

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

Final Report

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Final Report

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ABSTRACT

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

Paperwork Reduction Act

This NUREG provides guidance for implementing the mandatory information collections in 10 CFR Parts 20, 30, 32, 35, 40, and 70 and the voluntary information collections in Form 313 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collection requirements were approved by the Office of Management and Budget (OMB), approval numbers 3150-0014, 3150-0017, 3150-0001, 3150-0010, 3150-0020, 3150-0009 and 3150-0120. 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, (3150-0014, 3150-0017, 3150-0001, 3150-0010, 3150-0020, 3150-0009 and 3150-0120) Office of Management and Budget, Washington, DC 20503,

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FOREWORD

The U.S. Nuclear Regulatory Commission's (NRC's) NUREG–1556 technical report series provides a comprehensive source of reference information about various aspects of materials licensing and materials program implementation. These reports, where applicable, describe a risk-informed, performance-based approach to licensing consistent with the current regulations. The reports are intended for use by applicants, licensees, license reviewers, and other NRC personnel. The NUREG–1556 series currently includes the following volumes:

Volume No.	Volume Title
1	Program-Specific Guidance About Portable Gauge Licenses
2	Program-Specific Guidance About Industrial Radiography Licenses
3	Applications for Sealed Source and Device Evaluation and Registration
4	Program-Specific Guidance About Fixed Gauge Licenses
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers
8	Program-Specific Guidance About Exempt Distribution Licenses
9	Program-Specific Guidance About Medical Use Licenses
10	Program-Specific Guidance About Master Materials Licenses
11	Program-Specific Guidance About Licenses of Broad Scope
12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses
18	Program-Specific Guidance About Service Provider Licenses
19	Guidance for Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)
20	Guidance About Administrative Licensing Procedures
21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator

The current document, NUREG–1556, Volume 7, Revision 1, "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," 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 7, issued December 1999.

This report takes a risk-informed, performance-based approach to licensing academic, research and development, and other licenses of limited scope (ARDL). 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 ARDL users.

NUREG–1556, Volume 7, Revision 1, is not a substitute for NRC or Agreement State regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable if they include a basis for the staff to make the determinations needed to issue or renew a license.

The comments received during the public comment period for NUREG–1556, Volume 7, Revision 1, were summarized and addressed in a document that can be located on the NRC's Agencywide Documents and Management System (ADAMS) under ML16308A182. Access to ADAMS is available on the public Web site at: <http://www.nrc.gov/reading-rm/adams.html>. The comments received by NRC included general corrections, comments on training, and comments on safety culture.

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ABBREVIATIONS

ADAMS	Agencywide Documents Access Management System
AEA	Atomic Energy Act
ALARA	as low as is reasonably achievable
ALI	annual limit of intake
ANSI	American National Standards Institute
ARDL	academic, research and development, and other licenses of limited scope
AU	authorized user
bkg	background
Bq	becquerel
CD-ROM	compact disk-read only memory
CFR	<i>Code of Federal Regulations</i>
Ci	curie
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
ECD	electron capture detector
FA	financial assurance
GBq	gigabecquerel
GC	gas chromatograph
h	hour
IN	Information Notice
IP	Inspection Procedure
kBq	kilobecquerel
L/C	license condition
LLW	low-level radioactive waste
LSC	liquid scintillation counter
MARSAME	Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MBq	megabecquerel
mCi	millicurie
MDA	minimum detectable activity
MDC	minimum detectable concentration
mGy	milligray
mR	milliroentgen
mrads	millirads
mrem	millirem
mSv	millisievert
μCi	microcurie
μGy	microgray
μR	microroentgen
NaI	sodium iodide
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards

NORM	naturally occurring radioactive material
NRC	U.S. Nuclear Regulatory Commission
NSTS	National Source Tracking System
NSTTR	National Source Tracking Transaction Reports
NVLAP	National Voluntary Laboratory Accreditation Program
OMB	Office of Management and Budget
PII	personally identifiable information
P&GD	policy and guidance directive
Q	quality factor
RIS	Regulatory Issue Summary
RQ	reportable quantities
RSO	radiation safety officer
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSD	sealed source and device
std	standard
Sv	sievert
TEDE	total effective dose equivalent
TI	Transportation Index
UN	United Nations
XRF	X-ray fluorescence analyzer

1 PURPOSE OF REPORT

This report provides guidance to an applicant in preparing an academic, research and development, and other licenses of limited scope (ARDL) application for use of unsealed radioactive materials in laboratory studies or similar activities, veterinary uses of licensed materials, and small sealed sources such as in electron capture devices (ECDs) and X-ray fluorescence analyzers (XRFs). This report also provides the U.S. Nuclear Regulatory Commission (NRC) staff with the criteria for evaluating such license applications. It is not intended to address licenses of broad scope, licenses for manufacturing and distribution of byproduct material, or licenses for the use of large sealed sources and devices. Within this document, the phrases or terms, “byproduct material,” “licensed material,” or “radioactive material,” are used interchangeably.

This NUREG is designed for applicants to use in applying for a specific license of limited scope that the Commission issues under Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” which is characterized by a listing of the following specific items:

- radionuclides
- chemical and physical form
- possession limits
- radiation safety officer (RSO)
- Authorized User (AU)
- authorized locations of use

Byproduct material, as defined in 10 CFR 30.4, “Definitions,” is used for a variety of purposes in research, industry, and other fields. The following are typical uses:

- *in vivo* studies (in living organisms other than humans)
- *in vitro* studies (outside a living organism, such as in a petri dish or test-tube)
- analytical work and studies, including use of ECDs and XRFs
- veterinary medicine
- instrument calibration of applicant’s instruments
- field studies

The NRC’s past practice was to issue a separate license to authorize the possession and use of other types of radioactive materials, such as source material and special nuclear material, and larger sealed sources such as self-shielded irradiators. However, the NRC will now allow many self-shielded irradiators and other such materials to be listed on a single license. Applicants for such materials should use the appropriate guidance documents to submit the information needed to support the requested activities, such as NUREG–1556, Vol. 5, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses,” which provides guidance on licensing self-shielded irradiators.

Although this NUREG does not explicitly cover source material and special nuclear material, applicants and licensees may request to list small amounts of source or special nuclear materials on the ARDL license when use of these materials is directly related to the use of byproduct material under the limited scope license (e.g., laboratory-scale research and development, or the use of depleted uranium as shielding). Applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related

to the use of byproduct material under the limited scope license (e.g., sub-critical assemblies using plutonium-beryllium sources and testing of depleted uranium munitions). Applicants also should refer to NUREG–1556, Volume 17, “Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses.”

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

Chapter 8, “Contents of an Application,” of this NUREG identifies the information needed to complete NRC Form 313, “Application for Materials License” (see Appendix A of this NUREG), for the use of byproduct material for ARDL applicants. The Office of Management and Budget (OMB) has approved the information collection requirements in 10 CFR Part 20, “Standards for Protection Against Radiation;” 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;” and NRC Form 313 under OMB Clearance Nos. 3150-0014, 3150-0017, 3150-0016, 3150-0001, and 3150-0120, respectively.

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

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

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

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

Appendix B of this NUREG is a checklist that the NRC staff uses to review applications and that applicants can use to check for completeness. Appendices D through S of this NUREG contain additional information on various radiation safety and other topics.

Appendix C of this NUREG provides specific guidance for licensing sealed sources in devices such as ECDs used in gas chromatographs or chemical detectors and XRFs and may be used independently from Volume 7 for requesting a license only for these devices.

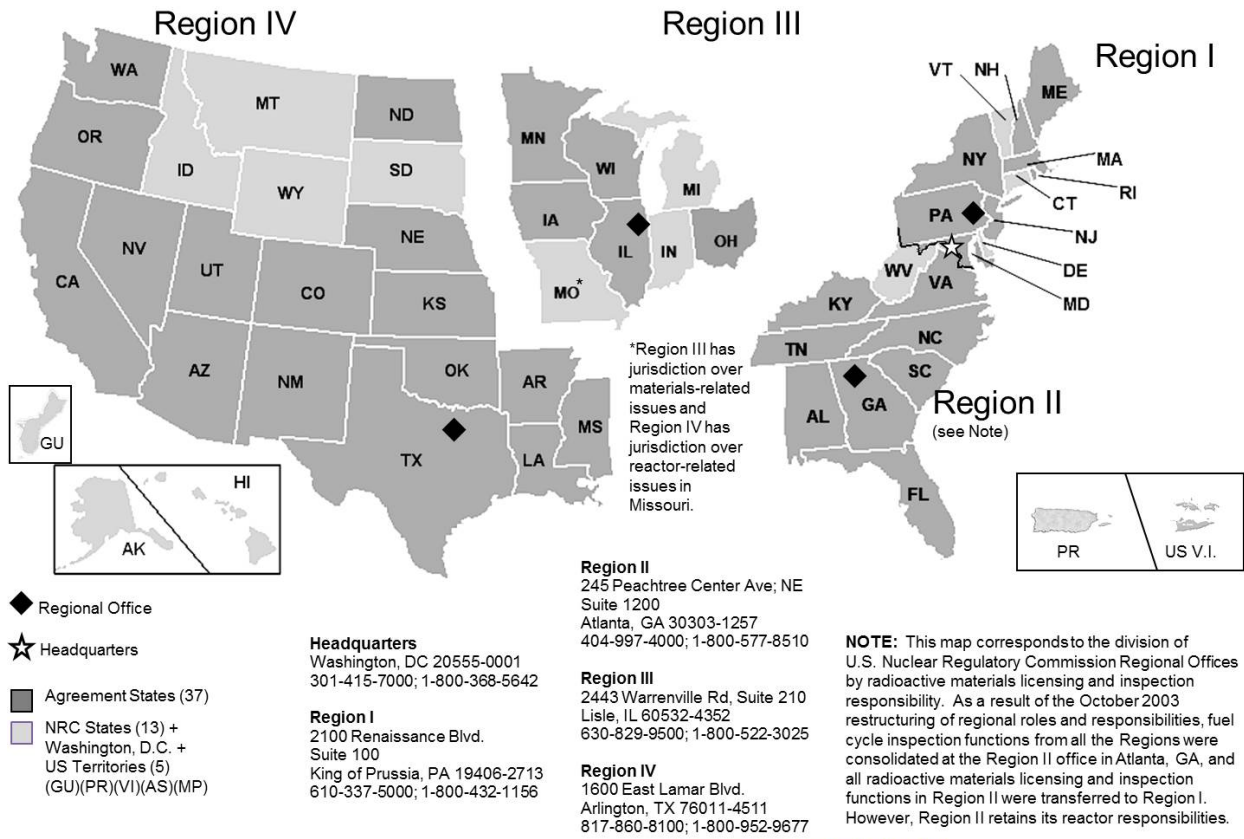
In this document, “dose” or “radiation dose” means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE), as defined in 10 CFR Part 20, “Standards for Protection Against Radiation.” To describe units of radiation exposure or dose, rem and its International System of Units (SI) equivalent, sievert (Sv) ($1 \text{ rem} = 0.01 \text{ Sv}$), are used. This is done because 10 CFR Part 20 sets dose limits in terms of rem (sievert), 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 1004(b).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



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

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

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

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

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) 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 at <https://scp.nrc.gov>. A request for the list can also be made to an NRC regional office.

2.2 Reciprocal Recognition of Specific Licenses

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

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

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

3 MANAGEMENT RESPONSIBILITY

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

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

3.1 Commitments and Responsibilities

Pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR 30.32(c), 40.31(b), and 70.22(d), each application must be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee. If it is not clear whether the application was signed by someone duly authorized to act for and on behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual who signed the application is duly authorized to act for and on behalf of the applicant or licensee. The signature on an application acknowledges the applicant’s or licensee’s commitments and responsibilities, including the following:

- to ensure radiation safety, security, and control of radioactive materials and compliance with regulations;
- to ensure that radiation safety records and all information provided to the NRC are complete and accurate (10 CFR 30.9, 40.9, and 70.9, “Completeness and accuracy of information”);
- to affirm the licensee’s knowledge about the contents of the license and application;
- to comply with current NRC and U.S. Department of Transportation (DOT) regulations, the licensee’s operating, emergency, and security procedures, and NRC license commitments;
- 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;
- to report defects, noncompliances, or reportable events in accordance with regulations;
- to select and assign 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;
- to ensure that radiation workers have adequate training;

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

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

3.2 Safety Culture

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

“Nuclear safety culture” is defined in the NRC’s safety culture policy statement (76 FR 34773; June 14, 2011) as “the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.” Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal-conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). Refer to Table 3-1 for the traits of a positive safety culture from NRC’s safety culture policy statement.

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

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, NRC's safety culture policy statement and traits are not incorporated into the regulations. Safety culture traits may be inherent to an organization's existing radiation safety practices and programs. For instance, licensees who handle unsealed materials must perform surveys to identify skin contamination so that prompt actions may be taken to minimize the dose to the individual and reduce the spread of the contamination. The need to perform the personnel surveys may correspond with the safety culture trait specified in Table 3-1 as "Work Processes" (the process of planning and controlling work activities is implemented so that safety is maintained). However, licensees should be aware that this is just an example, and should consider reviewing their radiation safety programs in order to develop and implement a safety culture commensurate with the nature and complexity of their organizations and functions.

Refer to Appendix R of this NUREG for the NRC's safety culture policy statement. More information on NRC activities relating to safety culture can be found at:

<http://www.nrc.gov/about-nrc/safety-culture.html>.

Table 3-1. Traits of a Positive Safety Culture		
Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Issues 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 the use of licensed material by academic, research and development, and other licenses of limited scope (ARDL) licensees. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

The current versions of these 10 CFR regulations can be found under the "Basic References" link at the U.S. Nuclear Regulatory Commission's (NRC's) online library at <http://www.nrc.gov/reading-rm.html>; if 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 37](#) "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- [10 CFR Part 40](#) "Domestic Licensing of Source Material"
- [10 CFR Part 51](#) "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"
- [10 CFR Part 70](#) "Domestic Licensing of Special Nuclear Material"
- [10 CFR Part 71](#) "Packaging and Transportation of Radioactive Material"
- [10 CFR Part 170](#) "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"

- [10 CFR Part 171](#) “Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC”

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

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

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

5 HOW TO FILE

5.1 Application Preparation

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix A of this NUREG) Items 1 through 4, 12, and 13 on the form itself. A link to the form is available at <http://www.nrc.gov/reading-rm/doc-collections/forms/>.
- Complete NRC Form 313 Items 5 through 11 on supplementary pages or use Appendix B (or Appendix C, as applicable) of this NUREG.
- Provide sufficient detail for the NRC to determine that the equipment, facilities, training, experience, and the 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 (or Appendix C, as applicable) of this NUREG, 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) Part 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 the 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").

5.4 Electronic Applications

Applications may be submitted in electronic form via the NRC's Electronic Information Exchange or CD-ROM. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of non-public information.

6 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

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

The applicant or licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. License applications that contain sensitive information should be marked as indicated in the list that follows, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 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 (IN) 2013-22, “Recent Licensing Submittals Containing Personally Identifiable Information,” dated November 15, 2013, which can be found on the NRC’s Generic Communications Web page under “Regulatory Issue Summaries” and “Information Notices,” respectively: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.
- **Security-Related Information:** Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities and associated security measures are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information and the top of every page of a document that contains such information should be clearly marked: “Security-Related Information—Withhold under 10 CFR 2.390.” For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, 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”: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>. Additional

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

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

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

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

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

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

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

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

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

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

7 APPLICATION AND LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to Title 10 of the *Code of Federal Regulations* (10 CFR) 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 the 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 U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix A of this NUREG).

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

Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR 20.1101(b) states: "The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Regulatory Guide 8.10, Rev. 2, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," discusses the ALARA concepts 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-XXXXX-XX
<input type="checkbox"/> C. Renewal	XX-XXXXX-XX

Check Box A for a new license request. Note that a precicensing visit may be required prior to issuance of the license.

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

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

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

8.2 Item 2: Name and Mailing Address of Applicant

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

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

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

8.2.1 Notification of Bankruptcy Proceedings

Regulations: 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 be notified when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). The NRC shares the results of its determinations with other involved entities (e.g., trustee), so that health and safety issues can be resolved before bankruptcy actions are completed and the NRC may request that the U.S. Department of Justice represent the NRC’s interests in the bankruptcy proceeding.

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

Reference: See NUREG–1556, Volume 15, “Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses.”

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

Specify the street address, city, and State, or other descriptive address (e.g., 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 (e.g., include locations for field studies

or other off-site locations; list activities to be conducted at each location). 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.

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

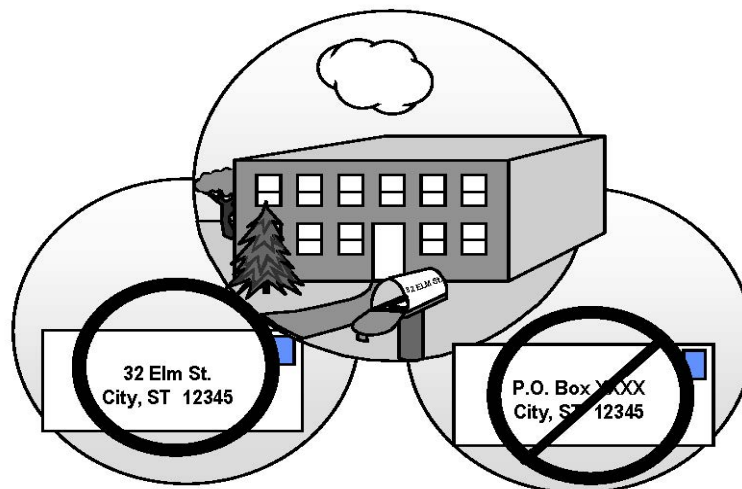
If byproduct material (e.g., portable analytical devices) will be used at temporary jobsites, so indicate, and describe the scope of these activities. To conduct operations at temporary jobsites (i.e., locations where work is conducted for limited periods of time), the address may be stated as “temporary jobsites anywhere in the United States where the NRC maintains jurisdiction.”

If byproduct material is to be used in field studies, the activities must be specifically identified and authorized on the license. Section 8.6, “Purposes for which Licensed Material Will Be Used,” contains information required of applicants before granting authorization for field use of licensed material.

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.



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

Figure 8-1. Location of Use or Possession

Note: As discussed in Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning,” licensees must maintain permanent records describing where licensed material was used or stored while the license was in effect. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches, written descriptions of specific locations 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 using the model procedures in this NUREG will facilitate the NRC’s review.

8.5 Item 5: Radioactive Material

8.5.1 Unsealed or Sealed Byproduct Material

Regulations: 10 CFR 30.14, 10 CFR 30.15, 10 CFR 30.18, 10 CFR 30.19, 10 CFR 30.20, 10 CFR 30.32(g), 10 CFR 30.32(i), 10 CFR 30.33, 10 CFR 30.72, 10 CFR 31.5, 10 CFR 31.8, 10 CFR 31.11, 10 CFR 32.210, 10 CFR 40.22, 10 CFR 40.31, 10 CFR 40.32, 10 CFR 40.34, 10 CFR 70.19, 10 CFR 70.21, 10 CFR 70.22, 10 CFR 70.23

Criteria: An application for a specific license will be approved if the requirements of 10 CFR 30.33 and/or 10 CFR 40.32 and 10 CFR 40.34 (if required), are met. An application for a license to receive, possess, use, and transfer special nuclear material will be approved if the requirements of 10 CFR 70.23 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 the NRC or an Agreement State.

Discussion: Each authorized radionuclide is listed on the NRC license by its element name, chemical and/or physical form, and the maximum possession limit.

The applicant should list each requested radionuclide by its element name and its mass number (e.g., carbon-14 or C-14) in Item 5. It is necessary to specify whether the material will be acquired 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 if the requested radionuclides will be acquired in free

(volatile) or bound (non-volatile) form, because additional safety precautions are required when handling and using free-form volatile material. For example, when requesting authorization to use tritium (H-3) or iodine-125 (I-125), the applicant 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 specified by the applicant.

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

Applicants who plan 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," 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). Applicants who plan to possess greater than 2 curies of unsealed plutonium 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 (ii) an emergency plan for responding to the release 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.

Applicants should specify the anticipated possession limit in millicuries (mCi) or 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. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radionuclide with a half-life greater than 120 days. These requirements are discussed in the section on "Financial Assurance and Decommissioning."

Radionuclide	Chemical and Physical Form	Maximum Possession Limit	Proposed Use
H-3	Unbound and volatile	100 millicuries	Labeling of compounds
H-3	Bound and nonvolatile	100 millicuries	<i>In vitro</i> studies; research and development, including animal studies; teaching and training
P-32	Any	30 millicuries	<i>In vitro</i> studies; labeling of compounds
I-125	Unbound and volatile	30 millicuries	Protein iodination
I-125	Bound and nonvolatile	50 millicuries	<i>In vitro</i> studies; studies in small lab animals; calibration of instruments
Cs-137	Sealed source, Mfg. name/model number	20 millicuries per source and 40 millicuries total	Calibration of instruments

A separate listing should be submitted for sealed sources and/or devices containing sealed sources, such as self-contained irradiators, or calibration and check sources. Applicants must provide the manufacturer's name and model number for each requested sealed source and/or device so that the NRC can verify that they have been evaluated in a Sealed Source and Device (SSD) registration certificate. The SSD registration certificate documents the safety evaluation of sealed sources and devices that the NRC or an Agreement State performs before authorizing a manufacturer (or distributor) to distribute them to specific licensees. Accordingly, applicants should obtain a copy of the certificate and review it with the manufacturer or distributor, or with the NRC or the issuing Agreement State, to ensure that they use sources and devices according to the registration certificates. If the manufacturer and supplier are no longer in service, a copy of the SSD registration certificate may be requested from the NRC or the issuing 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 registration certificates, without obtaining NRC's prior permission in a license amendment.

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 source is a small calibration or reference source containing less than 1 mCi of a beta/gamma emitter or 10 microcuries (μCi) 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."

Although this document does not explicitly cover source material and special nuclear material, applicants and licensees may request to list small amounts of source or special nuclear materials on the academic, research and development, and other licenses of limited scope (ARDL) license when use of these materials is directly related to the use of byproduct material under the limited scope license (e.g., laboratory-scale research and development, or the use of depleted uranium as shielding). Applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of byproduct material under the limited scope license (e.g., sub-critical assemblies using plutonium-beryllium sources and testing of depleted uranium munitions). Applicants also should refer to NUREG-1556, Volume 17, "Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses."

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 (EPAct), the NRC and the Agreement States through their agreements with the NRC, regulate discrete sources of radium (Ra)-226, accelerator-produced radioactive materials, and other discrete sources of NORM that pose a threat similar to that of a discrete source of Ra-226, as described in the definition of byproduct material in 10 CFR 30.4. Notwithstanding the EPAct, 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.

Before proceeding further, applicants should determine if their proposed uses of licensed material meet the criteria for exemptions listed in 10 CFR 30.14, "Exempt concentrations," 10 CFR 30.18, "Exempt quantities," or 10 CFR 40.13, "Unimportant quantities of source material." If so, it is not necessary to submit an application to the NRC for byproduct materials or source material that are covered by the exemptions.

Similarly, applicants should determine if their proposed uses of licensed material meet the requirements for a general license listed in 10 CFR Part 31. Such "generally licensed" materials may be acquired, possessed, used, or transferred without obtaining a specific license from the NRC. Examples are:

- Certain prepackaged units (typically called kits) containing byproduct material for conducting *in vitro* clinical or laboratory tests may be possessed and used under a general license, as provided by 10 CFR 31.11, "General license for use of byproduct material for certain in vitro clinical or laboratory testing." Eligibility for this general license is limited to physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, and hospitals; however, these persons are required to register with the NRC before acquiring or using these units, unless they have an NRC license under 10 CFR Part 35.
- Certain devices containing sealed sources of byproduct material, such as electron capture detectors (ECDs) in gas chromatographs (GCs) and EXIT signs containing tritium, are authorized by the NRC or Agreement States for distribution to persons who are generally licensed (as well as to persons who are specifically licensed). Regulatory requirements for such devices possessed under a general license are provided in 10 CFR 31.5, "Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere." Distributors of such devices must provide users with appropriate information related to the acquisition, use, and transfer of these generally licensed devices. The generally licensed devices also have labeling requirements that are different from those that are possessed under a specific license.

Response from Applicant:

- For unsealed materials:
 - For each radionuclide, provide the element name with mass number, the chemical and/or physical form, and the 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.

- For sealed 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 for each radionuclide.
 - Provide the manufacturer's or distributor's name and model number for each sealed source and device requested.
 - Confirm that each sealed source, device, and source and device combination is registered as an approved sealed source or device by the NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available.
 - 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.
- Provide an emergency plan, if required by 10 CFR 30.32(i) and 30.72 or 10 CFR 70.22(i)

Note: Licensees who are authorized to possess small quantities of material, below the Category 2 quantities described in Appendix A to 10 CFR Part 37 are not subject to access control and physical protection requirements described in 10 CFR Part 37. If applicants or licensees plan to acquire a Category 1 or Category 2 quantity, they should visit the NRC's public Web site (www.nrc.gov) for additional information regarding access control and security program requirements for Category 1 and Category 2 licensed material. Please contact the appropriate regional office for questions regarding the security of licensed material. Information on 10 CFR Part 37 is also given in Section 8.10.9 of this NUREG, "Security Program for Category 1 and Category 2 Radioactive Material."

References:

- Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," Revision 1, April 2011
- 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 30.36(k)(4), 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 40.42(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 70.36, 10 CFR 70.38(e), 10 CFR 70.38(g)(4)(v), 10 CFR 70.51(a)(3), 10 CFR 70.51(b)

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25—all titled "Financial assurance and

recordkeeping for decommissioning”—must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (FA) for decommissioning.

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

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

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

Financial Assurance

The regulations in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25 that require a certification of 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 such that unrestricted use of the facilities is possible at the conclusion or termination of licensed activities.

These requirements, if applicable, specify that a licensee either sets aside funds for decommissioning activities or provides a guarantee through a third party that funds will be available. Applicants are required to submit a certification of FA or a DFP when the possession of radioactive material with a half-life greater than 120 days exceeds certain limits. Criteria for determining if an applicant is required to submit a DFP or has the option of submitting either a DFP or a certification of FA are stated in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25, all entitled, “Financial assurance and recordkeeping for decommissioning.” A DFP contains a site-specific cost estimate and a certification of FA. A certification of financial assurance includes a certification that the licensee has provided the required FA and an acceptable FA instrument.

A DFP is required to be submitted by ANY licensee that identifies residual contamination levels that, if uncorrected, would exceed the criteria for release for unrestricted use (that which is distinguishable from background radiation and would result in a dose that would exceed 25 millirem in one year to a member of the critical group). If a licensee identifies such residual contamination during the required surveys of its facilities, a DFP must be submitted within one year of the survey.

Acceptable FA methods include prepayment in the form of a trust fund; a surety, insurance, or other guarantee method (e.g., letters of credit, surety bonds, parent company guarantees, insurance policies); and, in the case of government licensees, a statement of intent from the Government entity. Criteria for parent company guarantees and self-guarantees can be found in 10 CFR Part 30, Appendix A, Appendix C, Appendix D, and Appendix E. Applicants should refer to 10 CFR 30.35(f) for the current list of acceptable FA methods.

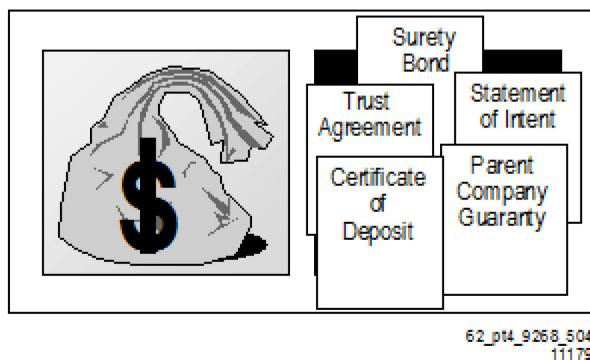


Figure 8-2. Methods of Certification of Financial Assurance for Decommissioning

Table 8-2 is a partial list of radionuclides of half-life greater than 120 days with their corresponding limits in excess of which a certification of FA or a DFP is required. Applicants can use Table 8-2 and the guidance in NUREG–1757, Volume 3, “Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness,” to determine if FA is required and the amount required. When one or more of these radionuclides is requested, a sum-of-fractions calculation must be performed (unity rule). If the sum exceeds 1, then FA is required. Most ARDL licensees use a small number of these radionuclides; and in many cases, such licensees may be able to adjust the amounts of these radionuclides so that FA is not required. If other long-lived radionuclides are used, the applicant should refer to 10 CFR 30.35 and Appendix B to Part 30 for the applicable quantities.

Column 1: Radionuclide	Column 2: Limit for FA (millicuries*)
calcium-45	10
carbon-14	100
chlorine-36	10
hydrogen-3	1,000
zinc-65	10

*1 millicurie = 37 megabecquerel (MBq)

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 FA for decommissioning and a standard format for presenting the information. Note that FA is required for four types of licensed materials: (i) unsealed byproduct material (10 CFR 30.35); (ii) sealed byproduct material (10 CFR 30.35); (iii) dispersible source material (10 CFR 40.36); and (iv) unsealed special nuclear material (10 CFR 70.25). The total amount of FA required is the sum of the FA required for each of these types of materials.

Recordkeeping for Decommissioning

The requirements for maintaining records important to decommissioning, including the types of information required, are stated in 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g). Such records include decommissioning records related to structures and equipment in which licensed materials are used and stored, as well as records related to spills, leaking sources, or other events that may result in residual contamination.

The regulations in 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g) also require that all licensees maintain records important for decommissioning in an identified location until the site is released for unrestricted use (see Figure 8-3). In the event that the licensed activities are transferred to another NRC or Agreement State licensee, these records must be transferred to the new licensee before transfer of the licensed activities, in accordance with 10 CFR 30.34(b), 40.46(b) and 70.36(b). The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records must be transferred to the NRC.

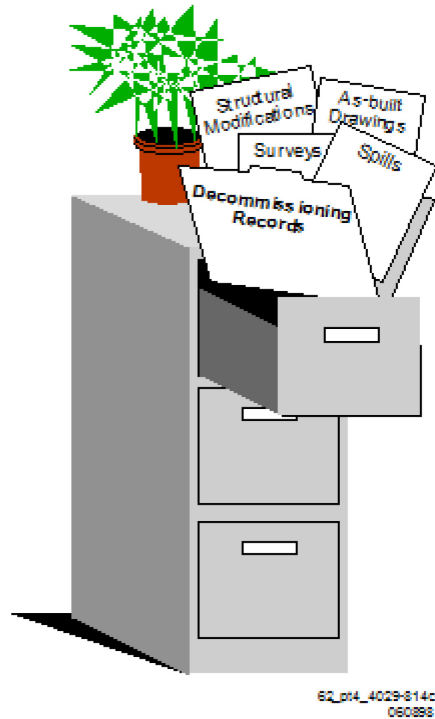


Figure 8-3. Types of Records that Must Be Maintained for Decommissioning Response from Applicants:

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

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

Regulations: 10 CFR 30.4, 10 CFR 30.33(a)(1), 10 CFR 51.21, 10 CFR 51.22

Criteria: An application for a license will be approved if the proposed activity is 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 used only for the purpose for which they are designed, and according to manufacturer's and distributor's instructions and recommendations for use, as specified in the SSD registration certificate, unless otherwise authorized in the license.

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

Research and development, as defined in 10 CFR 30.4, "Definitions," does not include research involving the use of licensed material in or on humans. Applicants planning to 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, Volume 9, "Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses."

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

Use of licensed materials in animals: Applicants should clearly specify if the licensed material will be used in animals for research studies, or by veterinarians for diagnostic and therapeutic purposes. 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., dogs, pigs, horses). Similarly, the veterinary use should specify whether the material will be used in pets (e.g., cats, dogs) or in farm animals (e.g., cattle, horses, pigs). Appendix D of this NUREG provides guidance for developing radiation safety procedures for these studies and describes additional information to be submitted with the application.

Use of licensed materials in tracer studies: If the material will be used in tracer and field studies in which licensed material is deliberately released into the environment, or in animal studies that may result in the release of licensed material into the environment, an environmental assessment may be needed, according to 10 CFR 51.21, "Criteria for and Identification of Licensing and Regulatory Actions Requiring Environmental Assessments." NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," addresses procedures that staff should use in conducting environmental reviews and is available on the NRC Web site under "Document Collections." A memorandum dated October 20, 2009 (ADAMS Accession No. ML092321078), provides further guidance for distinguishing between simple and complex environmental assessment actions. Applicants for tracer or field studies must provide the NRC with a description of the study for review and approval before performing such studies.

Applicants who want to perform field studies in which licensed material is deliberately released to the environment for the purposes of studies should provide the following information:

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

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

Response from Applicant: List the specific use or purpose of each radionuclide. Provide a description of uses in animals, if applicable. Provide a description of tracer or field studies, if applicable.

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

8.7.1 Radiation Safety Officer

Regulations: 10 CFR 30.33(a)(3), 10 CFR 30.34(e), 10 CFR 40.32(b), 10 CFR 70.22(a)(6)

Criteria: The Radiation Safety Officer's (RSO's) training and experience should be applicable to and generally consistent with the types and quantities of licensed material listed on the license for which the individual's authorization as an RSO is requested.

Discussion: The person responsible for the radiation protection program is the RSO. The RSO is key to overseeing and ensuring safe operation of the licensee's radiation protection program. 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 his or her duties and responsibilities to ensure that radioactive materials are 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 8-4 and described in Appendix E 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 identified and that the named individual knows of his or her designation as RSO. Appendix E of this NUREG

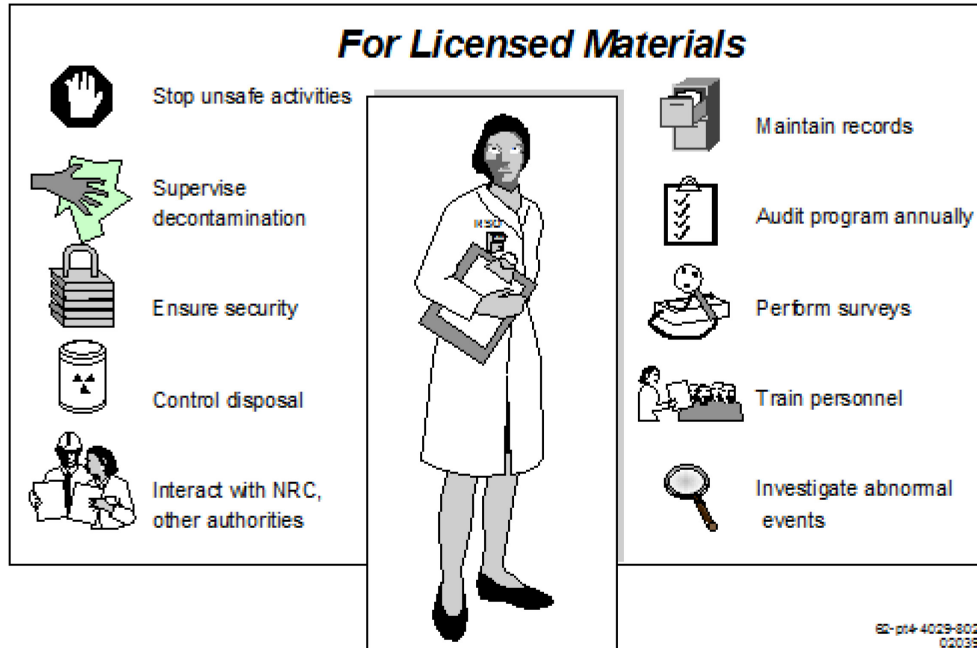


Figure 8-4. Typical Duties and Responsibilities of RSOs.

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.

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

Training should include the following subjects:

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

Experience should include the following areas:

- planning and conducting evaluations, surveys, and measurements similar to those that the licensee's radiation safety program requires

- use of licensed materials similar in types, forms, and quantities to those proposed for use under the license
- security and control of licensed materials
- monitoring inventory of materials possessed under the license; maintaining records of receipts, transfers, and disposal of licensed materials
- storage, handling, disposal, and documentation of radioactive waste materials
- planning, conducting, and documenting audits and other evaluations of the radiation safety program
- evaluation and documentation of radiation exposures
- maintaining required records of the radiation safety program and providing required reports
- other applicable duties and responsibilities, as described in Appendix E 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 instance, in addition to a college degree, RSOs at ARDL licensees may need at least 40 hours of radiation safety training specific to their job duties, as well as a year of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be an RSO. The RSO designee should have obtained the above training in formal course(s) designed for RSOs, presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts. In addition, the proposed RSO's experience should be sufficient to identify and control the anticipated radiation hazards. For example, the RSO should have experience planning and conducting evaluations, surveys, and measurements similar to those required by the licensee's radiation safety program.

Response from Applicant: Provide the following:

- name of the proposed RSO
- information demonstrating that the proposed RSO is qualified by training and experience; information should include, as a minimum
 - formal training or education in radiation safety [topics covered, duration of training, when training was received, identity and 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 an RSO (activities, duration of experience, scope of program)

Applicants should provide information about the proposed RSO's training and experience that is relevant to the licensed material requested in the application. Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships. Submittal of unrelated material only serves to slow the review process. In addition, the information submitted should not contain personally identifiable information (see Chapter 6, "Identifying and Protecting Sensitive Information").

Note: Notify the NRC and obtain a license amendment before making changes in the designation of the RSO listed on the license.

8.7.2 Authorized User

Regulations: 10 CFR 20.1101(b), 10 CFR 30.33(a)(3), 10 CFR 40.32, 10 CFR 70.22

Criteria: Authorized users (AU) must have adequate training and experience with the types and quantities of licensed material they propose to use.

Discussion: An AU (also known as "principal investigator," "permit holder," "source custodian," or by other licensee designations) is an individual whose training and experience have been reviewed and approved by the NRC, who is named on the license, and who uses or directly supervises the use of licensed material. The AU's primary responsibility is to ensure that radioactive materials used in his or her particular lab or area are used safely and according to regulatory requirements (see Figure 8-5). The AU 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 and appropriate training to provide reasonable assurance that they will use licensed material safely. Training for AUs should include: maintaining security of, and controlling access to, licensed material; and responding appropriately to events or accidents involving licensed material to prevent the spread of contamination.



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

An AU should have (i) a college degree at the bachelor's level or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (ii) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection instrumentation
- biological hazards of exposure to radiation (appropriate to the types and forms of byproduct material to be used)
- 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.

An AU is 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.

Applicants must name at least one individual who is qualified to use the requested licensed materials. In general, AUs must demonstrate training and experience with the type and quantity of material 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.

Response from Applicant:

Applicants should provide the following:

- name of each proposed AU with the types and quantities of licensed material to be used
- information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials; information should include, as a minimum:
 - formal training or education in radiation safety [topics covered; duration of training; when training was received; identity and 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. Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material serves only to slow the review process.

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

Regulations: 10 CFR 19.11, 10 CFR 19.12, 10 CFR 19.13, 10 CFR 30.9, 10 CFR 30.33(a)(3), 10 CFR 40.9, 10 CFR 40.32(b), 10 CFR 70.9, 10 CFR 70.23(a)(2)

Criteria: Individuals whose assigned duties involve exposure to radiation or radioactive material (from both licensed and unlicensed sources) and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 millisievert (mSv) [100 millirem (mrem)], must receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12, "Instructions to Workers."

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 (mrem)] in a year must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic (for example, annual) refresher training.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals.

Particular attention should be given to persons performing work with radioactive materials that may require special procedures, such as hot cell work, waste processing, and animal handling. Also, ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately.

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

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

Response from Applicant: 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 40.32(c), 10 CFR 40.36(f), 10 CFR 70.23(a), 10 CFR 70.25(g)

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. 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 their 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 that will 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 prelicensing 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 unrestricted release criteria at 20.1402 are met. Therefore, careful facility design is important to prevent contamination or facilitate decontamination, reducing the costs needed for decommissioning. For further information, see the section entitled, "Financial Assurance and Record Keeping for Decommissioning."

Appendix G of this NUREG provides additional guidance on facilities and equipment.

If radioactive materials will be used with animals, include a description of the animal handling housing facilities. (See Appendix D of this NUREG)

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 laboratory bench tops and flooring
- ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction
- use of appropriate plumbing materials with minimal pipe lengths and traps
- minimization of the number of disposal sites (sinks) where liquid waste is disposed

Response from Applicant:

- Describe the facilities and equipment that will be available at each location where radioactive material will be used (see Appendix G of this NUREG for topics to consider).
- Include a description of the area(s) assigned for the receipt, storage, security, preparation, measurement, use, and disposal 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.
 - 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. The same scale should be used for all sketches and drawings. The recommended scale is 1/4 inch = 1 foot. Sketches or drawings 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.
 - Specialized facilities such as waste storage rooms or hot labs, and locations of specialized facilities or equipments such as waste compactors, hot cells and shielded storage for high activity sources, should be included on the diagrams.
- Describe how facility design and procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste.

8.10 Item 10: Radiation Safety Program

8.10.1 Audit Program

Regulations: 10 CFR 20.1101, 10 CFR 20.2101 through 10 CFR 20.2110, 10 CFR 21.21(a)

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

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

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

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

It is essential that once problems are identified, comprehensive corrective actions are taken in a timely manner. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. The NRC routinely reviews licensee's records to verify whether appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. The NRC can opt to exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented. The NRC's Enforcement Policy may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The Enforcement Manual may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html>. For examples of the NRC's use of discretion in issuing a notice of violation, refer to the most recent version of NRC's enforcement documents at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

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: (i) date of audit, (ii) name of person(s) who conducted the audit, (iii) persons contacted by the auditor(s), (iv) areas audited, (v) audit findings, (vi) corrective actions, and (vii) followup.

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 (ADAMS Accession No. ML052730315)
- Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," May 1, 1996
- Enforcement guidance and policy, available online at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/>

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)

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
- contamination surveys
- sealed source leak tests
- air sampling measurements
- bioassay measurements
- effluent release measurements
- unrestricted area dose rate measurements

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

- portable or stationary count rate meters
- portable or stationary dose rate or exposure rate meters
- single or multichannel analyzers
- liquid scintillation counters (LSC)
- gamma counters
- proportional counters
- solid state 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 equipment includes:

- rotometers
- anemometers
- other devices that measure flow rates, volumes, and time

The choice of instrument should be appropriate for the type of radiation to be measured and for the type of measurement to be taken (count rate, dose rate, etc.). Figure 8-6 illustrates some common survey instruments used for contamination surveys. Applications should include descriptions of the instrumentation available for use and the instrumentation the applicants plan to purchase before starting licensed activities. The description should include the type of instrument and probe and the instrument's intended purpose.

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

Calibration of an instrument should be performed before it is used for the first time, and at least annually thereafter. Calibration should also be performed after any repair to the instrument. NRC regulations require that survey instruments used for quantitative measurements be calibrated periodically. Calibrations requiring the use of radioactive sources should be

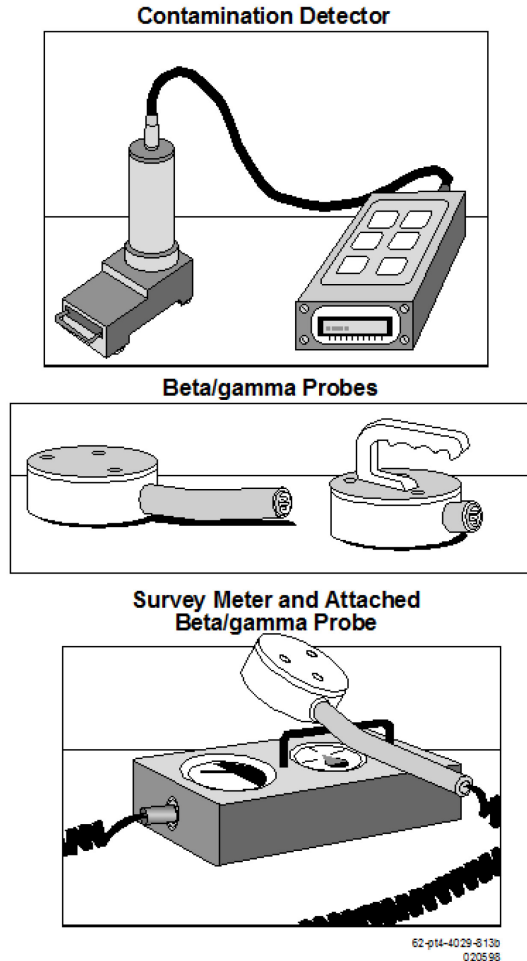


Figure 8-6. Examples of Portable Instruments Used in Laboratory Settings

performed by the instrument manufacturer or persons specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations will need to submit procedures for review. Appendix I of this NUREG provides information about instrument specifications and model calibration procedures. Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts an authorized firm to perform calibrations, the licensee must retain records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made in accordance with 10 CFR 20.2103(a).

Response from Applicant:

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 I in NUREG-1556, Volume 7, Revision 1, 'Program-Specific Guidance

About Academic, Research and Development, and Other Licenses of Limited Scope.’ We reserve the right to upgrade our 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 meter calibration program published in Appendix I in NUREG–1556, Volume 7, Revision 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’”

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 30.34(e), 10 CFR 30.35(g), 10 CFR 30.41, 10 CFR 30.51, 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 30.11, 10 CFR 31.5(c)(8), 10 CFR 31.11, 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.
- 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.
- 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.

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 also should be established for the procurement of licensed materials that may be obtained outside normal channels (e.g., through the loan or other transfer of materials without purchase or through surplus). Appendix J of this NUREG includes a model procedure for ordering and receiving radioactive material.

Licensed material becomes 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 returning 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 arrange 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. A model procedure for safely opening packages containing licensed materials is included in Appendix J of this NUREG.

In 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 (Receiving), 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/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 8-3, below.

Package	Contents	Survey Type	Survey Time*
Damaged	Licensed Material	Radiation Level and Radioactive Contamination	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 and Radioactive Contamination	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	As soon as practicable, but not later than 3 hours after receipt of package

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

Regulations in 10 CFR 20.1906(d) require the licensee to notify immediately the final delivery carrier and the NRC Operations Center (310-816-5100), by telephone, when removable radioactive surface contamination exceeds the limits specified in 10 CFR 71.87(i), or when external radiation levels exceed the limits of 10 CFR 71.47, "External radiation standards for all packages." These limits that are applicable to most packages that ARDL licensees receive are (i) radiation levels shall not exceed 2mSv/h [200 mrem/h] at any point on the external surface of the package; and (ii) removable radioactive surface contamination for beta/gamma emitters and low-toxicity alpha emitters must not exceed 4 Bq/cm² [240 disintegration per minute per centimeter squared (dpm/cm²)]; or for all other alpha emitters 0.4 Bq/cm² [24 dpm/cm²] on the external surfaces of the package.

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.

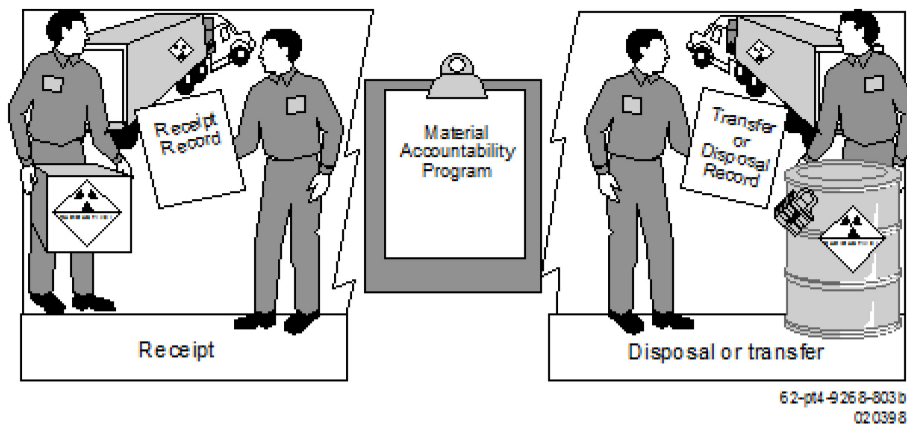


Figure 8-7. Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal of licensed material.

Licensees are required under 10 CFR 20.1801 and 10 CFR 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 material.

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

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 that is under a general license or distributed to them as an exempt quantity or item. Regulations in 10 CFR Part 31 provide information on 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 continue to possess materials under a general license. A specific license does not automatically remove general licensee status nor automatically “move” 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 regulator.

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

Similarly, radioactive material received by specific licensees, that is distributed to them under an exemption from the requirements for a license, is not subject to the terms and conditions of the specific license. Any person may receive byproduct material that is exempt from the requirements of a license under 10 CFR 30.11, “Specific exemption,” through 10 CFR 30.21, “Radioactive drug: Capsules containing carbon-14 urea for “in vivo” diagnostic use for humans.” Such materials may include “exempt quantities” of byproduct materials that do not exceed the applicable quantity listed in 10 CFR 30.71, “Schedule B,” as well as items such as smoke detectors and self-luminous watches, which are distributed in accordance with other NRC regulations. Most licensees do not possess or control these types of devices under the provisions of their specific license, and the NRC does not require or encourage this practice; however, as stated above, the specific licensee always has the option to add these materials to its license and control them under the conditions of the specific license. In any case, licensees are required to ensure that dose limits are not exceeded, whether the dose results from licensed sources or unlicensed sources.

Inventory and Accountability of Radioactive Materials

Licensees who use or possess sealed sources are required by license condition to perform inventories of sealed sources every 6 months. Some sealed sources may not be in use or are rarely used and are placed in storage. In these cases, licensees should confirm at least every 6 months that these sealed sources have not been disturbed. Licensees also are 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, leak test records may be used as part of an inventory and accountability program.

ARDL 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 method 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 ARDL 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 appropriate waste containers awaiting disposal. The RSO should periodically update 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, "Transfer of byproduct material." Sample policy transfer statements are included in Appendix J 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 removal of these items for maintenance, repair, or disposal.

Licensees must maintain records of receipt, transfer, and disposal (as waste) of all licensed material. Table 8-4 lists each type of record and how long the record must be maintained. Other records, such as transfer records, could be linked to radioactive material inventory records. Receipt records also should document cases in which excessive radiation levels or radioactive contamination were found on packages or containers of material received and describe the action taken.

Lost Source Policy is the NRC's policy that a civil penalty may be issued for violations resulting in regulated material being out of the control of the licensee, regardless of the use, license type, quantity, or type of regulated material (e.g., loss, abandonment, improper transfer, or improper disposal of regulated material). The Lost Source Policy is described in Section 2.3.4 of NRC's Enforcement Policy and in Section 3.1 in NRC's Enforcement Manual.

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed and for 3 years following the transfer or disposal of the material
Inventory	For 3 years from the date of the inventory in accordance with license conditions
Transfer	For 3 years after each transfer unless a specific requirement dictates otherwise
Disposal	Until NRC terminates the license
Important to decommissioning*	Until the site is released for unrestricted use

*Information about locations where licensed material is used or stored are among the records important to decommissioning and required by 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g). See also the section on "Financial Assurance and Recordkeeping for Decommissioning."

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

- radionuclide and activity (in units of becquerels or curies) and date of measurement of byproduct material in unsealed form
- 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 unsealed material and each sealed source and device
- for inventories, the date of inventory and the name and signature of the individual conducting the inventory
- for materials transferred, the date of the transfer, the name and license number of the recipient, and description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number)
- for licensed materials disposed of as waste, include the radionuclide, activity, date of disposal, and method of disposal (decay, sewer, etc.)

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

Information on locations where licensed material is used or stored are among the records important to decommissioning and are required by 10 CFR 30.35(g), 40.36(f), and 70.25(g). See also Section 8.5.2 "Financial Assurance and Record Keeping for Decommissioning," for more details.

Response from Applicant:

- Provide the following statement: "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times."
- If applicable, provide the following statement: "We will comply with the National Source Tracking System (NSTS) reporting requirement as described in 10 CFR 20.2207."

AND

- Provide either of the following:
 - A statement that “Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer’s name and model numbers, and the date of the inventory.”

OR

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

Note:

- No response is needed from applicants for package opening procedures. Package opening procedures are reviewed during NRC inspections to ensure compliance with 10 CFR 20.1906.
- Alternative responses will be evaluated using the guidance in this section.

References:

- NUREG–1516, “Management of Radioactive Material Safety Programs at Medical Facilities,” May 1997
- NCRP Report No. 114, “Maintaining Radiation Protection Records,” 1992
- NCRP Report No. 105, “Radiation Protection for Medical and Allied Health Personnel,” 1989
- NCRP Report No. 127, “Operational Radiation Safety Program,” 1998
- NCRP Report No. 157, “Radiation Protection in Educational Institutions,” 2007

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 2104, 10 CFR 20.2106, 10 CFR 20 Appendix B

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

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

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

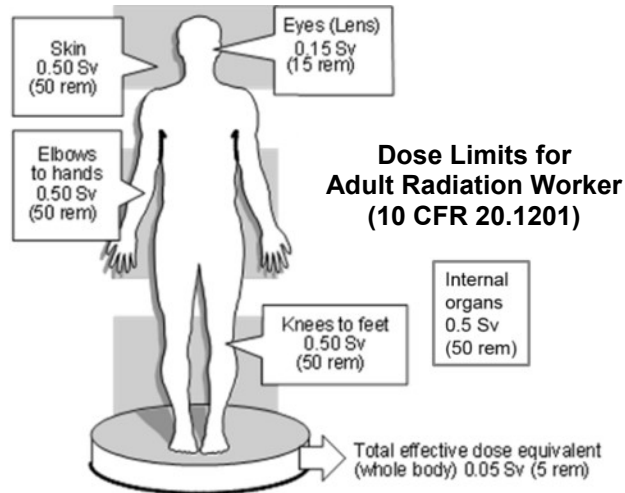
Internal exposure monitoring is required, pursuant to 10 CFR 20.1502(b), for the following:

- adults likely to receive in, 1 year, an intake in excess of 10 percent of the applicable annual limit on intake (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]

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.



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.

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 is determined that monitoring is 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.

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

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

Licenses 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, licenses must supply and require the use of individual monitoring devices to monitor external

exposures and monitor the occupational intake of radioactive material when the results of prospective dose evaluations exceed the doses specified in 10 CFR 20.1502.

When personnel dosimeters that require processing to determine the radiation dose are used to comply with the individual monitoring requirement for external doses in 10 CFR 20.1502(a), dosimeters must be processed by a 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 8-5.

Table 8-5. 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
Regulatory Guide 8.36	Radiation Dose to the Embryo/Fetus
Regulatory Guide 8.37	ALARA Levels for Effluents from Materials Facilities
ANSI N13.30-2011	Performance Criteria for Radiobioassay
Information Notice 2000-10	Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits

Additional Reference for Further Reading:

- U.S. Department of Energy (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 the section titled, 'Radiation Safety Program—Occupational Dose' in NUREG–1556, Volume 7, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development and Other Licenses of Limited Scope.'"

OR, IN LIEU OF THESE STATEMENTS,

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

Note:

- 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).

References:

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

8.10.5 Public Dose

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

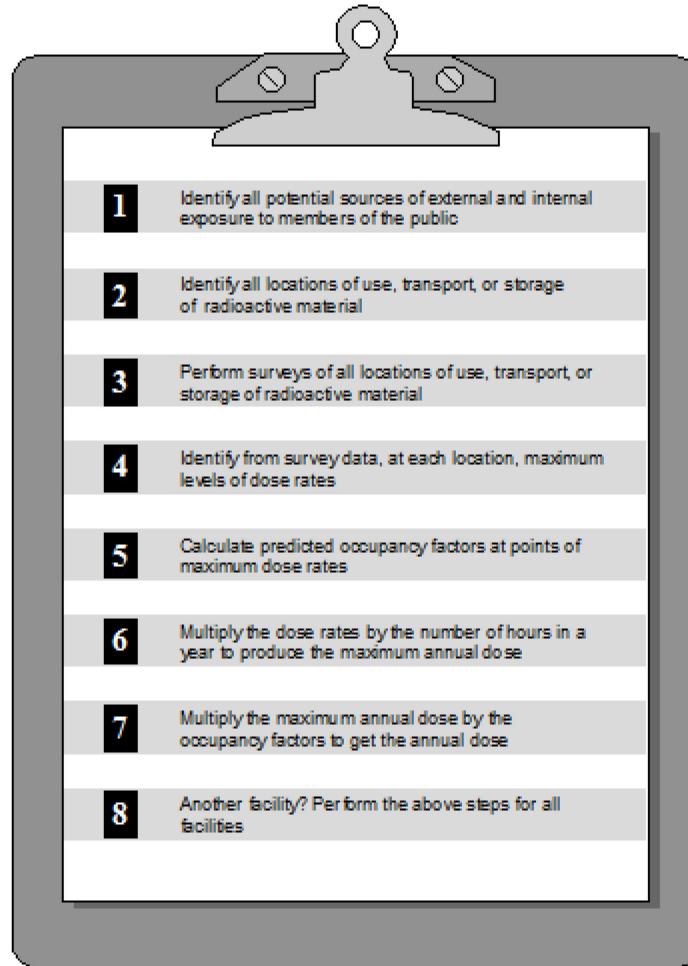
Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv [100 mrem] in 1 year, and the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any 1 hour, from licensed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

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.

Appendix K of this NUREG provides guidance on accepted methodologies for determining dose to members of the public.

Figure 8-9 shows the steps to calculate the annual dose to an individual member of the public.

Calculating the Annual Dose to an Individual Member of the Public



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

Many possible internal dose pathways 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 20.1301. Specific requirements on demonstrating compliance with dose limits for individual members of the public are provided in 10 CFR 20.1302. The extent and frequency of monitoring will depend on each licensee's needs. Refer to Section 8.10.7, "Radiation Safety Program—Surveys" for additional guidance on monitoring of effluents. Regulations in 10 CFR 20.2107, "Records of

dose to individual members of the public,” require licensees to maintain records sufficient to demonstrate compliance with the dose limits for members of the public until the Commission terminates the license. These records should be available for review during NRC inspections. Appendix K of this NUREG provides additional guidance on compliance with the recordkeeping requirements.

Response from Applicant: No response is required from the applicant in a license application, but compliance will be examined during inspection. During NRC inspections, licensees must be able to demonstrate, by measurement or calculation, that the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See Appendix K of this NUREG for examples of methods to demonstrate compliance.

8.10.6 Safe Use of Radionuclides, Security, 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 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 the NRC.

Discussion: Licensees are responsible for the security and safe use of all licensed material from the time it arrives at their facility, during its use and storage, and until it is transferred or disposed. Licensees should develop, implement, and maintain written procedures to ensure safe use of licensed material. The procedures also should 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.

General Safety 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 (see Appendix Q of this NUREG, “Incident Notifications and Reporting”)
- responsibilities

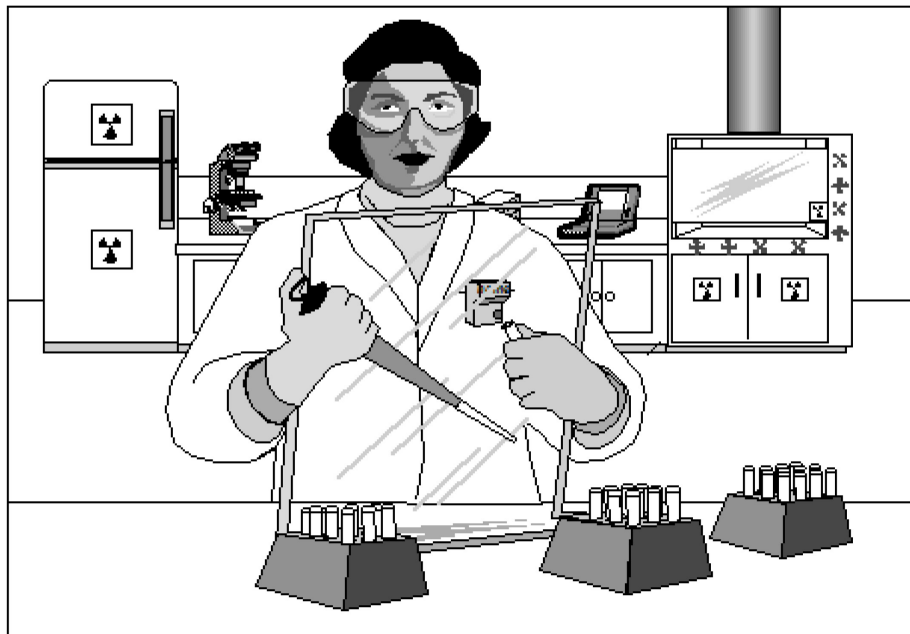
These procedures should include policies for

- 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 the laboratory

Applicants also should develop radionuclide-specific procedures based on the respective hazards associated with the radionuclides. Appendix L of this NUREG describes general safety guidelines. 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, “Posting requirements,” unless they meet the criteria listed in 10 CFR 20.1903, “Exceptions to posting requirements.” Also, containers of licensed material (including radioactive waste) must be labeled, in accordance with 10 CFR 20.1904, “Labeling containers,” unless they meet the exemptions in 10 CFR 20.1905, “Exemptions to labeling requirements.”

Working Behind a Shield



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

Security Procedures

Per 10 CFR 20.1801 requirements, licensees must secure all licensed materials stored in controlled or unrestricted areas from unauthorized access or removal. When any licensed materials are in controlled or unrestricted areas, but are not in storage, the licensee must control and maintain them through constant surveillance of the materials, per 10 CFR 20.1802. These security requirements are intended to ensure that individuals who are not knowledgeable about radioactive materials cannot be exposed to or contaminated by the material and unauthorized individuals cannot take the material. Acceptable methods for securing material will vary among facilities. Some alternatives licensees use include: storage and use of licensed materials only in restricted areas; limiting access to an entire facility, building, or portion of the building only to radiation workers; providing locked storage areas to prevent access to the material; and implementing procedures that require a radiation worker to be within the "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 to security procedures may be required at facilities that have unusual needs because of the activities performed, such as hot cells, animal care facilities, and waste processing facilities.

Emergency Procedures

Accidents and emergencies can happen during any operation with radionuclides, including their transportation, use, 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 also may 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 should establish written procedures to handle events ranging from a minor spill (see Figure 8-11) to a major accident that may require outside emergency response personnel intervention. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency and equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that the user can control and clean up, the licensee's staff should have a clear understanding of their role in an emergency, with step-by-step instructions and clear direction of whom to contact.

Licensees should have a sufficient number of appropriate and calibrated survey instruments readily available. Emergency spill kits should be strategically placed in well-marked locations for all users and radiation safety staff trained in their use. All equipment should be inspected periodically for proper operation and replenished as necessary. Appendix L 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

Surveys, such as scanning hands for skin contamination with a radiation detection instrument or evaluation of nasal swipes for contamination through inhalation, may identify that an individual is

contaminated and radioactive material was taken into the body through skin absorption or other means. If the 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, in which the radioactive material in the body can be directly measured using appropriate instruments. Bioassays also may be performed indirectly 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:

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

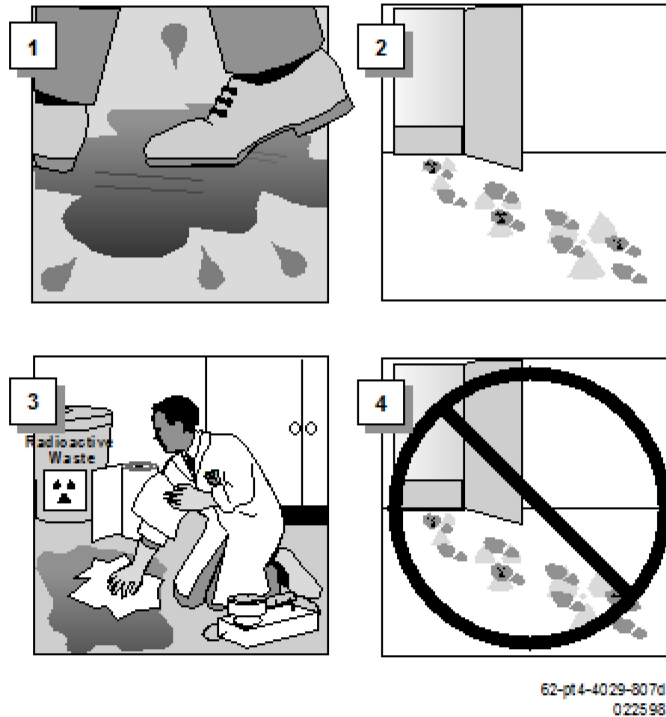


Figure 8-11. Proper Handling of Minor Spill. *Panels 1 and 2 indicate how contamination can be spread if the incident is not handled properly, as in panels 3 and 4.*

Response from Applicant:

State that: “We will develop, implement, and maintain procedures for safe use, security and emergencies.”

OR

State that: “We will adopt the procedures for the safe use of radionuclides, security and emergencies as published in Appendix L in NUREG–1556, Volume 7, Revision 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’”

OR

Provide procedures for safe use of radionuclides, security of materials and emergencies.

- If required by 10 CFR 30.32(i) and 30.72 or 10 CFR 70.22(i), provide an emergency plan for responding to the release of radioactive material, in accordance with the criteria listed in 10 CFR 30.32(i)(3) or 10 CFR 70.22(i)(3), as a separate part of the application.

8.10.7 Surveys and Leak Tests

Regulations: 10 CFR 30.36(j) and (k), 10 CFR 30.53, 10 CFR 20.1501, 10 CFR 20.1906, 10 CFR 20.2103, 10 CFR 40.42(j) and (k), 10 CFR 40.63, 10 CFR 70.38(j) and (k), 10 CFR 70.56

Criteria: Licensees are required by 10 CFR 20.1501 to make surveys of potential radiological hazards in their workplace. The NRC requires testing to determine whether there is any radioactive leakage from sealed sources. Licensees must 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 8-12). 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, gamma) and compared to the appropriate limits.

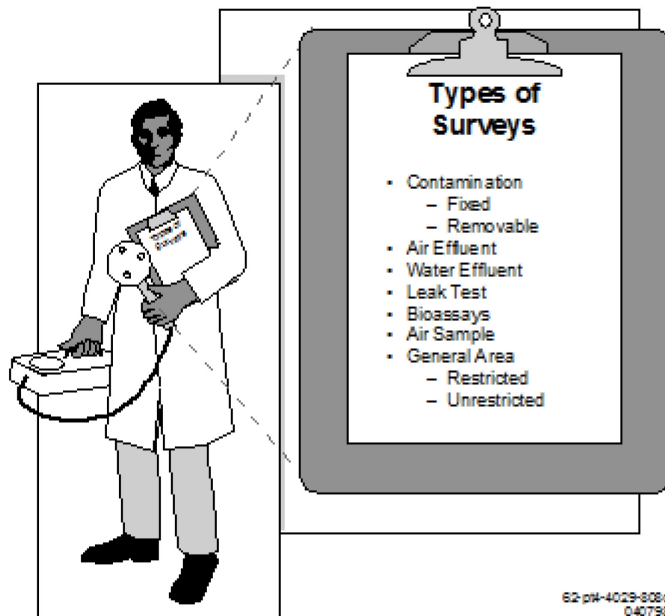


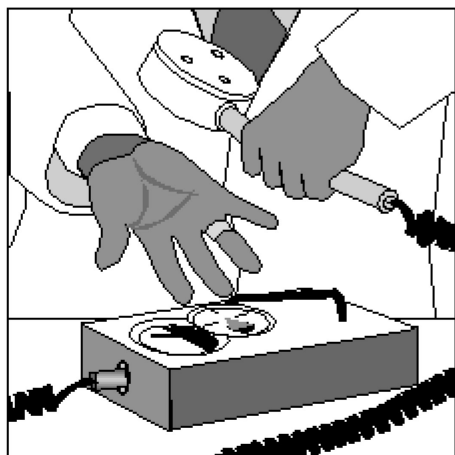
Figure 8-12. Types of Surveys. ARDL licensees perform many different types of surveys.

Unsealed Materials

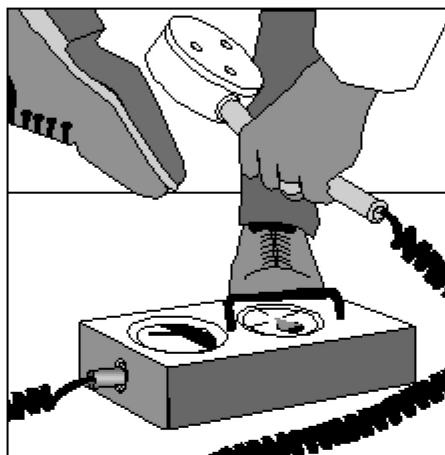
Radiation surveys are used to detect and evaluate contamination of

- facilities
- equipment
- personnel (during use, transfer, or disposal of licensed material) (see Figure 8-13)
- restricted and unrestricted areas

Surveying arm and hand using survey meter and beta/gamma probe.



Surveying feet and legs using survey meter and beta/gamma probe.



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Figure 8-13. Personnel Surveys. *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the laboratory.*

As stated in 10 CFR 20.1501, surveys are required 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. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment.
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form and where operations could expose workers to the inhalation 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)

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 what removable surface contamination limits will be allowable before decontamination will be performed in each work area. Table M-2 and Table M-3 in Appendix M of this NUREG contain contamination limits acceptable to the NRC.

Sealed Source and Plated Foil Leak Test

When issued, a license will require performance of leak tests of sealed and plated foil sources [e.g., ECD/X-ray fluorescence analyzer (XRF)] 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 becquerels (Bq) [0.005 μ Ci] of the radionuclide contained in the source or foil.

Manufacturers, distributors, consultants, and other organizations may be authorized by the NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample, according to the sealed source or plated foil manufacturer's (distributor's) and the kit supplier's instructions, and return 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 licensees 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 are specified in a license condition. Typically, leak tests are not required if

- sources contain only H-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 μ Ci] or less of beta-emitting or gamma-emitting material or 370 kilobecquerel (kBq) [10 μ Ci] 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)

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 according to NRC requirements. 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.

See Appendix N of this NUREG for more information on leak tests.

Response from Applicant for Unsealed Materials: Choose 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 in NUREG–1556, Volume 7, Revision 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’”

OR

- Submit a description of an alternate radiation survey program, including survey frequencies and contamination levels, to evaluate a radiological hazard.

Response from Applicant for Sealed Source and Plated Foils: Choose one of the following:

- State: “Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the SSD registration certificate.”

AND

- If leak tests will be analyzed by an outside entity, state: “Leak tests will be analyzed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee, using the instructions from the manufacturer (or distributor) of the sealed source or plated foil and the leak test kit supplier. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services.”

OR

- If leak tests will be analyzed by the applicant, state: “We will implement the model leak test program published in Appendix N in NUREG–1556, Volume 7, Revision 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope.’”

OR

- Submit a description of alternative equipment or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foil.

Note:

- Alternative responses will be reviewed using the guidance in this section.
- If a sealed source or plated foil is added to an existing license, then 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 NUREG–1556, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses,” Volume 18, for guidance on obtaining a license to perform leak testing as a service to others.

8.10.8 Transportation

Regulations: 10 CFR 71.5; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14, 10 CFR 71.47, and 10 CFR 71.87; 49 CFR Parts 171-178; 10 CFR 20.1101; 10 CFR Part 20, Appendix G; 10 CFR 30.41; 10 CFR 30.51; 10 CFR 40.51; 10 CFR 40.61; 10 CFR 70.42; 10 CFR 70.51.

Criteria: Applicants that 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.

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 that ARDL licensees ship frequently meet the “Limited Quantity” criteria as described in 49 CFR 173.421, “Excepted packages for limited quantities of Class 7 (radioactive) materials.” Therefore, they may be subject to DOT requirements, which may include 49 CFR 173.422, “Additional requirements for excepted packages containing Class 7 (radioactive) materials,” and 49 CFR 173.424, “Excepted packages for radioactive instruments and articles.” See Appendix O of this NUREG for more information. Packages requiring a DOT White-I, Yellow-II, or Yellow-III label have additional DOT requirements. Under 49 CFR 172.704—“Training requirements,” each person (shipper or carrier) involved in the transportation of radioactive materials must receive appropriate training for the jobs the employee performs related to transportation, every 3 years. These jobs include activities such as packaging radioactive materials, loading and securing the package on a vehicle, or preparation of paperwork for shipping the material.

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 ALARA.

All domestic shipping papers and labels must be in International System of Units (SI) units only or must be in SI units first with English units in parentheses.
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Licensees shipping radioactive waste for disposal must prepare appropriate documentation, as specified in Appendix G, “Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests” to 10 CFR Part 20.

Response from Applicant: No response is needed from applicants during the licensing phase. Transportation issues will be reviewed during inspections.

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 <http://www.nrc.gov/about-nrc/regulatory/enforcement/moudot.pdf>.

8.10.9 Security Program for Category 1 and Category 2 Radioactive Material

Regulations: 10 CFR Part 37

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

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

Discussion:

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

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

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

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

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

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

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

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

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

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

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1301, 10 CFR 20.1904, 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2008, 10 CFR 20.2108, 10 CFR Part 20, Appendices B and G, 10 CFR 30.51, 10 CFR 40.61, 10 CFR 61.52, 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 authorizes 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 ARDL 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
- extended interim storage

Licensees may choose one or more of these methods to dispose of their radioactive waste. The NRC has observed that most ARDL facilities 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 Incinerator 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 also may 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, also may 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.

Licensees may have to store waste for long periods of time. 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 prior to disposal as ordinary trash, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed. Applicants must maintain accurate records of such disposals.

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.

Release into Sanitary Sewerage

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

- Material is readily soluble (or is readily dispersible biological material) in water.
- Quantity of licensed material or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer does not exceed the concentration specified in 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 gigabecquerels (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 20," dated January 28, 1994, provides acceptable criteria for evaluating solubility of wastes released to the sewer. Liquid scintillation media and ash are examples of material that may or may not be "readily dispersible." Careful consideration should be given to the possibility of reconcentration of radionuclides released into the sewer. The NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewerage systems in IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted under 10 CFR 20.303 (now 10 CFR 20.2003)," dated December 21, 1984.

The regulations in 10 CFR 20.2003 are not applicable to releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas, pursuant to 10 CFR 20.1301. However, if licensed material is released to a private sewage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludges may be required to be disposed of as radioactive waste, using one of the methods described in Section 8.11 of this NUREG.

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 describes a model program for disposal of radioactive waste through sanitary sewer.

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 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 shipment 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 also may 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

Licensees should exhaust all possible alternatives for disposal of radioactive waste and rely on onsite extended interim storage of radioactive waste only as a last resort. Disposal, rather than storage, enhances the protection of workers and the public. Licensees also may 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 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. 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, updated this information. In addition, the NRC issued RIS 2011-09, "Available Resources Associated with Extended Storage of Low-Level Radioactive Waste," dated August 16, 2011, which refers to other helpful guidance documents.

Response from Applicant:

State that: "We will use the model waste procedures published in Appendix P in NUREG-1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"

OR

If the applicant wishes to use only selected model procedures, 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 in NUREG-1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"

AND

If the applicant wishes to compact or incinerate radioactive waste, provide the requested information concerning these activities in Appendix P to 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 by transfer to an authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14, as authorized by 10 CFR 20.2005.

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

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

References:

- Information Notice 94-23, “Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of a Minimization Program,” March 1994
- Information Notice 94-07, “Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20,” 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),” December 1984
- Information Notice 90-09, “Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees,” February 1990
- Regulatory Issue Summary 2004-17, “Revised Decay-in-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material,” Revision 1, September 2005

- Regulatory Issue Summary 2008-12, “Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees,” May 2008
- Regulatory Issue Summary 2011-09, “Available Resources Associated with Extended Storage of Low-Level Radioactive Waste,” August 2011
- Regulatory Issue Summary 2016-11, “Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002,” November 13, 2016
- 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)
- 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 (ADAMS Accession No. ML092460058)

8.12 Item 12: License Fees

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

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

8.13 Item 13: Certification

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

Notes:

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

9 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date refer to Title 10 of the *Code of Federal Regulations* (10 CFR) 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 or C of this NUREG, as applicable. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application.

9.1 Timely Notification of Transfer of Control

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

Criteria: Licensees must provide all supporting information and obtain the NRC's *prior, written consent* before transferring control of the license, also referred to as a "change of ownership" 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.
- Adequate financial assurance is provided for compliance with the applicable NRC requirements, if required.
- 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.

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

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

10 APPLICATIONS FOR EXEMPTIONS

Regulations: Title 10 of the *Code of Federal Regulations* (10 CFR) 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, 10 CFR 40.14, and 10 CFR 70.17, "Specific exemptions"). These regulations state that the NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

Exemptions are not intended to revise regulations or 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.

Until 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) 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 area is unsuitable for release according to NRC requirements
- Submit a decommissioning plan, if required by 10 CFR 30.36(g), 10 CFR 40.42(g), and/or 10 CFR 70.38(g).
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j), 10 CFR 40.42(h) and (j), and/or 10 CFR 70.38(h) and (j).
- Submit to the appropriate NRC regional office a completed NRC Form 314, "Certificate of Disposition of Materials" (or equivalent information), and information demonstrating that the premises are suitable for release for unrestricted use (e.g., final status surveys for facilities using unsealed materials; results of final leak tests of sealed sources).

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

- Before a license is terminated, send records important to decommissioning that are required by 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g) to the appropriate NRC regional office in accordance with 10 CFR 30.51(f), 40.61(f), and 70.51(a)(3), respectively.
- Before a license is terminated, send records of disposal of licensed material made under 10 CFR 20.2002, 20.2003, 20.2004, and 20.2005, and the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment to the appropriate NRC regional office in accordance with 10 CFR 30.51(d), 10 CFR 40.61(d), and/or 10 CFR 70.51(a)(1) and (2), if authorized to possess byproduct material with a half-life greater than 120 days in an unsealed form, source material in an unsealed form, and/or special nuclear material, respectively.

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

The permanent cessation of principal activities 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 further information about requirements that apply to the timeliness of decommissioning, see Regulatory Issue Summary (RIS) 2015-19, Revision 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. Most ARDL licenses should be able to use the methods found in Appendix B, "Simple Approaches for Conducting Final Radiological Surveys," of NUREG-1757, "Consolidated Decommissioning Guidance," Volume 2, "Characterization, Survey and Determination of Radiological Criteria." Licensees that have large facilities to decommission should review NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)." The computer code "DandD" offers an acceptable method for calculating screening values to demonstrate compliance with the unrestricted dose limits. Supplemental information on the implementation of the final rule on radiological criteria for license termination was published in the *Federal Register* (63 FR 64132) on November 18, 1998.

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

Response from Applicant: The applicant is not required to submit a response to the NRC during the initial application. The licensee's obligations in this matter begin when the license expires or at the time the licensee ceases operations, whichever is earlier. These obligations are to undertake the necessary decommissioning activities, to submit NRC Form 314 or equivalent information, and to perform any other actions summarized in "Criteria" above.

References:


- NRC Form 314 is available at <http://www.nrc.gov/reading-rm/doc-collections/forms>
- NUREG-1757, "Consolidated Decommissioning Guidance"
- NUREG-1575, Revision 1, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)"

APPENDIX A

U.S. NUCLEAR REGULATORY COMMISSION FORM 313

U.S. Nuclear Regulatory Commission Form 313

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

NRC FORM 313 (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 Infocollections.Resource@nrc.gov , and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.	EXPIRES: 06/30/2019		
INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-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/staffsr1656/. 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 1800 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.		11. WASTE MANAGEMENT.			
		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 _____	

NRC FORM 313 (10-2017)

APPENDIX B

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

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

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

The table below also may be used as a License Reviewer Checklist for applications for ARDL licenses.

Item No.	Suggested Response	Yes	Description Attached
5.	<p>RADIOACTIVE MATERIAL Unsealed or Sealed Byproduct Material</p> <ul style="list-style-type: none"> • For unsealed materials: <ul style="list-style-type: none"> — For each radionuclide, provide the element name with mass number, the chemical and/or physical form, and the maximum requested possession limit. * — For potentially volatile materials (e.g., I-125, I-131, H-3), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form. * • For sealed materials: <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 for each radionuclide. * — Provide the manufacturer's or distributor's name and model number for each sealed source and device requested. * — Confirm that each sealed source, device, and source/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, or source and device combination that is not registered, provide the applicable information, as described in 10 CFR 30.32(g) and 32.210. * • Provide an emergency plan, if required by 10 CFR 30.32(i) and 30.72 or 10 CFR 70.22(i) * 		<ul style="list-style-type: none"> [] [] [] [] [] [] []

Item No.	Suggested Response	Yes	Description Attached
5.	<p>RADIOACTIVE MATERIAL (Continued)</p> <p>Financial Assurance and Recordkeeping for Decommissioning 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 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)(3), 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> <p style="text-align: center;">AND</p> <p>If financial assurance is required, submit evidence of financial assurance following the guidance of NUREG–1757, Volume 3.</p>	<p>[]</p> <p>*</p>	<p>[]</p> <p>[]</p>
6.	<p>PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED</p> <p>List the specific use or purpose of each radionuclide.</p> <ul style="list-style-type: none"> — Provide a description of uses in animals, if applicable. — Provide a description of tracer or field studies, if applicable. 	<p>*</p> <p>*</p> <p>*</p>	<p>[]</p> <p>[]</p> <p>[]</p>
7.	<p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE</p> <p>Radiation Safety Officer (RSO)</p> <ul style="list-style-type: none"> • Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience. Information should include, at a minimum: <ul style="list-style-type: none"> — formal training or education in radiation safety [topics covered, duration of training, when training was received, identity and 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 an RSO (activities, duration of experience, scope of program) <p>Authorized Users (AUs) (persons who will use or supervise the use of licensed materials)</p> <ul style="list-style-type: none"> • Provide the name of each proposed AU, with the types and quantities of licensed material to be used. • Provide information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials. Information should include, at a minimum: 	<p>*</p> <p>*</p> <p>*</p>	<p>[]</p> <p>[]</p> <p>[]</p>

Item No.	Suggested Response	Yes	Description Attached
7.	<p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Continued) Authorized Users (AUs) (persons who will use or supervise the use of licensed materials) (Continued)</p> <ul style="list-style-type: none"> — formal training or education in radiation safety [topics covered, duration of training, when training was received, identity and 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 (Occupationally Exposed Individuals and Ancillary Personnel) Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.</p>	*	[]
9.	<p>FACILITIES AND EQUIPMENT</p> <ul style="list-style-type: none"> — Describe the facilities and equipment that will be available at each location where radioactive material will be used (see Appendix G of this NUREG for topics to consider). Include the area(s) assigned for the receipt, storage, security, preparation, measurement, use, and disposal of radioactive materials. — Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. — When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. — Diagrams should be drawn to a specified scale, or dimensions should be indicated. — For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted. — Describe how facility design and procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste. 	* * * * *	[] [] [] [] []
10.	<p>RADIATION SAFETY PROGRAM Audit Program The applicant is not required to, and should not, submit its audit program to the NRC for review during the licensing phase. However, the audit program may be reviewed during NRC inspections.</p>	N/A	N/A

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>Radiation Monitoring Instruments Describe the instrumentation that will be used to perform required surveys</p> <p style="text-align: center;">AND</p> <p>State that: “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix I in NUREG–1556, Volume 7, Revision 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’ We reserve the right to upgrade our survey instruments as necessary.”</p> <p>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.</p> <p style="text-align: center;">OR</p> <p>State that: “We will implement the model radiation survey meter calibration program published in Appendix I in NUREG–1556, Volume 7, Revision 1 ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’”</p> <p style="text-align: center;">OR</p> <p>Submit equivalent procedures for instrument calibrations.</p> <p>Material Receipt and Accountability</p> <ul style="list-style-type: none"> • State that: “We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times.” • If applicable, provide the following statement: “We will comply with the National Source Tracking System (NSTS) reporting requirement as described in 10 CFR 20.2207.” <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Provided either of the following: <ul style="list-style-type: none"> — 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 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer’s name and model numbers, and the date of the inventory.” <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> — Provide a description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced. 	<p style="text-align: center;">*</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">*</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">*</p>	<p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p>

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>Occupational Dose 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.”</p> <p style="text-align: center;">OR</p> <p>“We will monitor individuals in accordance with the guidance in the section titled, ‘Radiation Safety Program–Occupational Dose’ in NUREG–1556, Volume 7, Revision 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development and Other Licenses of Limited Scope.’”</p> <p style="text-align: center;">OR, IN LIEU OF THESE STATEMENTS,</p> <p>Provide a description of an alternative method for demonstrating compliance with the referenced regulations.</p> <p>Public Dose No response is required from the applicant in a license application, but compliance will be examined during inspection. During NRC inspections, licensees must be able to demonstrate, by measurement or calculation, that the TEDE to an individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See Appendix K of this NUREG for examples of methods to demonstrate compliance.</p> <p>Safe Use of Radionuclides, Security, and Emergency Procedures State that: “We will develop, implement, and maintain procedures for safe use, security and emergencies.”</p> <p style="text-align: center;">OR</p> <p>State that: “We will adopt the procedures for the safe use of radionuclides, security and emergencies as published in Appendix L in NUREG–1556, Volume 7, Revision 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’”</p> <p style="text-align: center;">OR</p> <p>Provide procedures for safe use of radionuclides, security of materials and emergencies.</p> <p>Emergency Plan If required by 10 CFR 30.32(i) and 30.72 or 10 CFR 70.22(i), provide an emergency plan for responding to the release of radioactive material, in accordance with the criteria listed in 10 CFR 30.32(i)(3) or 10 CFR 70.22(i)(3), as a separate part of the application.</p>	<p>[]</p> <p>[]</p> <p>*</p> <p>N/A</p> <p>[]</p> <p>[]</p> <p>*</p> <p>*</p>	<p>[]</p> <p>[]</p> <p>[]</p> <p>N/A</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p>

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>Surveys State: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"</p> <p style="text-align: center;">OR</p> <p>Submit a description of an alternate radiation survey program, including survey frequencies and contamination levels, to evaluate a radiological hazard.</p> <p>Leak Tests State: "Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the SSD registration certificate."</p> <p style="text-align: center;">AND</p> <p>If leak tests will be analyzed by an outside entity, state: "Leak tests will be analyzed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee, using the sealed source or plated foil manufacturer's (distributor's) and the leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services."</p> <p style="text-align: center;">OR</p> <p>If leak tests will be analyzed by the applicant, state: "We will implement the model leak test program published in Appendix N in NUREG–1556, Volume 7, Revision 1 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope.'"</p> <p style="text-align: center;">OR</p> <p>Submit a description of alternate equipment or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foils.</p> <p>Transportation No response is needed from applicants during the licensing phase. Transportation issues will be reviewed during inspections.</p> <p>Security Program for Category 1 and Category 2 Radioactive Material 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>[]</p> <p>*</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>*</p> <p>N/A</p> <p>N/A</p>	<p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>N/A</p> <p>N/A</p>

Item No.	Suggested Response	Yes	Description Attached
11.	<p>WASTE MANAGEMENT</p> <p>State that: “We will use the model waste procedures published in Appendix P in NUREG–1556, Volume 7, Revision 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’”</p> <p style="text-align: center;">OR</p> <p>If the applicant wishes to use only selected model procedures, 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 in NUREG–1556, Volume 7, Revision 1, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.’”</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 in Appendix P to this NUREG.</p> <p style="text-align: center;">OR</p> <p>If needed, the applicant should request authorization for extended interim storage of waste.</p>	<p>[]</p> <p>*</p> <p>*</p> <p>*</p>	<p>[]</p> <p>[]</p> <p>[]</p>

APPENDIX C

ELECTRON CAPTURE DETECTORS AND X-RAY FLUORESCENCE ANALYZER APPLICATIONS

Electron Capture Detectors and X-Ray Fluorescence Analyzer Applications

The U.S. Nuclear Regulatory Commission (NRC) has designed this Appendix to assist the applicant who needs to obtain a license only for a small source or device. Typical items include an electron capture detector (ECD), such as those used in a gas chromatograph (GC) or chemical agent detection or monitoring instrument, as well as small sealed sources used in an X-ray fluorescence analyzer (XRF). This appendix also may be used as guidance for completing a license application that may be for these sources or devices, as well as other requested radionuclides and proposed uses that have a similarly low radiation safety hazard level.

Regulations

Licensees are subject to all applicable provisions of the regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR Parts 20, 21, 30, 71, and 170, as they pertain to ECDs and XRFs.

This NUREG has already provided information for completing Items 1 through 4 of the application.

Additional information for Item 3 is requested below.

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

Specify the street address, city, and State, or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility where licensed material will be used or stored. A post office box address is not acceptable. In addition, state whether ECD/XRFs will be used at temporary jobsites.

Item 5: Radioactive Material

- (1) Provide the radionuclide(s) that each ECD/XRF will use.
- (2) Provide the manufacturer and model number of the detector cell, foil source, plated source, or sealed source that each ECD/XRF will use.
- (3) Specify the quantity (activity) of radioactive material that will be in each foil source, plated source, or other sealed source. Provide the number of sources of each foil source, plated source, or sealed source that will be possessed, if known. If the total number for each type of source is unknown, provide an anticipated total.

Note: ECDs that contain titanium tritide foils or scandium tritide foils require operating temperature control mechanisms and venting to the outside. Provide information on operating temperature controls and venting information with the application, if the application requests these types of foils.

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

Specify the purpose for which each ECD/XRF will be used.

Note: For use of portable ECDs and XRFs, refer to NUREG–1556, Volume 1, for additional guidance on portable devices containing licensed material.

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

Provide the name of the person(s) who will be responsible for the ECDs/XRFs. That person(s) will be specifically named on the license. If more than one person is named, designate a single person to be the Radiation Safety Officer (RSO).

If the applicant does not propose ECD or XRF repair or maintenance, then no specific training and experience in using and handling radioactive materials is necessary for individuals who will use the device(s) or supervise their use. No special training or experience is needed to perform leak tests using a leak test kit or to clean detector cells used in ECD devices, provided the source or foil is not removed from the detector cell.

Item 8: Training for Individuals Working In or Frequenting Restricted Areas

If the applicant proposes to perform any operations that involve removal of sources containing radioactive material from the device or maintenance and repair of a device that involves the source, then they must ensure a “responsible individual” performs these operations. The responsible individual will have received instruction and training in the principles and practices of radiation safety, the use of radiation detection instruments, and the performance of these operations. Such training may normally be accomplished in 1 or 2 days. In the application, provide the following information:

- Name of each responsible individual who will perform the operations.
- Outline of the instruction and training each responsible individual has received in the principles and practices of radiation safety, the use of radiation detection instruments, and the operations that will be performed, including actual practice in performing the operations. Specify the amount of time spent on each topic in the training.

Persons who will only use an ECD or XRF under the supervision of the responsible individual named in Item 7 need no special training, and their names do not need to be submitted. These supervised individuals should not be permitted to perform any maintenance or repair operations. Only responsible individuals specifically named in Item 7 may perform such operations.

Item 9: Facilities and Equipment

10 CFR 30.33(a)(2) states that an application will be approved if the applicant’s proposed equipment and facilities are adequate to protect health and to minimize danger to life or property. As stated in 10 CFR 20.1801 and 10 CFR 20.1802, licensed material stored in an unrestricted area must be secured from unauthorized removal, and licensed materials in an unrestricted area and not in storage must be under the constant surveillance and immediate control of the licensee. These requirements also apply when such devices are used at temporary job sites.

The room, laboratory, or storage area where the device is located should be (i) accessible only to persons authorized to use the device and (ii) locked when an authorized person is not physically present. The application should state that the laboratory or area will be locked or

secured when an authorized person is not present. The room, laboratory, or storage area cannot be considered a restricted area if it is accessible to unauthorized persons.

Describe the facilities where ECD/XRFs will be used and stored. State that the laboratory or area where devices are stored will be locked or secured when an authorized person is not present. Additional information on the use and storage of ECD/XRFs at a temporary jobsite also should be included in the response.

Item 10: Radiation Safety Program

10.1 Audit Program

Licensees must review the content and implementation of their radiation protection programs annually to ensure compliance with NRC regulations and with the terms and conditions of the license. Appendix H of this NUREG contains a suggested audit program that is acceptable to the NRC. All areas indicated in Appendix H of this NUREG may not be applicable to every licensee and may not need to be addressed during each audit.

The applicant is not required to, and should not, submit its audit program to the NRC for review during the licensing phase. However, the audit program may be reviewed during NRC inspections.

10.2 Radiation Monitoring Instruments

A radiation survey instrument for routine uses of ECD/XRF is not required.
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If maintenance and repair operations are proposed as described in Item 7, and the operations involve the sealed source, provide information about the surveys to be performed, the type of radiation survey meter to be used for conducting surveys, the range of the survey instrument, and calibration information, including frequency of calibration. It is not necessary to specify the manufacturer and model number of the radiation survey meter. For more information on radiation survey meters, see "Radiation Safety Program—Instruments," in Section 8.10.2 and Appendix I of this NUREG.

10.3 Material Receipt and Accountability

Licensees are required to maintain records of receipt, transfer, and disposal of licensed material. Loss, theft, or misplacement of licensed material can occur; therefore, control and accountability of ECDs or XRFs must be ensured. License conditions require licensees that use or possess sealed sources to perform inventories of sealed sources every 6 months. Some sealed sources may not be in use or rarely used and are placed into storage. In these cases, licensees should confirm at least every 6 months that these sealed sources have not been disturbed. If authorization is requested to use the devices at temporary jobsites, the licensee should develop procedures that address sign-out of devices for use in the field, control and security of the device in the field, and use of the device to ensure protection of members of the public.

10.4 Occupational Dose

Personnel monitoring devices are not required for the following:

- routine use and normal operation of ECDs/XRFs
- maintenance and repair operations described in Item 7, if the radiation source in the ECD/XRF is in a gaseous form or is nickel-63 (Ni-63)

If proposed uses of ECDs/XRFs include maintenance and repair operations described in Item 7, and these operations involve sealed sources other than in gaseous form, tritium [H-3], or Ni-63, an evaluation for personnel monitoring devices is required for persons performing these operations.

The application should indicate that maintenance and repair personnel will be provided with appropriate personnel dosimeters for use while performing service operations or a dose evaluation indicating that personnel will not be required to wear monitoring devices.

10.5 Public Dose

The applicant is not required to submit a response to the public dose section during the licensing phase. Public dose will be reviewed during inspections to determine compliance with NRC regulations.

10.6 Leak Tests

The NRC requires testing to determine if there is any radioactive leakage from sealed or plated foil sources. Records of surveys and leak test results must be maintained.

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

The NRC or an Agreement State may authorize manufacturers, consultants, and other organizations to perform the entire leak test sequence for other licensees or to provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample, according to the sealed source or plated foil manufacturer's (distributor's) and the kit supplier's instructions and return the sample to the leak test service provider for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees also may be authorized to conduct the entire leak test sequence. For more information about leak testing sealed and plated foil sources, see Section 8.10.7, "Surveys and Leak Tests," in the main body of this NUREG.

10.7 Maintenance

If authorization has been requested to perform maintenance and repair operations as stated in Item 8, then state in the application that the written procedures that the device manufacturer provided will be followed for each operation requested. If a procedure other than that provided

by the device manufacturer will be followed, submit a proposed procedure for each operation requested.

10.8 Transportation

If the application requests authorization to use ECDs or XRFs at a temporary jobsite, the applicant must take into consideration U.S. Department of Transportation regulations, particularly blocking and bracing the device containing licensed material. The applicant is not required to submit transportation information with the application. However, transportation issues will be reviewed during inspections.

Item 11: Waste Management

Because of the nature of the licensed material contained in ECD or XRF devices, the usual disposal option is to transfer the licensed material to an authorized recipient. State in the application that disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it, or provide information for an alternate method of disposal for NRC review.

Authorized recipients are the original supplier of the device, a commercial firm that the NRC or an Agreement State has licensed to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to receive licensed material.

Applicants should submit the NRC Form 313, which can be found in Appendix A of this NUREG. Provide the information requested in Items 1 through 4 directly on the form. Information for the remainder of the application should be attached.

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

C.5 ITEMS 5 & 6: RADIOACTIVE MATERIAL & PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Yes	No	Radionuclide	Manufacturer and Model No.	Quantity (activity per source, number of sources in device, and maximum number of sources)	Purpose of Use	Specify Other Uses Not Listed on SSD Certificate
X		EXAMPLE Nickel 63	EXAMPLE: Good Company Model A1	EXAMPLE: 15 mCi	EXAMPLE Sample analysis	EXAMPLE [x] Not applicable [] Uses are:

Yes	No	Radionuclide	Manufacturer and Model No.	Quantity (activity per source, number of sources in device, and maximum number of sources)	Purpose of Use	Specify Other Uses Not Listed on SSD Certificate
		Hydrogen-3 ¹				<input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are:
		Iron-55				<input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are:
		Cobalt-57				<input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are:
		Nickel-63				<input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are:
		Americium-241				<input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are:
		Other (specify)				

¹If titanium tritide foils or scandium tritide foils are requested, provide operating temperature control and venting information. (See "Note" in Item 5 of this appendix.)

C.6 ITEMS 7 THROUGH 11: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE, TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS, FACILITIES AND EQUIPMENT, RADIATION SAFETY PROGRAM, AND WASTE MANAGEMENT

Item No.	Title and Criteria	Yes	Description Attached
7.	INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE RSO Name: _____ Name(s): _____ _____ _____ _____		

Item No.	Title and Criteria	Yes	Description Attached
8.	<p>TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS</p> <p>If persons will perform any operations that involve removal of sources containing radioactive material from the device or maintenance and repair of a device that involves the source, then</p> <ul style="list-style-type: none"> • Provide the name of each responsible individual who will perform the operations. • Provide an outline of the instruction and training each responsible individual has received in the principles and practices of radiation safety, the use of radiation detection instruments, and the operations that will be performed, including actual practice in performing the operations. Specify the amount of time spent on each topic in the training. <p>Individuals working under the supervision of a responsible person named in Item 7, above, are not required to have any specific radiation safety training before using an ECD/XRF.</p>		Submit description with application
9.	<p>FACILITIES AND EQUIPMENT</p> <p>Describe the facilities where ECD/XRFs will be used and stored. State that the laboratory or area where devices are stored will be locked or secured when an authorized person is not present. Additional information on the use and storage of ECD/XRFs at a temporary jobsite also should be included in the response.</p>		Submit description with application
10.	<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 during the licensing phase. However, the audit program may be reviewed during NRC inspections.</p> <p>Radiation Monitoring Instruments</p> <p>A radiation survey instrument for routine uses of ECD/XRF is not required.</p> <p style="text-align: center;">OR</p> <p>If the applicant proposes to perform maintenance and repair operations, provide information about the surveys to be performed, the type of radiation survey meter to be used for conducting surveys, the range of the survey instrument, and calibration information, including frequency of calibration.</p>		N/A
		[]	[]

Item No.	Title and Criteria	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>Material Receipt and Accountability 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.</p> <p>If the devices will be used at temporary job sites, confirm that procedures will be developed and implemented to address sign-out of devices for use in the field, control and security of the device in the field, and use of the device to ensure protection of members of the public.</p> <p>Occupational Dose Personnel monitoring devices are not required for the routine use and normal operation of ECDs/XRFs.</p> <p style="text-align: center;">OR</p> <p>If the applicant proposes to perform maintenance and repair operations of a device that involves a source (other than in gaseous form, H-3 or Ni-63), state that: "We will maintain, for NRC inspection, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20," or state "We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Volume 7, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development and Other Licenses of Limited Scope.'"</p>	<p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p>	
	<p>Public Dose The applicant is not required to submit a response to the public dose section during the licensing phase. Public dose will be reviewed during inspections to determine compliance with NRC regulations.</p>		N/A
	<p>Leak Tests Leak tests will be performed at intervals specified in the SSD registration certificate. Leak tests will be performed by an organization that the NRC or an Agreement State has authorized to provide leak testing services for other licensees, or they will be performed using a leak test kit that an organization authorized by the NRC or an Agreement State has supplied to provide leak test kits to other licensees.</p>	[]	

Item No.	Title and Criteria	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>Maintenance If authorization has been requested to perform the maintenance and repair operations described in Item 7, state in the application that the written procedures that the device manufacturer provided will be followed for each such operation requested.</p> <p style="text-align: center;">OR</p> <p>If a procedure will be followed other than that the device manufacturer provided, submit a proposed procedure for each operation</p> <p>Transportation The applicant is not required to submit its response to transportation during the licensing process. However, transportation issues will be reviewed during inspections.</p>	<p>[]</p> <p>*</p>	<p>[]</p>
		N/A	
11.	<p>WASTE MANAGEMENT</p> <p>ECDs/XRFs Disposal and Transfer Disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it.</p> <p style="text-align: center;">OR</p> <p>Provide information for an alternate method of disposal.</p>	<p>[]</p> <p>*</p>	<p>[]</p>

APPENDIX D
GUIDANCE FOR LABORATORY ANIMAL AND VETERINARY
MEDICINE USES

Guidance for Laboratory Animal and Veterinary Medicine Uses

This appendix provides additional information on the use of byproduct materials in laboratory animals, in animals used for research in the environment, and by veterinarians.

Applicants should note that authorization from the U.S. Nuclear Regulatory Commission (NRC) to use licensed material in animal studies does not relieve them of their responsibilities to comply with any other applicable Federal, State, or local regulatory requirements.

Use of Licensed Materials in Animals for Research

Many animal studies are performed with radioactive materials used as tracers in pharmaceutical research, metabolism studies, and other areas of scientific research. Many tracer studies use low-energy beta-emitters such as tritium or carbon-14, but pharmaceutical studies may be performed with gamma-emitters, such as technetium-99m, fluorine-18, and other radioactive materials typically found in nuclear medicine. In addition to the typical laboratory animals, such as mice, rats, and rabbits, animal use may involve insects, fish, birds, or large animals, such as dogs, pigs, or cows. Licensed materials typically are administered to animals by injection, but other methods may be used. The type, form, and quantity of licensed material used in the study, and the types of animals in which they will be used, will determine which radiation safety procedures will be implemented. If a researcher wants to use radioactive material as a tracer or as part of a field study involving the release of the animals into the environment, the researcher may be required to perform an assessment of the effect the byproduct material will have on the environment. See Section 8.6, "Purpose(s) for Which Licensed Material Will Be Used."

Use of Licensed Materials in Veterinary Treatment for Diagnosis or Therapy

The use of licensed materials in animals for diagnosis and therapy is similar in many ways to medical use of licensed materials in humans. The most common veterinary uses of licensed material in animals are the administration of iodine-131 for therapeutic treatment of cats and the administration of technetium-99m for diagnostic studies in horses. Although Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR Part 35 establishes the requirements and provisions for the medical use of byproduct material for humans, the regulations in Part 35 are not applicable to veterinary use of licensed materials. However, many veterinary applicants use safety equipment and procedures similar to those used in treating patients under Part 35. Also, many veterinarians obtain radioactive compounds, radiopharmaceuticals, or sealed sources for diagnosis and therapy of animals from the same suppliers as do medical facilities licensed under Part 35.

The applicant should describe how licensed materials will be obtained, such as in unit doses from a radiopharmacy. The requirements for training veterinary staff, and the procedures for contamination control and waste disposal for diagnosis and therapy, are the same as for laboratory use in research studies on animals. Note that veterinary treatment of animals must be performed under the direction of a licensed veterinarian, in accordance with State regulations, so that the applicant should include at least one veterinarian in its list of proposed Authorized Users (AUs). Most animals that veterinarians treat are pets that will be returned to their owners, and special care must be taken to ensure that doses to the owners, who are members of the public, will be as low as is reasonably achievable (ALARA). Therefore, the veterinary facility must also provide instructions to the pet owner on the care and handling of the animal when it is released.

Training for Staff Using Radionuclides in Animals

Before allowing an individual to care for animals that are used in studies or treated with licensed material, the radiation safety officer or AU must ensure that he or she has sufficient training and experience to, among other things, maintain doses ALARA, control contamination, and handle waste appropriately. AUs may be, for example, veterinarians, researchers, other laboratory staff, and animal handlers.

Classroom training may be by traditional lecture, online or recorded presentations, self-study, or other appropriate forms, and should cover the following subject areas:

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and using instruments
- mathematics and calculations basic to using and measuring radioactivity
- biological effects of radiation

Appropriate on-the-job-training should consist of

- Observing authorized personnel perform licensed activities with animals, including administration of the radioactive material to the animal, using survey equipment, proper contamination control techniques, and proper methods for disposal of radioactive material.
- Performing licensed activities with animals under the supervision of, and in the physical presence of, an individual authorized to handle animals treated with licensed material or otherwise containing licensed material. It is recommended that an individual practice new procedures without the use of radioactive materials prior to performing licensed activities. Activities should include the administration of radioactive material to an animal, use of survey equipment, proper contamination control techniques, and proper disposal of radioactive material.
- Training that is specific to the radionuclides (types, forms, and quantities; radiations emitted; chemical composition) used under the license, the procedures that will be performed, the animals used, and the surveys and contamination control activities necessary for the materials used and procedures performed.

Contamination Control

To minimize the spread of contamination, the animals administered licensed material should be housed in cages or stalls separate from other animals. The facilities, stalls, or cages should be secured to prevent unauthorized access to the animals. Animal housing should be clearly posted or labeled so that caretakers know which animals have been involved in radioactive material studies. Care should be taken when posting/labeling cages to ensure that the posting or labeling does not become an ingestion or choking hazard to the animal. Individuals caring for these animals should reduce the chance of personal contamination by wearing gloves, lab coat, eye protection, or other protective clothing, as appropriate.

Special care should be observed when cleaning a cage or stall that may contain radioactive material in the bedding and waste (excreta) from the animal. Any radioactive material should be properly disposed of as described in Section 8.11, "Waste Management."

The use of some compounds in animals may require special procedures, equipment, or facilities. For example, carbon-14 labeled compounds used in animals may be eliminated as carbon dioxide in the animals' breath, and the animals may need to be contained in a facility with special ventilation and air-handling capabilities. Studies of fish with licensed materials may require separate water handling and testing. Special precautions also may be needed for handling of animals and performing surveys if alpha-emitting radionuclides are used.

Waste Handling

Disposal of animal carcasses that contain radioactive material may require special procedures. Animal carcasses that contain less than 1.85 kilobecquerels [0.05 microcuries] of carbon-14 or hydrogen-3 per gram of animal tissue, averaged over the weight of the entire animal, may be disposed of by the same method as nonradioactive animal carcasses. Animal carcasses that contain byproduct material with a half-life of less than 120 days may be allowed to decay-in-storage (DIS). The DIS animal carcasses may be disposed of as nonradioactive, if radiation surveys (performed with an appropriate radiation survey instrument, in a low background area, and without any interposed shielding) of the carcasses at the end of the holding period indicate that radiation levels are indistinguishable from background. Animal carcasses containing other long-lived radioactive materials must be disposed of as radioactive waste.

Disposal of contaminated items such as animal bedding, syringes, protective gloves, booties, and paper coverings may be by DIS if the licensed materials have half-lives of 120 days or less, or by transfer to a licensed waste broker for long-lived radioactive materials. Some wastes may be suitable for disposal to the sanitary sewer, such as animal excreta, which is readily dispersible biological material and could meet the criteria in 10 CFR 20.2003. See Section 8.11, "Waste Management," and Appendix P of this NUREG for more information on waste disposal.

Release of Animals for Unrestricted Use

Any animal that has been injected with a radioactive compound or has had radioactive sources implanted cannot be released until the researcher or veterinarian ensures that the dose that members of the public will receive from the animal is within limits of 10 CFR 20.1301, "Dose limits for individual members of the public." Regulations in 10 CFR 20.1301 require that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 millisievert (mSv) [0.1 rem or 100 millirem (mrem)] in a year and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv [0.002 rem or 2 mrem] in any 1 hour. **A member of the public is any individual, except when that individual is receiving an occupational dose. Members of the public, therefore, include bystanders, pet owners, family members, or other caretakers of the animal after the researcher or veterinarian has released it.**

Scientists or veterinarians may release animals that received radioactive material for diagnostic, therapeutic, or research purposes to animal caretakers after treatment. These animals are considered "radioactive" and placed in cages and rooms that are posted/labeled with appropriate warning signs until the animals can be released to the "uncontrolled" population or their owners. Criteria should be developed by the licensee for assessing this release. Items to be considered for release of the animals include the type of radionuclide and concentration in the urine and/or feces; and the dose rate on contact (or at some distance from) the accessible side of the cage.

The most common example of a situation in which animals are treated with licensed materials and then released is the administration of iodine-131 (I-131) to cats for the treatment of hyperthyroidism. Therefore, this treatment will be used as an example for release of animals following administration of licensed material.

Cats can be released after treatment with I-131 when:

- cats are held not less than 4 complete days [96 hours] after administration

AND

- the dose rate is less than 0.01 mSv per hour (mSv/h) [1 milliroentgen (mR)/hour (h)] at 6 inches {or 0.0025 mSv/h [0.25 mR/h] at 1 foot}

AND

- written instructions are provided to the owners

AND

- the licensee can demonstrate that a member of the public would not receive a dose from the cat that would exceed 0.02 mSv [0.002 rem or 2 mrem] in any one hour or 1 mSv [0.1 rem or 100 mrem] in a year (the limits of 10 CFR 20.1301)

The licensee must ensure that the dose from a cat treated with I-131 to individual members of the public (including members of the family) does not exceed the 0.02 mSv [0.002 rem or 2 mrem] in any one hour, and 1 mSv [0.1 rem or 100 mrem] annual public dose limit specified in 10 CFR 20.1301. The licensee should provide the owner with written instructions (to avoid confusion) to reduce the dose to members of the public. The instructions should provide a margin for dose reduction but should not be relied upon as the primary way of keeping the dose to members of the public below the 1 mSv [0.1 rem or 100 mrem] public dose limit.

In applying the above criteria for release of cats, patient-specific information and radiation data should also be considered. The dose rate of 0.0025 mSv/h [0.25 mR/h] at 1 foot is a conservative release criteria. If the owner follows instructions to limit interaction with the cat for the first few days, it is unlikely that a person would receive a 1 mSv [0.1 rem or 100 mrem] dose. The applicant must include criteria for release of cats treated with licensed materials from veterinary or laboratory activities in its application for review and approval, before implementation. The NRC may accept alternate proposed criteria for veterinary cat release if (i) the instructions pertaining to the extent and duration of contact permitted with the cat are easy for the owner to comply with, and (ii) the potential dose would be well below 0.02 mSv [0.002 rem or 2 mrem] in any one hour and 1 mSv [0.1 rem or 100 mrem] in a year. Such proposals will be reviewed on a case-by-case basis. Additional consideration may be necessary when establishing the date for release of a cat treated with I-131 to a home with small children.

For cats, release criteria above 0.5 mR/h at 1 foot are not recommended because it is unlikely that, if release criteria is less restrictive, doses to members of the public will be less than 0.02 mSv [0.002 rem or 2 mrem] in any one hour, and less than 1 mSv [0.1 rem or 100 mrem] in a year. In addition, cats released at higher radiation levels also may contain enough radioactive material that I-131 contamination of the owner and home from saliva, urine, and feces may be of concern.

Criteria for release of cats and other animals treated with licensed materials from veterinary or laboratory activities must be included in the application for review and approval, before implementation. Regardless of the release level used, the licensee should have records to document that the veterinary patient release criterion used for an individual veterinary patient will result in compliance with 10 CFR 20.1301.

Instructions to Animal Caretaker upon Release

Once the veterinarian determines that the animal meets the dose criteria for release, instructions should be given to the animal's caretaker. Written instructions should address, at a minimum: (i) waste handling, (ii) contamination, and (iii) human interaction with instructions for isolation of the animal.

These instructions should be specific to the type of treatment given, such as permanent implants, or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. The instructions should not, however, interfere with or contradict the best medical judgment of the veterinarian. The instructions should include the name of a knowledgeable person to contact and that person's telephone number, in case the caretaker has any questions.

Although it is acceptable to immediately dispose of nonradioactive animal excreta in a landfill, radioactive waste may not be disposed of in this way. For animals treated with short-lived radioactive materials, instructions to caretakers should include storing animal excreta in an appropriate location for a designated period of time to allow the radioactive material to decay. Many solid waste disposal facilities have installed radiation detectors to prevent the disposal of radioactive material at landfills. If the detectors indicate that there is radioactive material in the waste truck, the waste disposal facility staff or a contractor must search the truck and remove the radioactive material, which is a hazardous, costly, and time-consuming process.

Items to consider including in the instructions are

- the regulatory limits and the need to keep doses ALARA
- the potential radiation fields surrounding the animal and potential dose with time at various distances
- maintaining distance from people in public places and the home
- minimizing time in public places (e.g., walks on public sidewalks, parks, beaches, grooming salons)
- precautions to reduce the spread of radioactive contamination
- the handling and storage of animal excreta, and the duration of storage if held for decay
- the permitted extent and duration of contact by individuals with the animal, and handling of contaminated bedding and other objects with which the animal comes into contact.
- the length of time each of these precautions should be in effect

Sample Instructions to Caretakers of Animals Administered Radiopharmaceuticals or Other Unsealed Radionuclides

The animal has been treated with radioactive material [Insert isotope] and still contains a low level of radioactivity. The present level of radioactivity is below the regulatory agency level necessary for isolating the animal from humans. Because some radioactivity will be present for the next few days, it is necessary that the following safety precautions be exercised for the next days:

- Avoid public transportation; avoid staying in public accommodations (e.g., hotels). Transport your animal in its carrier as far from passengers as is reasonable and safe for the animal.
- The animal should be kept inside or in his cage or stall following hospital discharge.
- The animal should not be permitted to have prolonged contact with children under the age of 12 for ___ days following hospital discharge. Close contact should be limited to less than ___ minutes per day.
- Pregnant women should avoid ANY contact with the animal or its urine and feces for at least ___ days after discharge.
- Family members should not be permitted to sleep with the animal for ___ days after discharge. They also should limit close contact with the animal (being within 1 meter or 3 feet of the animal) for the next ___ day(s) to no more than ___ minutes a day. Preferably, contact with the animal should be kept to a distance of more than 1 meter or 3 feet for this period.
- Use plastic litter pan liners and scoopable litter (for cats).
- Disposable gloves should be worn whenever handling animal waste, including changing the litter box for the next _____ days after discharge.
- Wash hands after contact with the animal or the litter.
- Call _____ to discuss any other radiation safety concerns.

Sample Instructions to Caretakers of Animals Implanted with Radioactive Sealed Sources

A small radioactive source has been placed (implanted) inside the animal. The source actually consists of many small metallic pellets or seeds, which are each about 1/4-inch to 1/3-inch long, similar in size and shape to a grain of rice.

The following precautions should be taken for ___ days, to minimize exposure to radiation to humans from the source inside the animal:

- Stay at a distance of _____ feet from _____.
- Avoid public transportation.
- Transport your animal in its carrier as far away from passengers as is reasonable.
- Maintain separate sleeping arrangements, and avoid staying in public accommodations (e.g., hotels).
- Minimize time that children and pregnant women are with the animal.
- Do not hold or cuddle the pet.
- Examine any bandages that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.

If a seed or pellet has fallen out, do the following:

- Do not handle it with fingers. Use something like a spoon or tweezers to place it in a jar or other container that can be closed with a lid.
- Place the container with the seed or pellet in a location away from people.
- Call _____ to discuss disposal of the released seed or pellet and any other radiation safety concerns.

APPENDIX E

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 (see Figure 8-5). Typically, these duties and responsibilities include the following:

- Ensure that licensed material that the licensee possesses is limited to the types and quantities of byproduct material listed on the license.
- Maintain documentation demonstrating 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) 10 CFR 20.1301.
- Ensure security of radioactive material.
- Post documents as required by 10 CFR Parts 19.11, "Posting of notice to workers," and 10 CFR 21.6, "Posting requirements."
- 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 used.
- Act as liaison with the 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 institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material before use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping of 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 that the license authorizes.
- Immediately terminate any unsafe condition or activity found to be a threat to public health and safety or property.
- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above, for example, records of receipts, transfers, and surveys as required by 10 CFR 30.51, "Records," and 10 CFR Part 20, Subpart L, "Records."
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all radioactive materials users are properly trained.
- Perform periodic audits of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license (e.g., leak tests; inventories; use limited to trained, approved users); 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 required records are 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; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all radiation workers, including ancillary personnel.
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or 10 CFR Part 20 limits are investigated and reported to the NRC and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and keep up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to NRC during the licensing process.
- Develop, implement, maintain, and distribute, as appropriate, up-to-date operating, emergency, and security procedures.

Model Delegation of Authority for Radiation Safety Officer

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

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

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads

APPENDIX F
RADIATION SAFETY TRAINING TOPICS

Radiation Safety Training Topics

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

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
- 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. Ordering and receiving radionuclides
- C. Applicable regulations and license conditions
- D. Areas where radioactive material is used or stored

- E. Potential hazards associated with radioactive material in each area where the individuals will work
- F. Appropriate radiation safety procedures
- G. Licensee's in-house work rules (For instructions on laboratory safety and uses of radionuclides, see Section IV.)
- H. Each individual's obligation to report unsafe conditions to the RSO.
- I. Appropriate response to spills, emergencies, or other unsafe conditions
- J. Workers' right to be informed of occupational radiation exposure and bioassay results, if applicable
- K. Locations where the licensee has posted or made available (i) notices, (ii) copies of pertinent regulations and licenses, and (iii) license conditions (including applications and applicable correspondence), as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR Part 19
- L. Emergency procedures
 1. RSO name and telephone number
 2. immediate steps to prevent or control spread of contamination
 3. cleanup instructions, decontamination
- M. Survey program
 1. survey instrument accessibility
 2. who is responsible
 3. types, contamination, and area
 4. frequency
 5. levels of contamination
 6. personnel, hands, shoes
 7. records
- N. 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. incineration
 9. records
- O. Dosimetry
 1. whole body
 2. extremities
 3. lens of eye
 4. lost or replacement badges and dose assessment
 5. bioassay procedures
 6. records

- P. Instrumentation
 - 1. radiation survey meters—use, calibration frequency, use of check sources
 - 2. analytical instruments—gas chromatographs, liquid scintillation counters
- Q. 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
- R. Procedures for opening and examining packages
 - 1. leakage and contamination
 - 2. monitoring packages
 - 3. monitoring packing materials
 - 4. gloves
 - 5. transferring material to users
- S. 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
 - 4. security
- T. Sealed sources
 - 1. leak test requirements
 - 2. inventory requirements
 - 3. exempt quantities
 - 4. records
- U. Other topics, as applicable
- V. Question and answer period

For Laboratory Safety and Use of Radionuclides

- A. Control procedures for obtaining permission to use radioactive materials at the facility; give limitations on quantity to be handled per user, allowed per experiment, etc.
- B. Protective clothing and what laboratory apparel to wear and which equipment to use.
- C. Limitations and conditions relative to handling unsealed licensed material and which laboratory equipment to use when working with such material. As an example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or gloveboxes. Explain what shielding or remote handling equipment should 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, or 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 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 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 used.

APPENDIX G
FACILITIES AND EQUIPMENT CONSIDERATIONS

Facilities and Equipment Considerations

Below is a list of topics that should be considered when developing a description of the facilities and equipment that an academic, research and development, and other licenses of limited scope (ARDL) licensee will use or otherwise have available. Not every ARDL applicant will need to address each topic in its application.

- Restricted areas are defined as areas where the licensee limits access to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.
- 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 nonporous to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems. Ventilation systems for these facilities should be designed so that airborne radioactive material work areas are at negative pressure compared to 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 Title 10 of the *Code of Federal Regulations* (10 CFR) 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 containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.
- For the most efficient operation of hoods and glove boxes, minimize storage of materials and equipment inside the work areas.

- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity. If appropriate, supply and exhaust fans can be interlocked such that if exhaust fans shutdown, the shutdown of supply fans is also triggered. This interlock system prevents laboratory and work areas from becoming positively pressurized with respect to the surrounding parts of the facility.
- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow, rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- To reduce radiation exposure from gamma-emitting radioactive materials, shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods, or in glove boxes.
- To reduce the exposure from high-energy beta-emitting materials, shielding of low atomic number material, such as high-density plastic, may be used.
- Shielded shipping containers frequently are used for continued storage after receipt of materials.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (as low as is reasonably achievable). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination buildup.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of 10 CFR Part 20, Subpart H, "Respiratory protection and controls to restrict internal exposure in restricted areas."

- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on the number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded, as necessary, placed near the waste-generating areas and away from areas that personnel frequently occupy. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited. If radioactive waste materials are volatile, the containers should be stored in ventilated areas.
- If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed, per 10 CFR 20.1204.
- 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 H
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) 10 CFR 20.1101 for an annual review of the content and implementation of the licensee's radiation protection 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 a 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 also should evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement.

The form in this appendix can be used to document the annual audit of the radiation protection program. Guidance on completing each section of the form is listed 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 if the radiation safety officer (RSO) is the person identified on 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.

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 survey instruments available, that the instruments are calibrated (at the required

frequency) in accordance with license conditions and in accordance with 10 CFR 20.2103. Calibration records must be retained for 3 years after the record is made. Verify compliance with 10 CFR 20.1301. Check that radiation levels in areas adjacent to use are within regulatory limits and records are in accordance with 10 CFR 20.2103. Records of surveys must be retained for 3 years after the record is made.

Section 10–Receipt and Transfer of Radioactive Material (Includes Waste Disposal).

Verify that packages containing byproduct material, received from others, are received, opened, and surveyed in accordance with 10 CFR 20.1906, “Procedures for receiving and opening packages.” Ensure that transfers are performed in accordance with 10 CFR 30.41, 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 U.S. Department of Transportation (DOT) requirements, if applicable.

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 that the licensee made or used.

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 20.1501(b) and 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, and Office of Nuclear Material Safety and Safeguards (NMSS) newsletters) issued since the previous audit and applicable to academic, research and development, and other licenses of limited scope have been reviewed. Check whether the licensee took appropriate action (e.g., training, updating procedures, etc.) 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 or deficiencies identified during last two audits or 2 years,
whichever is longer Y N

C. Open problems or deficiencies from previous audits:

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

D. Any previous problem or deficiency not corrected or repeated Y N N/A
 Explain:

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Briefly describe organizational structure

- 1. Structure is as described in license documents Y N
- 2. Multiple authorized locations of use Y N
- 3. Briefly describe scope of activities involving byproduct material, frequency of use, staff size, etc. Y N
- 4. Amendments and program changes Y N

B. Radiation safety officer Y N

- 1. Authorized on license Y N
- 2. Fulfills duties as RSO Y N

C. Use only by authorized individuals Y N

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

- A. Instructions to workers per 10 CFR 19.12 Y N
- B. Training program required Y N
- C. Training records maintained Y N
- D. Evaluation of individuals' understanding of procedures and regulations based on interviews, observation 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:
 - Current safe use procedures Y N
 - Emergency procedures Y N

E. 10 CFR Part 20

Workers cognizant of requirements for:

- 1. Radiation Safety Program (10 CFR 20.1101) Y N
- 2. Annual dose limits (10 CFR 20.1301, 20.1302) Y N
- 3. New NRC Forms 4 and 5 Y N
- 4. 10 percent monitoring threshold (10 CFR 20.1502) Y N
- 5. Dose limits to minors (10 CFR 20.1207) Y N
- 6. Dose limits to embryo or fetus and declared pregnant women (10 CFR 20.1208) Y N
- 7. 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 annually [10 CFR 20.1101(c)] Y N

- C. Records maintained (10 CFR 20.2102) Y N

5. FACILITIES

- A. Facilities as described in license application

- B. Commensurate security procedures implemented (20.1801, 20.1802; Part 37 if applicable) Y N

Remarks:

6. MATERIALS

Isotopes, quantities, and use as authorized on license Y N

Remarks:

7. LEAK TESTS

A. Leak test performed as described in correspondence with the NRC (consultant, leak test kit, licensee performed) Y N

B. Frequency: every 6 months or other interval, as approved by NRC or Agreement State Y N

C. Records with appropriate information maintained Y N

Remarks:

8. INVENTORIES

A. Conducted at 6-month intervals Y N

B. Records with appropriate information maintained Y N

Remarks:

9. RADIATION SURVEYS

A. Instruments and Equipment: Y N

1. Appropriate operable survey instrumentation possessed or readily available Y N

2. Calibrated as required (10 CFR 20.1501) Y N

3. Calibration records maintained [10 CFR 20.2103(a)] Y N

B. Briefly describe survey requirements [10 CFR 20.1501(a)]

1. Airborne radioactive material – effluents released and/or worker personal area monitoring

2. Waterborne radioactive material – effluents released to unrestricted areas and/or sewer releases

3. External exposure of public and/or workers – contamination and/or ambient radiation and/or bioassay

4. Facilities and equipment – restricted and unrestricted areas

5. Decommissioning – release of equipment for unrestricted use and/or release of facilities for unrestricted use

C. Performed as required [10 CFR 20.1501(a)] Y N

1. Radiation levels within regulatory limits Y N

2. Corrective action taken and documented Y N

D. Records maintained (10 CFR 20.2103) Y N

E. Protection of members of the public

1. Adequate surveys made to demonstrate either (a) that the total dose equivalent (TEDE) to the individual likely to receive the highest dose does not exceed 100 millirem (mrem) in a year, or (b) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 50 mrem in a year [10 CFR 20.1301(a)(1), 20.1302(b)] Y N

2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [10 CFR 20.1301(a)(2)] Y N

3. Records maintained (10 CFR 20.2103, 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 established and followed [10 CFR 20.1906(e)] Y N

C. If package shows evidence of degradation, monitor for contamination and radiation levels Y N N/A

D. Monitoring of degraded packages performed within time specified [10 CFR 20.1906(c)] Y N N/A

E. Transfer(s) between licensees (including “disposal”) performed per (10 CFR 30.41, 40.51, 70.42) Y N N/A

F. Records of receipt or transfer maintained (10 CFR 20.2103(a), 30.51, 40.61, 70.51) Y N

G. Transfers within licensee’s authorized users or locations performed as required [license condition (L/C)] Y N N/A

H. Package receipt or distribution activities evaluated for compliance with (10 CFR 20.1301, 20.1302) Y N N/A

Remarks:

11. TRANSPORTATION [10 CFR 71.5(a) and 49 CFR 170-180] N/A

A. Licensee shipments are

1. Delivered to common carriers Y N N/A

2. Transported in licensee's own private vehicle Y N N/A

3. No shipments 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

C. Packages N/A

1. Authorized packages used [49 CFR 173.415, 173.416(b)] Y N N/A

2. Closed and sealed during transport [49 CFR 173.475(f)] Y N

D. Shipping Papers N/A

1. Prepared and used [49 CFR 172.200(a)] Y N

2. Proper shipping name, hazard class, United Nations (UN) number, quantity, package type, nuclide, reportable quantities, radioactive material, physical and chemical form, activity, category of label, Transportation Index (TI), shipper's name, certification, and signature, Emergency response phone number, "Cargo Aircraft Only" (if applicable) (49 CFR 172.200-204) Y N

3. Readily accessible during transport [49 CFR 177.817(e)] Y N

E. Vehicles Y N

1. Cargo 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 (shipping name, UN Number, labeled, statement indicating that inner package complies with specification package) (49 CFR 173.25) Y N

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

Remarks:

12. PERSONNEL RADIATION PROTECTION

A. ALARA considerations are incorporated into the Radiation Protection Program [10 CFR 20.1101(b)] Y N

B. Prospective evaluation performed showing that unmonitored occupationally exposed individuals are not likely to receive >10 percent of allowable limit [10 CFR 20.1502(a)] Y N N/A

OR

C. External dosimetry provided and required Y N N/A

1. Supplier _____ Frequency _____

2. Supplier is National Voluntary Laboratory Accreditation Program-approved [10 CFR 20.1501(c)] Y N

3. Dosimeters exchanged at required frequency (L/C) Y N

D. Occupational intake monitored and assessed [10 CFR 20.1502(b)] Y N N/A

E. Reports N/A

1. Reviewed by _____ Frequency _____

2. Auditor reviewed personnel monitoring records for period _____ to _____

3. Prior dose determined for individuals likely to receive doses (10 CFR 20.2104) Y N

4. Maximum exposures TEDE _____ Other _____

5. NRC Forms or equivalent [10 CFR 20.2104(d), 20.2106(c)]

a. NRC Form 4 "Cumulative Occupational Exposure History" Y N

Complete: Y N

b. NRC Form 5, "Occupational Exposure Record for a Monitoring Period" Y N

Complete: Y N

6. Worker declared her pregnancy in writing during inspection period (review records) Y N N/A
- If yes, determine compliance with (10 CFR 20.1208) Y N
- Check for records per [10 CFR 20.2106(e)] Y N
- F. Records of exposures, surveys, monitoring, and evaluations maintained (10 CFR 20.2102, 20.2103, 20.2106, L/C) Y N

Remarks:

13. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)

- | | | | |
|--|------------|------------------|---|
| A. Survey instrument | Serial No. | Last calibration | |
| B. Auditor's measurements compared to licensee's | | | <input type="checkbox"/> Y <input type="checkbox"/> N |
| C. Describe the type, location, and results of measurements: | | | |

14. NOTIFICATION AND REPORTS N/A

- A. Licensee in compliance with (10 CFR 19.13) (reports to individuals, public and occupational, monitored to show compliance with Part 20) Y N N/A
- B. Licensee in compliance with (10 CFR 20.2201) (theft or loss) Y N None
- C. Licensee in compliance with (10 CFR 20.2202, 30.50, 40.60, 70.50) (incidents) Y N None
- D. Licensee in compliance with (10 CFR 20.2203, 30.50, 40.60, 70.50) (overexposures and high radiation levels) Y N None
- E. Licensee aware of telephone number for NRC Emergency Operations Center (301-816-5100) Y N
- F. Licensee in compliance with 10 CFR 20.2207, if applicable (reports of transactions involving nationally tracked sources) 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 Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted (10 CFR 19.11, 21.6) Y N

- C. Other posting and labeling per (10 CFR 20.1902, 1904) and the license is not exempted by (10 CFR 20.1903, 1905) Y N

Remarks:

16. RECORDKEEPING FOR DECOMMISSIONING (if needed) N/A

- A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination Y N
- B. Records include all information outlined in [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) issued since last audit have been reviewed Y N
- B. Appropriate actions taken in response to RISs, bulletins, information notices Y N

Remarks:

18. SPECIAL LICENSE CONDITIONS OR ISSUES N/A

- A. Review special license conditions or other issues, and describe findings:
- B. Problems or deficiencies identified at licensee facilities other than at audit location:
- C. Evaluation of compliance:

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

20. PROBLEMS OR DEFICIENCIES NOTED; RECOMMENDATIONS N/A

Note: Briefly state (i) the requirement and (ii) how and when violated. Provide recommendations for improvement.

21. EVALUATION OF OTHER FACTORS

- A. Senior licensee management is appropriately involved with the radiation safety program or RSO oversight Y N
- B. RSO has sufficient time to perform his or her radiation safety duties and is not too busy with other assignments Y N

C. Licensee has sufficient staff

Y N

Remarks and recommendations:

APPENDIX I

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

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

This appendix covers the types of instrumentation that may be used by academic, research and development, and laboratory facilities for radiation safety and compliance activities. It also covers the calibration of dose and dose rate measurement instruments, surface contamination measurement instruments, and instruments used to collect samples for indirect dose measurements such as air sampling.

Radiation Monitoring Instrument Specifications

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

Table I-1. Typical Survey Instruments* (Instruments Used to Measure Radiological Conditions at Licensed Facilities)			
Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-ray	μR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
BF ₃ Proportional Tube*	Neutron	Thermal neutron	High
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
LSC*†	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High

Table I-1. Typical Survey Instruments* (Instruments Used to Measure Radiological Conditions at Licensed Facilities) (Continued)			
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
	Beta	All energies	Moderate
	Gamma	All energies	< 1%
*Table adapted from "The Health Physics and Radiological Health Handbook, Revised Edition," edited by Bernard Shleien, 1992 (except for * items). †liquid scintillation counter			

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

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

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

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

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

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

This simplified equation is:

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

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

Example:

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

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

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

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

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

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

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

Model Radiation Survey Instrument Calibration Program

Training

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

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

- radioactivity measurements, monitoring techniques, and the use of radiation detection instruments
- mathematics related to the use and measurement of radioactivity
- biological effects of radiation
- On-the-job training will consist of the following:
 - observing authorized personnel performing radiation survey instrument calibration
 - conducting radiation survey meter calibrations under the supervision and in the physical presence of an individual already authorized to perform calibrations

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 device has changed, by repair or alteration, or whenever system performance is observed to change significantly.
- Routine maintenance 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.

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

- To reduce doses received by individuals not calibrating radiation survey instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
- The calibration source should be well-collimated, and the calibration area should be designed to minimize scatter of radiation, which could affect the calibration process.
- The calibration area should be appropriately controlled so that persons entering the area will be aware if a radiation source is in use.
- Evaluate posting of the calibration area with appropriate radiation warning signs, as required by Subpart J of 10 CFR 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.

Calibration Sources for Dose or Dose Rate Measuring Instruments

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

- The sources should approximate a point source.
- Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 microgray/hour ($\mu\text{Gy}/\text{h}$) [0.1 millirad/hour (mrad/h)] and 10 percent for dose rates less than 1.0 $\mu\text{Gy}/\text{h}$ [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 or dose rate radiation survey meters. These are calibrated as follows:

- **Linear readout instruments** with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on each scale. After adjustment, the response of the instrument should be checked at approximately 20 percent and 80 percent of full scale. Instrument's readings should be within $\pm x$ (noted below) of the conventionally true value for the following ranges:
 - Background to 10 $\mu\text{Gy}/\text{h}$ [1.0 mrad/h]; $\pm x = \pm 30\%$
 - 10 $\mu\text{Gy}/\text{h}$ (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 the linear readout instruments.

- **Digital readout instruments** should be calibrated the same as linear display instruments.

Note: For most licensees, readings above 50 microcoulomb/kilogram/hour [200 milliroentgen per hour] 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 meter 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 reading should be adjusted at mid-scale on one of the scales and the responses on the other scales should be observed. The radiation survey 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 sample 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 instrument, including the manufacturer's name, model number, serial number, and type of detector
- a description of the calibration source, including the exposure rate at a specified distance or activity on a specified date
- for each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument
- the exposure reading indicated with the radiation survey instrument in the "battery check" mode (if available on the instrument)
- for radiation survey instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
- for radiation survey instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument
- for radiation detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure
- the exposure rate or count rate from a check source, if used
- the name of the person who performed the calibration and the date on which the calibration was performed

The following information should be attached to the instrument as a calibration sticker or tag:

- for exposure rate meters, the source radionuclide used to calibrate the instrument (with correction factors) for each scale
- for surface contamination measurement instruments, the efficiency of the radiation survey instrument, for each of the radionuclides 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

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

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

Frequency of Calibration of Air Sampling Equipment

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

Error Limit for Measurement of Air Sample Volume

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

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

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

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

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

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

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

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

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

where

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

V₁ = volume measured at conditions P₁ and T₁

T₁ = temperature of V₁ in °K

P₁ = pressure of V₁ 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

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.

estimates of accuracy of the calibrated metering devices. All instruments should be labeled clearly 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, "Air Sampling in the Workplace," Revision 1, 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 Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments"
- "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 9th Edition, 2001

APPENDIX J
MATERIAL RECEIPT AND ACCOUNTABILITY

Material Receipt and Accountability

The academic, research, and development licensee is authorized to possess only the radionuclides in the types and forms listed on the license, and the total quantity possessed under the license must not exceed the maximum possession limit listed on the license. Therefore, the radiation safety officer (RSO) must know how much material is possessed under the license, in all locations, at any time. The licensed inventory includes all radioactive materials in use, in storage, and in waste. The regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 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 (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 relock the door.

Radiation Safety Officer: _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

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

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

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

Name: _____

Phone: _____

For additional information on worker training, see Section 8.8, "Training for Individuals Working in or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)."

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

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

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

Sample Procedure for Safely Opening Packages Containing Licensed Materials

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

- Wear gloves to prevent hand contamination.
- Visually inspect the package for any sign of damage (e.g., crushed, punctured). If damage is noted, stop and notify the RSO.
- Monitor the external surfaces of a labeled package according to specifications in Table 8-3, "Package Monitoring Requirements, Section 8.10.3."
- Check U.S. Department of Transportation (DOT) White I, Yellow II, or Yellow III label or packing slip for activity of contents, to ensure that the shipment 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). 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 before discarding in the regular trash.
- Maintain records of receipt, package survey, and wipe test results.
- Notify the final delivery carrier and the NRC Operations Center at 301-816-5100, by telephone, when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) or external radiation levels exceed the limits of 10 CFR 71.47, "External radiation standards for all packages."

Sample Procedure for Accountability for Unsealed Materials

- The RSO should maintain an accountability log (inventory) of all radioactive materials possessed under the license, which demonstrates that the license limits are not exceeded; that all materials received are accounted for; and that material is disposed of or transferred before 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 Unit (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, order, or by some other unit that can be "counted."
- Each AU should maintain records of the locations and quantities of licensed materials for which the AU is responsible. For example, material may be present in stock vials,

ampoules, thin layer chromatography or high pressure liquid chromatography samples, and in various waste forms; materials may be stored in such places as refrigerators, freezers, cold rooms, or lab rooms.

- Each AU should periodically 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, which may be weekly, monthly, quarterly, or after each order, depending on the frequency of use and the amount of materials on hand). Each AU should indicate if material possessed was disposed of or transferred from his or her responsibility (e.g., waste in containers may be transferred to a common DIS location under the responsibility of the RSO; or another AU; or the AU may have disposed of licensed materials 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. The RSO should develop a written transfer procedure to ensure that transfers are done in accordance with the license conditions. 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 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.

Donations

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

APPENDIX K
PUBLIC DOSE

Public Dose

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

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in 1 calendar year resulting from the licensee's possession or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv [2 mrem] in any 1 hour.
- Air emissions of radioactive materials to the environment, excluding radon-222 and its daughters, do not result in doses greater than 0.1 mSv [10 mrem] per year total effective dose equivalent (TEDE). As required by Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR 20.1101(d), if the licensee exceeds the 10 mrem per year air emission dose constraint, the licensee shall 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 byproduct material is used or stored and employees whose assigned duties do not include the use of byproduct 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 • voluntary participation in medical research

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

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

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

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 iodinations, but the discharge usually is not continuous since 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 a conservative 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 K-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 K-1 are general guidance values and may be used if more detailed information is not available.

Table K-1. Standard Occupancy Factors¹

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

Records

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

Records demonstrating the dose to an individual member of the public 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 L

GENERAL TOPICS FOR SAFE USE OF RADIONUCLIDES AND MODEL EMERGENCY PROCEDURES

General Topics for Safe Use of Radionuclides and Model Emergency Procedures

General Topics for Safe Use of Radionuclides

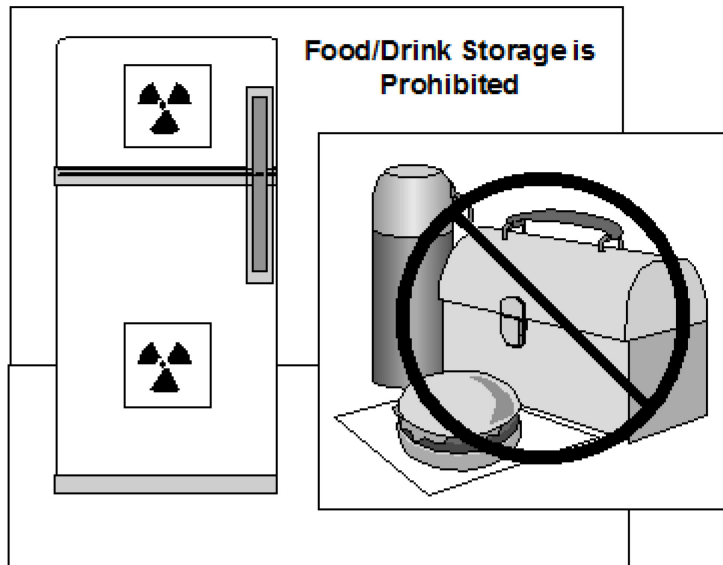
Each laboratory or area where radioactive material is used or stored should have general rules, so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used.
- Wear disposable gloves at all times when handling licensed materials.
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area.
- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Do not store food, drink, or personal effects in areas where licensed material is stored or used (see Figure L-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.
- Safely handle sealed sources.
- Secure all licensed material when it is not under the constant surveillance and immediate control of the users.

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



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Figure L-1. Storage of Food and Drink. Food or drink shall not be stored in refrigerators with radionuclides.

Radionuclide-specific Procedures

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

Example 1:

If requesting more than 37 megabecquerel (MBq) [1 millicurie (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 storage of millicurie quantities of radioiodine
- a dry run before the performance of unfamiliar procedures, to preclude unexpected complications. In addition, the U.S. Nuclear Regulatory Commission (NRC) recommends that the radiation safety officer (RSO) be present during new procedures.
- procedures for measuring the concentration of radioiodine effluents from the hoods

Example 2:

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

- the use of shielding 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 before the performance of unfamiliar procedures to preclude unexpected complications. In addition, the NRC recommends that the RSO be present during new procedures.
- the use of eye protection for procedures that involve 370 MBq [10 mCi] or more

Sample Procedures for Handling Emergencies

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

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, the likelihood of spread of contamination, the types of surfaces contaminated, and the

radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access, pending complete decay. The applicant should establish criteria for determining when to use the major spill procedure versus the minor spill procedure.

Minor Spills of Liquids and Solids

- Instructions to Workers
 - Notify persons in the area that a spill has occurred.
 - Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)
 - Clean up the spill, wearing disposable gloves and using absorbent paper.
 - Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
 - Survey the area with an appropriate low-range radiation detector, 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 the cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
 - If necessary, notify the 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 system and other parts of facility, unless it is determined that the room ventilation system needs to be used to clear the area for access purposes.
 - Vacate the room. Seal the area, if possible.

- Notify the RSO immediately.
 - Ensure that all access doors to the area are closed and posted with appropriate warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area.
 - Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO.
 - Promptly report suspected inhalations and ingestions of licensed material to the RSO.
 - Decontaminate the area only when advised 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 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 is suspected to have been ingested, inhaled, or absorbed through the skin. Document incident.
 - If necessary, notify the NRC.

Minor Fires

- Instructions to Workers (Licensees should develop procedures and instructions in accordance with local fire safety requirements, Occupational Safety and Health Administration regulations, etc. and provide training as needed).
 - Immediately attempt to put out the fire by approved methods (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 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 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 incident.
 - If necessary, notify the NRC.

Fires, Explosions, or Major Emergencies

- Instructions to Workers
 - Notify all persons in the area to leave immediately.
 - Notify the fire department.
 - Notify the RSO and other facility safety personnel.
 - Upon arrival of firefighters, inform them where radioactive materials are stored or where radionuclides were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc.

- Cooperate with the RSO and the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Allow no one to return to work in the area unless approved by the RSO.
- Follow the instructions of the RSO and the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Coordinate activities with facility's industrial hygienist or environmental health and safety office, and with local fire department.
 - Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished.
 - Once the fire is extinguished, advise the firefighters not to enter the potentially contaminated areas where radioactive sources may be present or radiation areas until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas.
 - Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary.
 - Supervise decontamination activities.
 - Consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin. Document incident.
 - If necessary, notify the NRC.

Incidents Involving Sealed Sources

For an emergency situation that may occur concerning a sealed source that has been exposed unintentionally, is unshielded, or 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.

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 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 allowing an individual to perform surveys, the radiation safety officer (RSO) will ensure that he or she has sufficient training and experience to perform surveys independently.

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

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and using instruments
- usage and basic mathematics and calculations for measuring radioactivity
- biological effects of radiation.

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

- observing authorized personnel using survey equipment, collecting samples, and analyzing samples
- using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- A gamma counter system with a single or multichannel analyzer can be used to count samples containing gamma-emitters (e.g., iodine-125, cesium-137, cobalt-60).
- A liquid scintillation counter (LSC) 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 millisieverts (mSv) [2.5 millirem per hour (mrem/hour)] or more [50 millisieverts per year (mSv/year) divided by 2,000 hour/year].

- Title 10 of the *Code of Federal Regulations* (10 CFR) 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 1 year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv [2 mrem] in any one hour.

The frequency of ambient surveys depends on the quantity and use of radioactive materials, as well as the specific facilities, equipment, and procedures 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 and 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 in Table M-2 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. (See 63 FR 64132, November 18, 1998).

Table M–2 provides the maximum acceptable residual levels for potentially contaminated equipment that is to be released for unrestricted use. 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 used as acceptable criteria for contamination in facilities during facilities in operation.

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

Nuclide¹	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]
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 square centimeters (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.

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 is 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.

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

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

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

Table 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 DandD v2.1 to develop site-specific screening criteria. The most recent version of the DandD code can be installed by downloading the self-extracting program file, setup.exe, accessed through the Web site: http://www.marssim.com/Dose_Modeling.htm. Links to other useful software and guidance documents are also found at that Web site.

Table 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,” in the *Federal Register* 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) for use in determining acceptable screening values are for radionuclides not listed in the first two *Federal Register* notices.

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

Survey Record Requirements

Each survey record should include the following:

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

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor’s signature. In addition, 10 CFR 30.35(g), 40.46(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.

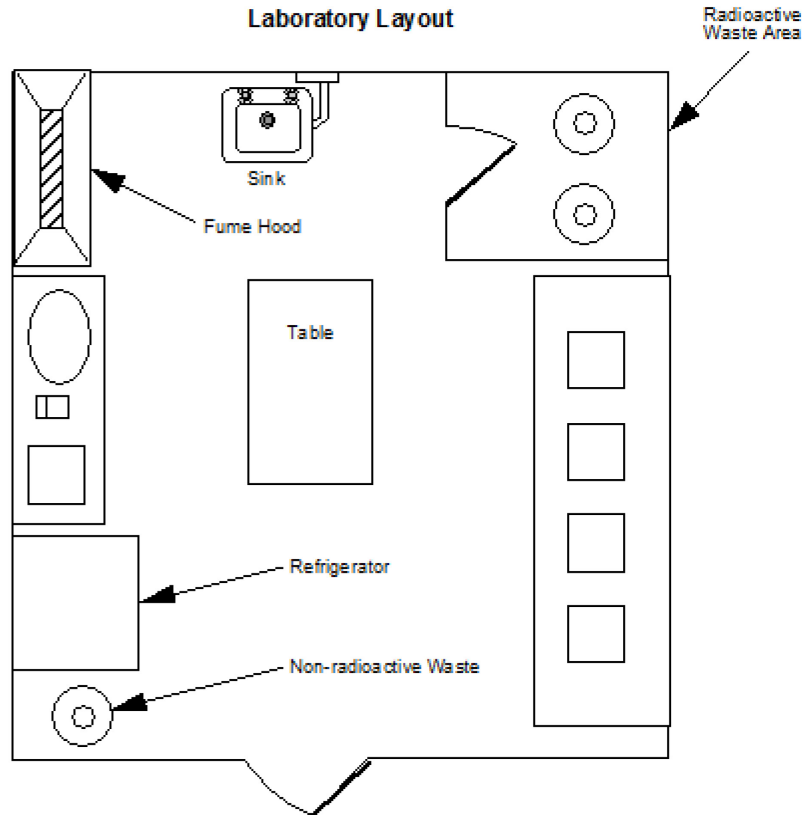


Figure M-1. Laboratory Layout. *This is an example of a laboratory survey map.*

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 U.S. Nuclear Regulatory Commission (NRC) Agencywide Documents Access Management System (ADAMS) at Accession No. ML003739616 and ML13051A671, respectively, for further guidance on the air sampling.

Airborne Effluent Release Monitoring

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

Regulatory Guide 4.20, Revision 1, "Constraints on Releases of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors," Revision 1, 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 or the number of procedures performed or other appropriate methods. The unmonitored effluents should not exceed 30 percent of the total estimated effluent releases or 10 percent of the permissible air effluent concentrations found 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 sanitary sewer and to the environment. These releases must meet the limits in 10 CFR 20.2003 and 10 CFR 20.1302, respectively.

The topic of sanitary sewerage releases is more fully discussed in 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) 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 sometimes can 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:

- 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,” dated 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
- NUREG-1400, "Air Sampling in the Workplace," September 1993, ADAMS Accession No. ML13051A671
- *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
- 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 Doses," July 1992
- Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," July 1993
- 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

This appendix provides applicants and licensees with model leak test procedures and sample calculations for determining activity on a wipe test sample.

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, or self-study, and should cover the following subject areas:

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and using instruments
- 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 (TI) well-counter system for gamma-emitters; liquid scintillation for beta-emitters; gas-flow proportional counters for alpha-emitters].
- If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) should be determined. The MDA may be determined using the following formula:

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

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

For example:

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

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

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

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

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 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 [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 that of 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 Bq [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 the transportation of licensed material including the preparation of shipments of licensed material. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, transportation requirements change; therefore, licensees should consult the regulations for definitive information about current requirements. Additional information on transportation requirements may be found at the DOT Web site: <http://www.dot.gov/>.

Title 10 of the *Code of Federal Regulations* (10 CFR) 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 172.403—Class 7 (radioactive) material
- 49 CFR 172.406—Placement of labels
- 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
- 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>Basic description (in sequence):</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>Additional description:</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>Additional entry requirements:</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>Materials-based Requirements:</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>Package-based Requirements:</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>Shipment- and Administrative-based Requirements:</p> <ul style="list-style-type: none"> • Specify “exclusive use shipment” as required • Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use • Specify the notation “DOT–SP” followed by the special permit number for a special permit shipment 	<ul style="list-style-type: none"> • The weight in grams or kilograms may be inserted instead of activity units for fissile radionuclides, except for Pu-239 and Pu-241 • The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units • Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information

Special Considerations/Exceptions for Shipping Papers

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

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


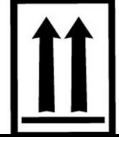
[2] For mixtures of radionuclides, the radionuclides to be shown must be determined in accordance with § 173.433(g), which is commonly known as the 95% rule; abbreviations (symbols) are authorized.

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

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

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

Markings on Packages

Markings Always Required Unless Excepted ^[1]	Additional Markings Sometimes Required	Optional Markings
<p>For Non-bulk Packages:</p> <ul style="list-style-type: none"> • Proper shipping name • Identification number (preceded by "UN" or "NA," as appropriate) • Name and address of consignor or consignee, unless the package is: <ul style="list-style-type: none"> ▪ highway only and no motor carrier transfers; or ▪ part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee <p>For Bulk Packages:</p> <ul style="list-style-type: none"> • Identification number on orange panel or white square-on-point display [see §§ 172.332 or 172.336]: <ul style="list-style-type: none"> ▪ on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more^[2], or ▪ on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons)^[2] 	<p>Package-based marking requirements:</p> <ul style="list-style-type: none"> • Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 lb) • Package type as appropriate, i.e., "TYPE IP-1," "TYPE IP-2," "TYPE IP-3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"^[1] • Marked with international vehicle registration code of country of origin for IP-1, IP-2, IP-3 or Type A package design (e.g., "USA") • Radiation (trefoil) symbol^[3] on outside of outermost receptacle of each Type B(U) or Type B(M) <div align="center"></div> • 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] <div align="center"></div> • 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.




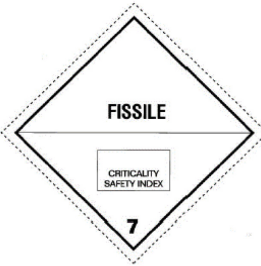
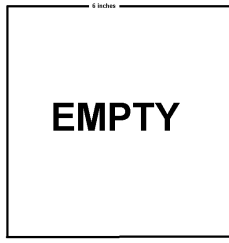
[1] Some marking exceptions exist for excepted packages, as specified in §§ 173.421, 173.422, 173.424, 173.426 and 173.428.
[2] If the identification number marking on a bulk package is not visible, the transport vehicle or freight container must be marked on each side and each end [see § 172.331].
[3] 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

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

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

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

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

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

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

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

Visibility and Display of Radioactive Placards [§ 172.516]

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

Radioactive Placards

PLACARD (FOR OTHER THAN HRCQ)



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

PLACARD FOR HRCQ



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

General Specifications for Placards and Subsidiary Hazard Placarding

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

[1] See § 172.512 for exceptions and variations to the placarding requirements for freight containers and aircraft unit load devices.

[2] See § 173.403 for the definition of Highway Route Controlled Quantity (HRCQ). A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels [see §§ 172.403(c) and 172.507(a)].

[3] Required placarding of the front of a motor vehicle may be on the front of a truck-tractor instead of or in addition to the placarding on the front of the cargo body to which a truck-tractor is attached § 172.516(b).

8. Requirements/Guidance for Registration, Emergency Response and Action for Class 7 (Radioactive) Materials: (49 CFR 107, Subpart G; 49 CFR 171.15; 49 CFR 172, Subparts F and G)

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

Provisions for Persons Who Offer or Transport Class 7 (Radioactive) Materials (49 CFR 107, Subpart G)

- Any person, other than those excepted by § 107.606, who offers for transportation, or transports, in foreign, interstate or intrastate commerce any of the following Class 7 (radioactive) materials must satisfy registration and fee requirements of Part 107, Subpart G:
 - a highway route-controlled quantity of radioactive material;
 - a shipment in a bulk packaging with a capacity \geq 13,248 L (3,500 gallons) for liquids or gases, or $>$ 13.24 cubic meters (468 cubic feet) for solids; or
 - any quantity of radioactive material that requires placarding, under provisions of Part 172, Subpart F.
- Any person required to register must submit a complete and accurate registration statement on DOT Form F 5800.2 by June 30th for each registration year, or in time to have on file a current Certificate of Registration in accordance with § 107.620.
- Each registrant or designee must maintain for a period of 3 years from the date of issuance a copy of the registration statement and Certificate of Registration issued by PHMSA and must furnish its Certificate of Registration (or a copy thereof) and related records to an authorized representative or special agent of DOT upon request.
- Each motor carrier subject to registration requirements of this subpart must carry a copy of its current Certificate of Registration or another document bearing the registration number on board each truck and truck tractor, and the Certificate of Registration or document must be made available, upon request, to enforcement personnel.
- The amount of fees to be paid and procedures to be followed are found at §§ 107.612 and 107.616.

Provisions for Providing and Maintaining Emergency Response Information (49 CFR 172, Subpart G)

- When shipping papers for the transportation of radioactive materials are required [see Part 172, Subpart C], emergency response information shall
 - be provided and maintained during transportation and at facilities where materials are loaded for transportation, stored incidental to transportation, or otherwise handled during any phase of transportation;
 - be provided by persons who offer for transportation, accept for transportation, transfer or otherwise handle hazardous materials during transportation;
 - be immediately available for use at all times the hazardous material is present; and
 - include and make available the emergency response telephone number [see § 172.604] to any person, representing a Federal, State or local government agency, who responds to an incident involving the material or is conducting an investigation which involves the material.
- Emergency response information is information that can be used in mitigating an incident involving radioactive materials. It must contain at least the information specified in §§ 172.602 and 172.604; and includes an emergency response telephone number that is monitored at all times the material is in transportation by (a) knowledgeable person, or (b) a person who has immediate access to a knowledgeable person, or (c) an organization capable of accepting responsibility for providing the necessary detailed information concerning the material.
- Each carrier who transports or accepts for transportation radioactive material for which a shipping paper is required shall instruct, according to the requirements of § 172.606, the operator of a conveyance to contact the carrier in the event of an incident involving the material.

Actions to be Taken in the Event of Spillage, Breakage, or Suspected Contamination by Radioactive Material

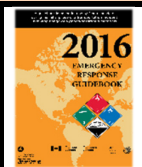
- If there is evidence of a leaking package or conveyance, access to the package or conveyance must be restricted, the area impacted and the extent of the contamination must be determined, and appropriate measures must be taken to minimize impact to persons and the environment [see § 173.443(e)].
- Except for a road vehicle used solely for transporting Class 7 (radioactive) material [see § 173.443(d)], each aircraft used routinely, and each motor vehicle used for transporting radioactive materials under exclusive use, must be (a) periodically checked for radioactive contamination, (b) taken out of service if contamination levels are above acceptable limits, and (c) remain out of service until the radiation dose rates at accessible surfaces are less than 0.005 mSv/h (0.5 mrem/h) and non-fixed radioactive surface contamination levels are below the limits in §§ 173.443(a), Table 9; and 173.443(c) for exclusive use vehicle provisions [see Chart 3].
- Following any breakage, spillage, release or suspected radioactive contamination incident, any rail or air carrier shall notify, as soon as possible, the offeror (i.e. the consignor); special provisions apply for buildings, areas, and equipment that might become contaminated during rail transport. Alternative provisions may apply for motor vehicles transporting radioactive materials under exclusive use [see §§ 174.750(a), 175.705(e), and 177.843(b)].

Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (§§ 171.15 and 171.16)

- Each person in physical possession of radioactive material must provide notice in the event of a reportable incident (see § 171.15(b)) as soon as practical, but no later than 12 hours after the occurrence of the reportable incident, to the National Response Center (NRC) by telephone at 800-424-8802 (toll free) or 202-267-2675 (toll call) or online at <http://www.nrc.uscg.mil>.
- Each notice must include the information specified in § 171.15(a)(1) – (a)(7).
- A detailed incident report must also be submitted as required by § 171.16.

Guidance on Responding to Emergencies (Emergency Response Guidebook)

- The DOT issues guidance to aid first responders in quickly identifying the hazards of the dangerous goods involved in an accident or incident, and for protecting themselves and the general public during the initial response to the accident or incident. For each proper shipping name or UN ID Number, the user is led to a specific guide that provides insight into potential hazards and steps to be taken for public safety and emergency response.
- The current edition of the Emergency Response Guidebook is available at <http://phmsa.dot.gov/hazmat/outreach-training/erg>.



9. Requirements for Training and Safety and Security Plans for Class 7 (Radioactive) Materials: (49 CFR 172, Subparts H and I, 49 CFR 173, and 10 CFR 37)

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

Training (49 CFR 172, Subpart H)

- For any person who is employed by an employer or is self-employed, and who directly affects hazardous materials transportation safety, a systematic program shall be established to ensure that the person:
 - has familiarity with the general provisions of [Part 172, Subpart H](#);
 - is able to recognize and identify radioactive materials;
 - has knowledge of specific requirements of [Part 172](#) that are applicable to functions performed by the employee;
 - has knowledge of emergency response information, self-protection measures and accident prevention methods and procedures; and
 - does not perform any function related to the requirements of [Part 172](#) unless instructed in the requirements that apply to that function.
- The person shall be trained pursuant to the requirements of [§ 172.704\(a\)](#) and [\(b\)](#), may be trained by the employer or by other public or private sources, and shall be tested by appropriate means. The training must include the following:
 - (a) general awareness training providing familiarity with applicable regulatory requirements;
 - (b) function-specific training applicable to functions the employee performs;
 - (c) safety training concerning emergency response information, measures to protect the employee from hazards, and methods and procedures for avoiding accidents;
 - (d) security awareness training providing awareness of security risks and methods designed to enhance transportation security; and
 - (e) in-depth security training if a security plan is required for the shipment(s) involved.
- Initial and recurrent training shall comply with the requirements of [§ 172.704\(c\)](#).
- Records of training shall be created and retained in compliance with the requirements of [§ 172.704\(d\)](#).

Security (49 CFR 172, Subpart I, 49 CFR 173, and 10 CFR 37)

- A security plan for hazardous materials that conforms to the requirements of [Part 172, Subpart I](#) must be developed and adhered to by each person who offers for transportation in commerce or transports in commerce in a motor vehicle, rail car, or freight container any of the following radioactive materials:
 - (a) IAEA Code of Conduct Category 1 and 2 materials (see [§§ 172.800\(b\)\(15\)](#) and [10 CFR 37](#));
 - (b) a highway route controlled quantity (HRCQ) of radioactive material as defined in [§ 173.403](#) [see [§ 172.800\(b\)\(15\)](#)];
 - (c) known radionuclides in forms listed as radioactive material quantities of concern (RAM-QC) by the NRC [see [§§ 172.800\(b\)\(15\)](#) and [10 CFR 37](#)]; or
 - (d) a quantity of uranium hexafluoride requiring placarding under [§ 172.505\(b\)](#) [see [§ 172.800\(b\)\(14\)](#)].
- The security plan must include an assessment of possible transportation security risks and appropriate measures to address the assessed risks.
- Specific measures put into place by the plan may vary commensurate with the level of threat at a particular time.
- At a minimum, a security plan must address personnel security, unauthorized access, and enroute security.
- The security plan must be
 - (a) in writing;
 - (b) retained for as long as it remains in effect;
 - (c) available as copies or portions thereof to the employees who are responsible for implementing it, consistent with personnel security clearance or background investigation restrictions and a demonstrated need to know;
 - (d) revised and updated as necessary to reflect changing circumstances; and
 - (e) maintained (all copies) as of the date of the most recent revision, when it is updated or revised.
- Security plans that conform to regulations, standards, protocols, or guidelines issued by other Federal agencies, international organizations, or industry organizations may be used to satisfy the requirements in [Part 172](#), provided such security plans address the requirements specified in [Part 172, Subpart I](#).
- Additional security planning requirements may apply for rail transport of a highway route controlled quantity of radioactive material [see [§§ 172.820](#) and [173.403](#)].

APPENDIX P
MODEL WASTE MANAGEMENT PROCEDURES

Model Waste Management Procedures

General Guidelines

- All radioactivity labels must be defaced or removed from containers and packages before disposal in ordinary (nonradioactive) waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- Remind workers that nonradioactive waste such as leftover reagents, boxes, and packaging material 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 that 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) 10 CFR Part 20, Appendix G, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests."

Model Procedure for Disposal by Decay-in-Storage

Applicants should ensure that adequate space and facilities are available for the storage of waste for decay-in-storage (DIS). Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
- Short-lived waste should be segregated from long-lived waste (half-life greater than 120 days) at the source.
- 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 radionuclide(s) in the container and estimated amounts, and the initials 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 that 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.
- Before disposal as ordinary trash, each container should be monitored with an appropriate radiation detection instrument, on the lowest setting, as follows:
 - Check the radiation detection survey meter for proper operation.
 - Survey the contents of each container in a low background area.
 - Remove any shielding from around the container.
 - Monitor all surfaces of the container.
 - Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity (i.e., surface readings are indistinguishable from background).
 - If the surveys indicate residual radioactivity, return the container to DIS area and contact the radiation safety officer for further instructions.
 - If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (e.g., used or unused material, gloves, etc.), survey instrument used, and the initials 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 before 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 before delivery to the waste disposal firm and delivered directly from the licensee's facility; labels are removed from the waste barrels and containers; the waste is incinerated, not placed in a landfill; and the waste disposal firm is cautioned not to open the container before incineration.

Model Procedure for Disposal of Liquids into Sanitary Sewerage

- Confirm that the sewerage system is a public system, not a private sewerage system, septic system, or leach field.

- Confirm that the liquid waste being discharged is either soluble material, or a biological material that is readily dispersible in water.
- Calculate the amount of each radionuclide that can be discharged by using the information from previous, 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 in 10 CFR Part 20, Appendix B, Table 3 (records for individual users/laboratories).
- 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 gigabecquerels (GBq) [5 curies (Ci)] of H-3 (tritium), 37 GBq [1 Ci] of C-14, and 37 GBq [1 Ci] of all other radionuclides combined.
- Record the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the initials of the individual discharging the waste.
- Liquid waste should be discharged only through designated sinks or toilets, or 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 noncommercial 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 how any ash generated exceeding regulatory limits will be disposed of.

Model Procedure for Compaction

The following information should be provided from 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.
- State the location of any compactors within the waste processing area(s), and provide 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.
- Describe the instruction provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and instruction for examining containers for defects

APPENDIX Q
INCIDENT NOTIFICATIONS AND REPORTING

Incident Notifications and Reporting

Table Q-1. 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 Q-1. Typical NRC Notification and Reporting Requirements for Incidents			
Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of licensed material	Immediate	30 days	10 CFR 20.2201(a)(1)(i) 10 CFR 20.2201(b)(1)
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	10 CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Gy (250 rads)	Immediate	30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 0.5 Sv [50 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems]	None	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv [0.1 rem]	None	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i) & (ii)
Event that prevents immediate protective actions necessary to avoid exposures to radioactive materials that could exceed regulatory limits	Immediate	30 days	10 CFR 30.50(a) & (c)(2)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2) & (c)(2)
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)

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

Event	Telephone Notification	Written Report	Regulatory Requirement
Package received with removable radioactive surface contamination exceeding the limits of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) 10 CFR 71.87(i) or external radiation levels exceeding the limits of 10 CFR 71.47	immediate [U.S. Nuclear Regulatory Commission (NRC)] and final delivery carrier must be notified.)	none	20.1906(d)
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 the 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)
Determination that any licensee that has not previously implemented the Security Orders (i.e., orders issued by the NRC to require licensees to implement interim security measures) or been subject to the provisions of 10 CFR Part 37, Subpart C will aggregate radioactive material to a quantity that equals or exceeds the Category 2 threshold	none	90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold	10 CFR 37.41(a)(3)

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

Event	Telephone Notification	Written Report	Regulatory Requirement
Coordination with local law enforcement agency (LLEA) has failed, either because the LLEA has not responded or because the LLEA does not plan to participate	3 business days	Submittal of a written report concerning failures of coordination with LLEA as described in 10 CFR 37.45(b) is not required; however, licensees must document their efforts to coordinate with the LLEA and keep this documentation for 3 years	10 CFR 37.45(b)&(c)
Determination that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material	As soon as possible (but not at the expense of causing delay or interfering with the LLEA response), but no later than 4 hours after discovery	30 days	10 CFR 37.57(a) & (c)
Assessment of any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material	As soon as possible, but no later than 4 hours after notifying the LLEA	none	10 CFR 37.57(b)
Determination that a shipment containing a Category 1 quantity of material is lost or missing in transport	Within 1 hour of the determination. Also notify LLEA within 1 hour of determination	30 days and periodic updates (if subsequent substantive information)	10 CFR 37.81(a)(g)&(h)

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

Event	Telephone Notification	Written Report	Regulatory Requirement
Determination that a shipment containing a Category 2 quantity of material is lost or missing in transport	Within 4 hours of the determination and again within 24 hours if the material has not yet been located and secured	30 days and periodic updates (if subsequent substantive information)	10 CFR 37.81(b)(g)&(h)
Discovery along the route of any actual or attempted theft or diversion, or suspicious activity, related to a Category 1 quantity of material in transport	As soon as possible upon discovery. Also notify LLEA as soon as possible upon discovery	30 days (except no report for suspicious activity) and periodic updates after report (if subsequent substantive information)	10 CFR 37.81(c)(g)&(h)
Discovery of any actual or attempted theft or diversion, or suspicious activity, related to a Category 2 quantity of material in transport	As soon as possible	30 days (except no report for suspicious activity) and periodic updates after report (if subsequent substantive information)	10 CFR 37.81(d)(g)&(h)
Upon recovery of any lost or missing Category 1 quantity of material	As soon as possible. Also notify the LLEA as soon as possible.	To be included in the 30-day report of an event described in 10 CFR 37.81(g), if recovered during that time or in a subsequent update	10 CFR 37.81(e)&(h)

Table Q-1. Typical NRC Notification and Reporting Requirements for Incidents (Continued)			
Event	Telephone Notification	Written Report	Regulatory Requirement
Upon recovery of any lost or missing Category 2 quantity of material	As soon as possible	To be included in the 30-day report of an event described in 10 CFR 37.81(g), if recovered during that time or in a subsequent update	10 CFR 37.81(f)&(h)

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

APPENDIX R
SAFETY CULTURE POLICY STATEMENT

Safety Culture

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

Safety Culture Policy Statement

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

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

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

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

The following are traits of a positive safety culture:

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

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

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

APPENDIX 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) 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 assist applicants and licensees in preparing applications for materials licenses for academic, research and development, and other licenses of limited scope (ARDL). 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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