREG–1556, Volume 12, Revision 1, were summarized and addressed in a document that can be located on the NRC's Agencywide Documents and Management System (ADAMS) under ML18010B155. Access to ADAMS is available on the public Web site at: <https://www.nrc.gov/reading-rm/adams.html>. The comments received by NRC included general corrections, comments on sources and devices containing byproduct material, and comments on security of nuclear materials.

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ABBREVIATIONS

ADAMS	Agencywide Document Access and Management System
AEA	Atomic Energy Act
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANSI	American National Standards Institute
AU	authorized user
bkg	background
Bq	becquerel
C-14	carbon-14
Ci	curie
CFR	<i>Code of Federal Regulations</i>
cpm	counts per minute
DAC	derived air concentration
DFP	decommissioning funding plan
DIS	decay-in-storage
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
dpm	disintegrations per minute
EA	environmental assessment
ECD	electron capture devices
EDE	effective dose equivalent
EPA	U.S. Environmental Protection Agency
EPAct	Energy Policy Act
FA	financial assurance
FDA	U.S. Food and Drug Administration
Fe-59	iron-59
FR	<i>Federal Register</i>
GBq	gigabecquerel
Gy	Gray
h	hour
I-125	iodine-125
I-131	iodine-131
IAEA	International Atomic Energy Agency
IN	information notice
L/C	license condition
LLEA	local law enforcement agency
LLW	low-level radioactive waste
LSA	low specific activity
LSC	liquid scintillation counting
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
mBq	millibecquerel
mCi	millicurie
MDA	minimum detectable activity
mR	milliroentgen
mrem	millirem
mSv	millisievert
NaI(Tl)	sodium iodide crystal doped with thallium
NCRP	National Council on Radiation Protection and Measurements
ND	not detectable

NMSS	Office of Nuclear Material Safety and Safeguards
NORM	naturally occurring radioactive material
NR	not required
NRC	U.S. Nuclear Regulatory Commission
NSTS	National Source Tracking System
NSTTR	National Source Tracking Transaction Report
NVLAP	National Voluntary Laboratory Accreditation Program
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PII	personally identifiable information
QA	quality assurance
R	roentgen
Ra-226	radium-226
RG	regulatory guide
RIS	regulatory issue summary
RQ	reportable quantities
RSO	Radiation Safety Officer
Se	selenium-75
SI	International System of Units (abbreviated SI from the French “Systeme Internationale d’Unites”)
SSD	Sealed Source and Device [registration certificate]
std	standard
Sv	sievert
TEDE	total effective dose equivalent
TI	transportation index
μGy	microGray
U.S.C.	United States Code
UN	United Nations

1 PURPOSE OF REPORT

This report provides guidance to an applicant applying for several types of licenses associated with the manufacturing and distribution of radioactive materials and products containing radioactive materials and also provides the U.S. Nuclear Regulatory Commission (NRC) staff with the criteria for evaluating such applications. This NUREG uses the terms “byproduct material,” “licensed material,” and “radioactive material” interchangeably.

This report addresses the variety of radiation safety issues associated with manufacturing and distribution. This NUREG provides guidance to applicants preparing a license application for possession and use for manufacturing and distribution or an application for possession incident to distribution only. Because some licensees subject to this report possess aggregated Category 1 or Category 2 quantities of radioactive material subject to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37, this NUREG additionally addresses security requirements associated with possession of that material. Appendix R of this NUREG provides guidance for the distribution and transfer of radioactive drugs, sealed sources, and devices directly to medical-use licensees by nonradiopharmacy entities. This guidance does not apply to those quantities of special nuclear material exceeding those listed in 10 CFR 70.22(h)(2)(i)(1).

For the purpose of this NUREG, manufacturers and distributors are those licensees that process raw material and/or sources and distribute those processed materials or manufactured products to users as finished products. Examples include major radiopharmaceutical processor/manufacturers (not radiopharmacies), sealed source fabricators, device manufacturers, and other manufacturing licensees that possess and use irradiated bulk quantities of raw materials or sources.

Distribution-only licensees are not involved in the processing of raw materials or sources or in the manufacturing of devices. Normally, imported products require a distribution and possession license to enable imported products to be distributed within the U.S. states and territories.

Quality control for finished products are described in the regulations of 10 CFR Part 32. The distribution of materials to persons exempt from licensing and distribution of materials to generally licensed persons and additional quality control guidance for these products are described in NUREG–1556, Vol. 8, “Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Exempt Distribution Licenses” and NUREG–1556, Vol. 16, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees.”

Chapter 8, “Contents of an Application,” of this report identifies the information needed to complete NRC Form 313, “Application for Material License” (see Appendix A of this NUREG) for the possession and use of byproduct, source, and special nuclear materials for manufacturing and distribution, and for distribution (only) for medical use (not radiopharmacies). If a license of broad scope is being sought under 10 CFR Part 33, “Specific domestic licenses of broad scope for byproduct material”, also refer to NUREG–1556, Vol. 11, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.” The Office of Management and Budget has approved the information collection requirements in Title 10 CFR Part 30, Part 32, Part 40, Part 70, and NRC Form 313 under the Clearance Nos. 3150-0017, 3150-0001, 3150-0020, 3150-0009, and 3150-0120, respectively.

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

- Regulations—references the regulations applicable to the item.
- Criteria—outlines the criteria used to evaluate the applicant’s response.
- Discussion—provides additional information about the topic.
- Response from Applicant—provides suggested response or responses, offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

Notes and references are self-explanatory and may not be found for each item on NRC Form 313. Sentences in this NUREG containing “must” and “will” are usually associated with NRC regulations. If these sentences are not tied to a regulatory requirement, they likely refer to a license condition or other obligation associated with the license. See NUREG–1556, Volume 20, “Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures,” for further information on license conditions.

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

Appendices C through S of this NUREG contain additional information on various radiation safety topics. Appendix C of this NUREG provides information on the types of licenses. Appendix R of this NUREG provides guidance in applying for distribution (only) to medical use licensees.

In this NUREG, “dose” or “radiation dose” means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE), as defined in 10 CFR Part 20, “Standards for protection against radiation.” To describe units of radiation exposure or dose, rem and its International System of Units equivalent, sievert (Sv) (1 rem = 0.01 Sv), are used. They are used 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.

¹Locations of NRC Offices and Agreement States

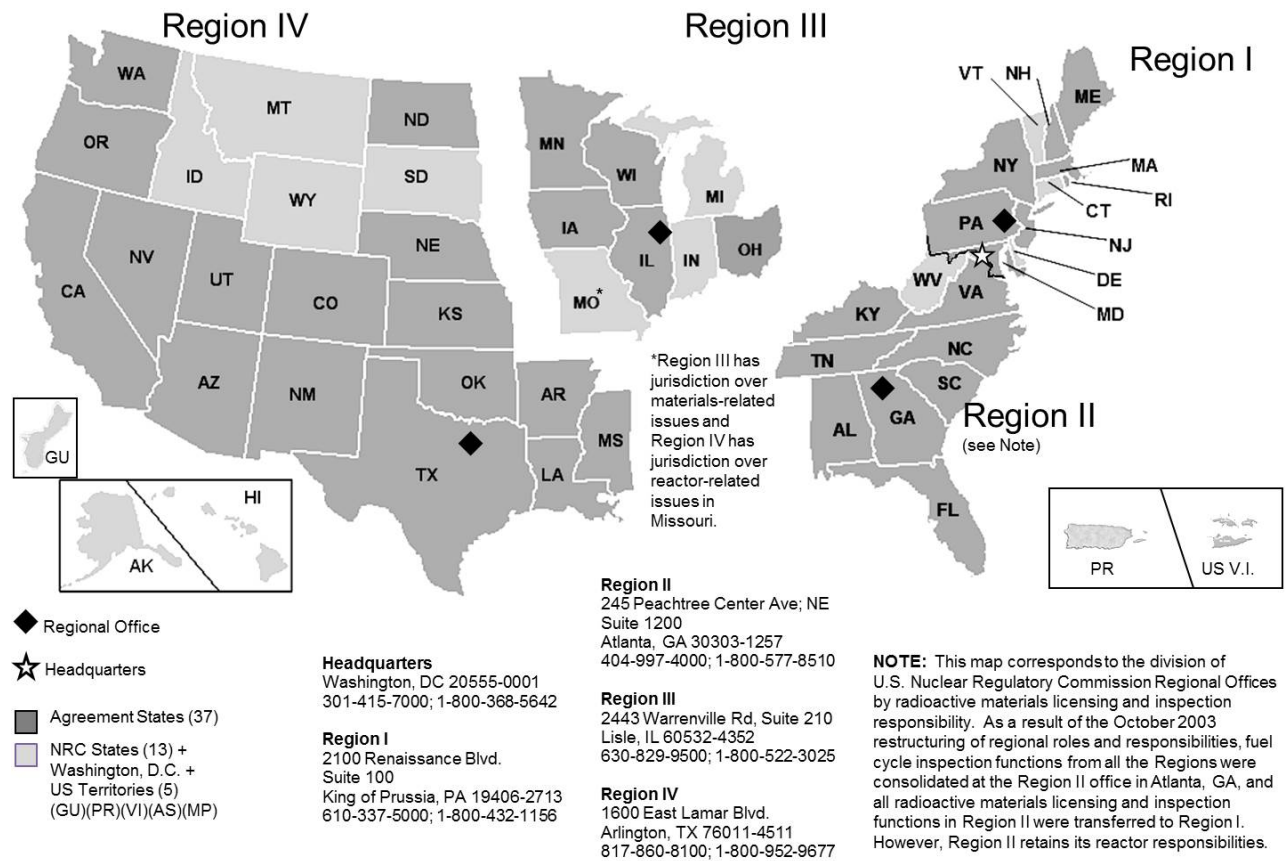


Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

In the special situation of work at Federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement

State has regulatory authority. These areas can also include Tribal lands of Federally recognized Indian Tribes.²

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

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

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 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

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

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

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

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). NRC licensees and Agreement State licensees are subject to the regulations of the regulatory authority as indicated in Section 2.1. To ensure compliance with an Agreement State’s reciprocity requirements, licensees are advised to request authorization from the appropriate Agreement State radiation control program office well in advance of the scheduled use of licensed material.

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

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

3 MANAGEMENT RESPONSIBILITY

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

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

3.1 Commitments and Responsibilities

Pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 30.32(c), 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 the behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual who signed the application is duly authorized to act for and on the behalf of the applicant or licensee. The signature on an application acknowledges the applicant’s or licensee’s commitments and responsibilities for the following:

- radiation safety, security, and control of radioactive materials and compliance with regulations
- completeness and accuracy of the radiation safety records and all information provided to the NRC (10 CFR 30.9, 40.9, and 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 regulations, the licensee’s operating, emergency, and security procedures, and NRC license commitments
- commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and compliance with regulations is maintained
- commitment to report defects, noncompliances, or reportable events, in accordance with regulations
- selection and assignment of 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, 40.7, and 70.7, “Employee protection”)
- commitment to provide information to employees about deliberate misconduct provisions (10 CFR 30.10, 40.10, and 70.10, “Deliberate misconduct”)
- commitment to obtain NRC’s prior written consent before transferring control of the license (see Section 9.1, “Timely Notification of Transfer of Control,” of this NUREG)
- notification of the appropriate NRC regional administrator, in writing, immediately following the filing of petition for voluntary or involuntary bankruptcy [10 CFR 30.34(h), 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 NRC’s safety culture policy statement (76 FR 34773; June 14, 2011) as “the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.” Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal-conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). Refer to Table 3-1 for the traits of a positive safety culture from NRC’s safety culture policy statement.

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

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, NRC's safety culture policy statement and traits are not incorporated into the regulations. Many of the safety culture traits may be inherent to an organization's existing radiation safety practices and programs. For instance, manufacturers and distributors develop production and quality assurance procedures for providing goods to others may correlate 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). 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 Q of this NUREG for the NRC's safety culture policy statement. More information on NRC activities relating to safety culture can be found at <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 licenses associated with the manufacturing and distribution of radioactive materials and products containing radioactive materials. 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 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 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 these documents may be obtained by calling the Government Publishing Office Customer Contact Center toll-free at 866-512-1800, in Washington, DC; calling 202-512-1800; or ordering online at <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 × 11-inch or legal-sized paper that will feed easily into a document scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura.
- Use 11-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

Applications must be signed by the applicant, licensee, or a person duly authorized, as required by 10 CFR 30.32(c), 40.31(b), and 70.22(d) (see Section 8.13, "Certification").
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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 (NRC) Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit www.nrc.gov.

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

- **Proprietary Information and Trade Secrets:** If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Appendix S of this NUREG provides a checklist for requests for withholding proprietary information from public disclosure.
- **Personally Identifiable Information:** Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII and the top of every page of a document that contains PII should be clearly marked as follows: “Privacy Act Information—Withhold Under 10 CFR 2.390.” For further information, see Regulatory Issue Summary (RIS) 2007-04, “Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission,” dated March 9, 2007, and Information Notice 2013-22, “Recent Licensing Submittals Containing Personally Identifiable Information,” dated November 15, 2013, which can be found on the NRC’s Generic Communications Web page under “Regulatory Issue Summaries” and “Information Notices,” respectively: <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.
- **Security-Related Information:** Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive, unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information, and the top of every page of a document that contains such information should be clearly marked: “Security-Related Information—Withhold under 10 CFR 2.390.” For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, Rev. 1, “Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material,” dated December 26, 2017, which can be found on the NRC’s Generic Communications Web page under “Regulatory Issue Summaries”: <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.

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

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

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

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

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

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

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

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

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

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

7 APPLICATION AND LICENSE FEES

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

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

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

8 CONTENTS OF AN APPLICATION

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

All items in the application should be completed in enough detail for the U.S. Nuclear Regulatory Commission (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, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," discusses the ALARA concept and philosophy. The application should document ALARA considerations, including establishing administrative action levels and monitoring programs.

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

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

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

8.1 Item 1: License Action Type

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

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

Check box A for a new license request. Note that a preclicensing visit may be required prior to issuance of the license. Also note that an initial on-site security review may be conducted in accordance with NRC Inspection Manual Chapter 2800, "Materials Inspection Program," before issuance of the license.

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

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

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

8.2 Item 2: Name and Mailing Address of Applicant

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

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

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

8.2.1 Notification of Bankruptcy Proceedings

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

Criteria: Immediately following the filing of a voluntary or involuntary petition for bankruptcy 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 know 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 its 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

Regulations: 10 CFR 30.34(c); 10 CFR 40.41(c); 10 CFR 70.41(a)

Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility at which licensed material will be used or stored. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable (see Figure 8-1). In addition, applicants are encouraged to provide global positioning system coordinates, as appropriate.

If licensed material is to be possessed or possessed and used at more than one location, give the specific address of each location. Applicants for a broad scope license need not identify each facility at a particular address where licensed material will be possessed or possessed and used. For example, broad scope applicants can specify that licensed material will be possessed or possessed and used on the manufacturing campus of ABC Corporation located on Presidential Avenue in Anytown, State.

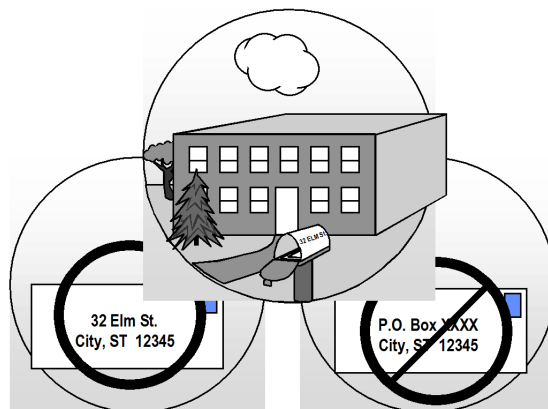


Figure 8-1. Location of Possession or Possession and Use. *An acceptable location of use or possession specifies street address, city, State, and zip code and does not include a post office box number.*

Applicants should identify all facilities designed or established for special uses (e.g., panoramic irradiators, interim or long-term waste storage facilities, high-activity laboratories, iodination facilities, alpha laboratories, and incinerators).

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

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

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

Note: As discussed in Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning,” licensees must maintain permanent records 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 as well as business cell phone numbers and e-mail addresses. This individual, usually the radiation safety officer (RSO), will serve as the point of contact during the review of the application. If this individual is not a full-time employee of the licensed entity, his or her position and relationship to the licensee should be specified. The NRC should be notified if the person assigned to this function changes or if his or her telephone number, cell phone number, or e-mail address changes. Notification of a contact change is only provided for informational purposes and would not be considered an application for license amendment, unless the notification involves a change in the contact person who is also the RSO.

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

8.5 Item 5: Radioactive Material

8.5.1 Sealed Sources and Devices or Unsealed Radioactive Material

Regulations: 10 CFR 20.2207; 10 CFR 30.6; 10 CFR 30.11; 10 CFR 30.32; 10 CFR 30.33; 10 CFR 30.36; 10 CFR 30.37; 10 CFR 30.38; 10 CFR 30.72; 10 CFR 32.11; 10 CFR 32.14; 10 CFR 32.18; 10 CFR 32.21; 10 CFR 32.22; 10 CFR 32.26; 10 CFR 32.30; 10 CFR 32.51; 10 CFR 32.53; 10 CFR 32.57; 10 CFR 32.61; 10 CFR 32.71; 10 CFR 32.72; 10 CFR 32.74; 10 CFR 32.210; 10 CFR Part 33; 10 CFR Part 37; 10 CFR 40.13; 10 CFR 40.31; 10 CFR 40.32; 10 CFR 40.34; 10 CFR 40.35; 10 CFR 40.36; 10 CFR 40.38; 10 CFR 40.41; 10 CFR 40.44; 10 CFR 51.20; 10 CFR 51.21; 10 CFR 51.22; 10 CFR 70.22; 10 CFR 70.39; 10 CFR 70.40; 10 CFR 70.41; 10 CFR 110.9; 10 CFR 110.9a; 10 CFR 110.31; 10 CFR 110.32; 10 CFR 150.7

Criteria: An application for a specific license will be approved if the requirements of 10 CFR 30.33, 10 CFR 40.32, 10 CFR 51.20, 10 CFR 70.39, 10 CFR 110.31, and/or 10 CFR 110.32 are met. In addition, licensees will be authorized to possess and use only those sealed sources and devices that are specifically approved or registered by NRC or an Agreement State pursuant to 10 CFR 32.210 or equivalent Agreement State regulations. Licensees must also protect aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5, from theft, diversion, and sabotage.

Discussion:

Materials That Must Be Listed in the Application

Each authorized radionuclide is listed on the NRC license by its element name, chemical and/or physical form, and the maximum possession limit (see Table 8-1). If a license of broad scope is being sought (under 10 CFR Part 33, "Specific domestic licenses of broad scope for byproduct material"), also refer to NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."

The applicant should list each requested radionuclide by its element name and its mass number {e.g., carbon-14 [C-14]} in Item 5. It is necessary to specify whether the material will be acquired and possessed and used in unsealed or sealed form. The name of the specific chemical compound that contains the radionuclide is not required. For potentially volatile radioactive material, however, it is necessary to specify whether the requested radionuclide will be acquired in free (volatile) or bound (nonvolatile) form because additional safety precautions are required when handling and using volatile material. For example, when requesting authorization to possess and use tritium (H-3) or iodine-125 (I-125), the applicant must 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 must be requested by the applicant. The applicant must provide evidence (or information) that demonstrates that the material obtained will be nonvolatile. NRC may issue the license with separate or combined possession limits, depending on the reviewer's analysis of the information provided.

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

If an applicant plans to possess radioactive materials 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," then they must provide with the application either (i) an evaluation showing that the maximum offsite dose because of a release of radioactive materials would not exceed 1 rem [0.01 Sievert (Sv)] effective dose equivalent or 5 rem [0.05 Sv] to the thyroid, or (ii) an emergency plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3). Pursuant to 10 CFR 70.22(i)(1)(i)(ii), applicants who plan to possess greater than 2 curies of plutonium in unsealed form or on foils or plated sources must provide with the application either (i) an evaluation showing that the maximum dose to a member of the public offsite due to a release of radioactive materials would not exceed 1 rem [0.01 Sievert (Sv)] effective dose equivalent or (ii) an emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and any associated chemical hazards directly incident thereto in accordance with the criteria listed in 10 CFR 70.22(i)(3). Refer to Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," Revision 1, issued April 2011, for additional information on emergency plans.

Applicant should specify the anticipated possession limit in megabecquerels (MBq) [millicuries (mCi)] or gigabecquerels (GBq) [curies (Ci)] for each radionuclide. 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.

If materials are expected or requested to be returned from customers, then these materials must be factored into the inventory. 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 Section 8.5.2, Financial Assurance and Decommissioning.

A safety evaluation of sealed sources and devices is performed by NRC or an Agreement State before authorizing a manufacturer or distributor to distribute them. The safety evaluation is documented in a Sealed Source and Device (SSD) registration certificate. Before the formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to possess and use those sources and devices specifically listed on their licenses. Applicants must provide the manufacturer's name and model number, as registered under 10 CFR 32.210 or similar Agreement State regulation, for each requested sealed source and device so that NRC can verify that they have been evaluated in an SSD registration certificate or specifically approved on a license. See also NUREG-1556, Vol. 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

Licensees should consult with the proposed manufacturer or distributor to ensure that requested sources and devices are compatible with and conform to the SSD designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining NRC's prior permission in a license amendment. To ensure that sources and devices are possessed and used in accordance with the registration certificates, applicants and licensees should request a copy of the certificate from the manufacturer or distributor, review it, and discuss it with the manufacturer or distributor. If the manufacturer and distributor are no longer in service, a copy of the SSD registration certificate may be requested from the NRC or the issuing Agreement State.

If a source is not listed in the SSD registry, applicants may be able to have the sources or devices authorized on a license under one of the following conditions:

- They submit all the information identified in 10 CFR 32.210 that is usually provided by the manufacturer when the source or device is registered.
- The item was manufactured prior to October 23, 2012, and the applicant submits as much of the 10 CFR 32.210 information as known, and all the additional information listed in 10 CFR 30.32(g)(2) to assure that the source and/or device can be used safely.
- The sealed source is a small calibration or reference source containing less than 1 mCi [37 MBq] of a beta or gamma emitter or 10 microcuries [μ Ci] (0.37 MBq) of an alpha emitter that is not required to be registered pursuant to 10 CFR 30.32(g)(3) and 32.210(g)(1).
- The applicant meets one of the criteria listed in 10 CFR 32.210(g)(2).

The submitted information will allow the NRC to conduct a case-by-case review to ensure that the material will not breach its containment. Material that is not registered in the SSD registry will be considered as unsealed until the applicant provides sufficient safety-related information that demonstrates that the source can be categorized as sealed. For additional guidance related to sealed sources and devices, see also NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

For sealed sources and devices not registered, as allowed by 10 CFR 32.210(g)(2), the applicant must demonstrate that they have adequate training and experience and facilities and equipment to handle comparable quantities of material in other forms under 10 CFR 30.33(a)(2) and (3) and should propose constraints about unregistered sealed sources and devices, in accordance with 10 CFR 30.32(g)(4).

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

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

Applicants must provide the manufacturer's name and model number, as registered under 10 CFR 32.210 or similar Agreement State regulation, for each requested sealed source or device containing Ra-226 or accelerator produced radioactive material. For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007, that are not registered with the NRC or Agreement State, the applicant must provide the information required in 10 CFR 30.32(g)(3).

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 8.10.10, "Security Program for Category 1 and Category 2 Radioactive Material," of this NUREG for more information on the applicability and requirements of 10 CFR Part 37.

Response from Applicant:

- For unsealed materials
 - For each radionuclide, provide the element name with mass number, chemical and/or physical form, and maximum requested possession limit.
- For potentially volatile materials (e.g., I-125, I-131, H-3, Kr-85)
 - Specify whether the material will be free (volatile) or bound (nonvolatile) and the requested possession limit for each form.

- For sealed radioactive materials
 - Identify each radionuclide (element name and mass number) that will be used and specify the maximum activity per source. Also, specify the maximum number of sources or total activity of each radionuclide.
 - Provide the manufacturer's or distributor's name and model number for each sealed source and device requested.
 - Confirm that each sealed source, device, and source and device combination is registered as an approved sealed source or device by NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available.
 - For each sealed source, device, and source and device combination that is not registered, provide the applicable information, as described in 10 CFR 30.32(g) and 32.210.
- Identify the largest quantity of each radionuclide to be possessed at one time under the license, including receipts, in-process materials, and waste.
- In accordance with 10 CFR 30.32(i), applications to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities listed in 10 CFR 30.72 must include either of the following:
 - an evaluation showing that the maximum offsite dose caused by a release of radioactive materials would not exceed 0.01 Sv [1 rem] effective dose equivalent or 0.05 Sv [5 rem] to the thyroid
 - an emergency plan for responding to the release, in accordance with the criteria listed in 10 CFR 30.32(i)(3)
- In accordance with 10 CFR 70.22(i), applications to possess in excess of 2 Ci of plutonium in unsealed form or on foils or plated sources must contain either of the following:
 - an evaluation showing that the maximum dose to a member of the public offsite due to a release of radioactive materials would not exceed 0.01 Sv [1 rem] effective dose equivalent
 - an emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and any associated chemical hazards directly incident thereto, in accordance with the criteria listed in 10 CFR 70.22(i)(3)

References: See the Notice of Availability (on the inside front cover of this report) to obtain copies of Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities." Regulatory Guide 3.67 is available on NRC's Web site at <https://www.nrc.gov>.

See also NUREG–1140, “A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees, Final Report,” January 1988 (ADAMS Accession No. ML062020791)

8.5.2 Financial Assurance and Recordkeeping for Decommissioning

Regulations: 10 CFR 30.32(h); 10 CFR 30.34(b); 10 CFR 30.35; 10 CFR 30.36(e); 10 CFR 30.36(g)(4)(v); 10 CFR 30.51(d); 10 CFR 30.51(e); 10 CFR 30.51(f); 10 CFR 40.31(i); 10 CFR 40.36; 10 CFR 40.41(b); 10 CFR 40.42(e); 10 CFR 40.42(g)(4)(v); 10 CFR 40.46; 10 CFR 40.61(d); 10 CFR 40.61(e); 10 CFR 40.61(f); 10 CFR 70.22(a)(9); 10 CFR 70.25; 10 CFR 70.32(a)(3); 10 CFR 70.36; 10 CFR 70.38(e); 10 CFR 70.38(g)(4)(v); 10 CFR 70.51(a); 10 CFR 70.51(b)(3).

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

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

Before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and/or 10 CFR 70.36, licensees must transfer records important to decommissioning to the new proposed licensee in accordance with 10 CFR 30.35(g), 10 CFR 40.36(f) and/or 10 CFR 70.51(b)(3), respectively. Furthermore, before a license is terminated, the licensee must send records important to decommissioning that are required by 10 CFR 30.35(g), 10 CFR 40.36(f) and/or 10 CFR 70.25(g) to the appropriate NRC regional office in accordance with 10 CFR 30.51(f), 10 CFR 40.61(f), and/or 10 CFR 70.51(a), respectively.

Discussion: NRC seeks to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment (53 FR 24018, June 28, 1988). There are two parts to the rule: financial assurance that applies to some licensees; and recordkeeping, which applies to all licensees.

Financial Assurance

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

Acceptable FA includes prepayment options (trusts, escrow accounts, government funds, certificates of deposit, or deposits of government securities); surety, insurance, or other

guarantee methods (e.g., letters of credit, surety bonds, lines of credit, parent company guarantees, insurance policies); and statements of intent from Government entities. Criteria for parent company guarantees and self-guarantees can be found in 10 CFR 30, Appendix A, Appendix C, Appendix D, and Appendix E. Refer to 10 CFR 30.35(d) for a table of required amounts of financial assurance for decommissioning by quantity of material.

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

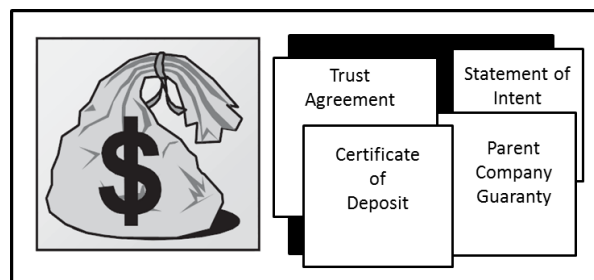


Figure 8-2. Methods of Providing Financial Assurance for Decommissioning

Most manufacturer licensees do not need to provide *financial assurance* for decommissioning. Large manufacturers may need one of several approved financial mechanisms.

Recordkeeping for Decommissioning

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



Figure 8-3. Records Important to Decommissioning. *All possession for manufacturing and distribution licensees must maintain records important to decommissioning, regardless of whether they need financial assurance for decommissioning.*

In accordance with 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g), licensees must transfer records important to decommissioning to the new licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b), 40.46(b) and 70.36(b).

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), respectively, to the appropriate NRC regional office.

Response from Applicants:

- 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 records important to decommissioning and will transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and 10 CFR 70.36, as appropriate. 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.”

AND

- If financial assurance is required, submit the required documents, as described in NUREG–1757, Volume 3, “Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness.”

References: See the Notice of Availability (on the inside front cover of this report) to obtain copies of NUREG–1757.

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

Regulations: 10 CFR 30.4; 10 CFR 30.33(a)(1); 10 CFR 30.41; 10 CFR 32.2; 10 CFR 32.11; 10 CFR 32.14; 10 CFR 32.18; 10 CFR 32.21; 10 CFR 32.22; 10 CFR 32.26; 10 CFR 32.51; 10 CFR 32.53; 10 CFR 32.57; 10 CFR 32.61; 10 CFR 32.71; 10 CFR 32.72; 10 CFR 32.74; 10 CFR 32.210; 10 CFR 40.4; 10 CFR 40.32; 10 CFR 51.20; 10 CFR 51.21; 10 CFR 51.22; 10 CFR 70.4; 10 CFR 70.39; 10 CFR 70.42; 10 CFR 110.2; 10 CFR 110.20; 10 CFR 110.42; 10 CFR 110.43; 10 CFR 110.50.

Criteria: Requested radionuclides must be possessed and used for purposes authorized by the Atomic Energy Act of 1954, as amended. The applicant must specify the purpose of use for each sealed and unsealed radionuclide requested. Sealed sources and devices containing licensed material must be possessed and used only for the purpose for which they are designed and according to manufacturer’s and distributor’s instructions and recommendations for possession and use, as specified in the SSD registration certificate, unless otherwise authorized in the license.

In order to have a license for distribution of sources and devices containing radioactive materials, the applicant normally must first apply for and receive a sealed source and device registration, in accordance with the procedures in NUREG–1556, Volume 3, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration.”

Note: If distributing sealed sources and devices to medical use licenses, also see Appendix R of this NUREG, “Medical Distribution.”

Discussion: Applicants should clearly specify the purpose for which each radionuclide will be used. The description should be detailed enough to allow NRC to determine the potential for exposure to radiation and radioactive materials to those working with radioactive materials and to members of the public.

Applicants should pay particular attention to the applicable regulations listed above when applying for a license to manufacture and distribute licensed material. However, this list is not exhaustive, nor does it relieve the applicant from complying with applicable Federal, State, and local requirements.

Applicants should clearly specify if the licensed material will be used in animal studies or tracer studies as part of manufacturing. Use of licensed material in animals may be in quality control or research studies. Applicants should also state whether the studies will be limited to small animals (e.g., rats, mice) or may also include larger animals (e.g., pigs, dogs, horses). Applicants including animal studies, tracers, or research and development can include the

requested licensed materials in this application and should refer to NUREG–1556, Vol. 7, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers.” Applicants intending to possess and use licensed materials for medical research involving humans must be authorized to do so pursuant to a license issued under 10 CFR Part 35 and should refer to NUREG–1556, Vol. 9, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.” Applicants intending to become a broad-scope licensee should refer to NUREG–1556, Vol. 11, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope,” for instructions.

Licensees who possess and use licensed materials to support the process of manufacturing or distribution must have the appropriate possession and uses described in their licenses. An example may be that a manufacturer of depleted uranium counterweights or shields possesses and uses a cesium-137 level gauge to detect blockage in the raw material hopper feed line. The manufacturer would need authorization not only to possess, use, and distribute the uranium for the counterweights and the shields, but also a line authorization to possess and use the level gauging device. If the licensee wishes to calibrate its own radiation survey meters and perform leakage and contamination tests, then they should submit separate line authorizations for the sources and devices that they will need to perform these tasks. The licensee should have procedures for these sources, devices, and uses.

Applicants may use the format given in Table 8-1 below to provide the requested information.

Table 8-1. Sample Format for Providing Information About Requested Radionuclides			
Radionuclide	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Manufacturing—Internal Uses			
Any byproduct material with atomic numbers 1 through 83	Any	Not to exceed 370 GBq [10 Ci] per radionuclide and 3,700 GBq [100 Ci] total	Research and development as defined in 10 CFR 30.4
Hydrogen-3	Unbound/volatile	3.7 GBq [100 mCi]	Labeling of compounds
Hydrogen-3	Bound/non-volatile	3.7 GBq [100 mCi]	In vitro studies; studies in small lab animals
Iodine-125	Unbound/volatile	1.11 GBq [30 mCi]	Protein iodination
Iodine-125	Bound/non-volatile	1.85 GBq [50 mCi]	In vitro studies; studies in small lab animals; calibration of instruments
Cesium-137	Sealed source, Mfg. name/model number	0.74 GBq [20 mCi]	Calibration of instruments

Table 8-1. Sample Format for Providing Information About Requested Radionuclides (Continued)

Radionuclide	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Manufacturing and Distribution			
Hydrogen-3	Unbound/volatile	3.7 GBq [100 mCi]	Labeling of compounds
Iodine-125	Unbound/volatile	1.11 GBq [30 mCi]	Protein iodination
Any byproduct material with atomic numbers 1 through 83	Any	Not to exceed 370 GBq [10 Ci] per radionuclide and 3,700 GBq [100 Ci] total	For possession, use, and processing for manufacturing of radiochemicals, radiopharmaceuticals, and sealed sources
Any byproduct material with atomic numbers 84 through 94	Any	Not to exceed 1.85 GBq [50 mCi] per radionuclide and 2 curies total	For storage prior to distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources
Hydrogen-3 Carbon-14 Phosphorus-32 Phosphorus-33 Sulfur-35	Any Any Any Any Any	3700 TBq [100,000 Ci] 18.5 TBq [500 Ci] 3.7 TBq [100 Ci] 0.74 TBq [20 Ci] 14.8 TBq [400 Ci]	For storage prior to distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources
Hydrogen-3 Carbon-14 Phosphorus-32 Phosphorus-33 Sulfur-35	Any Any Any Any Any	3700 TBq [100,000 Ci] 18.5 TBq [500 Ci] 3.7 TBq [100 Ci] 0.74 TBq [20 Ci] 14.8 TBq [400 Ci]	For packaging and distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses
Molybdenum-99/Technetium-99m	Any	18.5 TBq [500 Ci]	For possession, use, and processing for manufacturing of radiochemicals and radiopharmaceuticals

Table 8-1. Sample Format for Providing Information About Requested Radionuclides (Continued)

Radionuclide	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Distribution			
Xenon-133	Prepackaged Units	1.85 TBq [50 Ci]	For possession incident to commercial redistribution of unopened containers to authorized recipients
Hydrogen-3	Any	3700 TBq [100,000 Ci]	Distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources
Carbon-14	Any	18.5 TBq [500 Ci]	
Phosphorus-32	Any	3.7 TBq [100 Ci]	
Phosphorus-33	Any	0.74 TBq [20 Ci]	
Sulfur-35	Any	14.8 TBq [400 Ci]	

Applicants requesting a license for distribution only may need to refer to the information in Appendix C of this NUREG, which describes the different types of distribution licenses (i.e., General “G” Distribution License, Medical “MD” Distribution License, and Exempt “E” Distribution License), in order to determine whether this guidance document should be used for their application. Applicants for medical distribution licenses must refer to 10 CFR 32.72 and 32.74, in addition to the guidance specified in Appendices C and R of this NUREG. Some “manufacturers” that are importers of materials and devices from abroad may not require the same extent of information submission and review as a facility that produces an item. However, they are required to have a manufacturer or distributor license as the initial importer and distributor in the U.S. The device distributor may be the sponsor of the “Sealed Source and Device Registry” certificate. The general distribution-only license (“G”) and the exempt distribution-only license (“E”) application requirements are not covered in this document. Applicants for these licenses are referred to NUREG–1556, Vol. 16, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees,” and NUREG–1556, Vol. 8, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses.”

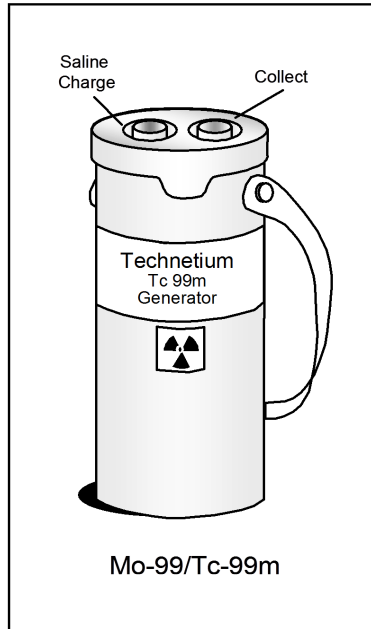


Figure 8-4. Example of a Product Produced Under Possession for Manufacturing and Distribution Authorization

Response from Applicant:

- List the specific use or purpose of each radionuclide that will be possessed and used.¹
- Provide the manufacturer name and model number for each device, manufactured article, or material that becomes the product, by manufacturer and model number.
- Provide the manufacturer and model number of each sealed source proposed for possession and use or incorporation into a manufactured article.
- Submit information requesting authorization to possess and use any other licensed materials in support of the manufacturing and distribution license.

Note: Applicants intending to manufacture sealed sources or devices for medical use should refer to Appendix R of this NUREG, Item 10.2, for sealed source and device licensing criteria for evaluation of design and construction.

¹See Table 8-1.

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

Regulations: 10 CFR 30.33(a)(3); 10 CFR 40.32(b); 10 CFR 70.22(a)(6); 10 CFR 70.23(a)(2)

Criteria: Executive management, the Radiation Safety Officer (RSO) (and his or her staff, as necessary), and authorized users work as a team to implement the Radiation Protection Program. Each individual and position plays a critical role within his or her area of responsibility. The roles and responsibilities of executive management, the RSO, the Radiation Safety Office staff, authorized users, and others in restricted areas are discussed in the sections that follow. Refer to the subsequent sections specific to the RSO and Authorized Users described above.

Note: NUREG–1516, “Management of Radioactive Material Safety Programs at Medical Facilities,” describes the role of executive management and the RSO at medical facilities and contains information that may be useful to licensees authorized for possession for manufacturing and distribution.

Discussion: The applicant or licensee must be qualified by training and experience to possess and use the material for the purpose requested in a manner that will protect health and minimize danger to life or property before an application for a license is approved.

Each program in which radioactive materials are possessed and used under an NRC license must have someone responsible for radiation safety and compliance with the NRC’s regulations. In a small program, the responsibility may be combined with or assigned to (or assumed by) the same individual using radioactive materials; therefore, an authorized user may serve as an RSO. In a medium-sized program, the responsibility may be assigned to an individual on a part-time basis with that person’s primary responsibility being in another area of work. For large programs, the many facets of occupational and environmental radiation safety will often require that responsibility for the Radiation Safety Program be assigned to a qualified individual on a full-time basis. His or her training and experience must be commensurate with his or her duties and responsibilities. Supporting staff should be provided, as appropriate, for the size and scope of the program. A large program may have some or all of the following characteristics:

- in-house calibration of radiation survey, monitoring, and measurement instruments
- possession and use of multiple chemical and physical forms of multiple radionuclides for various purposes
- program flexibility with regard to the possession and use of radionuclides, their chemical and physical form, and the uses to be made of such radionuclides
- accurate detection, identification, and measurement of radioactivity in various types of effluents (gas, liquid, solid) containing varying amounts of different radionuclides and for evaluation of these effluents against NRC regulatory requirements and limitations
- radioactive effluent treatment by filtration, absorption, adsorption, holdup, etc.
- selection, evaluation, design, fabrication, maintenance, and use of radioactive effluent treatment systems

- selection, evaluation, and maintenance of radiation measurement and analysis equipment
- potential for the contamination of facilities, equipment, and personnel accompanied by the need to control such contamination (including airborne contamination), decontaminate personnel and equipment, and evaluate possible internal dose (including determination of the need for bioassays and interpretation of bioassay results)

The licensee's senior management maintains the ultimate responsibility for the safety of licensed activities. NRC holds the licensee responsible for the Radiation Protection Program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted safely. Management responsibility and liability are sometimes underemphasized or not addressed in applications and are often poorly understood by licensee employees and managers. As discussed later in this guide, senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NRC regulations and license provisions and to terminate unsafe activities involving byproduct, source, and special nuclear material. Other responsibilities may be delegated to other individuals with adequate training and experience. Such delegations should be clearly communicated to all parties.

If a license of broad-scope is being sought (under 10 CFR Part 33, "Specific domestic licenses of broad scope for byproduct material"), also refer to NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."

Response from Applicant: Refer to the subsequent sections specific to the individuals described above. Applicants should submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO.

8.7.1 Radiation Safety Officer

Regulations: 10 CFR 30.33(a)(3); 10 CFR Part 37; 10 CFR 40.32(b); 10 CFR 70.23(a)(2)

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

Discussion: The person responsible for implementing the radiation protection program including overseeing and ensuring that the licensee's radioactive material is used and stored safely and securely is the RSO. For licensees possessing an aggregated Category 1 or Category 2 quantity of radioactive material, the RSO should participate in the development and implementation of a security program for radioactive material in accordance with 10 CFR Part 37. A "Category 1 quantity of radioactive material" and a "Category 2 quantity of radioactive material" are defined terms in 10 CFR 37.5, and the radionuclides referenced in these 10 CFR 37.5 definitions are listed in Appendix A to 10 CFR Part 37. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO should have independent authority to stop operations that he or she considers unsafe. He or she should have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are possessed and used in a safe manner, approved radiation safety procedures are being implemented, and the required records of licensed activities are

maintained. Typical RSO duties are illustrated in Figure 8-5 and described in Appendix D of this NUREG. 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 and that the named individual knows of his or her designation as RSO. Appendix D 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.

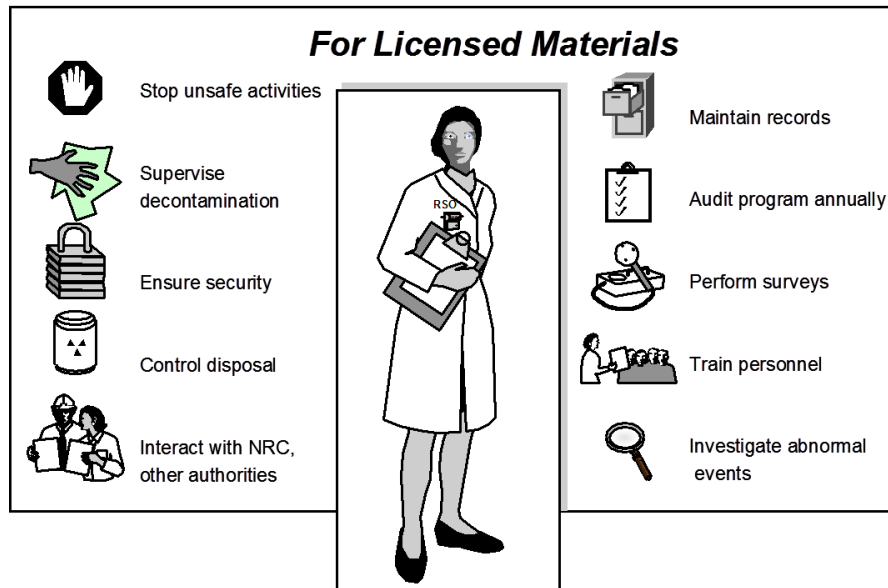


Figure 8-5. Typical Duties and Responsibilities of RSOs

The RSO should have at a minimum, (i) a college degree at the bachelor level or equivalent training and experience in the physical or biological sciences or in engineering; and (ii) training and experience commensurate with the scope of proposed activities.

Training should include the following subjects:

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

Experience should include the following areas:

- planning and conducting evaluations, surveys, and measurements similar to those required by the licensee's Radiation Safety Program
- using licensed materials that are similar in types, forms, and quantities to those proposed for use under the license
- securing and controlling licensed materials
- monitoring inventory of materials possessed under the license; maintaining records of receipts, transfers, and disposal of licensed materials
- storing, handling, disposing of and documenting radioactive waste materials
- planning, conducting, and documenting audits and other evaluations of the radiation safety program
- evaluating and documenting radiation exposures
- maintaining required records of the radiation safety program and providing required reports
- other applicable duties and responsibilities as described in Appendix D of this NUREG

The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested. For example, in addition to a college degree, RSOs at a manufacturing company where workers handle curie quantities of radioactive material should be specialists in the field of radiation protection and may need at least 40 hours of radiation safety training specific to their job duties, as well as 1 year of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be RSO. The proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. The RSO designee should have obtained the above training in formal course(s) designed for RSOs, presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts. Another example is for distributors who import sealed material that are distributed as exempt quantities; for these licensees, the RSOs may only need basic radiation safety and transportation training and no prior experience working with radioactive material.

Response from Applicant:

Provide the following:

- name of the proposed RSO
- information demonstrating that the proposed RSO is qualified by training and experience should include, as a minimum:
 - formal training and education in radiation safety (topics covered, duration of training, when training was received, identity/location of training provider)
(Note: a course outline may be provided)

- experience using licensed materials (types, forms, quantities handled, activities performed, duration of experience)
- experience performing the duties of a RSO (activities, duration of experience, scope of program)

Applicants should provide information about the proposed RSO's training and experience relative to the licensed material and uses requested in the application. Do not include personally identifiable information (PII) (e.g., home address, home telephone number, social security number, date of birth, and radiation dose information). For further information concerning PII, see Chapter 6, "Identifying and Protecting Sensitive Information." Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, and personal private information. Submittal of unrelated material may slow down the review process.

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

8.7.2 Authorized Users

Regulations: 10 CFR 20.1101(b); 10 CFR 30.33(a)(3); 10 CFR 40.32(b); 10 CFR 70.23(a)(2); 10 CFR 71.5; 10 CFR 110.26; 10 CFR 110.27; 10 CFR 110.28; 10 CFR 110.29; 10 CFR 110.30; 10 CFR 110.42; 10 CFR 110.43; 10 CFR 110.44; 49 CFR Parts 170 through 180 (appropriate to the mode of transport).

Criteria: Authorized Users (AUs) must have adequate training and experience with the types and quantities of licensed material that they propose to possess and use.

Discussion: Applicants must name at least one individual who is qualified to use the requested licensed materials. An AU is a person whose training and experience have been reviewed and approved by NRC, who is normally named on the license, and who uses or directly supervises the use of licensed material. The AU's primary responsibility is to ensure that radioactive materials are used safely and according to regulatory requirements. The AU is also responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

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

The NRC believes that the AU should have (i) a college degree at the bachelor level or equivalent training and experience in physical, chemical, or biological sciences or in engineering

and (ii) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection instrumentation
- biological hazards of exposure to radiation (appropriate to the types and forms of byproduct material that the licensee will use)
- hands-on use of radioactive materials

The amount of training and experience needed will depend upon the type, form, quantity, and proposed use of the licensed material requested, but it should cover the subjects stated.

For instance, in addition to a college degree, AUs at a manufacturing company where workers handle curie quantities of radioactive material should have 40 hours of radiation safety training and a minimum of 6 months of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be an authorized user. On the other hand, AUs at “manufacturers” who are importers of timepieces containing tritium that are received in the U.S. as completed products that will be distributed as exempt quantities may only require a few hours of radiation safety training and no prior experience with timepieces containing tritium to be qualified as an AU. In general, AUs must demonstrate training and experience with the type and quantity of material that they propose to use. For example, someone with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters.

An AU is considered to be supervising the use of radioactive materials when he or she directs personnel in operations involving the licensed material. Although the AU may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), he or she is responsible for the safe use of radioactive material to ensure that areas are not contaminated.

Response from Applicant: Provide the following:

- name of each proposed AU with the types and quantities of licensed material to be possessed or possessed and used
- information demonstrating that each proposed AU is qualified by training and experience to possess and use the requested licensed materials, including, as a minimum:
 - formal training and education in radiation safety (topics covered, duration of training, when training was received, identity/location of training provider)
(Note: a course outline may be provided)

- experience using licensed materials (types, forms, quantities handled, activities performed, duration of experience)

Applicants should provide information about the proposed AU's training and experience relative to the licensed material requested in the application. Do not include PII (e.g., home address, home telephone number, social security number, date of birth, and radiation dose information). For further information concerning PII, see Chapter 6, "Identifying and Protecting Sensitive Information." Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material may slow the review process.

Note: Applicants for broad scope programs should refer to NUREG–1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope." Broad-scope programs may be permitted to name authorized users without amending the license.

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 37.43; 10 CFR 40.32(b); 10 CFR 40.41(e); 10 CFR 70.23(a)(2); 10 CFR 70.32(b)

Criteria: Individuals whose assigned duties involve exposure to radiation or radioactive material (from both licensed and unlicensed sources), and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv [100 mrem], whether from all external sources, all internal sources, or any combination, must receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12. Any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material (as defined in 10 CFR 37.5) must implement a training program for those individuals implementing the security program.

Discussion: Before beginning work with or in the vicinity of licensed material, all individuals who are likely to receive an occupational dose in excess of 1 millisievert (mSv) [100 millirem] in a year must receive radiation safety training commensurate with their assigned duties and specific to the licensee's Radiation Safety Program. Each individual should also receive periodic (for example, annual) refresher training. Training should also be performed whenever there is a significant change in hazards, duties, procedures, regulations, or terms of the license.

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

Training may be in the form of lecture, demonstrations, videotape, online, or self-study, and should emphasize practical subjects important to the safe possession and use of licensed

material. If training is not conducted by an instructor, a method should be adopted whereby a trainee can ask questions and discuss topics relating to occupational radiation exposure. The guidance in Appendix E of this NUREG, "Radiation Safety Training," may be used to develop a training program. The program should consider all topics pertinent for each group of workers, as well as the method and frequency of training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. This assessment may be performed by a test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

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

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

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

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

8.9 Item 9: Facilities and Equipment

Regulations: 10 CFR 20.1101(b); 10 CFR 20.1406; 10 CFR 30.33(a)(2); 10 CFR 30.35(g); 10 CFR Part 37; 10 CFR 37.5; 10 CFR 37.49; 10 CFR 37.53; 10 CFR 40.27(b); 10 CFR 40.28(b); 10 CFR 40.31(h); 10 CFR 40.32(c); 10 CFR 40.34(a); 10 CFR 70.23(a)(3); 10 CFR 70.39(a).

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. Facilities and equipment must also provide enhanced physical protection of aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5. They must minimize the possibility of contamination and keep exposures to workers and the public ALARA. Applicants must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: Applicants must demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the uses of the types and quantities of radioactive materials to be used.

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

Applicants are reminded that records important to decommissioning as described in 10 CFR 30.35(g), 40.36(f), and 70.25(g) must include the following:

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

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

For additional guidance regarding facilities and equipment, refer to Appendix F of this NUREG, "Facilities and Equipment."

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

- implementation of and adherence to good health physics practices in operations
- minimization of areas, to the extent practicable, where licensed materials are used and stored
- maximization of the frequency of surveys, within reason, to minimize spread of contamination in the event of a spill
- choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition
- appropriate filtration of effluent streams

- use of nonporous materials for such areas as counter tops and flooring
- ventilation ductwork with minimal lengths and minimal abrupt changes in direction
- use of appropriate plumbing materials with minimal pipe lengths and traps
- minimization of the number of disposal sites (sinks) where liquid waste is disposed

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 the protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

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

Response from Applicant:

- Describe the facilities and equipment to be made available at each location where radioactive material will be possessed or possessed and used (see Appendix F of this NUREG for topics to consider). This information should be from the point of view of performance criteria. For example, state the purpose of any filtration equipment and the associated acceptance criteria to accomplish this purpose (such as the ventilation flow rate trying to be maintained).
- Include a description of the areas assigned for the receipt, shipping, storage, preparation, security, and measurement of radioactive materials.

- Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, areas containing flammable or hazardous materials, and other items related to radiation safety (see Figure 8-6).
 - When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems.
- Diagrams should be drawn to a specified scale or dimensions should be indicated. Sketches or drawing should also include a compass directional arrow to indicate “North”.
 - For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.
- If radioactive materials will be used with animals, include a description of the animal-handling housing facilities. NUREG–1556, Vol. 7 may also be used as guidance.
- Specialized facilities such as waste storage rooms or hot labs, and locations of specialized facilities or equipment such as waste compactors, hot cells, and shielded storage for high activity sources, should be included on the diagram.

Note: Diagrams of facilities should be marked: “Security-Related Information—Withhold under 10 CFR 2.390.”

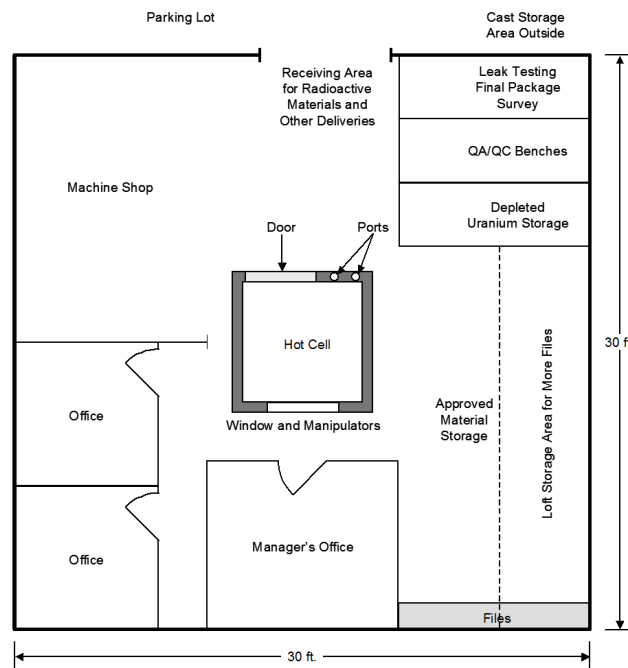


Figure 8-6. Diagram Showing Information Related to Radiation Safety. *This diagram is an example only and does not contain actual security-related information.*

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

8.10 Item 10: Radiation Safety Program

8.10.1 Audit and Review of Program

Regulations: 10 CFR 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 safety programs at least annually to ensure the program

- is commensurate with the scope and extent of licensed activities
- is compliant with NRC and DOT regulations (as applicable), and the terms and conditions of the license
- maintains occupational doses and doses to members of the public ALARA (10 CFR 20.1101)
- is documented, and appropriate records are maintained for the duration required by the regulations

Records of audits and other reviews of program content must be maintained for 3 years after the record is made, in accordance with 10 CFR 20.2102.

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

Discussion: Appendix G of this NUREG contains a suggested audit program that is specific to possession licenses for manufacturing and distribution and is acceptable to NRC. Because all areas indicated in Appendix G may not be applicable to every licensee and all items may not need to be addressed during each audit, licensees may wish to develop a program-specific audit checklist.

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

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

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

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

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

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

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

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

References:

- Inspection Procedure 87126, “Industrial/Academic/Research Programs,” September 2005
- Inspection Procedure 87125, “Materials Processor/Manufacturer Programs,” September 2005
- Information Notice 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” dated May 1, 1996

8.10.2 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)(3)

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

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

- package surveys
- measure personnel and facility contamination
- test for sealed source leaks
- take and measure air samples
- take bioassay measurements
- take effluent release measurements
- perform dose rate surveys

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

- portable or stationary count rate meters
- portable or stationary dose rate or exposure rate meters
- single or multichannel analyzers
- liquid scintillation counters
- gamma counters
- proportional counters
- solid state detectors
- neutron detectors

Other equipment and instrumentation associated with the radiation hazard assessment also must be calibrated periodically, in accordance with 10 CFR 20.1501(c). This includes equipment used to collect radiological samples to perform assessments of airborne hazards and other radiological hazards that cannot be directly assessed, such as

- rotameters
- anemometers
- other devices that measure air pump flow rates, volumes, and time
- liquid volume collection and measurement devices

The choice of instrument should be appropriate for the type of radiation to be measured, and for the type of measurement to be taken (e.g., count rate, dose rate). Applications should include descriptions of the instrumentation available for use and the instrumentation that applicants intend to purchase prior to starting licensed activities. The description should include the type of instrument and probe, and the instrument's intended purpose.

NRC regulation (10 CFR 20.1501) requires that radiation survey instruments used for quantitative measurements be calibrated periodically. Calibrations requiring the use of radioactive sources should be performed by the instrument manufacturer or persons specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests this authorization. Radiation survey instruments should be calibrated at least annually (every 12 months), unless another frequency is specified by regulation or license condition. Applicants seeking authorization to perform radiation survey instrument calibrations will need to submit procedures for review. The licensee may wish to review available industry standards for calibration of instruments, such as American National Standards Institute (ANSI) N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Appendix H of this NUREG provides radiation monitoring instrument specifications and a model

radiation survey instrument calibration program. Applicants should be aware that calibrations often require possession and use of a calibration source or device. Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts with 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).

Some instruments may only need to be checked periodically for operability and response to radiation rather than receive full calibration. For example, G-M detection instruments used to identify contamination in laboratories may only need to be checked for ability to detect low-level contamination. However, such instruments cannot be used for quantitative measurement of surface contamination or radiation levels without a calibration with appropriate radioactive sources, as described in Appendix H of this NUREG.

Response from Applicant:

For Radiation Monitoring Instruments

Describe the instrumentation that will be used to perform required surveys.

AND

State that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix H in NUREG-1556, Volume 12, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution." We reserve the right to upgrade our radiation survey instruments as necessary."

For Instrument Calibration

State that: "Instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration."

OR

State that: "We will implement the model radiation survey instrument calibration program published in Appendix H in NUREG-1556, Volume 12, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.""

OR

Submit equivalent procedures for instrument calibrations.

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

8.10.3 Material Receipt and Accountability

Regulations: 10 CFR 20.1501(a); 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 20.2001; 10 CFR 20.2108; 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 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 70.25(g); 10 CFR 70.32(b); 10 CFR 70.42; 10 CFR 70.51

Criteria: Licensees must do the following:

- develop, implement, and maintain written procedures for safely opening packages
- develop, implement, and maintain procedures to ensure security and accountability of licensed material
- maintain records of receipt, transfer, and disposal of licensed material
- update transactions in the National Source Tracking System (NSTS), including performing annual inventory reconciliation, if applicable
- before transferring aggregated Category 1 or Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37, use NRC's license verification system to verify that the recipient licensee is authorized to possess the radioactive material
- preplan, coordinate, and provide advance notification of shipment of Category 1 quantities of radioactive material, and coordinate shipment of Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37
- 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: To ensure that only trained, experienced, and authorized individuals use or supervise the use of licensed material, the RSO should know who has requested an order of licensed material and the types and amounts of licensed materials requested. Control procedures should also be established for the procurement of licensed materials that may be obtained outside the normal channels (e.g., through the loan or other transfer of materials without purchase or through surplus). A sample procedure for Ordering and Receiving Radioactive Material is included in Appendix I 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 is considered to become part of the licensee's inventory at the time that it is received by the licensee, be it during normal working hours or after hours when delivered by the carrier, in accordance with procedures established by the licensee. If through some error, the licensee receives material it is unauthorized to possess or receives quantities of material that would result in the total inventory being in excess of license possession limits, the licensee should place the package in secure storage and arrange for the return of these materials in a

timely manner. If return of the materials is not possible, the licensee should contact the NRC regional office and request issuance of an expedited license amendment. The materials must not be used until the amendment is granted.

Licensees 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, “Procedures for receiving and opening packages.” Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered. Sample procedure for safely opening packages containing licensed materials is included in Appendix I of this NUREG.

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

If the package of licensed material is delivered to the licensed facility’s receiving department, individuals working in that department 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.

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

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

Table 8-2. Package Monitoring Requirements

Package	Contents	Survey Type	Survey Time*
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Less Than or Equal to Type A	Radioactive Contamination [§20.1906(b)(1)]	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less Than or Equal to Type A	None [§20.1906(b)(1)]	None
Not Labeled	Licensed Material	None [§20.1906(b)]	None [†]

*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.

[†]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 a good health physics practice to perform an incoming survey on these packages, even though transportation regulations do not require it.

The licensee is required to immediately notify the final delivery carrier and the NRC Operations Center by telephone at 310-816-5100, pursuant to 10 CFR 20.1906(d), 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. The limits in 10 CFR 71.87(i) refer to 49 CFR 173.443, Table 9; for packages that are not transported by exclusive use shipment (i.e., most packages), the relevant limits will be for “Non-fixed external radioactive contamination limits for packages” for beta/gamma emitters and low-toxicity alpha emitters, 4 Bq/cm² [240 disintegrations per minute (dpm)/cm²], and for all other alpha emitters, 0.4 Bq/cm² [24 dpm/cm²] on the external surfaces of the package. The limits in 10 CFR 71.47 that are applicable to packages that are not transported by exclusive-use shipment (i.e., most packages) are 2 mSv/h [200 mrem/h] at any point on the external surface of the package and the transport index does not exceed 10.

As illustrated in Figure 8-7, licensed materials must be tracked from “receipt to disposal” in order to ensure accountability at all times; identify when licensed material may be lost, stolen, or misplaced; and to ensure that possession limits listed on the license are not exceeded.

Licensees are required under 10 CFR 20.1801 and 20.1802 to secure radioactive materials from unauthorized removal or access while in storage in controlled or unrestricted areas and to control and maintain constant surveillance over licensed material that is in a controlled or unrestricted area and is not in storage. Applicants for limited-scope licenses should establish policies and procedures for ensuring accountability of licensed materials.

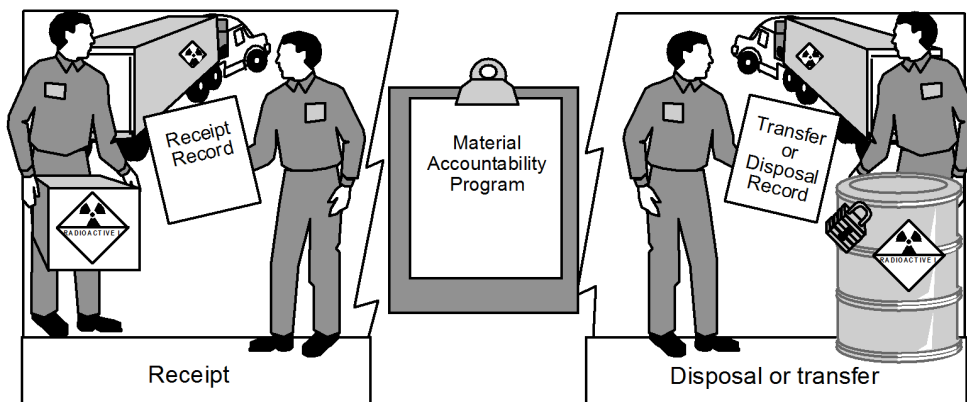


Figure 8-7. Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal of licensed material.

Inventory and Accountability of Radioactive Materials

Licensees who use or possess sealed sources are required by license condition to perform inventories of all sealed sources, including those that are in storage, every 6 months. Licensees are also required to conduct leak tests of sealed sources at 6-month intervals (or at longer intervals as specified in the SSD registration certificate). Since 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, log books) 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, or radioactive decay. The chosen methods should ensure that possession limits are not exceeded. Individual AUs 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 AU'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 perform periodic update of the total inventory of all unsealed materials possessed under the license. Depending on 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 stated in 10 CFR 30.41. Sample policy transfer statements are included in Appendix I of this NUREG. Transfer of licensed materials within the facility may require special procedures to ensure proper control. Licensees must consider potential contamination of laboratory equipment or components, such as refrigerators and freezers, and carefully control the removal of these items for maintenance, repair, or disposal.

Licensees who also possess Radioactive Materials Under a General License or an Exemption

In addition to radionuclides that are specifically listed on their license, licensees frequently possess radioactive material under a general license or that was distributed to them as an exempt quantity or item. 10 CFR Parts 31, 40, and 70 provide information regarding devices that may be possessed under a general license. Any person who acquires, receives,

possesses, uses, or transfers a device under a general license must do so in accordance with the provisions of the general license. A specific licensee may also possess material under a general license. A specific license does not automatically remove general licensee status nor automatically “move” licensed material from the general license to the specific license. The NRC recognizes that multiple authorizations can create some confusion; therefore, a specific licensee always has the option of receiving and possessing radioactive materials that “qualify” for a general license by adding these to its specific license as described in 10 CFR 31.5(c)(8)(iii) or other applicable regulations. Persons who wish to convert items from a general license to a specific license should discuss the process with the NRC.

Some facilities may have separate laboratories or locations that use material for in-vitro assay that may be possessed under the general license in 10 CFR 31.11. Each location is a separate general license from the other. The multiple locations are not considered to operate under a single general license and are not considered part of the specific license. In accordance with 10 CFR 31.11(c)(1), the possession limit of 7.4 MBq [200 µCi], only applies to a total amount of iodine-125 (I-125), iodine-131 (I-131), selenium-75 (Se-75), and iron-59 (Fe-59) used or stored in one location.

Similarly, radioactive material received by a specific licensee under an exemption from the requirements for a license is not subject to the terms and conditions of the specific license. NRC does not require that licensees possess or control these types of devices under the provisions of their specific license.

Receipt, inventory, transfer, and disposal records must be maintained for the times specified in Table 8-3. Typically, these records contain the following types of information:

- radionuclide and the activity (in units of becquerels or curies) of byproduct material in each sealed source
- manufacturer’s or distributor’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 conducting the inventory
- for materials transferred or disposed of, the date of the transfer or disposal, the name and license number of the recipient, and a description of the affected radioactive material (e.g., radionuclide, activity, manufacturer’s or distributor’s name and model number, serial number)

Manufacturers and distributors must also make reports to regulatory agencies for exempt and general licensed devices distributed so that these can be accounted for and registered in some cases. Please refer to NUREG–1556, Vol. No. 8, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses,” and NUREG–1556, Vol. 16, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees.”

Type of Record	How Long Record Must Be Maintained
Receipt	For as long as the material is possessed and for 3 years following transfer or disposal of the material
Inventory	For 3 years from the date of the inventory in accordance with license conditions
Transfer	For 3 years after each transfer unless a specific requirement dictates otherwise
Disposal	Until 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.

Information about locations where licensed material is used or stored are among the records important to decommissioning and required by 10 CFR 30.35(g). See also Section 8.5.2, "Financial Assurance and Record Keeping for Decommissioning."

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

There are additional security requirements for shipment and transfer of a Category 1 and Category 2 quantity of radioactive material listed in Appendix A to 10 CFR Part 37. Prior to transferring Category 1 or Category 2 quantities of radioactive material, licensees must use NRC's license verification system (or contact the licensing authority) to verify that the recipient licensee is authorized to possess the radioactive material.

Licensees that ship Category 1 or Category 2 quantities of radioactive material must preplan and coordinate such shipments in accordance with 10 CFR 37.75. Shipments of Category 1 quantities are also subject to the 10 CFR 37.77 advance notification requirements. For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

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

Response from Applicant:

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

AND

- State that: “We will develop, implement, and maintain procedures for ensuring accountability of license materials at all times.”

AND

- Provide either of the following:
 - State 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 3 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

- Provide a description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced.

Notes:

- No response is needed from applicants for package opening procedures. Package opening procedures will be reviewed during NRC inspections.
- Alternative responses will be evaluated using the guidance in this section.

References:

- NUREG–1516, “Management of Radioactive Material Safety Programs at Medical Facilities”
- NUREG–1556, Vol. No. 8, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses”
- NUREG–1556, Vol. 16, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees”
- NCRP Report No. 114, “Maintaining Radiation Protection Records” (1992)
- NCRP Report No. 105, “Radiation Protection For Medical and Allied Health Personnel” (1989)
- NCRP 127, “Operational Radiation Safety Program” (1998)

8.10.4 Occupational Dose

Regulations: 10 CFR 19.13, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1703, 10 CFR 20.2104, 10 CFR 20.2105, 10 CFR 20.2106, 10 CFR 20.2206, 10 CFR Part 20, Appendix B

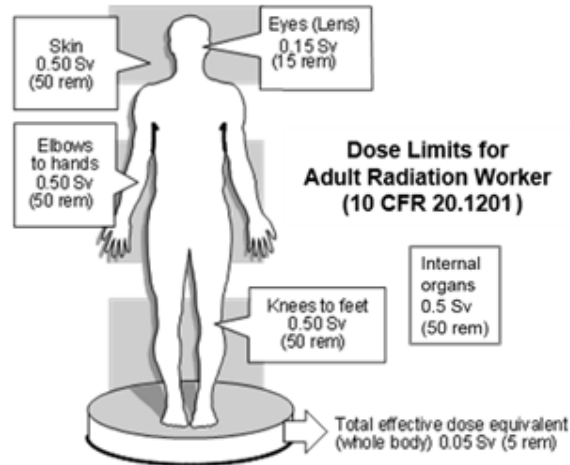
Criteria: Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure.

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

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

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

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



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

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

Some manufacturers and distributors must report individual monitoring. Licensees that process, manufacture, or distribute above the quantities specified in 10 CFR 20.2206(a)(7) must file a report annually.

Discussion: If an adult radiation worker is likely to receive in 1 year a dose greater than 10 percent of any applicable limit (see Figure 8-8 for annual dose limits), monitoring for occupational exposure is required. Monitoring is required for minors and declared pregnant women as shown in the criteria section. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

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

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

or skin doses). Where monitoring was provided but not measurable, the licensee should enter “ND,” for “Not Detectable.”

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

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

When personnel dosimeters that require processing to determine the radiation dose are used to comply with the individual monitoring requirement for external doses in 10 CFR 20.1502(a), dosimeters must be processed and evaluated by a NVLAP-accredited processor (10 CFR 20.1501(d)). The exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their NVLAP-accredited processor for its recommendations for exchange frequency and proper use of the dosimeter.

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

Table 8-4. Guidance on Personnel Monitoring and Bioassay	
Regulatory Guide 8.7, Revision 4	Instructions for Recording and Reporting Occupational Radiation Exposure Data
Regulatory Guide 8.9, Revision 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program
Regulatory Guide 8.20, Revision 2	Applications of Bioassay for Radioiodine
Regulatory Guide 8.21, Revision 1	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
Regulatory Guide 8.23, Revision 1	Radiation Safety Surveys at Medical Institutions
Regulatory Guide 8.25, Revision 1	Air Sampling in the Workplace
Regulatory Guide 8.32	Criteria for Establishing a Tritium Bioassay Program
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Radiation Doses
Regulatory Guide 8.35, Revision 1	Planned Special Exposures

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

For those manufacturers and distributors that need to report individual monitoring, the report must be submitted by April 30 for the preceding year. Please see www.reirs.com for details on how to submit this report.

Additional Reference for Further Reading:

- U.S. Department of Energy (DOE) G 441.1-1C, “Radiation Protection Programs Guide,” May 19, 2008

Response from Applicant: Provide one of the following statements:

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

OR

“We will monitor individuals in accordance with the guidance in Section 8.10.4, “Radiation Safety Program—Occupational Dose” in NUREG–1556, Vol. 12, Rev. 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.””

OR, IN LIEU OF THESE STATEMENTS,

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

Reference: The National Institute of Standards and Technology maintains a directory of laboratories that are NVLAP-accredited at <http://ts.nist.gov/standards/scopes/dosim.htm>.

Note:

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

8.10.5 Public Dose

Regulations: 10 CFR 20.1003; 10 CFR 20.1101(d); 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2107

Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv [100 mrem] in a year and that the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any 1 hour period from licensed operations in accordance with 10 CFR 20.1301(a). In addition, licensees must 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] (TEDE) in a year from those emissions in accordance with 10 CFR 20.1101(d).

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 medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual’s assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) where the individual is when he or she receives the dose.

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

For guidance about accepted methodologies for determining dose to members of the public, please refer to Appendix J of this NUREG, Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits.

Figure 8-9 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 TEDE. The TEDE can, however, be broken down into three major dose pathway groups:

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

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

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1302(b). The extent and frequency of monitoring will depend upon each licensee’s needs. For additional guidance regarding monitoring of effluents, refer to Section 8.10.7, Radiation Safety Program—Surveys and Leak Tests.

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

Calculating the Annual Dose to an Individual Member of the Public

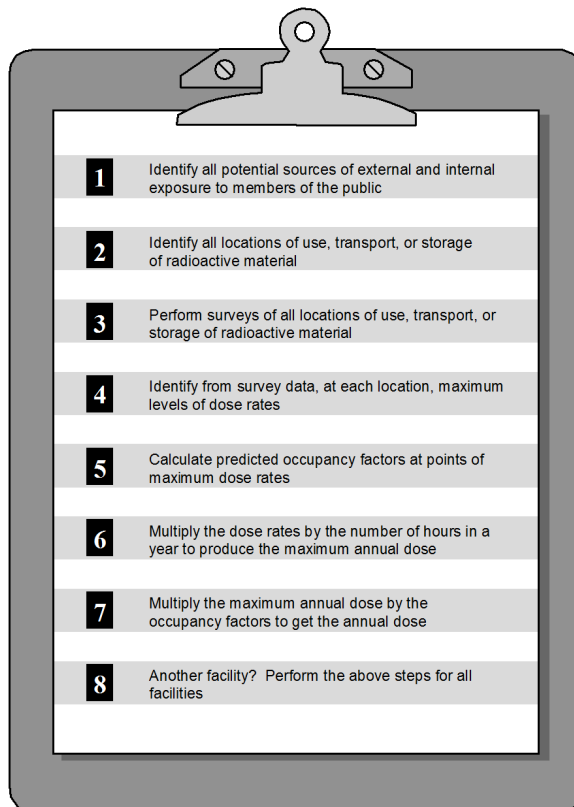


Figure 8-9. Calculating Public Dose. *Steps to calculate the annual dose to an individual member of the public (see Appendix J of this NUREG for more information about occupancy factors).*

Response from Applicant:

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

See Appendix J of this NUREG for examples of methods to demonstrate compliance.

8.10.6 Safe Use of Radionuclides and Emergency Procedures

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1406; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1902–1905; 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 32.11; 10 CFR 32.23; 10 CFR 32.27; 10 CFR 32.31; 10 CFR 37 (Subpart B); 10 CFR 37.21; 10 CFR 37.45; 10 CFR 37.49; 10 CFR 40.41(e); 10 CFR 40.60; 10 CFR 70.22; 10 CFR 70.32(b); 10 CFR 70.50

Criteria: Licensees must do all of the following:

- Keep radiation doses to workers and members of the public ALARA.
- Ensure security of licensed material.
- Make the required notifications of events to NRC.

Discussion: Licensees are responsible for developing and implementing procedures to ensure the security and safe possession and use of all licensed material from the time it arrives at their facility until it is used, transferred, or disposed. Licensees should develop, implement, and maintain written procedures to ensure safe possession and use of licensed material, and the procedures should also include operational and administrative guidelines. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public.

Licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material, listed in Appendix A to 10 CFR Part 37, must also establish, implement, and maintain its access authorization program; coordinate, to the extent practicable, with local law enforcement authorities, for responding to threats to the licensee's facility; and be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones.

General Safety and Manufacturing Process Procedures

The written procedures should include the following elements:

- contamination controls
- waste disposal practices
- personnel and area monitoring (including limits)
- use of protective clothing and equipment
- recordkeeping requirements
- reporting requirements
- responsibilities

These procedures should include policies for:

- frequency of personnel monitoring
- use of appropriate shielding (see Figure 8-10)
- frequent change of gloves to minimize exposure to the individual and to avoid spread of contamination in work areas

Applicants should also develop product and radionuclide-specific procedures, based on the respective hazards associated with the products and radionuclides. General safety guidelines are described in Appendix K of this NUREG, "General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures." Applicants should use these guidelines to develop procedures for the safe use of radionuclides.

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

Working Behind a Shield

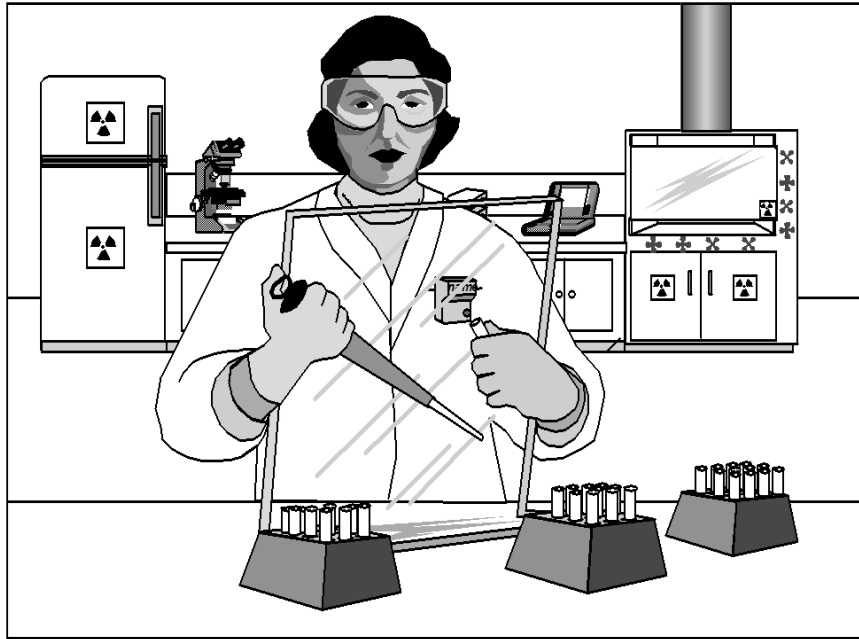


Figure 8-10. Use of Appropriate Shielding. *This worker is using high-density plastic shielding, which is appropriate for radionuclides that emit beta radiation.*

Manufacturing Process and Procedures

The licensee's manufacturing process and procedures should ensure that the product is manufactured and distributed in accordance with the manufacturer's quality assurance program. For registered sealed sources and devices, the manufacture and distribution should be in accordance with the representations made in the application and with the statements contained in the registration certificate for the product.

Security Procedures

All licensed materials stored in controlled or unrestricted areas must be secured from unauthorized access or removal so that individuals who may not be knowledgeable about radioactive materials cannot be exposed to or contaminated by the material, and so that unauthorized individuals cannot take the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material and prevent unauthorized persons from removing the material from the area. Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include (i) storage and use of licensed materials only in restricted areas; (ii) limiting access to an entire facility or building or portion of the building only to radiation workers; (iii) providing storage areas that can be locked to prevent access to the material; and (iv) implementing procedures that require a radiation worker to be within "line of sight" of the materials whenever licensed materials are in use. Applicants should develop procedures that clearly state acceptable methods to secure licensed material at their facility. Particular attention may need to be paid to security procedures at facilities that may have unusual needs due to the activities performed, such as hot cells, animal care facilities, and waste processing facilities.

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

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

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

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

Emergency Procedures

Accidents and emergencies can happen during any operation with radionuclides, including their transportation, use, production processes, transfer, and disposal. Such incidents can result in contamination or release of material to the environment and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material, sabotage, fires, floods, etc., can adversely affect the safety of personnel and members of the public. Therefore, it is necessary to develop written procedures to minimize, as much as possible, the effect of these incidents on personnel, members of the public, and the environment. Applicants that plan to possess quantities of material in excess of the applicable amounts listed in 10 CFR 30.72 Schedule C, or greater than 2 curies of unsealed plutonium may also be required to submit an "Emergency Plan for Responding to a Release," pursuant to 10 CFR 30.32(i) and 10 CFR 70.22(i). Applicants who need to submit an "Emergency Plan" should refer to Regulatory Guide 3.67, Revision 1, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities" and 10 CFR 70.22(i)(3) for assistance in preparing an emergency plan.

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee's staff should have a clear understanding of their limitations in an emergency, along with step-by-step instructions and clear guidelines for whom to contact. Typical notification and reporting requirements are described in Appendix L of this NUREG. Applicants should use these guidelines to develop procedures for notification and reporting of accidents and emergencies.

Licensees should have a sufficient number of appropriate and calibrated radiation survey instruments readily available. Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be inspected periodically for proper operation and replenished as necessary. Appendix K of this NUREG includes model emergency procedures. Applicants may adopt these procedures or develop their own, incorporating the safety features included in these model procedures.

Collection of Bioassay Samples

In the event of an emergency where an individual became contaminated and radioactive material was taken into the body through skin absorption or other means, or an individual is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. Frequently, this estimate is made by performing bioassay of the individual. Bioassays may be performed through direct methods, such as whole body counting or thyroid counting, where the radioactive material in the body can be directly measured using appropriate instruments. Bioassays may also be performed through indirect means by sampling urine or other excreta from the body and calculating the intake from the amount of material detected in the samples, the time between suspected intake and sample collection, and knowledge of the rate of excretion of the compound or radionuclide from the body. While there are many ways to perform the calculations, including using computer models, the method of calculation is only as good as the quality of the samples and analyses performed. Because a dose estimate may be required, bioassay procedures for a suspected intake may differ from those in a routine bioassay screening program, and the radiation safety program should include procedures and equipment for appropriate sample collection in an emergency. The following items should be considered in developing procedures for collecting bioassay samples:

- type of bioassay that must be performed (i.e., direct or indirect)
- number of samples or data points to be collected
- date and time of initial sample collection
- frequency of sampling (e.g., only once, hourly, daily, weekly)
- size of the sample to be collected (e.g., 24-hour urine collection, single-void grab sample, 1-liter breathing volume)
- ease/difficulty of sample collection
- need for written instructions to be provided to the sample collector (who may be the contaminated individual)

Response from Applicant:

The applicant should provide the following statements:

“Procedures for safe use, security of materials, and emergencies will be developed and documented before receipt of licensed material. Operating and emergency procedures will be implemented and maintained.”

AND

“Procedures will be revised only if (i) the changes are reviewed and approved by the licensee management and the RSO in writing; (ii) the licensee staff is provided training in the revised procedures prior to implementation; (iii) the changes are in compliance with NRC regulations and the license; and (iv) the changes do not degrade the effectiveness of the program.”

AND

Additionally, for licensees requiring an “Emergency Plan” under 10 CFR 30.32(i) and 30.72 or 10 CFR 70.22(i), applicants should submit it as a separate part of the application.

8.10.7 Surveys and Leak Tests

Regulations: 10 CFR 20.1501; 10 CFR 20.2103; 10 CFR Part 20, Subpart K; 10 CFR 30.53; 10 CFR 32.59; 10 CFR 40.63; 10 CFR 70.56

Criteria: Licensees are required by 10 CFR 20.1501 to make surveys of potential radiological hazards in their workplace. NRC requires testing to determine whether there is any radioactive leakage from sealed sources. Licensees must maintain records of surveys and leak test results in accordance with license conditions and NRC regulations.

Discussion: Survey is defined as an evaluation 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 8-11). 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, and gamma) and compared to the appropriate limits.

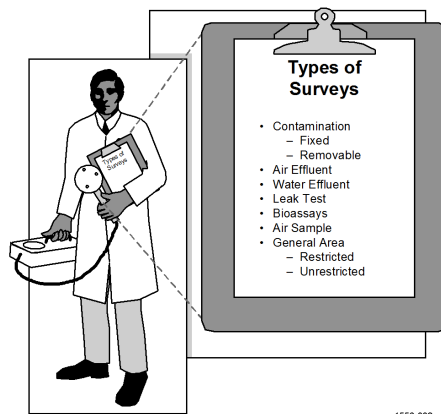


Figure 8-11. Types of Surveys. *There are many different types of surveys performed by manufacturer and distribution licensees.*

Radiation surveys are used to detect and evaluate contamination of:

- facilities
- equipment
- personnel (during use, possession, transfer, or disposal of licensed material) (see Figure 8-12)
- restricted and unrestricted areas
- products produced

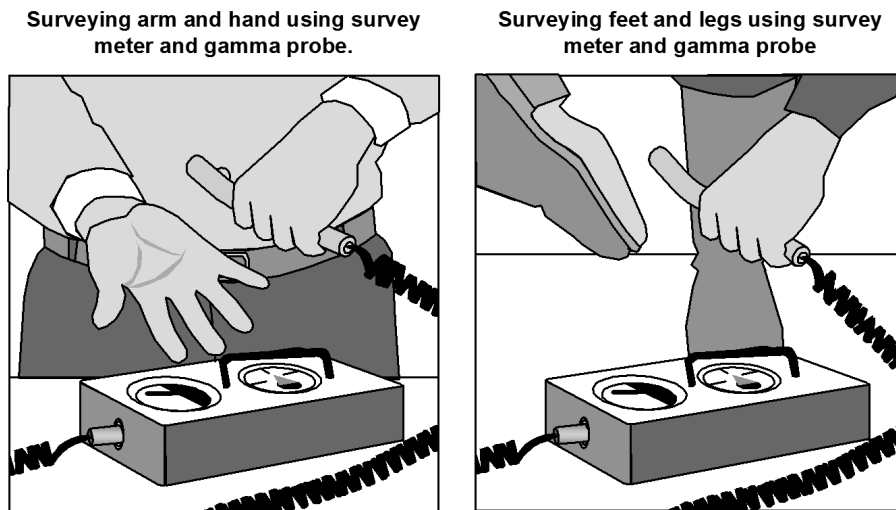


Figure 8-12. Personnel Surveys. *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the area of use.*

As required by 10 CFR 20.1501, surveys will be performed when it is reasonable, under the circumstances, to evaluate a radiological hazard and when necessary for the licensee to comply with the regulations. Many different types of surveys may need to be performed because of the particular use of licensed materials. Typical surveys may include:

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

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

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific facilities, equipment, and procedures designed to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above (see Appendix M of this NUREG, “Radiation Safety Survey Topics”).

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.

Regulations in 10 CFR Part 20 do not specify limits for surface contamination. Each applicant should propose and justify the removable surface contamination limits that will be allowed before decontamination will be performed in each work area. Contamination checks are required before distributing fabricated sources. Appendix M of this NUREG contains contamination limits that are acceptable to NRC.

Sealed Source and Plated Foil Leak Tests

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

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

Manufacturers, distributors, consultants, and other organizations may be authorized by NRC or an Agreement State to either to perform the entire leak test sequence on behalf of licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample using the instructions from the manufacturer, (or distributor) of the sealed source or plated foil, and the leak test kit supplier. The licensee returns the sample to the leak-test service provider for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. The NRC or an Agreement State may, in a license condition, specifically authorize manufacturers and distributors to conduct the entire leak-test sequence themselves.

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

- sources contain only hydrogen-3 (tritium)
- sources contain only byproduct material with a half-life of less than 30 days
- sources contain only a radioactive gas
- sources contain 3.7 MBq [100 µCi] or less of beta-emitting or gamma-emitting material or 370 kBq [10 µCi] or less of alpha emitting material
- sources are stored and not being used (but must be leak tested before use or transfer, or if stored more than 10 years)

For more information regarding leak tests, see Appendix N of this NUREG, “Model Leak Test Program.”

Service Licenses

If a licensee wants to perform leak tests for its customers, it must obtain a service license. This may also be accomplished by amending an existing license. For more information regarding service license applications, see NUREG–1556, Vol. 18, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.”

Response from Applicant: Do one of the following:

- State: “We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M to NUREG–1556, Vol. 12, Rev. 1, “Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution.”” If applicable, state, “We will perform contamination checks on all fabricated sealed sources prior to distribution. Also, leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or leak tests may be collected by the licensee using the sealed source or plated foil manufacturer’s, distributor’s, and leak test kit supplier’s instructions. Such leak test kits should be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services.”

OR

- State: “We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M to NUREG–1556, Vol. 12, Rev. 1, “Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution.”” If applicable, state, “We will perform contamination checks on all fabricated sealed sources prior to distribution. Also, leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate.

We will follow the model procedures in Appendix N of NUREG–1556, Vol. 12, Rev. 1, “Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution.””

OR

- Submit a description of alternative equipment and procedures to evaluate radiological hazards at the applicant’s facility, in accordance with 10 CFR 20.1501, and for determining whether there is radioactive leakage from sealed sources or plated foils. If applicable, state, “We will perform contamination checks on all fabricated sealed sources prior to distribution. Also, leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate.”

Notes:

- Alternative responses will be reviewed using the guidance in this section.
- If a sealed source or plated foil is added to an existing license, that license might already authorize the licensee to perform the entire leak test sequence. In this case, the licensee may perform the leak testing on the sealed source or plated foil according to the procedures previously approved on its license.

Reference: See the Notice of Availability (on inside front cover of this report) to obtain a copy of NUREG–1556, Vol. 18, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.”

8.10.8 Maintenance

Regulations: 10 CFR 20.1101; 10 CFR 30.34(e); 10 CFR 40.41(e); 10 CFR 70.32(b)

Criteria: Maintenance of devices and facilities should be planned and carried out as frequently as needed, using ALARA principles. Individuals performing maintenance should be trained in the procedures they implement. Procedures should be written to account for the skills of the implementing personnel. Ordinarily, individuals handling unshielded materials should have up to 40 hours of classroom and on-the-job training in radiation safety. Instructors should be more extensively qualified than the staff they teach.

Discussion: Maintenance of equipment and facilities is necessary in order to produce a quality product safely and efficiently and to ensure a safe environment for staff and the public. Manufacturing a product incorporating radioactive materials is an additional hazard, requiring attention to detail when incorporating maintenance information into procedures. Licensee staff should ensure that materials in the process stream are properly shielded, located, and protected to minimize the hazard to maintenance staff. Maintenance staff should be aware of the hazards and the procedures to minimize their exposure to radioactive materials that are possessed and used to control the manufacturing process. As examples (i) a radionuclide hot cell should have its contents moved or shielded before any maintenance requiring entry is begun, and the staff should survey the hot cell working area prior to entry; and (ii) a maintenance procedure should direct the shutdown and lockout of applicable process control gauges before beginning work in the area, which may be in the direct beam of the gauge, whether inside the process vessel or outside the vessel. Maintenance procedures should be prepared with the use of engineering controls first, using ALARA principles and administrative controls, as needed.

Response from Applicant: No response is required in the application process. The results of actions taken in the maintenance and repair of facilities and equipment process will be reviewed during inspection.

8.10.9 Transportation

Regulations: 10 CFR 20.1101; 10 CFR Part 20, Appendix G; 10 CFR 30.41; 10 CFR 30.51; 10 CFR Part 37 (Subpart D); 10 CFR 40.51; 10 CFR 40.61; 10 CFR 70.41; 10 CFR 70.51; 10 CFR 71.5; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38; 10 CFR 71.47; 10 CFR 71.87, Subpart H of 10 CFR Part 71; 49 CFR Parts 171-178

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

Discussion: Licensed material, including radioactive waste, must be packaged and transported in accordance with NRC and DOT requirements if the transportation involves common carriers or the use of public highways. Licensees should develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if it does not involve the use of public highways.

Packages shipped by licensees frequently meet the “Limited quantity” criteria, as described in 49 CFR 173.421 and, therefore, may be subject to other less restrictive DOT requirements (e.g., 49 CFR 173.422 and 173.424; also see Appendix O of this NUREG for more information) than packages requiring a DOT White I, Yellow II, or Yellow III label. Under DOT regulations, each person (shipper or carrier) involved in the transportation of radioactive materials is considered a “hazardous materials employee” who must receive appropriate training for the jobs they perform related to transportation every 3 years. Jobs related to transportation include activities such as packaging radioactive materials, loading and securing the package on a vehicle, or preparing paperwork for shipping the material.

Licensees should consider the safety of all individuals who may handle or may come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that the package integrity is not compromised during transport and that radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of 10 CFR 71.47, but are also ALARA.

All domestic shipping papers and labels must be in SI units only or must be in SI units first, with English units in parentheses.

Licensees shipping radioactive waste for disposal must prepare appropriate documentation, as specified in 10 CFR Part 20, Appendix G.

The general license in 10 CFR 71.17 provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Transporting licensed materials originating at some facilities involves quantities of radioactive material that require a Type B package. The manufacturer (or service licensee) who

is subject to the provisions of 10 CFR 71.17 or 10 CFR 71.19, as appropriate, is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

Licensees who use another manufacturer's Type B package must ensure that the other manufacturer (or service licensee):

- is authorized to possess the licensed material at temporary jobsites (i.e., at the facility location)
- actually takes possession of the licensed material under its license
- uses an approved Type B package
- is registered with NRC as a user of the Type B package
- has an NRC-approved QA plan

For each shipment, it must be clear who possesses the licensed material and is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

If a licensee plans to make shipments of licensed materials in Type B packages on its own, the licensee must be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, as required under the 10 CFR 71.17 general license. For information about QA plans, see Revision 2 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated March 2005. For further information about registering as a user of a package or submitting a QA program for review, contact the NRC's Office of Nuclear Material Safety and Safeguards, Division of Spent Fuel Storage and Transportation, by calling the NRC's toll free number, 800-368-5642, and asking for extension 415-9956. For information about any associated fees, contact the NRC's Office of the Chief Financial Officer, by calling the NRC's toll free number, 800-368-5642, and asking for extension 415-7554.

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 listed in Appendix O of this NUREG.

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 on its own in Type B packages, a licensee needs to have registered with 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 Material Regulations Review (December 2008)" is available from the DOT at:
<https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/training/hazmat/56526/ramreview2008.pdf>.

The Memorandum of Understanding with DOT on the Transportation of Radioactive Material (signed June 8, 1979) is available from the NRC on its public Web site under "Enforcement Guidance" at <https://www.nrc.gov/about-nrc/regulatory/enforcement/moudot.pdf>.

8.10.10 Security Program for Category 1 and Category 2 Radioactive Material

Regulations: 10 CFR Part 37

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

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

Discussion:

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

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

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

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

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

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

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

Any licensee that has not previously been made subject to the provisions of 10 CFR Part 37, Subpart C 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. Compliance with access authorization and security program requirements may be reviewed during NRC inspections.

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1301; 10 CFR 20.1904; 10 CFR 20, Subpart K; 10 CFR Part 20, Appendices B and G; 10 CFR 30.51; 10 CFR 37.11(c); 10 CFR 40.61; 10 CFR 61.52; 10 CFR 70.51

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

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

All radioactive waste must be stored in appropriate containers until its disposal. The integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal.

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

short-lived radioactive waste to be stored until it has decayed. 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 regulations in 10 CFR 20.2001–20.2008, the NRC requires licensees to dispose of radioactive waste generated at their facilities through one or more of the following methods:

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

Licensees may choose one or more of these methods to dispose of their radioactive waste. The NRC has observed that most of the possession licenses for manufacturing and distribution store or dispose of radioactive waste through a combination of the first four methods because of the types and amounts of licensed materials these facilities use. Applicants that want to dispose of radioactive waste by incineration should refer to Policy and Guidance Directive PG 8-10, “Disposal of Incineration Ash as Ordinary Waste,” issued January 1997. Applicants should note that compliance with NRC regulations does not relieve them of their responsibility to comply with any other applicable Federal, State, or local regulations. Furthermore, some of the radioactive waste may also include additional hazards (e.g., biohazard or chemical hazard). Such waste is called “mixed waste,” and its storage and disposal must also comply with all other applicable Federal, State, and local regulatory requirements.

Applicants should describe their program for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Regulations require that licensees maintain all appropriate records of disposal of radioactive waste. The U.S. Environmental Protection Agency issued guidance for developing a comprehensive program to reduce hazardous waste that, in many instances, may also include radioactive waste. The NRC transmitted these guidelines to licensees in IN 94-23, “Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program,” dated March 25, 1994.

The NRC has developed guidance for such extended interim storage of waste, discussed below.

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 DIS. The holding time of the waste should be based on the radionuclides, half-life, and the activity present when the waste was placed into storage. Such waste may be disposed of as ordinary trash if radiation surveys of the waste indicate that radiation levels are indistinguishable from background. The surveys should be performed with an appropriate radiation detection meter set on its most sensitive scale in a low background area and without

any interposed shielding. In accordance with 10 CFR 20.1904(b), all radiation labels must be defaced or removed from containers and packages before 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.

Applicants should ensure that adequate space and facilities are available for the storage of such waste. Licensees can minimize the need for storage space, if the waste is segregated according to physical half-life. Waste-containing radionuclides of physical half-lives within a certain range may be stored in one container and allowed to decay in the container. Procedures for management of such waste should include methods of segregation, surveys before 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 P of this NUREG provides a model procedure for disposal of radioactive waste by DIS, which incorporates the above guidelines.

Release Into Sanitary Sewerage

10 CFR 20.2003 authorizes disposal of radioactive waste by release into a public sanitary sewerage system if each of the following conditions is met:

- Material is readily soluble (or is readily dispersible biological material) in water.
- The quantity of licensed material or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer does not exceed the concentration specified in Table 3 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to 10 CFR Part 20.
- 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 Table 3 of Appendix B to 10 CFR Part 20 cannot exceed unity.
- Total quantity of licensed material and other radioactive material released into the sanitary sewerage system in a year does not exceed 185 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 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 28, 1994, provides acceptable criteria for evaluating solubility of wastes released to the sewer. Careful consideration should be given to the possibility of reconcentration of radionuclides released into the sewer. NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewage systems in IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted under 10 CFR 20.303 [now 10 CFR 20.2003]," dated December 21, 1984.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in 10 CFR 20.2003 and do not exceed the

monthly and annual limits specified in regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. Appendix P of this NUREG provides a model program for disposal of radioactive waste through sanitary sewer.

The regulations at 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 under 10 CFR 20.1301, "Dose limits for individual members of the public." However, if licensed material is released to a private sewerage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludges may be required to be disposed of as radioactive waste, using one of the methods described in Section 8.11, "Waste Management," of this document.

Release into Air and Water

Release of radioactive material into air and water must conform to the requirements described in 10 CFR 20.1302(b)(2) (see Figure 8-13). The applicant should describe the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the "constraint" on air emissions of radioactive material required by 10 CFR 20.1101(d), which effectively reduces the limits specified in 10 CFR 20.1302(b)(2) for release of gaseous effluents by a factor of 10. Applicants considering release of radioactive material into air and water should review Regulatory Guide 8.37, "ALARA Levels for Effluents From Materials Facilities," dated July 1993, which deals with the application of ALARA in controlling gaseous and liquid effluents and references documents with acceptable methods of effluent monitoring. Regulatory Guide 4-20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors," dated April 2012, also contains useful information.

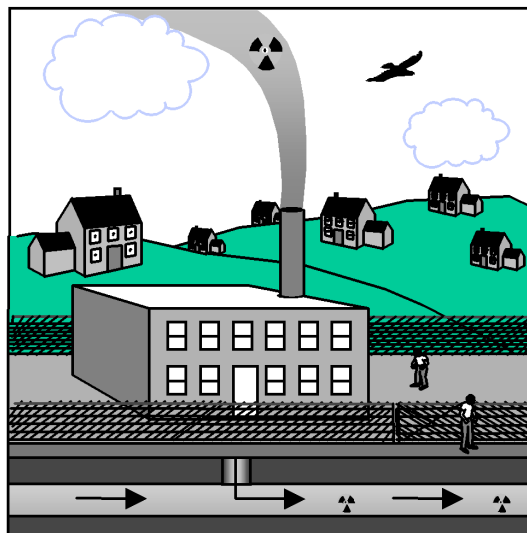


Figure 8-13. Air and Water Effluents from a Manufacturing Facility. *Also note the fence, creating a "controlled area."*

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. The licensee is responsible for verifying that the intended recipient is authorized to receive the radioactive waste before making any shipment. The waste must be packaged in approved containers for shipment, and each container must identify the radionuclides and the amounts contained in the waste. Additionally, packages must comply with the requirements of the particular burial site's license 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 Appendix G to 10 CFR Part 20. Each shipping manifest must include a certification by the waste generator, as specified in Section II of Appendix G. 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 of Appendix G.

Disposal of Specific Waste As If It Were Not Radioactive

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

- liquid scintillation media (including vials and other items contaminated with liquid scintillation media) containing no more than 1.85 kBq [0.05 μ Ci] of H-3 or C-14 per gram of the medium
- animal carcasses or animal tissue containing no more than 1.85 kBq [0.05 μ Ci] of H-3 or C-14 per gram averaged over the weight of the entire animal

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

Alternate Methods

Applicants may also request alternate methods under 10 CFR 20.2002, "Method for obtaining approval of proposed disposal procedures," for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, the nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits. An applicant cannot make such disposals until the NRC has reviewed and approved the request.

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. This information was updated by NRC Regulatory Issue Summary (RIS) 2008-12, "Considerations For Extended Interim Storage Of Low-Level Radioactive Waste By Fuel Cycle And Materials Licensees," dated May 9, 2008. 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.

Note: Before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), 10 CFR 40.46, 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, or special nuclear material, the licensees must, in accordance with 10 CFR 30.51(e), 10 CFR 40.61(e), or 10 CFR 70.51(b)(1)&(2), respectively, transfer the following records to the new licensee:

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

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

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

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

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

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

Response from Applicant:

State that: “We will use the model waste procedures and guidelines published in Appendix P to NUREG–1556, Vol. 12, Rev. 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.””

OR

If the applicant wishes to use only selected model procedures and guidelines, state that, “We will use the [specify either (i) decay-in-storage or (ii) disposal of liquids into sanitary sewerage] model waste procedures that are published in Appendix P to NUREG–1556, Vol. 12, Rev 1., “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.””

AND

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

OR

If needed, the applicant should request authorization for extended interim storage of waste.

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

Notes:

- Applicant should use the references listed below for guidance and submit the required information with the application.
- Applicants do not need to provide information to the NRC if they plan to dispose of LLW via transfer to an authorized recipient or to dispose of liquid scintillation media or animals

References:

- Information Notice 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program," dated March 1994
- Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," dated January 1994
- Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984
- Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990
- Regulatory Issue Summary 2008-12, "Considerations For Extended Interim Storage Of Low-Level Radioactive Waste By Fuel Cycle And Materials Licensees"
- Regulatory Issue Summary 2011-09, "Available Resources Associated With Extended Storage Of Low-Level Radioactive Waste"
- Policy and Guidance Directive PG 8-10, "Disposal of Incineration Ash as Ordinary Waste," January 1997, ADAMS Accession Nos. ML003744979 and ML003752866 and Addendum, ADAMS Accession Nos. ML003744984 and ML003744988.
- NRC Regulatory Issue Summary 2004-17, Revision 1, "Revised Decay-In-Storage Provisions For The Storage Of Radioactive Waste Containing Byproduct Material," September 2005
- State and Tribal Communication Letter FSME 12-025 dated March 13, 2012 "Clarification of the Authorization for Alternative Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR" (ADAMS Accession No. ML12065A038)
- Division of Waste Management and Environmental Protection, Environmental and Performance Assessment Directorate, Operating Procedures, EPPAD 3.5 (Draft for

Interim Use), "Review, Approval, and Documentation of Low-Activity Waste Disposals in Accordance with 10 CFR 20.2002 and 10 CFR 40.13(a)," dated August 2009

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

Information Notices and Regulatory Issue Summaries are available at <https://www.nrc.gov>.

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

8.13 Item 13: Certification

A representative of the corporation or legal entity filing the application should sign and date NRC Form 313. The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in Chapter 3, "Management Responsibility," signing the application acknowledges management's commitment to and responsibility for the radiation safety program. The NRC will return all unsigned applications for proper signature.

Notes:

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

9 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date [see Title 10 of *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 an U.S. Nuclear Regulatory Commission (NRC) Form 313 or a letter requesting amendment or renewal.
- Provide the license number and docket number.
- For renewals, provide a complete and up-to-date application, including all required program elements outlined in Appendix B of this NUREG. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application.

9.1 Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b); 10 CFR 40.41(b); 10 CFR 70.32(a)(3)

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, it is necessary for licensees to obtain prior NRC written consent to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses or Agreement State licenses.
- Materials are properly handled and secured.
- Persons using these materials are capable, competent, and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material.
- The transferee has the financial resources to decommission the license, if necessary.
- Public health and safety are not compromised by the use of such materials.

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

Response from Applicant: No response is required from an applicant for a new license. However, current licensees should refer to NUREG–1556, Volume 15, “Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses,” for more information about transfer of control (e.g., ownership.).

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

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 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 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"; 10 CFR 70.11, "Specific exemptions"). These regulations state that the NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

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

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

11 TERMINATION OF ACTIVITIES

Regulations: 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 40.46; 10 CFR 40.61(d); 10 CFR 70.25(g); 10 CFR 70.36; 10 CFR 70.38; 10 CFR 70.51

Criteria: The licensee must do the following:

- Notify the U.S. Nuclear Regulatory Commission (NRC), in writing, within 60 days of the occurrence of any of the following:
 - expiration of its license
 - a decision to permanently cease principal activities¹ at the entire site
 - for licensees subject to 10 CFR 30.36, a decision to permanently cease principal activities in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements
 - for licensees subject to 10 CFR 40.42 or 10 CFR 70.38, a decision to permanently cease principal activities in any separate building or outdoor area
 - no principal activities under the license have been conducted for a period of 24 months
 - no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release according to NRC requirements
- Submit a decommissioning plan, if required by 10 CFR 30.36(g), 10 CFR 40.42(g), 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), or 10 CFR 70.38(h) and (j).

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

- Submit to the appropriate NRC regional office a completed NRC Form 314, “Certificate of Disposition of Materials” (or equivalent information), and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final surveys and results of leak tests of sealed sources).
- Before a license is terminated, send records important to decommissioning that are required by 10 CFR 30.35(g), 10 CFR 40.36(f) and 10 CFR 70.25(g) to the appropriate NRC regional office in accordance with 10 CFR 30.51(f), 10 CFR 40.61(f), or 10 CFR 70.51(a)(3), respectively.
- Before a license is terminated, send records of disposal of licensed material made under 10 CFR 20.2002, 10 CFR 20.2003, 20.2004, or 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), 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, 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), or 10 CFR 70.38(d), the licensee must determine whether residual radioactivity is present and, if so, whether the levels make the building or outdoor area unsuitable for release, according to NRC requirements. A licensee’s determination that a facility is not contaminated is subject to verification by NRC inspection.

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

For information about requirements that apply to the timeliness of decommissioning, see Regulatory Issue Summary (RIS) 2015-19, Rev. 1, “Decommissioning Timeliness Rule Implementation and Associated Regulatory Relief,” dated September 27, 2016, which can be found on the NRC’s Generic Communications Web page under “Regulatory Issue Summaries”: <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 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning.”

NUREG–1757, “Consolidated Decommissioning Guidance,” contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Licensees that have large facilities to decommission should review NUREG–1575, “(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/nrc313.pdf>

NRC FORM 313 (10-2017) 10 CFR 30, 32, 33, 34, 35, 36, 37, 39, and 40	 <p>U.S. NUCLEAR REGULATORY COMMISSION</p> <p>APPLICATION FOR MATERIALS LICENSE</p>	APPROVED BY OMB: NO. 3150-0120 Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-2 F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov , and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.	EXPIRES: 06/30/2019		
INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1656 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/sr1656/. 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		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			
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,		IF YOU ARE LOCATED IN: ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,			
SEND APPLICATIONS TO: 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		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) <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____		2. NAME AND MAILING ADDRESS OF APPLICANT (Include zip code)			
3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION BUSINESS TELEPHONE NUMBER _____ BUSINESS CELLULAR TELEPHONE NUMBER _____ BUSINESS E-MAIL ADDRESS _____			
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.					
5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.		6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.			
8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.		7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.			
10. RADIATION SAFETY PROGRAM.		9. FACILITIES AND EQUIPMENT.			
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: <input type="text"/> AMOUNT ENCLOSED \$ <input type="text"/>			
PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html					
13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.					
CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE		SIGNATURE	DATE		
FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

APPENDIX B

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

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

The table below is designed to help applicants develop their applications. It may also be used as a License Reviewer Checklist for applications for Manufacturing and Distribution licenses. A box in a column () indicates that the licensee may agree to use a model procedure, or if not using a model procedure, the licensee is then expected to describe its program or submit its procedures for the particular item.

For broad scope usage applications, refer to NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," issued April 1999.

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
5.	<p>RADIOACTIVE MATERIAL</p> <p>Unsealed or Sealed Sources, or Both</p> <p>For unsealed materials, do the following:</p> <ul style="list-style-type: none"> • For each radionuclide, provide the element name with mass number, chemical and/or physical form, and maximum requested possession limit. — For potentially volatile materials (e.g., I-125, I-131, H-3, Kr-85), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form. <p>For sealed radioactive materials, do the following:</p> <ul style="list-style-type: none"> — Identify each radionuclide (element name and mass number) that will be used, and specify the maximum activity per source. Also, specify the maximum number of sources or total activity of each radionuclide. — Provide the manufacturer's or distributor's name and model number for each sealed source and device requested. — Confirm that each sealed source, device, and source and device combination is registered as an approved sealed source or device by NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available 	N/A	<input type="checkbox"/>
		N/A	<input type="checkbox"/>

Table B-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
5.	<p>RADIOACTIVE MATERIAL (Continued)</p> <p>Unsealed or Sealed Sources, or Both (Continued)</p> <p>For each sealed source, device, and source and device combination that is not registered, provide the applicable information, as described in 10 CFR 30.32(g) and 32.210.</p> <p>For Both Unsealed and Sealed Sources, do the following:</p> <ul style="list-style-type: none"> — Identify the largest quantity of each radionuclide to be possessed at one time under the license, including receipts, in-process materials, and waste. — In accordance with 10 CFR 30.32(i), applications to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities listed in 10 CFR 30.72, must include either of the following: <ul style="list-style-type: none"> — an evaluation showing that the maximum offsite dose caused by a release of radioactive materials would not exceed 0.01 Sv [1 rem] effective dose equivalent or 0.05 Sv [5 rem] to the thyroid <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> — an emergency plan for responding to the release, in accordance with the criteria listed in 10 CFR 30.32(i)(3) — In accordance with 10 CFR 70.22(i), applications to possess in excess of 2 curies of plutonium in unsealed form or on foils or plated sources must contain either of the following: <ul style="list-style-type: none"> — an evaluation showing that the maximum dose to a member of the public offsite due to a release of radioactive materials would not exceed 0.01 Sv [1 rem] effective dose equivalent 	N/A	<input type="checkbox"/>

Table B-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
5.	<p>RADIOACTIVE MATERIAL (Continued)</p> <p>Unsealed or Sealed Sources, or Both (Continued)</p> <p style="text-align: center;">OR</p> <p>— an emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and any associated chemical hazards directly incident thereto, in accordance with the criteria listed in 10 CFR 70.22(i)(3)</p> <p>Financial Assurance and Recordkeeping for Decommissioning</p> <p>State the following:</p> <ul style="list-style-type: none"> • “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 records important to decommissioning and will transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b), 10 CFR 40.46, and 10 CFR 70.36, as appropriate. 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.” <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • If financial assurance is required, submit the required documents, as described in NUREG-1757, Volume 3, “Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness.” 	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;">N/A</p>	<p style="text-align: center;">N/A</p> <p style="text-align: center;"><input type="checkbox"/></p>
6.	<p>PURPOSE FOR WHICH LICENSED MATERIAL WILL BE POSSESSED AND USED</p> <ul style="list-style-type: none"> • List the specific use or purpose of each radionuclide that will be possessed and used. 	<p style="text-align: center;">N/A</p>	<p style="text-align: center;"><input type="checkbox"/></p>

Table B-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
7.	<p>INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Continued)</p> <p>Authorized Users (Continued)</p> <p>Information should include, as a minimum:</p> <ul style="list-style-type: none"> • formal training and education in radiation safety (topics covered, duration of training, when training was received, identity/location of training provider) (Note: a course outline may be provided.) • experience using licensed materials (types, forms, quantities handled, activities performed, duration of experience) 		
8.	<p>TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS</p> <p>Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.</p>	N/A	<input type="checkbox"/>
9.	<p>FACILITIES AND EQUIPMENT</p> <p>Describe the facilities and equipment to be made available at each location where radioactive material will be possessed or possessed and used (see Appendix F of this NUREG for topics to consider). This information should be from the point of view of performance criteria. For example, state the purpose of any filtration equipment and the associated acceptance criteria to accomplish this purpose (such as the ventilation flow rate trying to be maintained).</p> <p>Include a description of the areas assigned for the receipt, shipping, storage, preparation, security, and measurement of radioactive materials.</p> <p>Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, areas containing flammable or hazardous materials, and other items related to radiation safety.</p>	<p>N/A</p> <p>N/A</p> <p>N/A</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

Table B-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
<p>9.</p>	<p>FACILITIES AND EQUIPMENT (Continued)</p> <ul style="list-style-type: none"> • When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. • Diagrams should be drawn to a specified scale, or dimensions should be indicated. Sketches or drawing should also include a compass directional arrow to indicate “North”. • For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted <p>If radioactive materials will be used with animals, include a description of the animal-handling housing facilities. NUREG–1556, Vol. 7 may also be used as guidance.</p> <p>Specialized facilities such as waste storage rooms or hot labs, and locations of specialized facilities or equipment such as waste compactors, hot cells, and shielded storage for high activity sources, should be included on the diagram.</p>		
<p>10.</p>	<p>RADIATION SAFETY PROGRAM</p> <p>Audit Program</p> <p>The applicant is not required to, and should not, submit its audit program to the NRC for review as part of a license application. However, this matter may be reviewed during NRC inspections.</p> <p>Radiation Monitoring Instruments</p> <p>Describe the instrumentation that will be used to perform required surveys.</p> <p>AND</p> <p>State that: “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix H in NUREG–1556, Volume 12, Rev.1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.” We reserve the right to upgrade our radiation survey instruments as necessary.”</p>	<p>N/A</p> <p>N/A</p> <p><input type="checkbox"/></p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p>

Table B-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>For Instrument Calibration</p> <p>State that: "Instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration."</p> <p style="text-align: center;">OR</p> <p>State that: "We will implement the model radiation survey instrument calibration program published in Appendix H in NUREG-1556, Volume 12, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.""</p> <p style="text-align: center;">OR</p> <p>Submit equivalent procedures for instrument calibrations.</p> <p>Material Receipt and Accountability</p> <p>State that: "We will comply with the NSTS reporting requirement, as described in 10 CFR 20.2207."</p> <p style="text-align: center;">AND</p> <p>State that: "We will develop, implement, and maintain procedures for ensuring accountability of license materials at all times."</p> <p style="text-align: center;">AND</p> <p>Provide either of the following</p> <p>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 3 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."</p> <p style="text-align: center;">OR</p> <p>a description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p>	<p>N/A</p> <p>N/A</p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p> <p><input type="checkbox"/></p>

Table B-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>Occupational Dose</p> <p>The applicant should provide one of the following statements:</p> <p>“We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502.”</p> <p style="text-align: center;">OR</p> <p>“We will monitor individuals in accordance with the guidance in Section 8.10.4, “Radiation Safety Program–Occupational Dose” in NUREG–1556, Vol. 12, Rev. 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.””</p> <p style="text-align: center;">OR, IN LIEU OF THESE STATEMENTS,</p> <p>Provide a description of an alternative method for demonstrating compliance with the referenced regulations.</p> <p>Public Dose</p> <p>No response is required from the applicant, but records and written materials documenting compliance will be examined during inspection.</p> <p>Safe Use of Radionuclides and Emergency Procedures</p> <p>The applicant should provide the following statements:</p> <p>“Procedures for safe use, security of materials, and emergencies will be developed and documented before receipt of licensed material. Operating and emergency procedures will be implemented and maintained.”</p> <p style="text-align: center;">AND</p> <p>“Procedures will be revised only if (i) the changes are reviewed and approved by the licensee management and the RSO in writing; (ii) the licensee staff is provided training in the revised procedures prior to implementation; (iii) the changes are in compliance with NRC regulations and the license; and (iv) the changes do not degrade the effectiveness of the program.”</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p> <p>N/A</p>

Table B-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>Safe Use of Radionuclides and Emergency Procedures (Continued)</p> <p style="text-align: center;">AND</p> <p>If an “Emergency Plan” is required for the license, pursuant to 10 CFR 30.32(i) and 30.72 or 10 CFR 70.22(i), submit it as a separate part of the application.</p> <p>Surveys and Leak Tests</p> <p>The applicant should provide one of the following statements:</p> <p>“We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M to NUREG-1556, Vol. 12, Rev. 1, “Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution.””</p> <p>If applicable, state, “We will perform contamination checks on all fabricated sealed sources prior to distribution. Also, leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or leak tests may be collected by the licensee using the sealed source or plated foil manufacturer’s, distributor’s, and leak test kit supplier’ instructions. Such leak test kits should be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services.”</p>	<p>N/A</p> <p><input type="checkbox"/></p>	<p><input type="checkbox"/></p> <p>N/A</p>

Table B-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>Surveys and Leak Tests (Continued)</p> <p style="text-align: center;">OR</p> <p>“We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M to NUREG-1556, Vol. 12, Rev. 1, “Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution.”” If applicable, state, “We will perform contamination checks on all fabricated sealed sources prior to distribution. Also, leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate. We will follow the model procedures in Appendix N of NUREG-1556, Vol. 12, Rev. 1, “Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution.””</p> <p style="text-align: center;">OR</p> <p>Submit a description of alternative equipment and procedures to evaluate radiological hazards at the applicant’s facility, in accordance with 10 CFR 20.1501 and for determining whether there is radioactive leakage from sealed sources or plated foils. If applicable, state: “We will perform contamination checks on all fabricated sealed sources prior to distribution. Also, leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate.”</p> <p>Maintenance</p> <p>No response is required in the application process. The results of actions taken in the maintenance and repair of facilities and equipment process will be reviewed during inspection.</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;">N/A</p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;">N/A</p>	<p style="text-align: center;">N/A</p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;">N/A</p>

Table B-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>Transportation</p> <p>No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials on its own in Type B packages, a licensee needs to have registered with NRC as a user of the package and obtained NRC’s approval of its QA program. Transportation issues will be reviewed during inspection.</p> <p>Security Program For Category 1 and Category 2 Radioactive Material</p> <p>No response is required from an applicant or licensee. Compliance with access authorization and security program requirements may be reviewed during NRC inspections.</p>	<p>N/A</p> <p>N/A</p>	<p>N/A</p> <p>N/A</p>
11.	<p>WASTE MANAGEMENT</p> <p>The applicant should provide one of the following statements:</p> <p>“We will use the model waste procedures and guidelines published in Appendix P to NUREG–1556, Volume 12, Rev. 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.””</p> <p style="text-align: center;">OR</p> <p>“We will use the [specify either (i) decay-in-storage or (ii) disposal of liquids into sanitary sewerage] model waste procedures that are published in Appendix P to NUREG–1556, Volume 12, Rev. 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.””</p> <p style="text-align: center;">AND</p> <p>If the applicant wishes to compact or incinerate radioactive waste, provide the requested information concerning these activities as stated in Appendix P of this NUREG.</p> <p style="text-align: center;">AND/OR</p> <p>If needed, the applicant should request authorization for extended interim storage of waste.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p> <p>N/A</p>	<p>N/A</p> <p>N/A</p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

APPENDIX C
LICENSE TYPES–GUIDANCE

License Types—Guidance

The following codes are used for each byproduct material license.

XX (State code)-XXXXX (institution code—a unique identifier for each licensee)-XX (sequential number of license for that licensee). Letters that follow the license number on distribution licenses include E, G, and MD. No letters indicates a possession license.

Manufacturer's Possession License

XX-XXXXX-XX

This specific license is issued to a manufacturer to normally possess, use, and manufacture licensed material for distribution (includes importers that may not manufacture but want a location for distribution) and for use by the licensee in process controls. It can include distribution to other specific licensees that are also specifically authorized to receive the materials pursuant to their specific license. The manufacturer's possession license contains conditions that prohibit distribution pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 32.72 and 32.74 and prohibit distribution to general licensees and to persons exempt from licensing.

General Distribution License

XX-XXXXX-XXG

This specific license is issued to manufacturers and distributors to distribute approved materials to persons who are generally licensed to possess and use the materials. This license does not authorize the possession of byproduct, source, or special nuclear material.

The most common products distributed to general licensees are

- 10 CFR 32.51, 51a, 52—Certain measuring, gauging, or controlling devices, including fixed gauges (e.g., density, thickness), and may include multi-curie sources, gas chromatograph electron capture devices (ECDs), X-ray fluorescence or other analytical devices, curie-quantity tritium light sources for exit signs, and similar devices. For possession and use by persons authorized by a General License pursuant to 10 CFR 31.5.
- 10 CFR 32.71—Kits for *in vitro* clinical or laboratory testing (e.g., microcurie quantities of H-3, C-14, Fe-55, I-125). For possession and use by persons authorized by a General License pursuant to 10 CFR 31.11.
- 10 CFR 40.34(a)—Distribution of industrial products or devices with small amounts of depleted uranium for possession and use by persons authorized by a General License pursuant to 10 CFR 40.25.
- 10 CFR 70.39—Distribution of calibration or reference sources containing plutonium for possession and use by persons authorized by a General License pursuant to 10 CFR 70.19.

Exempt Distribution License

XX-XXXXX-XXE

Specific license to distribute approved materials to persons who are not required to have any license in order to possess or use the material. Exempt Distribution is authorized by a specific

license issued by U.S. Nuclear Regulatory Commission Headquarters in Washington, D.C. This license does not authorize the possession of byproduct, source, or special nuclear material.

Medical Distribution License

(XX-XXXXX-XXMD)

10 CFR 32.72 and 32.74

Sources and devices for medical use pursuant to 10 CFR 35.65, 35.400, 35.500, 35.600, and 35.1000 for radiopharmaceuticals for medical use pursuant to 10 CFR 35.100, 35.200, 35.300, and 35.1000 (This license does not authorize the possession of byproduct, source, or special nuclear material.)

Manufacturers of medical devices may wish to plan for return shipments of licensed materials. Manufacturers of sealed source devices such as eye applicators or bone densitometers may wish to provide a return at the end of useful life service. Radiopharmaceutical manufacturers may wish to receive spent generator assemblies from their customers and dispose of them by decay-in-storage. Returned materials are possessed pursuant to the manufacturer's possession license.

APPENDIX D

RADIATION SAFETY OFFICER DUTIES AND RESPONSIBILITIES

Radiation Safety Officer Duties and Responsibilities

The radiation safety officer's (RSO's) duties and responsibilities include ensuring radiological safety, security, and compliance with both U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Transportation (DOT) regulations and the conditions of the license.

Typically, the RSO's duties and responsibilities include the following:

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of licensed material listed on the license.
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1301.
- Ensure security of radioactive material, and for licensees possessing an aggregated Category 1 or Category 2 quantity of radioactive material, develop and implement a security program for radioactive material in accordance with 10 CFR Part 37.
- Post documents as required by 10 CFR Parts 19.11 and 21.6.
- Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements.
- Ensure that radiation exposures are as low as is reasonably achievable (ALARA).
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is possessed or possessed and used.
- Act as liaison with NRC and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Parts 19 and 20, and any other applicable regulations.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the facility, as well as packaging and labeling all radioactive material leaving the facility.
- Distribute and process personnel radiation-monitoring equipment, determine the need for and evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching established limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct all personnel in the proper procedures for handling radioactive material prior to possession or possession and use, both at periodic intervals (refresher training), and as required by changes in procedures, equipment, and regulations.

- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radionuclides possessed under the license, and limit the quantity to the amounts authorized by the license.
- Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above (e.g., records of receipts; transfers; and surveys, as required by 10 CFR 30.51 and 10 CFR 20, Subpart L, "Records").
- Hold periodic meetings with and provide reports to licensee management.
- Perform periodic audits of the Radiation Safety Program to ensure that the licensee is complying with (i) all applicable NRC regulations; (ii) the terms and conditions of the license (e.g., leak tests; inventories; possession or possession and use limited to trained, approved users); (iii) the content and implementation of the Radiation Safety Program to achieve occupational doses and doses to members of the public that are ALARA, in accordance with 10 CFR 20.1101; and (iv) the requirement that all records be properly maintained.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least 3 years) and provided to management for review, and ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all personnel who possess or possess and use licensed material.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or Part 20 limits are investigated and reported to NRC and other appropriate authorities, if required, within the required time limits.
- Maintain an understanding of, and up-to-date copies of, NRC regulations, the license, and 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 NRC during the licensing process.
- Develop, implement, maintain, and distribute, as appropriate, up-to-date operating, emergency, and security procedures.

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

Signature of Management Representative

Date

I accept the above responsibilities.

Signature of Radiation Safety Officer

Date

cc: Affected department heads

APPENDIX E
RADIATION SAFETY TRAINING

Radiation Safety Training

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

The licensee should determine whether the training succeeded in conveying the desired information, and adjust the training program as necessary. This assessment may be performed by a test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

Frequency of Training

- A. before assuming duties with, or in the vicinity of, radioactive materials
- B. whenever there is a significant change in duties, regulations, or the terms of the license
- C. annually (refresher training)

General Information

- A. radiation safety
 - 1. radiation vs. contamination
 - 2. internal vs. external exposure
 - 3. biological effects of radiation
 - 4. as low as is reasonably achievable (ALARA) concept
 - 5. use of time, distance, and shielding to minimize exposure
 - 6. contact dose rates and dose rates at a distance from high activity sources
 - 7. dose reduction responsibilities
- B. regulatory requirements
 - 1. Radiation Safety Officer (RSO)
 - 2. material control and accountability
 - 3. personnel dosimetry
 - 4. Radiation Safety Program audits
 - 5. transfer and disposal
 - 6. recordkeeping
 - 7. surveys
 - 8. postings
 - 9. labeling of containers
 - 10. handling and reporting of incidents or events
 - 11. licensing and inspection by U.S. Nuclear Regulatory Commission (NRC)
 - 12. need for complete and accurate information
 - 13. employee protection
 - 14. deliberate misconduct

Licensee-Specific Program Elements

- A. authorized users and supervised users
- B. worker-specific manufacturing process tasks
- C. shipping
- D. ordering and receiving radionuclides
- E. applicable regulations and license conditions
- F. areas where radioactive material is used or stored
- G. potential hazards associated with radioactive material in each area where the individuals will work
- H. appropriate radiation safety procedures
- I. licensee's in-house work rules (for instructions on laboratory safety and uses of radionuclides, see Appendix K of this NUREG)
- J. each individual's obligation to report unsafe conditions to the RSO
- K. appropriate response to spills, emergencies, or other unsafe conditions
- L. workers' right to be informed of occupational radiation exposure and bioassay results, if applicable
- M. locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 19
- N. security of materials
 - 1. receiving materials
 - 2. using materials
 - 3. storing materials
 - 4. possessing Category 1 or Category 2 materials and then 10 CFR Part 37 security training.
- O. emergency procedures
 - 1. RSO name and telephone number
 - 2. immediate steps to prevent or control spread of contamination
 - 3. clean-up instructions, decontamination
- P. survey program
 - 1. radiation survey instrument accessibility
 - 2. who is responsible

3. types, contamination, and areas
 4. frequency
 5. levels of contamination
 6. personnel, hands, shoes
 7. records
- Q. radioactive waste
1. liquid
 2. solids
 3. sanitary sewer
 4. burial (transfer to low-level waste repository)
 5. storage
 6. decay-in-storage
 7. waste storage surveys
 8. records
- R. dosimetry
1. whole body
 2. extremities
 3. lens of eye
 4. lost or replacement badges and dose assessment
 5. bioassay procedures
 6. records
- S. Instrumentation
1. radiation survey meters—use, calibration frequency, use of check sources
 2. analytical instruments—gas flow counters, liquid scintillation counters
- T. Procedures for receiving packages containing radioactive materials
1. normal
 2. off-duty
 3. notification of user and RSO
 4. security
 5. exposure levels
 6. possession limit
 7. receipt of damaged packages
- U. Procedures for opening and examining packages
1. leakage and contamination
 2. monitoring packages
 3. monitoring packing materials
 4. gloves
 5. transferring material to users

- V. Animal experiments
 - 1. description of facilities
 - 2. procedures to be performed with animals
 - 3. safety instructions, including handling of animals, waste, carcasses, and cleaning and decontamination of cages
- W. Sealed sources
 - 1. leak-test requirements
 - 2. inventory requirements
 - 3. exempt quantities
 - 4. records
- X. NRC/State/Licensee audit findings
- Y. Other topics
- Z. Question and answer period

For Laboratory Safety and Use of Radionuclides

- A. Control procedures for obtaining permission to possess or possess and use radioactive materials at the facility; give limitations on quantity to be handled per user, or allowed per experiment, etc.
- B. Protective clothing and what laboratory apparel to wear and what equipment to use.
- C. Limitations and conditions relative to handling unsealed licensed material and what laboratory equipment to use when working with such material. For example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or glove boxes. Explain what shielding or remote handling equipment is to be used when beta or gamma-emitting licensed materials are handled.
- D. Routine survey and monitoring procedures to be followed for contamination control. Include where and how contaminated articles and glassware are to be handled and stored.
- E. Emergency procedures concerning spills, fires, release of material, and accidental contamination of personnel.
- F. Decontamination procedures to use and whom to contact in case of an emergency.
- G. Instructions concerning transfer of licensed materials between rooms, halls, or corridors, if applicable.
- H. Requirements for storage, labeling of containers, and identification of areas where licensed materials are possessed or possessed and used.
- I. Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.

- J. Waste disposal procedures to follow, limitations for disposal of liquid or solid wastes, and procedures to use for waste storage. If the program involves experiments with animals, procedures for cleaning animal quarters and handling animal excreta and carcasses for disposal.
- K. Records to be maintained on possession, use, and disposal of licensed materials.
- L. Prohibition of pipetting by mouth.
- M. Prohibition of eating, smoking, drinking, and application of cosmetics in areas where licensed materials are possessed or possessed and used.

APPENDIX F
FACILITIES AND EQUIPMENT

Facilities and Equipment

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

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

storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- For the most efficient operation of hoods and glove boxes, minimize storage of materials and equipment inside the work areas.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity. If appropriate, supply and exhaust fans can be interlocked such that if exhaust fans shut down, the shutdown of supply fans is also triggered, this interlock system is to prevent laboratory and work areas from becoming positively pressurized with respect to the surrounding parts of the facility.
- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- To reduce radiation exposure from gamma-emitting radioactive materials, shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods, or in glove boxes.
- To reduce the exposure from high-energy beta-emitting materials, shielding of low-atomic-number material, such as high-density plastic, may be used. In operations using large quantities (i.e., multi-millicurie quantities) of high-energy beta-emitting radionuclides or longer exposure times, it may be necessary to also reduce the bremsstrahlung by adding shielding containing high-atomic-number material such as lead. These shields generally are low-atomic-number materials closest to the source, enclosed by high-atomic-number material.
- Shielded shipping containers are used frequently for continued storage after receipt of materials.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials. In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.

- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination buildup.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of 10 CFR Part 20, Subpart H, "Respiratory protection and controls to restrict internal exposure in restricted areas."
- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on the number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary and placed near the waste-generating areas and away from areas that personnel frequently occupy. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited. If radioactive waste materials are volatile, the containers should be stored in ventilated areas.
- If compaction of waste is performed, ensure that the facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per 10 CFR 20.1204.
- Adequate air and water effluent-monitoring equipment should be used to demonstrate compliance with the limits found in 10 CFR Part 20, Appendix B, if applicable, and tested for operability at the frequency established by the manufacturer.

APPENDIX G
SAMPLE AUDIT PROGRAM

Sample Audit Program

An audit is conducted, in part, to fulfill the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1101 for an annual review of the content and implementation of the licensee's radiation safety program. Audits should be performance-based, and include observations of licensed activities, interviews with personnel, and inspection of facilities and equipment. Audits should also identify program weaknesses and allow licensees to take early corrective actions [before an U.S. Nuclear Regulatory Commission (NRC) inspection]. During an audit, the auditor needs to keep in mind not only the requirements of the NRC's regulations, but also the licensee's commitments in its applications and other correspondence with the NRC. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement.

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

Section 1 Audit History

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

Section 2 Organization and Scope of Program

Give a brief description of the organizational structure, noting any changes in personnel or procedures, and amendments to the license. Describe the scope of licensed activities at the audited location. Check whether the Radiation Safety Officer (RSO) is the person identified in the license and fulfills the duties specified in the license.

Section 3 Training, Retraining, and Instructions to Workers

Ensure that workers have received the training required by 10 CFR 19.12. Be sure that the user has received training and has a copy of the licensee's safe use and emergency procedures before being permitted to use byproduct material. 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 or observation of selected workers, that he or she can implement them.

Section 4 Audits

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 license documents.

Section 6 Materials

Verify that the license authorizes the quantities and types of byproduct material that the licensee possesses. Verify that the sealed source and devices are manufactured in accordance with the sealed source and device registration.

Section 7 Leak Tests

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

Section 8 Inventories

Verify that inventories are conducted at least once every 6 months to account for all sources; inventory records should be maintained.

Section 9 Radiation Surveys

Verify that the licensee has appropriate, operable, and calibrated radiation survey instruments available and that the instruments are calibrated (at the required frequency) in accordance with license conditions and in accordance with 10 CFR 20.2103. Calibration records must be retained for 3 years after the record is made. Check that radiation levels in areas adjacent to use are within regulatory limits and in accordance with 10 CFR 20.2103. Verify compliance with 10 CFR 20.1301. 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 received from others containing byproduct material 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, 10 CFR 40.51, and 10 CFR 70.42, as appropriate. 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, and 10 CFR 70.51, as appropriate.

Section 11 Transportation

Determine compliance with Department of Transportation (DOT) requirements.

Section 12 Personnel Radiation Protection

Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits. 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, and determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with 10 CFR 20.1208. Check whether records are maintained, as required by 10 CFR 20.2101, 2102, 2103, 2104, and 2106.

Section 13 Auditor's Independent Measurements (If Made)

The auditor should make independent survey measurements and compare the results with those made or used by the licensee.

Section 14 Notification and Reports

Check on the licensee's compliance with the notification and reporting requirements in 10 CFR Parts 19, 20, 30, 40 and 70. Ensure that the licensee is aware of the telephone number for NRC's Emergency Operations Center: 301-816-5100.

Section 15 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 16 Recordkeeping for Decommissioning

Check to determine compliance with 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.

Section 17 Bulletins and Information Notices

Check to determine if all NRC correspondence (e.g., regulatory issue summaries (RISs), bulletins, information notices, NMSS Newsletters) issued since the previous audit and applicable to possession licenses for manufacturing and distribution have been reviewed. Check whether the licensee took appropriate action (e.g., training, updating procedures) in response to this NRC correspondence.

Section 18 Special License Conditions or Issues

Verify compliance with any special conditions on the licensee's license. If the licensee has any unusual aspect of its work, review and evaluate compliance with regulatory requirements.

Section 19 Continuation of Report Items

This section is self-explanatory.

Section 20 Problems or Deficiencies Noted; Recommendations

This section is self-explanatory.

Section 21 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 Checklist

Audit Report No. _____

License No. _____

Licensee's name and mailing address:

Audit of activities at (address):

Contact at audit location: _____

Telephone No.: _____

Date of this audit: _____

Summary of Findings and Action:

No deficiencies

Deficiencies

Action on previous deficiencies

Recommendations:

Auditor: _____

Date: _____

(Signature)

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

A. Last audit of this location conducted

B. Problems/deficiencies identified during last 2 audits or 2 years, whichever is longer [] Y [] N

C. Open problems/deficiencies from 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

1. Structure described as in license documents [] Y [] N

2. Multiple authorized locations of use [License Condition (L/C)] [] Y [] N

3. Brief description of scope of activities involving byproduct material, frequency of use, staff size, etc. [] Y [] N

4. Amendments and program changes (L/C) [] Y [] N

B. Radiation Safety Officer [] Y [] N

1. Authorized on license (L/C) [] Y [] N

2. Fulfills duties as RSO [] Y [] N

C. Radioactive material used only by authorized individuals (L/C) [] Y [] N

D. Commensurate security program implemented (10 CFR 20.1801, 20.1802 and Part 37 if applicable) [] Y [] N

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

- A. Instructions to workers in accordance with (10 CFR 19.12) Y N
- B. Training program required Y N
- C. Training records maintained Y N
- D. Evaluation of individuals' understanding of procedures and regulations based on interviews and observations of selected workers Y N
1. Each has an up-to-date copy of the licensee's safe use and emergency procedures
2. Adequate understanding of the following:
- Current safe use procedures Y N
 - Emergency procedures Y N
- E. 10 CFR Part 20

Workers cognizant of requirements for the following:

1. Radiation Safety Program (10 CFR 20.1101) Y N
2. Annual dose limits (10 CFR 20.1301, 10 CFR 20.1302, and 10 CFR 20.1207) Y N
3. NRC Forms 4 and 5 Y N
4. Ten percent monitoring threshold (10 CFR 20.1502) Y N
5. Dose limits to embryo/fetus and declared pregnant women (10 CFR 20.1208) Y N
6. Procedures for opening packages (10 CFR 20.1906) Y N

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 [10 CFR 20.1101(c)]. [] Y [] N
- C. For programs possessing Category 1 or Category 2 materials:
 - 1. Access program content and implementation [10 CFR 37.33(a)] [] Y [] N [] N/A
 - 2. Security program review (10 CFR 37.55) [] Y [] N [] N/A
- D. Records are maintained (10 CFR 20.2102). [] Y [] N

5. FACILITIES

- A. Facilities are described as in the license application (L/C). [] Y [] N
- B. Security procedures implemented (20.1801, 20.1802; Part 37, if applicable) [] Y [] N

Remarks:

6. MATERIALS

- Isotopes, quantities, and use are as authorized on license (L/C). [] Y [] N
- For each SSD registration:
 - SSD application documents maintained [] Y [] N
 - Sealed source and devices model numbers being distributed currently on the SSD certificate [] Y [] N
 - Changes to registered devices/sealed source has been submitted to the NRC or Agreement State and approved [] Y [] N
 - The appropriate QA/QC checks are being performed as required by SSD registration application/references [] Y [] N
 - The products are being distributed for an active registration [] Y [] N
 - Inactivation request was submitted to the NRC or Agreement State for product no longer manufactured or distributed in accordance with 10 CFR 32.211 [] Y [] N

Remarks:

7. LEAK TESTS

- A. Leak test is performed as described in correspondence with the NRC (consultant, leak test kit, and licensee performed) (L/C). [] Y [] N
- B. Frequency of tests is every 6 months or another interval, as approved by the NRC or Agreement State (L/C). [] Y [] N
- C. Records with appropriate information are maintained (L/C). [] Y [] N

Remarks:

8. INVENTORIES

- A. Inventories are conducted at 6-month intervals (L/C). [] Y [] N
- B. Records with appropriate information are maintained (L/C). [] Y [] N

Remarks:

9. RADIATION SURVEYS

- A. Instruments and equipment: [] Y [] N
 - 1. Appropriate operable radiation survey instrumentation is possessed or is readily available. [] Y [] N
 - 2. Instruments and equipment are calibrated as required (10 CFR 20.1501). [] Y [] N
 - 3. Calibration records are maintained [10 CFR 20.2103(a)]. [] Y [] N
- B. Briefly describe survey requirements [10 CFR 20.1501(a)]:
- C. Surveys are performed as required [10 CFR 20.1501(a)]. [] Y [] N
 - 1. Radiation levels are within regulatory limits. [] Y [] N
 - 2. Corrective action was taken and documented. [] Y [] N
- D. Records are maintained (10 CFR 20.2103). [] Y [] N
- E. Protection of members of the public:
 - 1. Adequate surveys are made to demonstrate that
 - (i) the TEDE to the individual who is likely to receive the highest dose does not exceed 100 mrem in a year or
 - (ii) 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 [10 CFR 20.1301(a)(1) and 10 CFR 20.1302(b)]. [] Y [] N

- 2. Unrestricted area radiation levels do not exceed 2 mrem in any 1 hour [10 CFR 20.1301(a)(2)]. [] Y [] N
- 3. Records are maintained (10 CFR 20.2103 and 10 CFR 20.2107). [] Y [] N

Remarks:

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

- A. Procedures describe how packages are received and by whom. [] Y [] N
- B. Written package opening procedures are established and are followed [10 CFR 20.1906(e)]. [] Y [] N
- C. If a package shows evidence of degradation, it is monitored for contamination and radiation levels. [] Y [] N [] N/A
- D. Monitoring of degraded packages is performed within time specified [10 CFR 20.1906(c)]. [] Y [] N [] N/A
- E. A transfer(s) between licensees (including “disposal”) is performed in accordance with (10 CFR 30.41, 40.51, 70.42). [] Y [] N [] N/A
- F. Records of receipt/transfer are maintained [10 CFR 20.2103(a) and 10 CFR 30.51, 40.61, 70.51]. [] Y [] N
- G. Transfers within licensee’s authorized users or locations are performed as required [license condition (L/C)]. [] Y [] N [] N/A
- H. Package receipt/distribution activities are evaluated for compliance with (10 CFR 20.1301 and 10 CFR 20.1302). [] Y [] N [] N/A
- I. Reports of transactions involving nationally tracked sources are submitted as required (10 CFR 20.2207). [] Y [] N [] N/A

Remarks:

- 11. TRANSPORTATION [10 CFR 71.5(a) and 49 CFR 170-180] [] Y [] N [] N/A
 - A. Licensee shipments are as follows:
 - 1. Shipments were delivered to common carriers. [] Y [] N [] N/A
 - 2. Shipments were transported in licensee’s own private vehicle. [] Y [] N [] N/A
 - 3. No shipments were made since last audit. [] Y [] N [] N/A

B. Hazmat Training

1. Applicability and responsibility for training and testing (49 CFR 172.702). Y N N/A
2. Training requirements (49 CFR 172.704). Y N N/A

C. Packages N/A

1. Authorized packages were used [49 CFR 173.415, 173.416(b)]. Y N N/A
2. Packages were closed and sealed during transport [49 CFR 173.475(f)]. Y N

D. Shipping Papers N/A

1. Shipping papers were prepared and used [49 CFR 172.200(a)]. Y N
2. Papers included proper shipping name, hazard class, UN number, quantity, package type, radionuclide, reportable quantities, radioactive material, physical and chemical form, activity, category of the label, TI (Transport Index), shipper's name, certification and signature, emergency response phone number, and "Cargo Aircraft Only" (if applicable) (49 CFR 172.200 through 49 CFR 172.204). Y N
3. Papers were readily accessible during transport [49 CFR 177.718(e)]. Y N

E. Vehicles Y N

1. The cargo was blocked and braced [49 CFR 177.842(d)]. Y N
2. Placarded, if needed (49 CFR 172.504). Y N
3. Proper overpacks, if used (with shipping name, UN number, cargo labeled, and statement that indicates that the inner package complies with the specification package) (49 CFR 173.25). Y N

F. Any incidents reported to DOT (49 CFR 171.15 and 49 CFR 171.16). Y N

G. Physical protection of Category 1 or Category 2 quantity of radioactive material in transit (10 CFR Part 37, Subpart D). Y N N/A

Remarks:

12. PERSONNEL RADIATION PROTECTION

- A. ALARA considerations are incorporated into the Radiation Protection Program [10 CFR 20.1101(b)]. Y N
- B. Evaluations are performed showing that unmonitored individuals receive less than the limits in 10 CFR 20.1502(a). The evaluations consider doses to minors [10 CFR 20.1502(a)(2)] and declared pregnant women [10 CFR 20.1502(a)(3)]. Y N N/A
- C. Unmonitored individuals' activities changed during the year in a way that could put them over the limits in 10 CFR 20.1502(a). Y N N/A
- If yes, new evaluation was performed. Y N N/A
- D. External dosimetry is required [i.e., when individuals are likely to receive greater than the limits in 10 CFR 20.1502(a)], and provided to individuals. Y N
- If yes, address the following:
1. The dosimetry supplier is approved by the National Voluntary Laboratory Accreditation Program [10 CFR 20.1501(c)]. Y N N/A
2. Dosimeters are exchanged at the appropriate frequency. Y N N/A
3. Dosimetry reports are reviewed and signed by the RSO when they are received. Y N N/A
4. Records are based on NRC forms or the equivalent [10 CFR 20.2104(d) and 20.2106(c)]. Y N N/A
- a. NRC Form 4, "Cumulative Occupational Exposure History," are complete. Y N N/A
- b. NRC Form 5, "Occupational Dose Record for a Monitoring Period," are complete. Y N N/A
- E. Declared pregnant workers in the workforce. Y N
1. Dose equivalent to an embryo/fetus complied with 10 CFR 20.1208. Y N N/A
2. Records of doses to an embryo/fetus complied with 10 CFR 20.2106(e). Y N N/A

- F. Records of exposures, surveys, monitoring, and evaluations maintained (10 CFR 20.2102, "Records of radiation protection programs;" 10 CFR 20.2103, "Records of surveys;" 10 CFR 20.2106, "Records of individual monitoring results"). Y N N/A

Remarks:

13. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)

- A. Radiation survey instrument: Serial No.: Last calibration:
- B. The auditor's measurements were compared to the licensee's measurements. Y N N/A
- C. Describe the type, location, and results of the measurements:

14. NOTIFICATION AND REPORTS

- A. The licensee is in compliance with 10 CFR 19.13 (reports to individuals, public, and occupational, monitored to show compliance with 10 CFR Part 20). Y N N/A
- B. The licensee is in compliance with 10 CFR 20.2201 (theft or loss). Y N N/A
- C. The licensee is in compliance with 10 CFR 20.2202 and 10 CFR 30.50, 40.60, 70.50 (incidents). Y N N/A
- D. The licensee is in compliance with 10 CFR 20.2203 and 10 CFR 30.50, 40.60, 70.50 (overexposures and high radiation levels). Y N N/A
- E. The licensee is aware of the telephone number for the NRC Emergency Operations Center (301-816-5100). Y N
- F. Reporting of events (10 CFR 37.57) Y N N/A

15. POSTING AND LABELING

- A. NRC Form 3, "Notice to Workers," is posted (10 CFR 19.11). Y N
- B. 10 CFR 19, 20, 21; Section 206 of the Energy Reorganization Act of 1974; procedures adopted pursuant to Part 21; and license documents are posted, or a notice indicating the documents can be examined is posted (10 CFR 19.11 and 10 CFR 21.6). Y N
- C. Other posting and labeling activities, in accordance with 10 CFR 20.1902 and 10 CFR 1904, and the license are not exempted by 10 CFR 20.1903 and 10 CFR 1905. Y N

Remarks:

16. RECORD KEEPING FOR DECOMMISSIONING (IF NEEDED) N/A

A. Records of information important to the safe and effective decommissioning of the facility are maintained in an independent and identifiable location until license termination. Y N

B. Records include all information outlined in 10 CFR 30.35(g), 40.36(f), 70.25(g) and 70.51(b)(3). Y N

Remarks:

17. BULLETINS AND INFORMATION NOTICES

A. NRC Correspondence (e.g., RISs, bulletins, information notices, NMSS newsletters, etc.) issued since last audit have been reviewed. Y N

B. Appropriate action was taken in response to bulletins, information notices, and other communications. Y N

Remarks:

18. SPECIAL LICENSE CONDITIONS OR ISSUES N/A

A. Review special license conditions or other issues and describe findings (L/C):

B. Problems/deficiencies identified at the licensee's facilities other than at audit location (L/C):

C. Evaluation of compliance (L/C):

19. CONTINUATION OF REPORT ITEMS N/A

(If more space is needed, use separate sheets and attach them to the report.)

20. PROBLEMS OR DEFICIENCIES NOTED—RECOMMENDATIONS N/A

A. Briefly state the requirement and explain how and when it was violated.

B. Provide recommendations for improvement.

21. EVALUATION OF OTHER FACTORS

A. Senior licensee management is appropriately involved with the radiation safety program and/or RSO oversight Y N

B. The RSO has sufficient time to perform his/her radiation safety duties and is not too busy with other assignments.

Y N

C. The licensee has sufficient staff.

Y N

Remarks/recommendations:

APPENDIX H

RADIATION MONITORING INSTRUMENT SPECIFICATIONS AND MODEL RADIATION SURVEY INSTRUMENT CALIBRATION PROGRAM

Radiation Monitoring Instrument Specifications and Model Radiation Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications

Licensees should possess and use calibrated and operable radiation detection and measurement instruments that are sufficiently sensitive to detect and measure the type and energy of the radiation used. Applicants should determine the number and type of instruments necessary to support licensed activities by considering the scope of activities that will be performed at their facilities. Licensees typically possess one or more portable or handheld instruments to monitor radiological conditions, detect contamination, and perform package-preparation and receipt surveys. Portable instrumentation includes ionization chambers as well as other instrumentation, such as count-rate meters that are supported by a variety of handheld probes or detectors that can be used to detect various types of radiation. These include Geiger-Mueller (GM) detectors, sodium iodide [NaI(Tl)] scintillation detectors, and plastic scintillation detectors. Additionally, licensees may possess stationary or fixed instrumentation, such as well-type scintillation counters, area monitors, stack monitors, or continuous air monitors.

When deciding which types of instruments are appropriate for the intended use, licensees may wish to consult with the instrumentation or equipment manufacturer or vendor to obtain specifications. The instrument should be capable of detecting the type of radiation (e.g., alpha, beta, gamma) and be sensitive to the energy or energy range of the radiation to be measured (e.g., keV, MeV). The characteristics of the instrument, including principles of operation and expected efficiency for the type and energy of the radiation being measured, should be understood by the licensee prior to use.

Applicants may wish to consider the following instrument selection guidelines:

- Alpha emitters and low-energy beta emitters, such as carbon-14 and sulfur-35, may be detected with thin windowed proportional counters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys. Additionally, wipes should be taken and counted with a liquid scintillation counter to verify potential removable contamination.
- Medium- to high-energy beta emitters, such as phosphorus-32 and calcium-45, can be detected with a pancake GM. The efficiency ranges from 15 percent to 40 percent, depending on the beta energy.
- Low-energy gamma emitters, such as iodine-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20 percent. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower, and care should be taken to ensure that the GM probe is capable of detecting any established action levels.
- Medium- to high-energy gamma emitters, such as iodine-131 or high-energy photon emitters, such as fluorine-18, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.

- Neutron emitters, such as a neutron generator, californium 252, or beryllium ring on a high specific-activity alpha source such as americium 241, can be detected by tissue equivalent proportional counters or helium-3 proportional counters.

Further guidance regarding instrumentation can be found in Chapter 9 of the Handbook of Health Physics and Radiological Health, Fourth Edition, Edited by Thomas E. Johnson and Brian Kent Birky, 2012.

Model Radiation Survey Instrument Calibration Program

Training

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

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

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

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

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

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

Evaluate posting of the calibration area with appropriate radiation warning signs, as required by Subpart J of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20.

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

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

Frequency of Calibration of Radiation Measurement Instruments and Equipment

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

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

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

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

Calibration Sources for Dose and Dose Rate Measuring Instruments

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 $\mu\text{Gy/h}$ [0.1 mrad/h] and 10 percent for dose rates less than 1.0 $\mu\text{Gy/h}$ [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 millicuries] of cesium-137 or 780 megabecquerels [21 millicuries] of cobalt-60}.

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

Calibration of Dose or Dose Rate Measuring Instruments

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

- **Linear readout instruments** with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on

each scale. After adjustment, check the response of the instrument at approximately 20 percent and 80 percent of full scale. Instrument readings should be within $\pm x$ (noted below) of the conventionally true value for the following ranges:

- Background to 10 $\mu\text{Gy/h}$ [1.0 mrad/h]; $\pm x = \pm 30\%$
- 10 $\mu\text{Gy/h}$ [1.0 mrad/h] to 1.0 mGy/h [100 mrad/h]; $\pm x = \pm 20\%$
- 1.0 mGy/h [100 mrad/h] to 10 Gy/h [1,000 Rad/h]; $\pm x = \pm 10\%$

- **Logarithmic readout instruments**, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. Adjust the instrument for each scale according to site specifications or the manufacturer's specifications. After adjustment, check the calibration at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value as described for linear readout instruments.
- **Digital readout instruments** should be calibrated the same as linear readout instruments.

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

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

Calibration of Surface Contamination Measurement Instruments

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

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

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

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

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

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

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

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

Calibration Records

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

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

- for radiation detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure
- the exposure rate or count rate from a check source, if used
- the name and signature of the individual who performed the calibration and the date on which the calibration was performed

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

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

Air Sampler Calibration

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

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

Frequency of Calibration of Air Sampling Equipment

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

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

Error Limit for Measurement of Air Sample Volume

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

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

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

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

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

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%, respectively, and there are no other significant sources of error, the cumulative error would be:

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

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

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

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

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

Documentation of Calibration of Air Metering Devices

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

References:

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

APPENDIX I
MATERIAL RECEIPT AND ACCOUNTABILITY

Material Receipt and Accountability

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

Sample Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, (and for sealed sources and devices, the manufacturer and model of the source or device) 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 RSO (or designated receiving area).
- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages, in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

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

Any packages containing radioactive material that arrive between certain hours (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: _____

Home Phone: _____

- If a Category 1 or Category 2 sealed source listed in Appendix E to 10 CFR Part 20 (i.e., a “nationally tracked source,” as defined in 10 CFR 20.1003) is received, it 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 U.S. Nuclear Regulatory Commission (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.

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 a damaged package to the facility remain at the facility until they are monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries usually will be handled by security personnel (or other trained individuals), as described in the above procedures. Because certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. 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 the section titled, "Training for Individuals Working In or Frequenting Restricted Areas."

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 8-2 of Section 8.10.3.

- Check Department of Transportation White I, Yellow II, or Yellow III label or packing slip for activity of contents, to ensure that the shipment meets the activity as requested by the order and 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., inspecting 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, 301-816-5100, by telephone when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) or the external radiation levels exceed the limits of 10 CFR 71.47, External radiation standards for all packages.”

Sample Procedure for Accountability for Unsealed Materials

- The RSO should maintain an accountability log (inventory) of all radioactive materials possessed under the license that demonstrates that the license limits are not exceeded, that all materials received are accounted for, and that material is disposed of or transferred prior to being removed from the current inventory.
- For each radionuclide listed on the license, the RSO should maintain a record of each shipment of material received under the license and indicate the total amount possessed from all shipments.
- Each authorized user (AU) who receives material should maintain a log showing the receipt of each vial and the use and disposal of the material. Material may be tracked by vial, by order, or in some other unit that can be “counted.”
- Each AU should maintain records of the locations and quantities of licensed materials for which they are responsible. For example, material may be present in stock vials, ampoules, Thin Layer Chromatography or High Pressure Liquid Chromatography samples, etc., and in various waste forms; materials may be stored in refrigerators, freezers, cold rooms, lab rooms, etc.
- Periodically, each AU should submit to the RSO an inventory of all licensed materials in the laboratory. (**Note:** the licensee should state in its radiation safety program procedures the frequency of such inventory submissions. It may be weekly, monthly, or quarterly, or after each order, depending on the frequency of use and the amount of materials on hand). Each AU should indicate if material they possessed was disposed of or transferred from their responsibility (examples: waste in containers may be transferred to a common decay-in-storage (DIS) location under the responsibility of the

RSO or another AU; or the AU may have disposed of licensed material to the sewer; or the AU may have transferred a vial of material to another AU.)

- The license accountability log (inventory) may be maintained in hard-copy or electronic records.

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or laboratory or AU'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 completed 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 or shipments must be packaged and labeled in accordance with U.S. Department of Transportation (DOT), NRC, and U.S. Postal Service Regulations, whichever is applicable. Before any transfer from the licensee, 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.

If a Category 1 or Category 2 sealed source listed in Appendix E to 10 CFR Part 20 (i.e., a nationally tracked source) is being shipped, it must be tracked in the NSTS in accordance with 10 CFR 20.2207. The regulations in 10 CFR 20.2207 require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a 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.

Donations

On occasion, licensees may be offered or have donated licensed materials by other individuals (e.g., a retiring medical practitioner donating his cesium-137 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.

APPENDIX J

**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 doses to members of the public.

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in 1 calendar year resulting from the licensee's possession or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv [2 mrem] in any 1 hour.
- Air emissions of radioactive material to the environment, excluding radon-222 and its daughters, will not result in a total effective dose equivalent (TEDE) in excess of 0.1 mSv [10 mrem] per year. As required by in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1101(d), if the licensee exceeds the 0.1 mSv [10 mrem] per year air emission dose constraint, the licensee must report the exceedance, as provided in 10 CFR 20.2203, and promptly take appropriate corrective action to ensure against recurrence.

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

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

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

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

- demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose, in an unrestricted area from licensed operations, does not exceed 1 mSv [100 mrem] in a year, or
- demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in Table 2, “Effluent Concentrations,” of Appendix B to 10 CFR Part 20. The licensee must also show that if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv [2 mrem] in 1 hour and 0.5 mSv [50 mrem] in a year, and
- demonstrating that air emissions of radioactive materials to the environment, excluding radon-222 and its daughters, do not result in doses greater than the constraint limit of 0.1 mSv [10 mrem] TEDE from those emissions

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

Measurements

The licensee may use measurements to demonstrate that the average annual releases are within regulatory limits, as well as 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 effluents
- use of environmental dosimeters in unrestricted areas

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

Radioactivity releases may be determined by effluent monitoring or effluent sampling and analysis. Airborne effluents may be discharged when volatile materials are used, such as during iodination's, but the discharge 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 in an unrestricted area from licensed operations. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. The occupancy factor for an area is defined as the average fraction of time the maximally exposed individual is present and exposed to a radiation source. If a source is used intermittently, the occupancy factor is a fraction of the hours in a week that a given person would occupy the area. If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further evaluation.

If, however, the licensee would rather choose a more realistic assumption of the individual's occupancy at the points of highest internal and external exposures, then the licensee may use the occupancy factors in Table J-1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present. The occupancy factors in Table J-1 are general guidance values and may be used if more detailed information is not available.

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	Areas where individuals are present for a major part of the day
1/5	Corridors, employee lounges, staff rest rooms, and classrooms
1/20	Unattended waiting rooms, public rest rooms, unattended vending rooms, storage areas, janitor's closets, attics, outdoor areas with seating, and recreational areas
1/40	Outdoor areas with only transient pedestrian or vehicular traffic, unattended parking lots, vehicular drop off areas (unattended), stairways, and unattended elevators

Records

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

Records demonstrating the dose to an individual member of the public should identify the instruments used in the survey; the name of the surveyor; the date of the survey; the location of the surveys, including a description or drawing of the areas surveyed; survey results; and if applicable, the occupancy factors used and justification for their use. In addition, records demonstrating the dose to an individual member of the public that involve effluent sampling analysis should include information on concentrations of specific radionuclides, minimum detectable activity of the system, and the estimated uncertainty of measurements.

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

APPENDIX K

GENERAL TOPICS FOR SAFE POSSESSION AND USE OF RADIOACTIVE MATERIALS AND MODEL EMERGENCY PROCEDURES

General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures

This appendix describes general topics for safe possession and use of radioactive materials and procedures for handling and reporting emergencies.

General Topics for Safe Possession and Use of Radioactive Materials

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

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used.
- Wear disposable gloves at all times when handling licensed materials.
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area.
- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Do not store food, drink, or personal effects in areas where licensed material is stored or used (see Figure K-1).
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Store radioactive solutions in clearly labeled containers.
- Secure all licensed material when it is not under the constant surveillance and immediate control of the users.

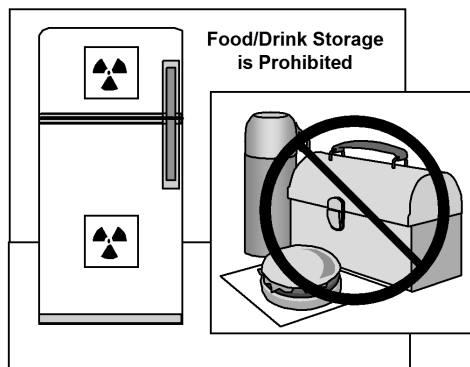


Figure K-1. Storage of Food and Drink. *Food or drink may not be stored in refrigerators with radionuclides.*

Security of Radioactive Materials

- Licensed materials in use in controlled or unrestricted areas must be under constant surveillance.
- Licensed materials will be secured by one or more of the following methods.
 - storing and using licensed materials only in restricted areas
 - limiting access to an entire facility or building or portion of the building to radiation workers
 - providing storage areas that can be locked to prevent access to the licensed material
 - implementing procedures that require a radiation worker to be within “line of sight” of the materials whenever licensed materials are in use

Radionuclide-specific Procedures

Licensees should develop written procedures for use of different radionuclides so that users know the types of shielding, protective clothing, radiation survey instruments, surveys, and decontamination activities that are required. Examples of such procedures are included below.

Example 1:

If requesting more than 37 MBq [1 mCi] of iodine-125 or iodine-131, special safety instructions should be provided to users, including the following:

- A mandatory radiation survey and wipe test for radioactive contamination after each use
- Bioassay procedures for individuals working with millicurie quantities of radioiodine
- The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications; also recommended that the Radiation Safety Officer (RSO) be present during new procedures
- Procedures for measuring the concentration of radioiodine effluents from the hoods

Example 2:

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

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

Sample Procedures for Handling Emergencies

Appropriate first aid and other immediate medical needs of injured individuals should not be neglected, delayed, or ignored due to suspected contamination.

General Safety Procedures to Handle Spills

- Name and telephone number of RSO or alternate persons should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies. The licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:
 - disposable gloves
 - housekeeping gloves
 - disposable lab coats
 - disposable head coverings
 - disposable shoe covers
 - roll of absorbent paper with plastic backing
 - masking tape
 - plastic trash bags with twist ties
 - “Radioactive Material” labeling tape
 - marking pen
 - pre-strung “Radioactive Material” labeling tags

- box of wipes
- instructions for “Emergency Procedures”
- clipboard with a copy of the Radioactive Spill Report Form for the facility
- pencil
- appropriate radiation survey instruments, including batteries (for radiation survey meters)

Minor Spills of Liquids and Solids

- Instructions to Workers
 - Notify persons in the area that a spill has occurred.
 - Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)
 - Clean up the spill, wearing disposable gloves and using absorbent paper.
 - Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
 - Survey the area with an appropriate low-range radiation survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.
 - Report the incident to the RSO promptly.
 - Allow no one to return to work in the area unless approved by the RSO.
 - Cooperate with RSO and RSO’s staff (e.g., investigation of root cause, provision of requested bioassay samples).
 - Follow the instructions of the RSO and RSO’s staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Follow up on the decontamination activities and document the results.
 - As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
 - If necessary, notify U.S. Nuclear Regulatory Commission (NRC).

Major Spills of Liquids and Solids

- Instructions to Workers
 - Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room.
 - Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
 - Shield the source only if it can be done without further contamination or significant increase in radiation exposure.
 - Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
 - Notify the RSO immediately.
 - Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap.
 - Allow no one to return to work in the area unless approved by the RSO.
 - Cooperate with RSO and RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
 - Follow the instructions of the RSO and RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination released by the perspiration.
 - Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results.
 - Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
 - If necessary, notify the NRC.

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

- Instructions to Workers
 - Notify all personnel to vacate the room immediately.
 - Shut down ventilation system, if appropriate, to prevent the spread of contamination throughout the system and other parts of the facility.
 - Vacate the room. Seal the area, if possible.
 - Notify the RSO immediately.
 - Ensure that all access doors to the area are closed and posted with appropriate warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area.
 - Survey all persons who could have possibly been contaminated. Decontaminate, as directed by the RSO.
 - Promptly report suspected inhalation and ingestion of licensed material to the RSO.
 - Decontaminate the area only when advised or supervised by the RSO.
 - Allow no one to return to work in the area unless approved by the RSO.
 - Cooperate with RSO and RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
 - Follow the instructions of the RSO and RSO's staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).
- Reminders to RSO
 - Supervise decontamination activities.
 - Perform air sample surveys in the area before permitting resumption of work with licensed materials.
 - Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc.
 - Consider the need for a medical exam or whole body count before permitting involved individuals to return to work with licensed material.
 - Determine cause and corrective actions needed; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin. Document the incident.
 - If necessary, notify the NRC.

Minor Fires

- Instructions to Workers (Licensees should develop procedures and instructions, in accordance with local fire safety requirements, Occupational Safety and Health Administration (OSHA) regulations, etc., and provide training as needed)
 - Immediately attempt to put out the fire by approved methods (i.e., fire extinguisher) if other fire hazards or radiation hazards are not present.
 - Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department (as instructed by the RSO).
 - Once the fire is out, isolate the area to prevent the spread of possible contamination.
 - Survey all persons involved in combating the fire for possible contamination.
 - Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap.
 - In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area.
 - Allow no one to return to work in the area unless approved by the RSO.
 - Cooperate with the RSO and RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
 - Follow the instructions of the RSO and RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Supervise decontamination activities.
 - If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination released by the perspiration.
 - Consult with fire safety officials to ensure that there are no other possibilities of another fire starting.
 - Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin. Document the incident.
 - If necessary, notify the NRC.

Fires, Explosions, or Major Emergencies

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

- Reminders to RSO
 - Coordinate activities with facility's industrial hygienist or environmental health and safety office, and with local fire department.
 - Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished.
 - Once the fire is extinguished, do not allow the firefighters to enter the radiation area until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas.
 - Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary.
 - Supervise decontamination activities.
 - Consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin. Document the incident.
 - Notify the NRC.

Incidents Involving Sealed Sources

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

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

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

If an individual becomes contaminated or exposed to radioactive material through skin absorption, ingestion, or inhalation, the RSO or a member of the RSO's staff should estimate the amount of material taken into the body. The following items should be considered in developing procedures for collecting bioassay samples:

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

APPENDIX L

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

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

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

Table L-1. Typical NRC Notification and Reporting Requirements for Incidents			
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 the final delivery carrier must be notified)	none	10 CFR 20.1906(d)
Theft or loss of licensed material	Immediate	30 days	10 CFR 20.2201(a)(1)(i) 10 CFR 20.2201(b)(1)
Whole body dose greater than 0.25 Sv [25 rems]	Immediate	30 days	10 CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Gy [250 rads]	Immediate	30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 0.5 Sv [50 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems]	None	30 days	10 CFR 20.2203(a)(2)(i)

Table L-1. Typical NRC Notification and Reporting Requirements for Incidents (Continued)

Event	Telephone Notification	Written Report	Regulatory Requirement
Dose to individual member of public greater than 1 mSv [0.1 rem]	None	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i) & (ii)
Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits	Immediate	30 days	10 CFR 30.50(a) & (c)(2); 40.60(a) & (c)(2); and 70.50(a) & (c)(2)
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)

Table L-1. Typical NRC Notification and Reporting Requirements for Incidents (Continued)

Event	Telephone Notification	Written Report	Regulatory Requirement
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2) & (c)(2); 40.60(b)(2) & (c)(2); and 70.50(b)(2) & (c)(2)
An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body	24 hours	30 days	10 CFR 30.50(b)(3) & (c)(2); 40.60(b)(3) & (c)(2); and 70.50(b)(3) & (c)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4) & (c)(2); 40.60(b)(4) & (c)(2); and 70.50(b)(4) & (c)(2)

Table L-1. Typical NRC Notification and Reporting Requirements for Incidents (Continued)

Event	Telephone Notification	Written Report	Regulatory Requirement
<p>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</p>	<p>None</p>	<p>90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold</p>	<p>10 CFR 37.41(a)(3)</p>
<p>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</p>	<p>3 business days</p>	<p>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</p>	<p>10 CFR 37.45(b)&(c)</p>

Table L-1. Typical NRC Notification and Reporting Requirements for Incidents (Continued)

Event	Telephone Notification	Written Report	Regulatory Requirement
Determination that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material	As soon as possible (but not at the expense of causing delay or interfering with the LLEA response), but no later than 4 hours after discovery	30 days	10 CFR 37.57(a)&(c)
Assessment of any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material	As soon as possible, but no later than 4 hours after notifying the LLEA	none	10 CFR 37.57(b)
Determination that a shipment containing a Category 1 quantity of material is lost or missing in transport	Within 1 hour of the determination; also notify LLEA within 1 hour of determination	30 days and periodic updates (if subsequent substantive information)	10 CFR 37.81(a)(g)&(h)
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)

Table L-1. Typical NRC Notification and Reporting Requirements for Incidents (Continued)

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

Note: Telephone notifications must be made to the NRC Operations Center at 301-816-5100 or by facsimile to 301-816-5151, except as noted. The Center is staffed 24 hours a day and accepts collect calls.

APPENDIX M
RADIATION SAFETY SURVEY TOPICS

Radiation Safety Survey Topics

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

Training

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

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

Facilities and Equipment

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

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits or where an individual is working in a dose rate of 0.025 mSv (millisievert) [2.5 mrem/h (millirem/hour)] or more [50 mSv/year divided by 2,000 h/year]. It is also recommended that area monitors be used in areas where high-energy gamma/photon-emitting radioactive materials or radiation are produced and handled.
- Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv [0.1 rem] in a year, and the dose in any unrestricted area from external sources does not exceed 0.02 mSv [2 mrem] in any 1 hour.

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

Contamination Surveys

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

Contamination surveys must be made as required by 10 CFR 20.1501. Surveys are usually performed:

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

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use (see Table M-1). If the activity used is greater than or equal to the smallest annual limit on intake (ALI) (for either inhalation or ingestion) as identified in 10 CFR Part 20, Appendix B, then documented surveys should be performed at least daily and records retained in accordance with 10 CFR 20.2103.

Table M-1 contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based on 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 M-1. Suggested Contamination Survey Frequency			
	< 0.1 ALI	≥ 0.1 ALI < 1.0	≥ 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months		

Contamination in Unrestricted Areas

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

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

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

Table M-2. Acceptable Surface Contamination Levels for Equipment

Nuclide ¹	Average ^{2,3,6}	Maximum ^{2,4,6}	Removable ^{2,5,6}
U-nat, U-235, U-238, and associated decay products	83.3 Bq/100 cm ² [5,000 dpm/100 cm ²]	250 Bq/100 cm ² [15,000 dpm/100 cm ²]	16.7 Bq/100 cm ² [1,000 dpm/100 cm ²]
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-125, I-129	1.7 Bq/100 cm ² [100 dpm/100 cm ²]	5.0 Bq/100 cm ² [300 dpm/100 cm ²]	0.3 Bq/100 cm ² [20 dpm/100 cm ²]
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133	16.7 Bq/100 cm ² [1,000 dpm/100 cm ²]	50.0 Bq/100 cm ² [3,000 dpm/100 cm ²]	3.3 Bq/100 cm ² [200 dpm/100 cm ²]
Other alpha emitters ⁷	8.33 Bq/100 cm ² (500 dpm/100 cm ²)	25 Bq/100 cm ² (1,500 dpm /100 cm ²)	1.67 Bq/100 cm ² (100 dpm/100 cm ²)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq/100 cm ² [5,000 dpm/100 cm ²]	250 Bq/100 cm ² [15,000 dpm/100 cm ²]	16.7 Bq/100 cm ² [1,000 dpm/100 cm ²]

¹Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

²As used in this table, disintegrations per minute (dpm) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

³Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

⁴The maximum contamination level applies to an area of not more than 100 centimeters squared (cm²).

⁵The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

⁶The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/h at 1 cm and 1.0 mrad/h at 1 cm, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

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

Decommissioning Surveys for Release for Unrestricted Use

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

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

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

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

Radionuclide	Symbol	Screening levels for unrestricted release (dpm/100 cm²)
Hydrogen-3 (Tritium)	H-3	1.2×10^8
Carbon-14	C-14	3.7×10^6
Sodium-22	Na-22	9.5×10^3
Sulfur-35	S-35	1.3×10^7
Chlorine-36	Cl-36	5.0×10^5
Manganese-54	Mn-54	3.2×10^4
Iron-55	Fe-55	4.5×10^6
Cobalt-57	Co-57	2.1×10^5
Cobalt-60	Co-60	7.1×10^3
Nickel-63	Ni-63	1.8×10^6
Zinc-65	Zn-65	4.8×10^4
Strontium-90	Sr-90	8.7×10^3
Technetium-99	Tc-99	1.3×10^6
Iodine-129	I-129	3.5×10^4
Cesium-137	Cs-137	2.8×10^4
Europium-152	Eu-152	1.3×10^4
Tungsten-181	W-181	1.1×10^6
Iridium-192	Ir-192	7.4×10^4

*Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100 percent of surface contamination is removable; and, therefore, the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10 percent to 100 percent range) may calculate site-specific screening levels using the DandD, Version 1 computer code.

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

Survey Record Requirements

Each survey record should include the following:

- a diagram of the area surveyed (see Figure M-1)
- a list of items and equipment surveyed
- specific locations on the survey diagram where wipe test was taken
- ambient radiation levels with appropriate units
- contamination levels with appropriate units
- make and model number of instruments used
- background levels
- name of the person making the evaluation and recording the results and date

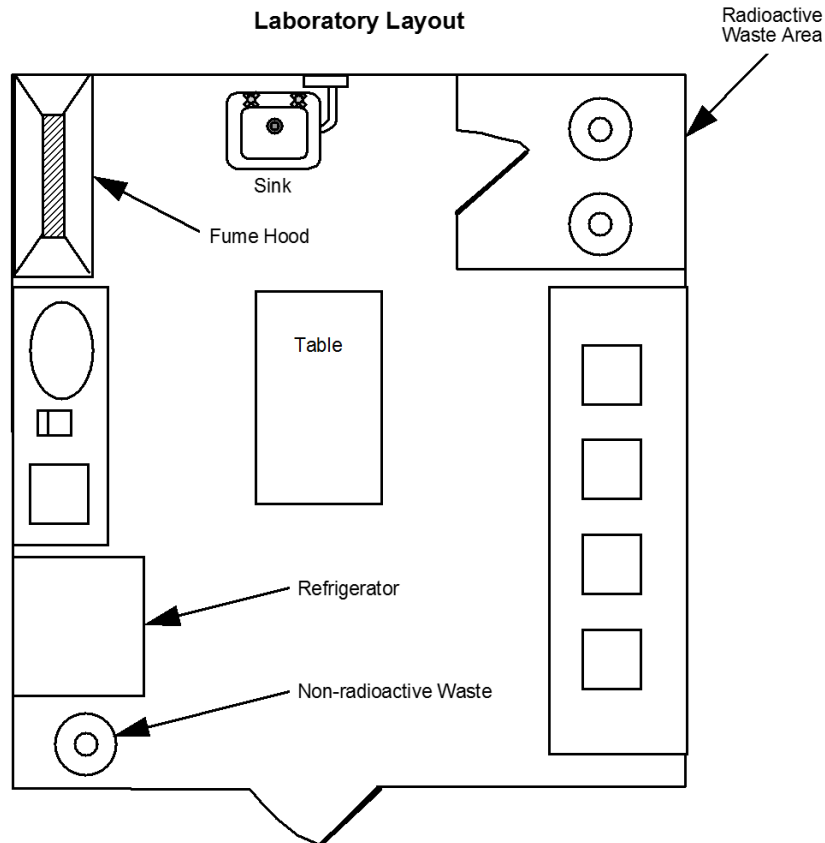


Figure M-1. Laboratory Layout. *This is an example of a laboratory survey map.*

Licenses 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) require, in part, that records of information important to the decommissioning of a facility, including records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site, must be maintained.

Air Monitoring in the Workplace

Air monitoring can be used to do the following:

- determine whether the confinement of radioactive materials is effective
- measure airborne radioactive material concentrations in the workplace
- estimate worker intakes of radioactive material
- determine posting requirements
- determine what protective equipment and measures are appropriate
- warn of significantly elevated levels of airborne radioactive materials

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

Refer to Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992 and NUREG-1400, "Air Sampling in the Workplace," dated September 1993, which are available in the NRC Agencywide Documents Access and Management System (ADAMS) at Accession Nos. ML003739616 and ML13051A671, respectively, for further guidance on air sampling.

Airborne Effluent Release Monitoring

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

Regulatory Guide 4-20, Revision 1, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors," dated April 2012, provides guidance on methods (calculation or COMPLY code) acceptable to the NRC for compliance with the constraint on air emissions to the environment.

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

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

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

Liquid Effluent Release Monitoring

The licensee 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 20.1302 and 20.2003, respectively.

The topic of sanitary sewerage releases is more fully discussed in Section 8.11 and Appendix P of this NUREG.

Bioassay Monitoring

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends on the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. The licensee should consider the following elements when determining the frequency of routine bioassay measurements:

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

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

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

Routine Bioassay Measurements

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

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

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

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive

material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

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

Special Bioassay Monitoring

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

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

References:

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

- Regulatory Guide 8.34, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses,” July 1992
- Regulatory Guide 8.37, “ALARA Levels for Effluents from Materials Facilities,” July 1993
- NUREG–1400, “Air Sampling in the Workplace,” September 1993
- NUREG–1549, Draft Report for Comment, “Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination,” July 1998, ADAMS Accession No. ML993250291
- NUREG–1575, “Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM),” Revision 1, August 2000
- NUREG–1575, Supplement 1, “Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME),” January 2009
- NUREG–1757, “Consolidated Decommissioning Guidance,”
 - Volume 1, Decommissioning Process for Materials Licensees (Revision 2), September 2006
 - Volume 2, Characterization, Survey, and Determination of Radiological Criteria (Revision 1), September 2006
- NUREG/CR-4884, “Interpretation of Bioassay Measurements,” July 1987
- NUREG/CR-5512, Volume 2, “Residual Radioactive Contamination from Decommissioning: User’s Manual DandD Version 2.1,” April 2001, ADAMS Accession No. ML010940257
- NUREG/CR–5512, Volume 3, “Residual Radioactive Contamination from Decommissioning: Parameter Analysis, Draft Report for Comment,” October 1999 [containing Tables 5.19 (surface contamination) and 6.91 (surface soil)], ADAMS Accession No. ML082460902
- *Federal Register*: “Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination,” 63 FR 67132-34, November 18, 1998
- *Federal Register*: “*Supplemental* Information on the Implementation of the Final Rule on Radiological Criteria for License Termination,” 64 FR 68395–96, December 7, 1999
- *Federal Register*: “Use of Screening Values to Demonstrate Compliance With the Final Rule on Radiological Criteria for License Termination,” 65 FR 37186, June 13, 2000
- ANSI N13.1-2011, “Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities,” 2011
- ANSI N13.30-2011, “Performance Criteria for Radiobioassay,” 2011

- ANSI N42.18-2004, “Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactivity in Effluents,” 2004
- NCRP Commentary No. 3, “Screening Techniques for Determining Compliance with Environmental Standards—Releases of Radionuclides to the Atmosphere,” published in January 1989, and the addendum published in October 1989
- U.S. Department of Energy, DOE G 441.1-1C, Admin Chg 1, “Radiation Protection Programs Guide for Use with Title 10, Code of Federal Regulations, Part 835, Occupational Radiation Protection,” July 8, 2011

APPENDIX N
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, and gas-flow proportional counter for alpha emitters).
- If the sensitivity of the counting system is unknown, determine the minimum detectable activity (MDA). The MDA may be determined using the following formula:

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

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

For example:

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

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

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

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

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

Frequency for Conducting Leak Tests of Sealed Sources

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

Procedure for Performing Leak Testing and Analysis

- For each sealed source to be tested, list identifying information such as the sealed source serial number, manufacturer, model 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 instrumentation that is sensitive enough to detect 185 becquerels (Bq) (0.005 microcurie) of the radionuclide contained in the sealed source.
- Using the selected instrument, count, and record background count rate.
- Check the counting efficiency of the instrument using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. The

calibration source should be in the same configuration as the sample. Accuracy of standards should be within plus or minus 5 percent of the stated value and traceable to primary radiation standards such as those maintained by the National Institute of Standards and Technology.

- Calculate the counting efficiency of the detector.

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

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

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries). 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 becquerels (0.005 microcuries) or greater, notify the radiation safety officer so that the source can be withdrawn from use and disposed of properly. Also, notify the U.S. Nuclear Regulatory Commission.

APPENDIX O

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS

U.S. Department of Transportation Regulations

Note: The following list of U.S. Department of Transportation (DOT) regulations is provided to inform licensees about typical requirements that apply to the transportation of licensed material including the preparation of shipments of licensed material. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, transportation requirements change; therefore, licensees should consult the regulations for definitive information about current requirements. Additional information on transportation requirements may be found at the DOT Web site: <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
 - 49 CFR 173.25—Authorized packagings and overpacks
 - 49 CFR 173.403—Definitions
 - 49 CFR 173.411—Industrial packages
 - 49 CFR 173.412—Additional design requirements for Type A packages
 - 49 CFR 173.413—Requirements for Type B packages
 - 49 CFR 173.415—Authorized Type A packages
 - 49 CFR 173.416—Authorized Type B packages
 - 49 CFR 173.433—Requirements for determining basic radionuclide values, and for the listing of radionuclides on shipping papers and labels
 - 49 CFR 173.435—Table of A₁ and A₂ values for radionuclides
 - 49 CFR 173.441—Radiation level limitations and exclusive use provisions
 - 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission approved packages
 - 49 CFR 173.475—Quality control requirements prior to each shipment of Class 7 (radioactive) materials
 - 49 CFR 173.476—Approval of special form Class 7 (radioactive) materials
- Carriage by Public Highway—49 CFR Part 177
 - 49 CFR 177.817—Shipping papers
 - 49 CFR 177.842—Class 7 (radioactive) material [includes requirement for blocking and bracing during transport]

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

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

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

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

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

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

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

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

2. Radiation Level, TI and CSI Limits for Transportation by Mode:^[1] (49 CFR 173 - 177, and 10 CFR 71)^[10]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The non-fixed contamination shall be determined by:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Shipping Paper Entries

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

Special Considerations/Exceptions for Shipping Papers

<ul style="list-style-type: none"> • For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, <u>or</u> 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, <u>or</u> 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)].
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[1] International Atomic Energy Agency (IAEA); International Air Transportation Association (IATA); International Civil Aviation Organization (ICAO); International Maritime Organization (IMO).

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


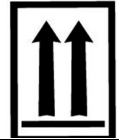
[3] The Shipper’s certification shall satisfy the requirements of § 172.204.

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

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

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

Markings on Packages

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

Special Considerations for Marking Requirements

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




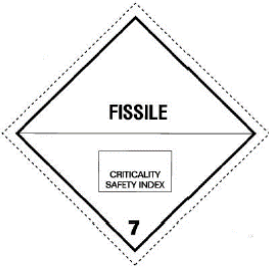
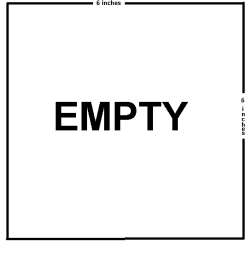
[1] Some marking exceptions exist for excepted packages, as specified in §§ 173.421, 173.422, 173.424, 173.426 and 173.428.
[2] If the identification number marking on a bulk package is not visible, the transport vehicle or freight container must be marked on each side and each end [see § 172.331].
[3] The radiation symbol shall be resistant to the effects of fire and water, plainly marked by embossing, stamping or other means resistant to the effects of fire and water and conform to the size requirements of Appendix B to Part 172.
[4] The arrows must be either black or red on white or other suitable contrasting background and commensurate with the size of the package; depicting a rectangular border around the arrows is optional.

**6. Hazard Communications for Class 7 (Radioactive) Materials:
Labeling of Packages (49 CFR 172.400-450)**

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

Requirements for Labels^[1]

- Label each package, except for (a) excepted packages of radioactive material; and (b) Low Specific Activity (LSA) material and Surface Contaminated Objects (SCO), packaged or unpackaged, when transported under exclusive use controls domestically and when the material or object contains less than an A₂ quantity.
- Labels are required to be (a) printed or affixed to a surface other than the bottom of the package, (b) placed near the proper shipping name marking, (c) printed or affixed to a background of contrasting color or have a dotted or solid line outer border, (d) clearly visible, (e) not obscured by markings or other attachments, (f) representative of the hazardous material content, and (g) in conformance with the label specifications of § 172.407.
- The appropriate radioactive label must be affixed to opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material.

Category of Radioactive Labels ^[3]				Other Radioactive Labels ^[2]	
					
White-I	Yellow-II	Yellow-III	Fissile	Empty	
Maximum Radiation Surface Level (RSL)				Fissile labels required for each package containing fissile material, other than fissile-excepted material; and labels must be affixed adjacent to radioactive category labels.	Empty labels required for empty Class 7 (radioactive) packages satisfying § 173.428; and any previously-used labels must not be visible.
mSv/h	RSL ≤ 0.005	0.005 < RSL ≤ 0.5	0.5 < RSL ≤ 2 ^[5]		
mrem/h	RSL ≤ 0.5	0.5 < RSL ≤ 50	50 < RSL ≤ 200 ^[5]		
Transport Index (TI):^[4]					
TI = 0	0 < TI ≤ 1	1 < TI ≤ 10 ^[5]			
Contents on Labels					
<ul style="list-style-type: none"> • 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)



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

PLACARD FOR HRCQ



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

General Specifications for Placards and Subsidiary Hazard Placarding

- Placards must conform to the specifications in § 172.519.
- A CORROSIVE placard is also required for each transport vehicle that contains 454 kg (1,001 pounds) or more gross weight of non-fissile, fissile-excepted, or fissile uranium hexafluoride [see § 172.505(b)].
- Placards are also required for subsidiary hazards of POISON INHALATION HAZARD, POISON GAS, or DANGEROUS WHEN WET [see § 172.505].

[1] See § 172.512 for exceptions and variations to the placarding requirements for freight containers and aircraft unit load devices.

[2] See § 173.403 for the definition of Highway Route Controlled Quantity (HRCQ). A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels [see §§ 172.403(c) and 172.507(a)].

[3] Required placarding of the front of a motor vehicle may be on the front of a truck-tractor instead of or in addition to the placarding on the front of the cargo body to which a truck-tractor is attached § 172.516(b).

8. Requirements/Guidance for Registration, Emergency Response and Action for Class 7 (Radioactive) Materials: (49 CFR 107, Subpart G; 49 CFR 171.15; 49 CFR 172, Subparts F and G)

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

Provisions for Persons Who Offer or Transport Class 7 (Radioactive) Materials (49 CFR 107, Subpart G)

- Any person, other than those excepted by § 107.606, who offers for transportation, or transports, in foreign, interstate or intrastate commerce any of the following Class 7 (radioactive) materials must satisfy registration and fee requirements of Part 107, Subpart G:
 - a highway route-controlled quantity of radioactive material;
 - a shipment in a bulk packaging with a capacity \geq 13,248 L (3,500 gallons) for liquids or gases, or $>$ 13.24 cubic meters (468 cubic feet) for solids; or
 - any quantity of radioactive material that requires placarding, under provisions of Part 172, Subpart F.
- Any person required to register must submit a complete and accurate registration statement on DOT Form F 5800.2 by June 30th for each registration year, or in time to have on file a current Certificate of Registration in accordance with § 107.620.
- Each registrant or designee must maintain for a period of 3 years from the date of issuance a copy of the registration statement and Certificate of Registration issued by PHMSA and must furnish its Certificate of Registration (or a copy thereof) and related records to an authorized representative or special agent of DOT upon request.
- Each motor carrier subject to registration requirements of this subpart must carry a copy of its current Certificate of Registration or another document bearing the registration number on board each truck and truck tractor, and the Certificate of Registration or document must be made available, upon request, to enforcement personnel.
- The amount of fees to be paid and procedures to be followed are found at §§ 107.612 and 107.616.

Provisions for Providing and Maintaining Emergency Response Information (49 CFR 172, Subpart G)

- When shipping papers for the transportation of radioactive materials are required [see Part 172, Subpart C], emergency response information shall
 - be provided and maintained during transportation and at facilities where materials are loaded for transportation, stored incidental to transportation, or otherwise handled during any phase of transportation;
 - be provided by persons who offer for transportation, accept for transportation, transfer or otherwise handle hazardous materials during transportation;
 - be immediately available for use at all times the hazardous material is present; and
 - include and make available the emergency response telephone number [see § 172.604] to any person, representing a Federal, State or local government agency, who responds to an incident involving the material or is conducting an investigation which involves the material.
- Emergency response information is information that can be used in mitigating an incident involving radioactive materials. It must contain at least the information specified in §§ 172.602 and 172.604; and includes an emergency response telephone number that is monitored at all times the material is in transportation by (a) knowledgeable person, or (b) a person who has immediate access to a knowledgeable person, or (c) an organization capable of accepting responsibility for providing the necessary detailed information concerning the material.
- Each carrier who transports or accepts for transportation radioactive material for which a shipping paper is required shall instruct, according to the requirements of § 172.606, the operator of a conveyance to contact the carrier in the event of an incident involving the material.

Actions to be Taken in the Event of Spillage, Breakage, or Suspected Contamination by Radioactive Material

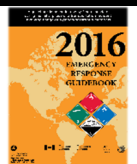
- If there is evidence of a leaking package or conveyance, access to the package or conveyance must be restricted, the area impacted and the extent of the contamination must be determined, and appropriate measures must be taken to minimize impact to persons and the environment [see § 173.443(e)].
- Except for a road vehicle used solely for transporting Class 7 (radioactive) material [see § 173.443(d)], each aircraft used routinely, and each motor vehicle used for transporting radioactive materials under exclusive use, must be (a) periodically checked for radioactive contamination, (b) taken out of service if contamination levels are above acceptable limits, and (c) remain out of service until the radiation dose rates at accessible surfaces are less than 0.005 mSv/h (0.5 mrem/h) and non-fixed radioactive surface contamination levels are below the limits in §§ 173.443(a), Table 9; and 173.443(c) for exclusive use vehicle provisions [see Chart 3].
- Following any breakage, spillage, release or suspected radioactive contamination incident, any rail or air carrier shall notify, as soon as possible, the offeror (i.e. the consignor); special provisions apply for buildings, areas, and equipment that might become contaminated during rail transport. Alternative provisions may apply for motor vehicles transporting radioactive materials under exclusive use [see §§ 174.750(a), 175.705(e), and 177.843(b)].

Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (§§ 171.15 and 171.16)

- Each person in physical possession of radioactive material must provide notice in the event of a reportable incident (see § 171.15(b)) as soon as practical, but no later than 12 hours after the occurrence of the reportable incident, to the National Response Center (NRC) by telephone at 800-424-8802 (toll free) or 202-267-2675 (toll call) or online at <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 be submitted as required by § 171.16.

Guidance on Responding to Emergencies (Emergency Response Guidebook)

- The DOT issues guidance to aid first responders in quickly identifying the hazards of the dangerous goods involved in an accident or incident, and for protecting themselves and the general public during the initial response to the accident or incident. For each proper shipping name or UN ID Number, the user is led to a specific guide that provides insight into potential hazards and steps to be taken for public safety and emergency response.
- The current edition of the Emergency Response Guidebook is available at <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 P
MODEL WASTE MANAGEMENT PROCEDURES

Model Waste Management Procedures

General Guidelines

- All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary “non-radioactive” waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- Remind workers that non-radioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the entire effect of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.
- The waste management program should include waste handling procedures for the users within their laboratories or assigned areas and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
- Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.
- A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, Appendix G, “Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests.”

Model Procedure for Disposal by Decay-in-Storage (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 radionuclide in the container, total activity, and the name of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after many half-lives and persons performing surveys should be aware of the potential for measurable radiation.
- The contents of the container should be allowed to decay for a period of time after which it is expected that the radiation levels would not be distinguishable from background. The period of time depends on both the half-life of the radionuclide(s) and the original amount present.
- Prior to disposal as ordinary trash, each container should be monitored with an appropriate radiation detection instrument, on the lowest setting, as follows:
 - Check the radiation survey meter for proper operation.
 - Survey the contents of each container in a low-background area.
 - Remove any shielding from around the container.
 - Monitor all surfaces of the container.
 - Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity (i.e., surface readings are indistinguishable from background).
 - If the surveys indicate residual radioactivity, return the container to DIS area and contact the radiation safety officer for further instructions.
 - If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (e.g., used or unused material, gloves, etc.), radiation 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 and needles placed into sealed waste containers for decay do not need to have 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 and 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 system, septic system, or leach field.

- Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.
- Calculate the amount of each radionuclide that can be discharged by using the information from prior, similar discharges and the information in 10 CFR Part 20, Appendix B.
- Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR Part 20, Appendix B, Table 3.
- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 must not exceed unity.
- Confirm that the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 gigabecquerel (GBq) [5 Curies (Ci)] of (tritium) H-3, 37 GBq [1 Ci] of C-14, and 37 GBq [1 Ci] of all other radionuclides combined.
- Record the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the name of the individual discharging the waste.
- Liquid waste should be discharged only via designated sinks, toilets, or other release points.
- Discharge liquid waste slowly to minimize splashing, with water running to be sure that the material moves out of the sink and into the sewer system.
- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.
- Decontaminate all areas or surfaces if found to be contaminated.
- Maintain records of releases of licensed material to the sanitary sewer system. These records should include, for each release, the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the name of the individual discharging the waste. For the licensed facility as a whole, records should be maintained of the quantity and concentration of radionuclides that are released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Model Procedure for Incineration

These guidelines apply to non-commercial waste disposal (i.e., incineration of a licensee's own waste). Specific U.S. Nuclear Regulatory Commission (NRC) approval to incinerate certain categories of radioactive waste is not needed. 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. If a review of the radioactive waste program identifies 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 incinerator and site location, including height of the stack, rated air flow (cubic feet per hour or similar units), proximity of the stack or other discharge to occupied areas (e.g., residences, 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 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.
- Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations and for monitoring all effluent generated by the incineration process. The procedures must ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant should describe the disposal method for any ash generated that exceeds regulatory limits.

Model Procedure for Compaction

The following information should be provided by licensees that propose to compact waste.

- Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations. Provide manufacturer's specifications, annotated sketches or photographs, and other information about the compactor's design.
- Describe the type, quantities, and concentrations of waste to be compacted.
- Provide an analysis of the potential for airborne release of radioactive material during compaction activities.
- Provide the location of any compactors within the waste processing area(s), as well as a description of the ventilation and filtration systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange.
- Discuss the methods used to monitor worker breathing zones and exhaust systems.
- Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.
- Discuss the instruction provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

APPENDIX Q
SAFETY CULTURE POLICY STATEMENT

Safety Culture

The Safety Culture Policy Statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011, and can be found at <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 Documents Access and Management System, Accession No. ML11146A047.

Safety Culture Policy Statement

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

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

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

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

The following are traits of a positive safety culture:

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

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

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

APPENDIX R
MEDICAL DISTRIBUTION

Medical Distribution

1. INTRODUCTION

1.1 Purpose of Appendix

The purpose of this appendix is to provide assistance in preparing applications for new licenses, license amendments, and renewals of medical distribution licenses under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32, “Specific domestic licenses to manufacture or transfer certain items containing byproduct material.” These are licenses that authorize the distribution of radioactive drugs and sealed sources containing byproduct material to the U.S. Nuclear Regulatory Commission’s (NRC’s) and Agreement States’ medical use licensees. Nuclear pharmacy applicants should refer to NUREG–1556, Vol. 13 in the preparation of an application for transfer for distribution of radioactive drugs for medical use instead of guidance in this appendix. Medical distribution by applicants registered or licensed with the U.S. Food and Drug Administration (FDA) or State Agency as a drug or sealed source manufacturer is provided for in 10 CFR 32.72 and 32.74 or equivalent provisions of an Agreement State. The medical distribution license normally only authorizes distribution; it does not authorize the possession of byproduct material.

NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses,” contains much of the information needed in preparing applications for medical distribution licenses. To avoid duplication, many sections in this appendix will refer to NUREG–1556, Vol. 13.

Several words and phrases used in this guide should be explained. The phrase “byproduct material” is defined in 10 CFR 30.4. The term “distribution” has the same meaning as in 10 CFR Part 32 (i.e., the routine transfer of licensed materials to others). For organizations licensed in accordance with 10 CFR 32.72 and 32.74, these transfers of licensed material are to specific licensees, in accordance with the requirements of 10 CFR 30.41. These organizations’ principal customers are medical use licensees. The phrase “medical use licensee” means a physician, podiatrist, dentist, or medical institution licensed under 10 CFR Part 35 for “medical use,” as defined in 10 CFR 35.2.

1.2 Filing an Application for Broad Scope Licenses to Manufacture and Distribute Radio Labeled Drugs to Medical Use Licensees for Research

Broad scope research and development licensees that wish to manufacture and distribute drugs containing byproduct material to medical use licensees for research purposes may request an exemption from 10 CFR 32.72(a)(2). The NRC may grant an exemption under 10 CFR 30.11(a), if the applicant or licensee specifically requests an exemption from 10 CFR 32.72(a)(2) and provides the following supporting information with regard to the requirements of 10 CFR 32.72(a)(2):

- 32.72(a)(2)(i)—The applicant or licensee must confirm that *only* radioactive drugs for which the FDA has accepted an Investigational New Drug (IND) application containing microcurie quantities of hydrogen-3 or carbon-14 will be prepared and distributed. (The FDA, in 21 CFR 207.13(e), exempts classes of persons who manufacture or process drugs not for sale, but solely for use in research, teaching, and chemical analysis, from registering with the FDA as a drug manufacturer.)

- 32.72(a)(2)(ii)—The applicant or licensee must confirm that it is not registered with the State as a drug manufacturer.
- 32.72(a)(2)(iii)—The applicant or licensee must confirm that it is not licensed as a pharmacy. The risk imposed by the radioactive drugs containing only microcurie quantities of hydrogen-3 or carbon-14 does not warrant imposing the additional burden of hiring an Authorized Nuclear Pharmacist for the license.
- 32.72(a)(2)(iv)—The applicant or licensee must confirm that it is not operating as a nuclear pharmacy within a Federal institution.
- 32.72(a)(2)(v)—The applicant or licensee must confirm that it is not operating as a Positron Emission Tomography drug production facility registered with a State Agency.
- The applicant or licensee must agree to meet all other *applicable* sections of 10 CFR 32.72. If the exemption is granted, the following authorized use will be added to the license for hydrogen-3 and carbon-14:
 - preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72

In addition, the following license condition will be added to the license:

- Notwithstanding 10 CFR 32.72(a)(2), the licensee is authorized to prepare radioactive drugs, in accordance with an accepted FDA IND application protocol, and to distribute them to medical use licensees in accordance with 10 CFR 32.72.

Since this exemption applies to broad scope research and development licensees, the broad scope licensee will not be required to obtain an exemption from 10 CFR 33.17(a)(4), which restricts broad scope licensees from adding byproduct material to drugs designed for human use when applying for 10 CFR 32.72 authorization. The addition of authorization to manufacture, prepare, or transfer radioactive drugs containing byproduct material for medical use (10 CFR 32.72) to a license authorizes Part 32 activities in addition to Part 33 (broad scope) activities. Preparation of radioactive drugs is done under the Part 32 authorization and not the Part 33 authorization.

2. CONTENTS OF AN APPLICATION

The following paragraphs are numbered as on NRC Form 313, "Application for Material License," Appendix A of this NUREG.

Item 1: License Action Type

See Section 8.1.

Item 2: Applicant's Name and Mailing Address

See Section 8.2.

Item 3: Locations of Use

See Section 8.3.

Item 4: Person to Be Contacted About the Application

See Section 8.3.

Items 5 and 6: Radioactive Materials and Uses

Apply for a license as stated in 10 CFR 30.32. Identify the materials the applicant wishes to be authorized to distribute to NRC and Agreement States medical use licensees. The regulatory requirements and the information that applicants must submit are different for radioactive drugs and for sealed sources.

For radioactive drugs, specify the radionuclide and chemical form (for generators, specify the parent and daughter radionuclides and the name and model number, if appropriate, of the generator). For sealed sources, specify the radionuclide, manufacturer's name and model number of each source, the maximum activity in each source, and the anticipated use of the sources. NRC needs to know the anticipated use of the source to perform its safety evaluation. If the sealed sources are usually used in a device (e.g., bone mineral analyzer), specify the manufacturer's name and the model number of the device.

The following examples show appropriate responses to Items 5 and 6.

- Radioactive Drugs
 - Chromium-51 as Sodium Chromate
 - Molybdenum-99 as Molybdenum-99/Technetium-99m Generator (Model MTG-1)
 - Maximum activity per radionuclide
- Sealed Sources
 - Cesium-137, XYZ Corp., Model 1234
 - Maximum activity per source: 100 mCi
 - To be used by medical use licensees as dose calibrator reference sources as authorized in 10 CFR 35.65. Strontium-90, ABC Corp., Model 567
 - Maximum activity per source: 150 millicuries
 - To be used as a strontium-90 beta eye applicator for treatment of superficial eye conditions
 - Iodine-125, FGH Corp., Model 890
 - Maximum activity per source: 300 millicuries
 - To be used in an FGH Corp. Model BMA-1 device for bone mineral analysis

Item 7: Individuals Responsible for Radiation Safety Program and Their Training and Experience

Enter “Not Applicable.”

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

Enter “Not Applicable.”

Item 9: Facilities and Equipment

Enter “Not Applicable.”

Item 10: Radiation Safety Program

According to 10 CFR 32.72 and 32.74, certain radiation safety information must be submitted regarding licensed material to be distributed to medical use licensees. The information to be submitted for each type of licensed material to be distributed to medical use licensees is identified in the following sections and in NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses.”

Item 10.1: Radioactive Drugs

If the applicant wishes to distribute radioactive drugs to medical use licensees, pursuant to 10 CFR 35.100, 35.200, 35.300 or, 35.1000, they need to provide the information identified below and, where applicable, in NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses,” for nuclear pharmacy license applicants.

Item 10.1.1: Radioactive Drugs—Commercial Distribution

Under 10 CFR 32.72(a)(2)(i) and 10 CFR 32.72(a)(2)(ii), the applicant must provide evidence that they are registered or licensed with either the FDA or a State Agency as a drug manufacturer. See NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses,” for nuclear pharmacy license applicants.

Item 10.1.2: Radioactive Drugs—Instrumentation

Under 10 CFR 32.72(c), the applicant must possess and use instrumentation to measure the radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. Measurements may be made by direct measurement or a combination of direct measurement and calculation (calculation only may be used for alpha and beta radiation). See NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses,” for nuclear pharmacy license applicants.

Item 10.1.3: Radioactive Drugs—Packaging and Shielding Licensing Criteria

See NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses.”

Item 10.1.4: Radioactive Drugs—Licensing Criteria for Labeling

See NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses.”

Item 10.1.5: Generators—Return Program

Some licensees offer a generator return program. Under this program, customers may return used or spent generators to the licensee. The applicant should develop and provide written procedures for customers that address the return of generators.

Item 10.1.5.1: Licensing Criteria

If the applicant wishes to offer a generator return program, it may be helpful to supply instructions (including instructions on labeling and shipping documents) to their customers. The shipper must comply with 10 CFR 71.5 and with U.S. Department of Transportation (DOT) regulations. As a minimum, these instructions should

- Establish the user’s responsibility and liability as the shipper.
- Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process.
- Discuss all the customer’s responsibilities as a shipper under 49 CFR Parts 170 to 189.

Response from Applicant:

Provide a response as indicated at the end of each relevant item of NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses.”

Item 10.2: Sealed Sources

If the applicant intends to distribute sealed sources to medical use licensees, provide the information identified in NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses.”

Item 10.2.1: Sealed Sources in Devices—Licensing Criteria for Evaluation of Design and Construction

If the applicant is a manufacturer or initial distributor of sealed sources (or devices containing sealed sources), they may need to submit a separate application for authorization to distribute the sealed sources or devices. This separate application will facilitate NRC’s review and evaluation of the radiation safety information for the sealed source or device and its certificate of registration. To submit a source or device design for a safety evaluation and registration use NUREG–1556, Vol. 3, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration.” This safety evaluation is required by 10 CFR 32.74 prior to the source or device being approved for distribution and medical use.

Item 10.2.2: Sealed Sources—Labeling

Item 10.2.2.1: Licensing Criteria

The applicant's product labeling must fulfill the requirements of 10 CFR 20.1901, 20.1904, 20.1905, and of 10 CFR 32.74(a)(2)(viii) and 32.74(a)(3).

A label, leaflet, or brochure accompanying the sealed source or device must contain appropriate instructions, from a radiation safety standpoint, for handling and storing the source or device. For example, the instructions may specify the use of extremity monitors, the use of tongs or other devices (rather than bare hands) to pick up sources, storage within auxiliary shielding, and any special procedures needed in the handling and sterilizing of "fragile" sources (e.g., iodine-125 seeds).

A label, leaflet, or brochure must also contain the licensing statement required by 10 CFR 32.74(a)(3). For sources, the statement should read, "The (name of source or device) is licensed by the NRC for distribution to persons licensed pursuant to use byproduct material identified in 10 CFR 35.65, 35.400, 35.500, and 35.600 as appropriate, and to persons who hold an equivalent license issued by an Agreement State."

For *each* type of sealed source or device the applicant intends to distribute, they should:

- Submit copies or facsimiles of the labels that will accompany the product and specify where each label will be placed (e.g., on the device, on the source shield).
- Submit copies of all leaflets and brochures that will accompany the product. For *each* type of source or device to be distributed, the applicant should provide a copy of correspondence to and from the FDA that clearly shows that the FDA finds the source or device to be safe and effective or "substantially equivalent" to sources or devices offered for sale in the U.S. before May 1976. (Note: An NRC registration will not be issued unless the applicant has submitted to NRC a substantially equivalent letter pursuant to Section 510(K) of the Food, Drug, and Cosmetic Act, as amended, or a similar indication of premarketing approval by the FDA.)

Devices and sources used in conjunction with medical applications involving computers and patient planning systems are within FDA jurisdiction and must also have a substantially equivalent letter, pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act, as amended, or a similar indication of premarketing approval by FDA.

Item 10.2.2.2: FDA and NRC Coordination

FDA and NRC signed a Memorandum of Understanding [Agencywide Document Access and Management System (ADAMS) Accession No. ML023520399] to coordinate existing FDA and NRC regulatory programs for medical devices, drugs, and biological products that make use of byproduct, source, or special nuclear materials. The principal statute under which the FDA regulates devices is the Food, Drug, and Cosmetic Act, as amended by the Safe Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices Act of 1992.

Under the Memorandum of Understanding, the Agencies agree to promptly inform each other whenever they receive a report or otherwise become aware of potential public health problems

involving products of mutual regulatory concern. Further, the Agencies will share information to the extent practicable. For NRC's Office of Nuclear Materials Safety and Safeguards (NMSS), this includes information on the design, manufacture, testing, quality assurance, and control, etc., used by FDA and NRC for its product approval.

Item 10.2.3: Sealed Sources—Return Program and Device Service

Item 10.2.3.1: Returns

Some licensees offer a source return program or a device service or both. In this program, customers may return unused sources for credit or may return used sources or devices for disposal, service, or replacement. Similar programs have been offered by manufacturers of other products. As indicated in Item 10.1.5.1 licensees may want to provide assistance to customers to remind customers of their responsibilities as shippers.

Item 10.2.3.2: Licensing Criteria

See Item 10.1.5.1 for information to be included in instructions that may be provided to the customers.

Item 10.2.4: Calibration or Reference Sources For Medical Use—Compatibility with 10 CFR 35.65 Licensing Criteria

The applicant must request authorization to distribute calibration or reference sources that are described in 10 CFR 35.65. These calibration or reference sources must not exceed the activity limits of 10 CFR 35.65, and according to 10 CFR 32.74, the applicant must confirm this in their license application.

If a source to be distributed contains byproduct material exceeding the activity limits of 10 CFR 35.65, source material, or special nuclear materials, it may not be distributed to medical licensees under the provisions of 10 CFR 35.65. In such cases, medical use licensees may purchase such sources only if their licenses specifically authorize possession and use of them. In these cases, the applicant or licensee may not use a license issued under 10 CFR 32.74 to distribute the sources; rather, they need a license issued pursuant to 10 CFR Part 30, 40, or 70, as appropriate, that authorizes them to distribute such sources to their proposed customers.

Response from Applicant:

Provide a response as indicated at the end of each relevant item of NUREG-1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."

Item 11: Waste Management

Enter "Not Applicable."

Item 12: License Fees

See Section 8.12.

Item 13: Certification

See Section 8.13.

Termination of Activities

See Section 11 of this report.

The distribution license does not authorize the possession and use of byproduct material; therefore, termination of the licensee's distribution license only requires a letter notifying NRC of the termination. If the licensee is also terminating their possession license, 10 CFR 30.36(b) requires that a licensee notify NRC promptly and request termination of the license. This notification normally requires (i) a completed form NRC-314, "Certificate of Disposition of Materials," certifying that all sources have been disposed of properly and (ii) the results of a final radiation survey of the premises where the licensed activities were carried out.

APPENDIX S

**CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY
INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)**

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

In order to request that the U.S. Nuclear Regulatory Commission (NRC) withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:

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

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This technical report contains information intended to provide program-specific guidance and to assist applicants and licensees in preparing applications for possession licenses for manufacturing and distribution. 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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