

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

Draft Report for Comment

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And X-Ray Fluorescence Analyzers

Draft Report for Comment

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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.

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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:

<i>Volume No.</i>	<i>Volume Title</i>
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
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

Volume No.	Volume Title
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	Program-Specific Guidance about Administrative Licensing Procedures
21	Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator
22	Reserved

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 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 continue a license.

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
ALI	annual Limit of Intake
AMAD	activity median aerodynamic diameter
ANSI	American National Standards Institute
ARDL	academic, research and development, and other licenses
AU	authorized user
bkg	background
BPR	business process redesign
Bq	becquerel
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CD-ROM	compact disk-read only memory
CFR	<i>Code of Federal Regulations</i>
Ci	curie
cpm	counts per minute
DAC	derived air concentration
DCF	dose conversion factor
DDE	deep dose equivalent
DFP	Decommissioning Funding Plan
DIS	decay-in-storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
dps	disintegrations per second
ECD	electron capture detector
EDE	effective dose equivalent
EPA	U.S. Environmental Protection Agency
F/A	financial Assurance
FR	<i>Federal Register</i>
GBq	gigabecquerel
GC	gas chromatograph
G-M	Geiger-Mueller
GPO	Government Printing Office
Gy	gray
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IN	Information Notice
LLW	low-level radioactive waste
LSA	low specific activity
LSC	liquid scintillation counter
MBq	megabecquerel
mCi	millicurie
mGy	milligray
ml	milliliter
mR	milliroentgen

mrem	millirem
mSv	millisievert
uCi	microcurie
uR	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
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
OSL	optically-stimulated luminescence dosimeter
OSP	Office of State Programs
P&GD	policy and guidance directive
R	roentgen
RAM	radioactive material
RG	regulatory guide
RPO	radiation protection officer
RQ	reportable quantities
RSO	radiation safety officer
SDE	shallow dose equivalent
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
TLD	thermoluminescence dosimeters
TODE	total organ dose equivalent
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 (XRF). This report also provides the U.S. Nuclear Regulatory Commission (NRC) criteria for evaluating the license application. 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 document 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) 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
- authorized users
- authorized locations

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 (labeling cells, studies involving animals, excluding humans)
- *in vitro* studies
- analytical work and studies, including use of ECDs and XRFs
- veterinary medicine
- 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 additional 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.

Chapter 8, “Contents of an Application,” of this report identifies the information needed to complete NRC Form 313, “Application for Materials License” (see Appendix A), 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 portable gauge applications, Appendix B, “Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313,” may be used to provide supporting information.

Appendix C is a checklist that the NRC staff uses to review applications and applicants can use to check for completeness. Appendices E through S contain additional information on various radiation safety topics.

Appendix D provides specific guidance for licensing sealed sources in devices such as electron capture detectors (ECDs) used in gas chromatographs or chemical detectors and X-Ray fluorescence analyzers (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. Rem and its International System of Units (SI) equivalent, sievert (Sv) (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. This is done because 10 CFR Part 20 sets dose limits in terms of rem (sievert), rather than rad or roentgen. When the radioactive material emits beta and gamma rays, 1 roentgen is assumed to equal 1 rad, which is assumed to equal 1 rem. For alpha and neutron-emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from alpha particles and neutrons requires the use of

an appropriate quality factor (Q) value. These Q values are used to convert absorbed dose (rad) to dose equivalent (rem). Tables 1004(b)(1) and (2) in 10 CFR 20.1004, "Units of radiation dose," address the Q values for alpha particles and neutrons.

2. AGREEMENT STATES

Certain States, called Agreement States (see Figure 2.1), have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, and special nuclear materials, in quantities not sufficient to form a critical mass, which are used or possessed within their borders. Any applicant, other than a Federal entity, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with the NRC. In areas under exclusive federal jurisdiction within an Agreement State, NRC continues to be the regulatory authority.

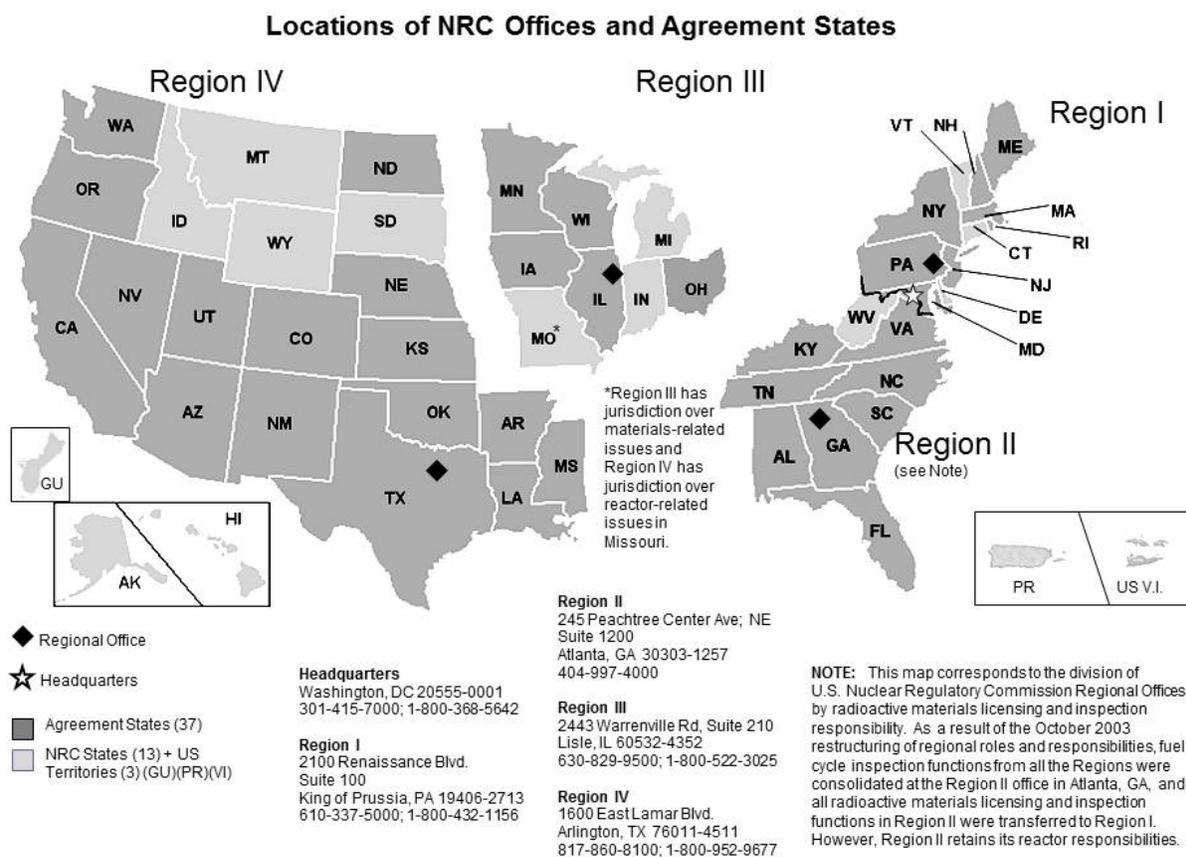


Figure 2.1 U.S. Map: Locations of NRC Offices and Agreement States

In the special situation of work at Federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the 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.¹

¹ For the purposes of this guidance, an "Indian tribe" is defined as an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994. A list of federally recognized tribes is available at www.bia.gov.

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. The NRC recommends that applicants contact their local office of the Federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) for assistance in determining the jurisdictional status of the land and to provide the information in writing to ensure compliance with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in the Office of Federal and State Materials and Environmental Management Program’s (FSME) procedures in the State Agreement (SA) series, SA-500, “Jurisdiction Determination,” which is available at <http://nrc-stp.ornl.gov/>. Once on the Web site, use the link for “FSME Procedures” in the left hand column under “Resources & Tools.” The link will take you to another Web page where you can search for FSME Procedures.

Table 2.1 provides a quick way to evaluate whether the NRC or an Agreement State has regulatory authority.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with 10 CFR 30.12, “Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts”)	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or tribal member on Indian Tribal land	NRC
Non-federal entity on Federally recognized Indian Tribal land	NRC ²
Federally recognized Indian Tribe or tribal member outside of Indian Tribal land in Agreement State.	Agreement State

² The NRC can exercise jurisdiction as the regulatory authority on tribal land of a Federally recognized Indian Tribe. Section 274b. Agreements do not give States the authority to regulate nuclear material in these areas. However, there are few 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.

Applicant and Proposed Location of Work	Regulatory Agency
Non-Federal entity in Agreement State	Agreement State ³
Non-Federal entity in Agreement State at Federally controlled site not subject to exclusive Federal jurisdiction	Agreement State ³
Non-Federal entity in Agreement State at Federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	NRC
Non-Federal entity in Agreement State using radioactive materials not directly connected with Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	Agreement State ³

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) is available at the Office of Federal and State Materials and Environmental Management Programs' public Web site, <http://nrc-stp.ornl.gov>. As an alternative, a request for the list can be made to an NRC regional office.

³ Section 274m. of the AEA gives the NRC regulatory authority over radioactive materials covered under the Section 274b. Agreement 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 at a site. (This is an uncommon situation which NRC usually evaluates on a case-by-case basis.) Companies that wish to possess or use licensed material at these sites should contact the licensee to determine the jurisdictional status for specific AEA radioactive materials they intend to possess or use at the site.

3. MANAGEMENT RESPONSIBILITY

The NRC recognizes that effective radiation safety program management is vital for 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 10 CFR 30.32(c), each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the behalf of the applicant or licensee. If it is not clear whether the application was signed by someone duly authorized to act for and on the behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual that signed the application is duly authorized to act for and on the behalf of the applicant or licensee. The signature on an application acknowledges the licensee’s commitments and responsibilities for the following:

- Radiation safety, security, and control of radioactive materials and compliance with regulations;
- Completeness and accuracy of the radiation safety records and all information provided to the NRC (10 CFR 30.9, “Completeness and accuracy of information”);
- Knowledge about the contents of the license and application;
- Compliance with current NRC and U.S. Department of Transportation (DOT) regulations and the licensee’s operating and emergency procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and compliance with regulations is maintained;
- Selection and assignment of a qualified individual to serve as the radiation safety officer (RSO) for licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities;
- Commitment to ensure that radiation workers have adequate training;
- Prevention of discrimination of employees engaged in protected activities (10 CFR 30.7, “Employee protection”);

- Commitment to provide information to employees about the employee protection and deliberate misconduct provisions in 10 CFR 30.7 and 10 CFR 30.10, “Deliberate misconduct,” respectively;
- Commitment to obtain the NRC’s prior written consent before transferring control of the license (see Section 9.1, “Timely Notification of Transfer of Control,” of this report); and
- Notification of the appropriate NRC regional administrator in writing, immediately following the filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)), as discussed further in Section 8.2.1, “Notification of Bankruptcy Proceedings,” of this report.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of the NRC’s Enforcement Policy and Inspection Procedures available in the NRC’s online library at <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 still consider reviewing their radiation safety programs and develop and implement a safety culture commensurate with the nature and complexity of their organizations and functions.

Refer to Appendix S 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/regulatory/enforcement/safety-culture.html>.

Table 3.1 Traits of a Positive Safety Culture

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

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 ARDL licensees. These parts will apply to many, if not all, licensees.

The current versions of these parts can be found under the "Basic References" link at the 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 the above documents may be obtained by calling the Government Printing Office order desk toll-free at (866) 512-8600, in Washington, DC, at (202) 512-1800 or 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 and amendments can also be accessed from the "NRC Library" link on the NRC's public Web site at <http://www.nrc.gov>. The NRC and all other Federal agencies publish amendments to their regulations in the *Federal Register*.

5. HOW TO FILE

5.1 Paper Application

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete NRC Form 313 (Appendix B) Items 1 through 4, 12, and 13 on the form itself.
- Complete NRC Form 313 Items 5 through 11 on supplementary pages or use Appendix C.
- Provide sufficient detail for the NRC to determine that 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 C submitted with the application, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Submit all documents, typed, on 8-1/2 x 11-inch paper.
- Avoid submitting proprietary information and personally identifiable information.
- If submitted, proprietary information and other sensitive information (e.g., personal privacy and security related) should be clearly identified per 10 CFR 2.390, "Public inspections, exemptions, requests for withholding" (see Chapter 6, "Identifying and Protecting Sensitive Information").
- Submit an original, signed application.
- Retain one copy of the license application for future reference.

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

5.2 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 Transfer to Electronic Format

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 printed or typewritten—not handwritten—text on smooth, crisp paper that will feed easily into the scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, or Univers (the text of this document is in the Arial font).
- Use 12-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).

The NRC will provide additional instructions as the agency implements new mechanisms for electronic license application filing.

6. IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

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

The licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. Licensing applications that contain sensitive information should be marked as indicated below in accordance with 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.
- **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, which can be found on the NRC's Generic Communications webpage under "Regulatory Issue Summaries": <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 release of information that terrorists could use to plan or execute an attack against facilities or citizens in the United States. As a result, certain types of information are no longer routinely released and are treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information and the top of every page of a document that contains such information should be clearly marked: "Security Related Information—Withhold under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g. an editorial note box) adjacent to that material. For further information, see RIS 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 22, 2005, which can be found on the NRC's Generic Communications webpage 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>.

7. APPLICATION AND LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to 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 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 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."

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

8. CONTENTS OF AN APPLICATION

The following comments apply to the indicated items on NRC Form 313 (Appendix B).

All items in the application should be completed in enough detail for the NRC to determine that 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 must 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.

10 CFR 20.1101(b) states: "The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," discusses the ALARA 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.

10 CFR 20.1801, "Security of stored material," states that licensees shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

10 CFR 20.1802, "Control of material not in storage," states that licensees shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

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

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

8.1 Item 1: License Action Type

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

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

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

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

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

See "Amendments and Renewals to a License" in Chapter 9 of this report.

8.2 Item 2: Applicant's Name and Mailing Address

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

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

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

8.2.1 Notification of Bankruptcy Proceedings

Regulations: 10 CFR 30.34(h)

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

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. The NRC must be notified when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). The NRC shares the results of its determinations with other involved entities (e.g. trustee), so that health and safety issues can be resolved before bankruptcy actions are completed and may request that the United States Department of Justice (DOJ) 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 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. 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 gauging devices) will be used at temporary job sites, so indicate, and describe the scope of these activities.

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, and storing licensed material at an address or location not included with the application or 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 materials greater than or equal to Category 2 quantities, as defined in 10 CFR 37.5, “Definitions,” the applicant should mark these documents as “Security-Related Information—Withhold under 10 CFR 2.390.” See Chapter 6, “Identifying and Protecting Sensitive Information,” for more details.

Note: As discussed later in Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning,” licensees must maintain permanent records describing where licensed material was used or stored while the license was in effect. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For fixed gauge licensees, acceptable records are leak test records, sketches, and written descriptions of specific locations where each gauge was used or stored and any information relevant to damaged devices or leaking radioactive sources.

8.4 Item 4: Person to Be Contacted about this Application

Identify the individual who can answer questions about the content of the application, and include a telephone number where the individual may be contacted. Also include business cell phone numbers and e-mail addresses. This individual, usually the 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 only provides information and would not be considered an application for license amendment, unless the notification involves a change in the contact person who is also the RSO.

As indicated on NRC Form 313 (Appendix B), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C for this purpose and should note that using the suggested wording of responses and committing to using the model procedures in this report 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 30.21, 10 CFR 30.32(g), 10 CFR 30.32(i), 10 CFR 30.33, 10 CFR 31.5, 10 CFR 31.8, 10 CFR 31.11, 10 CFR 32.210

Criteria: An application for a license will be approved if the requirements of 10 CFR 30.33, “General requirements for issuance of specific licenses,” 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(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 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.

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

If you 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," then you must provide with the application either (1) 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 (2) an emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(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.

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

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. Licensees may not make any changes to the sealed source and/or device that would alter the description or specifications from those indicated in the registration certificate, without obtaining permission from the NRC in a license amendment.

If a source is not listed in the SSD, 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 is an older source or device, 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 millicurie of a beta/gamma emitter or 10 microcuries 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)

Applicants should determine if the type, form, and amounts of any of the materials requested exceed those for Category 1 and Category 2 sources, which must be tracked in the National Source Tracking System (NSTS) in accordance with 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources." Such sources also may have additional requirements for security of these materials under 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Applicant and licensee information on manufacturers, model numbers, and possession limits is sensitive and should be marked accordingly (see Chapter 6, "Identifying and Protecting Sensitive Information"). Generally, ARDL licensees possess small quantities of material below the Category 2 quantities described in the IAEA's "Code of Conduct on the Safety and Security of Radioactive Sources." Refer to Appendix E, "Nationally Tracked Source Thresholds," to 10 CFR Part 20, "Standards for Protection against Radiation," for a list of radionuclides of interest and Category 2 quantities. If ARDL licensees acquire a Category 2 (or larger) quantity, applicants and licensees should refer to Item 8.10.9, "Security Program for Category 1 and Category 2 Materials," for more information.

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 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 should be made to the appropriate regulatory agency. The NRC does not regulate most naturally occurring radioactive material. The NRC will license NORM if it is a discrete source that poses a threat similar to that of a discrete source of radium-226, and only in consultation with other federal agencies as listed in 10 CFR 30.4 and is extracted or converted after extraction for use in commercial, medical, or research activity.

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,” or 10 CFR 30.18, “Exempt quantities.” If so, it is not necessary to submit an application to the NRC for byproduct materials that are covered by the exemptions, provided that they are received from entities that are licensed to distribute them.

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.” Persons eligible for this general license are 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 (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. Obtain a copy of the SSD certificate from the manufacturer or distributor and provide the SSD registry number with the application.
 - 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 and 32.210.
- Provide an emergency plan if required by 10 CFR 30.32(i) and 30.72

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. See Notice of Availability on the inside front cover of this report to obtain copies of these documents. They are also available on the NRC’s Web site at www.nrc.gov.

8.5.2 Financial Assurance and Recordkeeping for Decommissioning

Regulations: 10 CFR 30.32(h), 10 CFR 30.34(b), 10 CFR 30.35, 10CFR 30.34(b). 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 40.61(d), 10 CFR 40.61(e), 10 CFR 40.61(f), 10 CFR 70.22(a)(9), 10 CFR 70.25, 10 CFR 70.38(e), 10 CFR 70.38(g)(4)(v), 10 CFR 70.51(b)

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35, “Financial assurance and recordkeeping for decommissioning,” must provide evidence of financial assurance for decommissioning. Pursuant to 10 CFR 30.35(g), licensees must transfer records important to decommissioning to new licensees before licensed activities are transferred in according to 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, each licensee shall forward the records required by 10 CFR 30.35(g) to the appropriate NRC regional office.

Discussion: The NRC wants to ensure that decommissioning will be carried out with minimum effect on the public, occupational health and safety, and the environment. There are two parts to this rule: financial assurance that applies to some licensees, and record keeping that applies to all licensees.

NRC regulations requiring a certification of financial assurance (FA) or a decommissioning funding plan (DFP) are designed to provide reasonable assurance that the technical and environmental components of decommissioning are carried out and unrestricted use of the facilities is possible at the conclusion or termination of licensed activities.

These requirements, if applicable, specify that a licensee 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, or both, when the possession of radioactive material with a half-life ($T_{1/2}$) greater than 120 days exceeds certain limits. Criteria for determining if an applicant is required to submit a DFP and a certification of FA (or neither) are stated in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25 all entitled, "Financial assurance and record keeping for decommissioning." A DFP contains a site-specific cost estimate and a certification of FA. An FA certification includes a certification that the licensee has provided the required FA and an acceptable FA instrument.

A DFP also will be 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 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 includes trusts; surety, insurance, or other guarantee methods (letters of credit, surety bonds, parent company guarantees, insurance policies), and statements of intent for Government entities. Criteria for parent company guarantees and self-guarantees can be found in Appendices A, C, D, and E to 10 CFR Part 30.

Table 8.1 is a partial list of radionuclides of $T_{1/2} > 120$ days with their corresponding limits in excess of which a certification of FA or a DFP, or both, is required. However, it is the NRC's experience that most ARDL licensees use only a few of these radionuclides, and that the most frequently used radionuclides on this list are hydrogen-3 (H-3 or tritium) and carbon-14 (C-14) in unsealed form. The amount of such radionuclides ARDL licensees require rarely exceeds the limits that require submitting a DFP or a certification of FA. See Table 8.2 for possession limits and guidance for submitting either a DFP or a certification of FA. Radionuclides of $T_{1/2} > 120$ days are listed in column 1. Column 2 lists the corresponding possession limits of radionuclides in unsealed form requiring a certification of FA. These limits apply when only one of these radionuclides is possessed. If more than one radionuclide is possessed, the sum-of-fractions must be calculated to determine if a FA is required.

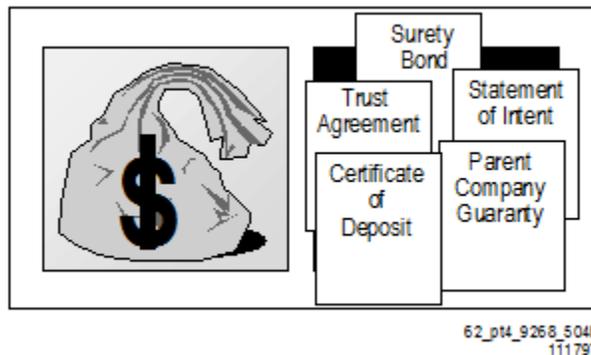


Figure 8.1 Methods of Certification of Financial Assurance for Decommissioning

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 the FA requirement is not applicable. 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.

Table 8.1 Commonly Used Unsealed Licensed Materials Requiring Financial Assurance and Decommissioning Funding Plan

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 MBq

NUREG-1757, Volume 3, provides guidance acceptable to the NRC staff on the information to be provided for establishing FA for decommissioning and a standard format for presenting the information. Note that FA is required for four types of licensed materials: unsealed byproduct material (10 CFR 30.35); sealed byproduct material (10 CFR 30.35); dispersible source material (10 CFR 40.36); and unsealed special nuclear material (10 CFR 70.25). The total amount of FA required is the sum of the FA required for each of these types of materials.

Recordkeeping

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g). 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.

All licensees are required to maintain these records in an identified location until the site is released for unrestricted use (see Figure 8.2). In the event that the licensed activities are transferred to another NRC or Agreement State licensee, these records shall be transferred to the new licensee before transfer of the licensed activities in accordance with 10 CFR 30.35(g). The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records shall be transferred to the NRC.

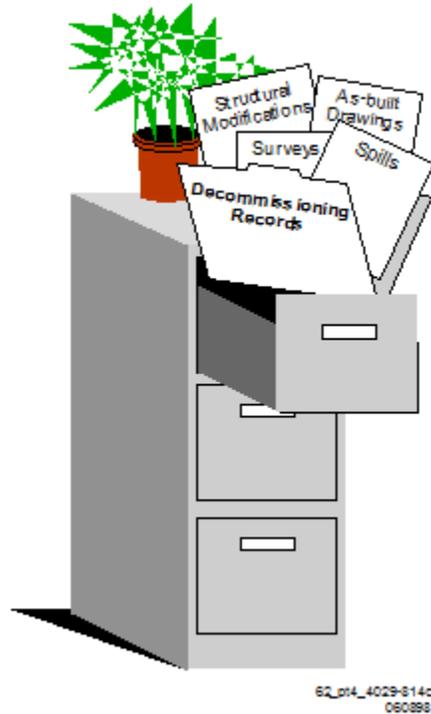


Figure 8.2 Types of Records that Must Be Maintained for Decommissioning

10 CFR 30.35(g), Requirements for Disposition of Records Important to Decommissioning

- Before licensed activities are transferred or assigned according to 10 CFR 30.34(b), transfer to the new licensee

OR

- Before the license is terminated, transfer records to the appropriate NRC regional office.

Response from Applicants:

- State the following: “Pursuant to 10 CFR 30.35(g), we shall transfer records important to decommissioning to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, we shall forward the records required by 10 CFR 30.35(g) to the appropriate NRC regional office. ”

AND

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

8.6 Item 6: Purposes 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: The applicant must specify the purpose of use for each sealed and unsealed radionuclide requested. All sealed sources and devices containing licensed material shall be used only for the purpose for which they are designed, and according to manufacturer’s (distributor’s) instructions and recommendations for use as specified in the SSD registration certificate.

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 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 8.2 to provide the requested information.

Table 8.2 Sample Format for Providing Information about Requested Radionuclides

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; studies in small lab animals
P-32	Any	30 millicuries	<i>In vitro</i> studies; labeling of compounds

Radionuclide	Chemical and Physical Form	Maximum Possession Limit	Proposed Use
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

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 (cats, dogs) or in farm animals (cattle, horses, pigs). Appendix E 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 (EA) may be needed according to 10 CFR 51.21, "Criteria for and Identification of Licensing and Regulatory Actions Requiring Environmental Assessments." NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," addresses procedures that staff should use in conducting environmental reviews, and is available on the NRC Web site under "Document Collections." Memoranda dated March 19, 2004 (ADAMS Accession No. ML040790751) and October 20, 2009 (ADAMS Accession No. ML092321078), provide further guidance. Both these memoranda are publicly available and can be accessed through the NRC's Agencywide Documents Access and Management System (ADAMS), which is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Applicants for tracer or field studies must provide the NRC with a description of the study for review and approval before performing such studies.

If you want to perform field studies in which licensed material is deliberately released to the environment for the purposes of studies, please 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 your application and concur with your 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.

Reference: Supplement to Policy and Guidance Directive FC 84-20, "Impact of Revision of 10 CFR Part 51 on Materials License Actions," dated March 1994, ADAMS Accession No. ML032590987.

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), 30.34(e)

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

Discussion: The person responsible for implementing the radiation protection program is the radiation safety officer, or RSO. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are illustrated in Figure 8.3 and described in Appendix F. The NRC lists the name of the RSO on the license to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

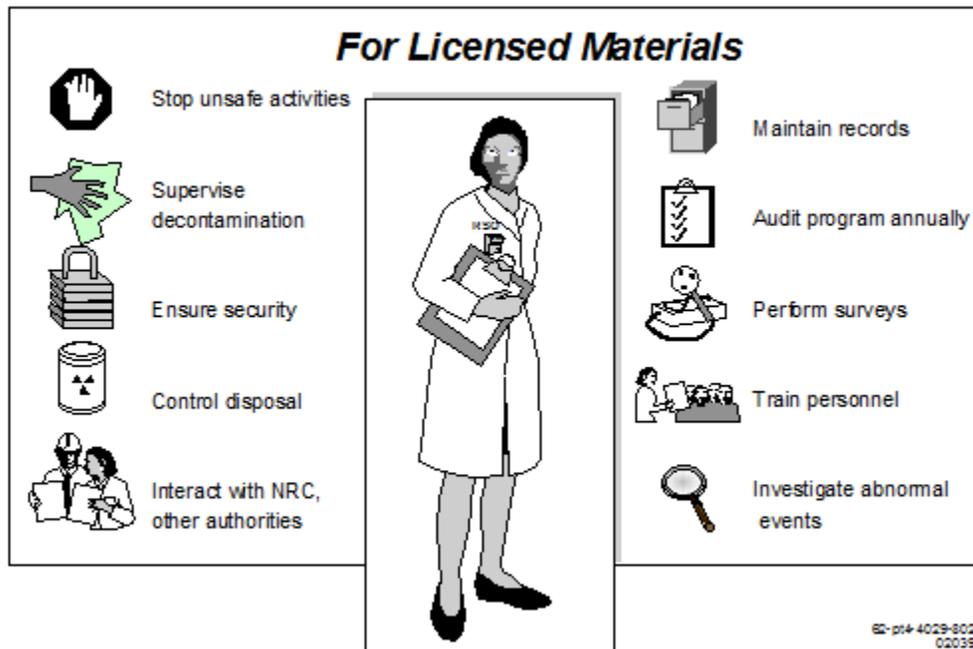


Figure 8.3 Typical Duties and Responsibilities of RSOs

The NRC believes that to demonstrate adequate training and experience, the RSO should have (1) at a minimum, a college degree at the bachelor's level, or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities.

Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection instrumentation
- biological hazards of exposure to radiation (appropriate to types and forms of byproduct material to be used)
- NRC regulatory requirements and standards
- 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 F

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 larger licenses where workers handle significant quantities of radioactive material may need additional training in the field of radiation protection and may need 40 hours of radiation safety training specific to their job duties. An individual also may need a year of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be an RSO. On the other hand, RSOs at licenses using microcurie and small millicurie quantities may only require a few hours of radiation safety training to be qualified as an RSO. The proposed RSO's training and experience must be sufficient to identify and control the anticipated radiation hazards. In addition, the RSO designee should have obtained the above training in a formal course designed for RSOs, presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts.

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 PII (see Chapter 6, "Identifying and Protecting Sensitive Information").

Note: It is important to notify the NRC, as soon as possible, of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to the NRC as part of an amendment request.

8.7.2 Authorized User

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

Criteria: Authorized users (AUs) 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 a person whose training and experience have been reviewed and approved by the NRC, who is named on the license, and who uses or directly supervises the use of licensed material. The AU's primary responsibility is to ensure that radioactive materials used in his or her particular lab or area are used safely and according to regulatory requirements (see Figure 8.4). 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.



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Figure 8.4 Authorized User

The AU is responsible for the safe use of licensed material in his or her laboratory or area.

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

The NRC believes that to demonstrate adequate training and experience, the AU should have (1) a college degree at the bachelor's level, or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection 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 30.7, 10 CFR 30.9, 10 CFR 30.10, 10 CFR 30.33(a)(3)

Criteria: Individuals whose assigned duties involve exposure to radiation or radioactive material (from both licensed and unlicensed sources), and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem),

must receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12, "Instructions to Workers."

Discussion: Before beginning work with licensed material, most individuals 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 G 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)

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, in case changes are required as a result of the application review.

This also ensures the adequacy of the facilities and equipment before the applicant makes a significant financial commitment. In all cases, the applicant may not possess or use licensed material until after the facilities are approved, equipment is procured, and the license is issued.

Applicants are reminded that records important to decommissioning as described in 10 CFR 30.35(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 are required to meet the NRC criteria prior to release. 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 H 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 E)

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 H 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, 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.

8.10 Item 10: Radiation Safety Program

8.10.1 Audit Program

Regulations: 10 CFR 20.1101, 10 CFR 20.2101 through 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 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 I contains a suggested audit program that is specific to ARDL licensees and is acceptable to the NRC. All areas indicated in Appendix I may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to their activities or activities that have not occurred since the last audit. Generally, audits are conducted at least once every 12 months. During inspection, the NRC observes work in progress. As a part of their audit programs, applicants should consider performing unannounced observations of byproduct material users to determine, for example, if safe use and emergency procedures are available and being followed.

If an audit identifies violations of NRC requirements, the licensee should first evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. Certain identified problems or potential violations may require notification or a report to the NRC. Licensees are encouraged to contact the NRC for guidance if there is any uncertainty about a reporting requirement. The NRC routinely reviews licensee's records to verify if appropriate corrective actions were implemented in a timely manner to address 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. For information on 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/>. The NRC's Enforcement Policy may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html> and the Enforcement Manual may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html>.

Licensees must maintain records of these audits and other reviews of program content and implementation for 3 years from the date of the record. Records of these audits should include the following information: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and followup. These records must be maintained for NRC inspections.

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

References:

- Inspection Procedure 87126, "Industrial/Academic/Research Programs," September 2005.
- 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)

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 shall 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

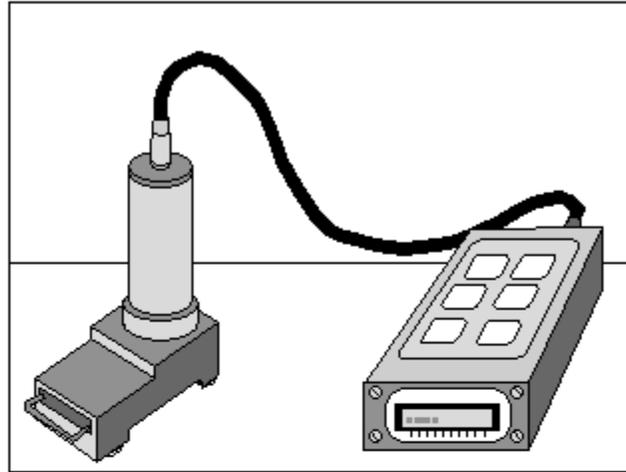
For the purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some survey instruments that may be used to perform the above functions include:

- 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

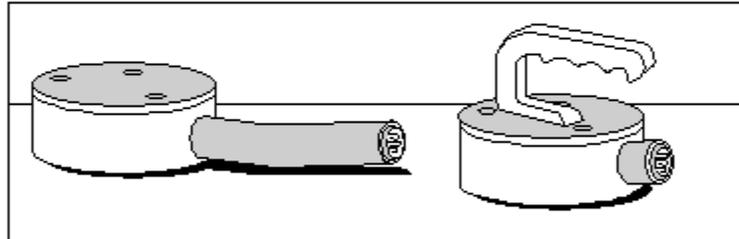
Other equipment and instrumentation associated with the radiation hazard assessment also must be calibrated periodically, in accordance with 10 CFR 20.1501(c). This includes equipment used to collect radiological samples to perform assessments of airborne hazards, and other radiological hazards that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

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

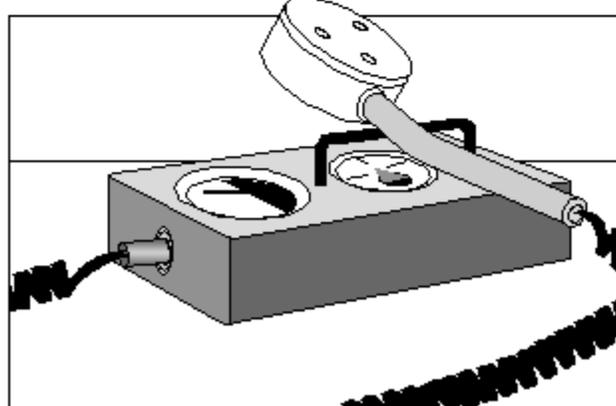
Contamination Detector



Beta/gamma Probes



Survey Meter and Attached Beta/gamma Probe



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Figure 8.5 Examples of Portable Instruments Used in Laboratory Settings

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 8.5 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 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 J.

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. The NRC requires that calibrations be performed by the instrument manufacturer, or a person specifically authorized by NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations shall submit procedures for review. Appendix J provides information about instrument specifications and model calibration procedures.

Response from Applicant: Provide one of the following:

A description of the instrumentation (as described above) that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix J in the NUREG-1556, Volume 7, Revision 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Laboratory Licenses of Limited Scope.' We reserve the right to upgrade our survey instruments as necessary. Additionally, instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."

OR

A description of the instrumentation (as described above) that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix J 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. Additionally, we will implement the model survey meter calibration program published in Appendix J NUREG-1556, Volume 7, Revision 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.'"

OR

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

Note: Alternative responses will be reviewed using the criteria listed above.

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 31.11

Criteria: Licensees must do the following:

- Develop, implement, and maintain written procedures for safely opening packages.
- Develop, implement, and maintain procedures to ensure security and accountability of licensed material.
- Maintain records of receipt, transfer, and disposal of licensed material.
- Update transactions in the National Source Tracking System (NSTS), including an 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 K 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 K.

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 by receiving 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.

Table 8.3 Package Monitoring Requirements

Package	Contents	Survey Type	Survey Time*
Damaged	Licensed Material	Radiation Level 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 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
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Less Than Type A	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.

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: (1) radiation levels shall not exceed 200 mrem/hour, and (2) removable radioactive surface contamination for beta/gamma emitters and low toxicity alpha emitters shall not exceed, 220 disintegration per minute per centimeter squared (dpm per cm²); or for all other alpha emitters 22 dpm/cm².

As illustrated in Figure 8.6, licensed materials must be tracked from "receipt to disposal" in order to ensure accountability and to ensure that possession limits listed on the license are not exceeded.

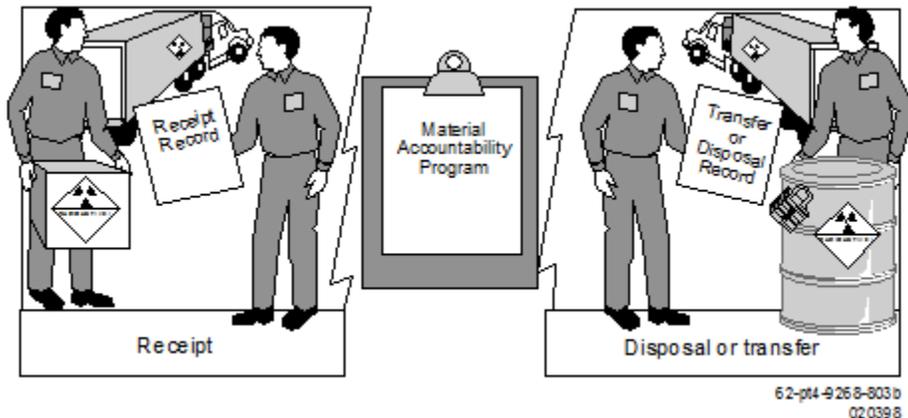


Figure 8.6 Material Receipt and Accountability

Licensees must maintain records of receipt, transfer, and disposal of licensed material.

Regulations in 10 CFR 20.1801 and 10 CFR 20.1802 require licensees to secure radioactive materials from unauthorized removal or access while in storage in controlled or unrestricted areas and to control and maintain constant surveillance over licensed material that is in a controlled or unrestricted area and is not in storage. Applicants for limited scope licenses should establish policies and procedures to ensure compliance with security requirements. It is recognized that loss, theft, or misplacement of licensed material can occur; however, licensees should have an accountability and control system in place for promptly detecting losses of licensed material.

As stated in 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources," each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking System Transaction

Report. The NSTS is a secure, accessible, and easy-to-use computer system that tracks high-risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay below threshold levels. Additional information on this subject is provided in Section 8.10.9, "Security Program for Category 1 and Category 2 Materials."

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 generally licensed or distributed to them as an exempt quantity or item. Regulations in 10 CFR Part 31 provide information on generally licensed devices. Any person who acquires, receives, possesses, uses, or transfers a generally licensed device must do so in accordance with the provisions of the general license. Generally, licensed material that a specific licensee possesses may continue to be possessed under a general license. A specific license does not automatically remove general licensee status nor automatically "move" generally licensed material 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 generally licensed items to a specifically licensed item 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 MBq (200 microcuries), 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 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 and/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. These methods help to ensure that possession limits are not exceeded. Individual AUs should be able to account for all materials in their possession, whether the material is in solid, liquid, or gas form; whether it is possessed in a stock vial or dispersed in samples, or placed into waste containers 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 the how often unsealed materials are received and used, the periodic update may be weekly, monthly, quarterly, or at less frequent intervals.

NRC regulations applicable to transfers are stated in 10 CFR 30.41, "Transfer of byproduct material." Sample policy transfer statements are included in Appendix K. Transfer of licensed materials within the facility may require special procedures to ensure proper control. In many facilities, pieces of laboratory equipment or components, including refrigerators and freezers, will become contaminated. Removal of these items for maintenance, repair, or disposal also should be carefully controlled.

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.

Table 8.4 Record Maintenance

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until NRC terminates the license
Important to decommissioning	Until the site is released for unrestricted use

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

- radionuclide and activity (in units of becquerels or curies), and date of measurement of byproduct material
- manufacturer, model number, location for each sealed source, and, if needed for identification, serial number, and as appropriate, manufacturer and model number of device containing the sealed source
- date of the transfer and name and license number of the recipient, and description of the affected radioactive material (e.g., radionuclide, 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 on "Waste Disposal" 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). See also the section on "Financial Assurance and Record Keeping for Decommissioning."

Response from Applicant:

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

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 shall be maintained for a period of 5 years from the date of each inventory, and shall 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 criteria listed above.

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 20.1501, 10 CFR 20.1502, 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 20.1703, 10 CFR 20.2105, 10 CFR 20.2206, 10 CFR Part 20, Appendix B

Criteria: The use of individual monitoring devices for external dose is required for:

- Adults likely to receive an annual dose in excess of any of the following (each evaluated separately):
 - 5 mSv (0.5 rem) deep-dose equivalent
 - 15 mSv (1.5 rems) eye dose equivalent
 - 50 mSv (5 rems) shallow-dose equivalent to the skin
 - 50 mSv (5 rems) shallow-dose equivalent to any extremity
- Minors likely to receive an annual dose 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) 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 likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period
- Individuals entering a high or very high radiation area

Internal exposure monitoring (not necessarily individual monitoring devices) is required for:

- Adults likely to receive in 1 year an intake in excess of 10 percent of the applicable ALIs for ingestion and inhalation.
- Minors and declared pregnant women likely to receive in 1 year a committed effective dose equivalent in excess of 1.0 mSv (0.1 rem).

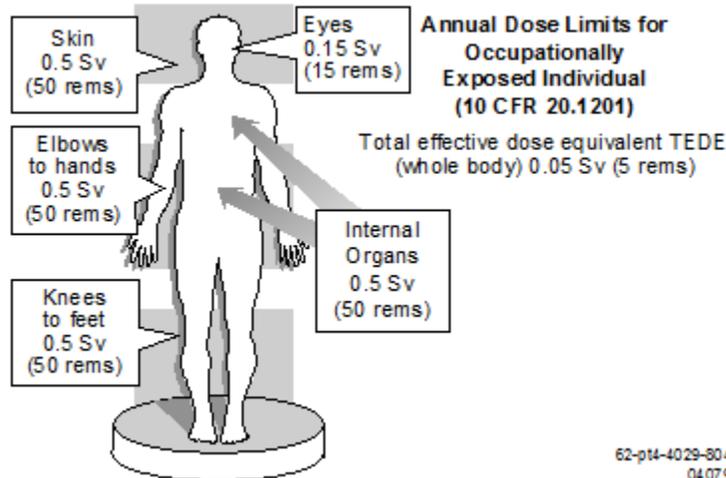


Figure 8.7 Annual Dose Limits for Occupationally Exposed Individuals

Discussion:

Total dose equivalent (TEDE) equals deep dose from external exposure plus dose from internally deposited radionuclides.

According to 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," if an adult (individual) is likely to receive in 1 year a dose greater than 10 percent of any applicable limit (see Figure 8.7 for annual dose limits), monitoring for occupational exposure is required. The licensee should perform an evaluation of the dose the individual is likely to receive before allowing the individual to receive the dose. This evaluation does not have to be made for every individual; evaluations can be made for employees with similar job functions or work areas. Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Doses," dated July 1992, provides further guidance on evaluating the need to provide monitoring.

If this prospective evaluation shows that the individual's dose is not likely to exceed 10 percent of any applicable regulatory limit, there are no recordkeeping or reporting requirements. For individuals who have received doses at other facilities in the current year, the previous dose does not have to be considered in this prospective evaluation. When determining the need for monitoring, only a dose that could be received at the applicant or licensee's facilities performing the evaluation needs to be considered, including any recordkeeping and reporting requirements. If an evaluation determined that monitoring was not required and a subsequent evaluation

indicates that the 10 percent regulatory threshold may or will be exceeded, the dose the individual received when monitoring was not provided should be estimated, recorded, and reported (if required). These estimates can be based on any combination of work location radiation monitoring, survey results, monitoring results of individuals in similar work situations, or other estimates to produce a “best estimate” of the actual dose received.

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 “NR” for “Not Required” in the blocks on NRC Forms 4 and 5 to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). The licensee should enter “ND” for “Not Detectable where monitoring was provided but not measurable.”

If the prospective dose evaluation shows that the individual is likely to exceed 10 percent of an applicable limit, monitoring is required (10 CFR 20.1502). Recordkeeping of the results of monitoring performed regardless of the actual dose received, is required by 10 CFR 20.2106(a).

A common method for dose evaluation is to monitor workers’ dose with whole body and extremity dosimetry (e.g., optically-stimulated luminescence dosimeter (OSL), thermoluminescent dosimeter (TLD), film, ring badge) that a National Voluntary Laboratory Accreditation Program (NVLAP)-approved dosimetry service provides. Workers typically are monitored for a year or more to determine actual annual dose. The monitoring results are then used to determine the need to continue monitoring workers. The dose to workers may need to be reevaluated if the licensee’s program changes (e.g., procedures, frequency of use, quantity of licensed material used, isotopes used).

Regulatory Guide 8.34 and Regulatory Guide 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,” dated July 1993, provide guidance on methodologies for determination of internal occupational dose and summation of occupational dose. The NRC also has developed additional regulatory guides for specific isotopes such as H-3 and iodine. Contact the appropriate NRC regional office or contact the NRC’s Web site, <http://www.nrc.gov>, for copies of these guidance documents.

Response from Applicant: Provide either of the following:

- A statement that: “We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20,” or “We will monitor individuals in accordance with the criteria in the section, ‘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

- A description of an alternate method for demonstrating compliance with the referenced regulations.

Note:

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

References: See the notice of availability on the inside front cover of this report to obtain copies of:

- Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Dose Data," dated November 2005.
- Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," Revision 1, July 1993.
- Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," July 1992.

8.10.5 Public Dose

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

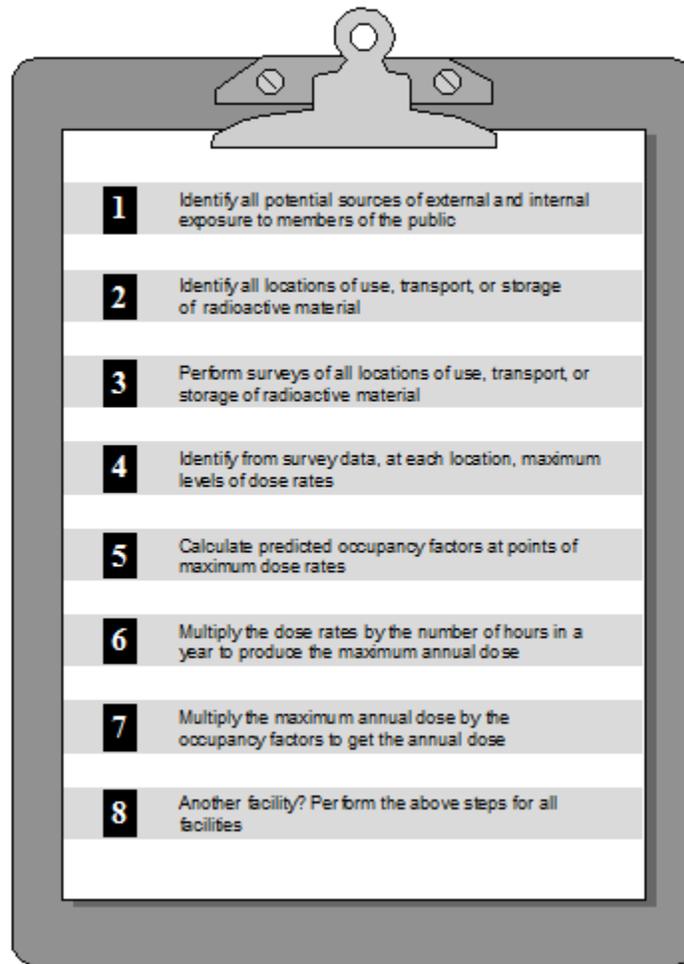
Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) in 1 year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour, from licensed operations.

Discussion: "Public dose" is defined in 10 CFR Part 20 as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation and medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

Appendix L provides guidance on accepted methodologies for determining dose to members of public.

Figure 8.8 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 8.8 Calculating Public Dose

Steps to calculate the annual dose to an individual member of the public (see Appendix L 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
- waterborne radioactive material
- external radioactive exposure

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

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1302(b). The extent and frequency of monitoring will depend 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 L 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 L for examples of methods to demonstrate compliance.

8.10.6 Safe Use of Radionuclides and Emergency Procedures

Regulations: 10 CFR 30.34(e), 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 30.32(i), 10 CFR 30.50, 10 CFR 30.72, 10 CFR 21.21, 10 CFR 19.11(a)(3)

Criteria: Licensees are required to 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
- responsibilities

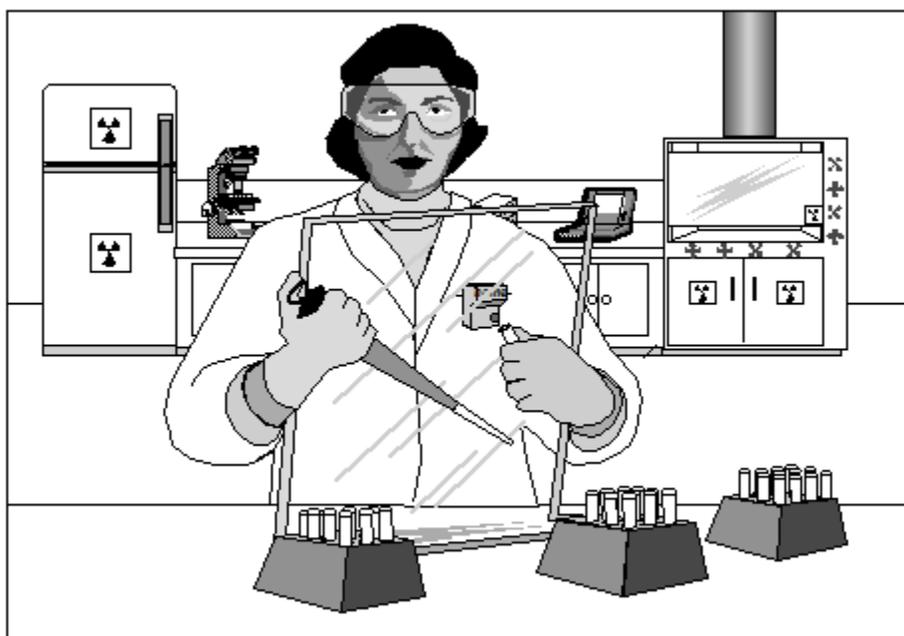
These procedures should include policies for:

- frequency of personnel monitoring
- use of appropriate shielding (see Figure 8.9)
- 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 M describes general safety guidelines. Applicants should use these guidelines to develop procedures for the safe use of radionuclides.

Licensees should determine if they have areas that require posting in accordance with 10 CFR 20.1902, "Posting requirements," unless they meet the exemptions 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 8.9 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 use, 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 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 with “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 may 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 also may be required to submit an “Emergency Response Plan for Responding to a Release.”

Applicants should establish written procedures to handle events ranging from a minor spill (see Figure 8.10) 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 on 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 to use. All equipment should be inspected periodically for proper operation and replenished as necessary. Appendix M includes model emergency procedures. Applicants may adopt these procedures or develop their own, incorporating the safety features included in these model procedures.

Collection of Bioassay Samples

In the event of an emergency in which an individual becomes contaminated and radioactive material is taken into the body through skin absorption or other means, or is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. 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
- frequency of sampling (e.g., hourly, daily, weekly, once,)
- size of the sample to be collected (24-hour urine collection?)
- ease or difficulty of sample collection
- need for written instructions for the sample collector, who may be the contaminated individual



Figure 8.10 Proper Handling of Incident

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: The applicant must state that procedures for safe use, security of materials, and emergencies have been developed, or will be developed before receipt of licensed material; and that the procedures will be implemented and maintained. If an “Emergency Response Plan” is required for your license under 10 CFR 30.32(i), submit it as a separate part of the application. If you want the option to make changes in the procedures, submit a statement that, “Procedures may be revised only if (1) the licensee management and the RSO have reviewed and approved the changes in writing; (2) the licensee staff is provided training in the revised procedures before implementation; (3) the changes are in compliance with the NRC regulations and the license; and (4) the changes do not degrade the effectiveness of the program.”

8.10.7 Surveys

Regulations: 10 CFR 30.36(j-k), 10 CFR 30.53, 10 CFR 20.1501, 10 CFR 20.1906, 10 CFR 20.2103

Criteria: Licensees are required by 10 CFR 20.1501, “General,” 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. Records of surveys and leak tests results must be maintained.

Discussion: Surveys are evaluations of radiological conditions and potential hazards (see Figure 8.11). These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. 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.

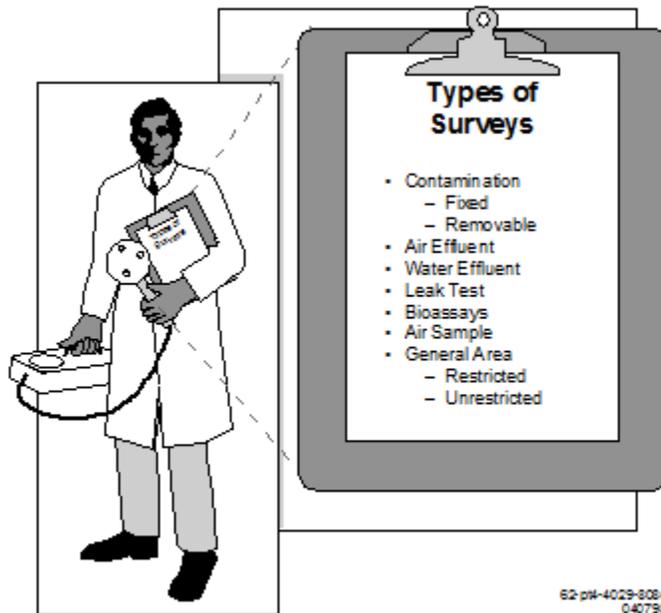


Figure 8.11 Types of Surveys

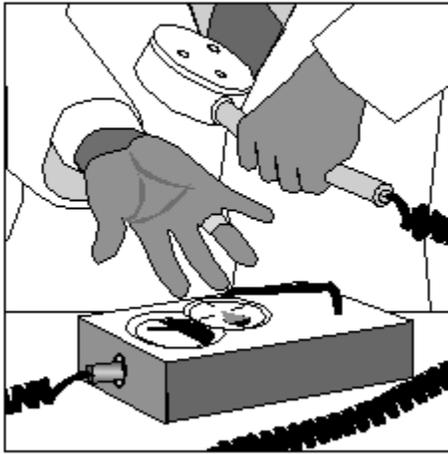
ARDL licensees perform many different types of surveys.

Radiation surveys are used to detect and evaluate contamination of:

- facilities
- equipment
- personnel (during use, transfer, or disposal of licensed material) (see Figure 8.12)
- restricted and unrestricted areas

Surveys also are used to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public.

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 8.12 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, 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 protective 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 N)

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 N.2 and Table N.3 in Appendix N 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/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 Bq (0.005 μ Ci) of the radionuclide contained in the source or foil.

The NRC or an Agreement State may authorize manufacturers, consultants, and other organizations 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 it to the kit supplier 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 themselves.

Leak tests are not required if:

- sources contain only H-3
- 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 kBq (10 μ Ci) or less of alpha-emitting material
- sources are stored and not being used (must be leak tested before use or transfer)

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 O for more information on leak tests.

Response from Applicant: 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 N in NUREG-1556, Volume 7, Revision 1, ‘Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope’ Leak tests will be performed at the intervals approved by 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 NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the applicant, using a leak test kit supplied by an organization authorized by the NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer’s (distributor’s) and kit supplier’s instructions.”

OR

- If leak tests will be analyzed by the applicant, state: “We will implement the model leak test program published in Appendix O 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 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 criteria listed above.
- 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, 71.47, 71.87, 49 CFR Parts 171-178, 10 CFR 20.1101, 10 CFR 30.41, 10 CFR 30.51, 49 CFR Parts 172, 173, 177.

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 for limited quantities of Class 7 (radioactive) materials,” and 49 CFR 173.424; “Excepted packages for radioactive instruments and articles”. See Appendix P 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 SI units only <u>or</u> must be in SI units first with English units in parenthesis.

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 are reviewed during inspections.

Reference: “A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 revision)” can be obtained by calling DOT’s Office of Hazardous Safety Administration Training at 202-366-4900. Publications, guidance, and training materials can be found at the DOT Web site <http://phmsa.dot.gov/hazmat/training/publications>.

8.10.9 Security Program for Category 1 and Category 2 Materials

Regulations: 10 CFR 20.2207, 10 CFR Part 37

Criteria: Licensees must ensure the security and control of licensed material.

Note: The requirements in 10 CFR 20.2207 are only applicable to those licensees that possess Category 1 and Category 2 sources. The regulations in 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,” apply to licensees that possess an aggregate amount of category 1 or category 2 quantity of radioactive material.

Discussion: 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 an NSTS report. The NSTS is a major security initiative of the NRC. The NSTS is a secure, accessible and easy-to-use computer system that tracks high-risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay enough to no longer be of concern.

In accordance with 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,” licensees authorized to possess Category 1 or Category 2 quantities of radioactive material must establish, implement, and maintain a security program to ensure physical protection of the radioactive material. For additional guidance 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.”

Table 1 of Appendix A, “Category 1 and Category 2 Radioactive Materials,” to 10 CFR Part 37 lists Category 1 and 2 threshold quantities of radioactive material. The applicant should refer to this table to determine if its program exceeds the Category 1 or Category 2 authorization thresholds.

If licensees possess, ship, or receive quantities of material exceeding Category 1, then they must also comply with requirements specific to Category 1 quantities. Refer to 10 CFR Part 37 for these additional requirements.

Per 10 CFR Part 37, Subpart B, licensees must establish an access authorization program to ensure that individuals who have unescorted access to Category 1 and 2 quantities of radioactive material and reviewing officials are trustworthy and reliable.

Per 10 CFR Part 37, Subpart C, licensees must establish a physical protection program 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 in use or storage.

Per 10 CFR Part 37, Subpart D, licensees must provide for physical protection of Category 1 or Category 2 quantity of radioactive materials in transit. These requirements apply to a person delivering material to a carrier for transport, as well as cases in which the person transports material.

Note: Refer to 10 CFR Part 37 and associated guidance in NUREG-2155 for additional details on security guidance.

Response from Applicant:

No response is required from an applicant or licensee that would become newly subject to 10 CFR Part 37.

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1904, 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2108, 10 CFR 30.51, 10 CFR 61.52

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, 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 waste to decay in storage (DIS). Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne

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

NRC requires ARDL licensees to dispose of radioactive waste generated at their facilities through one or more of the following methods:

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

Licensees may choose one or more of these methods to dispose of their radioactive waste. The NRC has observed that 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 that do not have access to a radioactive waste facility 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 radionuclide(s), half-life, and the activity present when the waste was placed into storage. Such waste may be disposed of as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that

radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages before disposal as ordinary trash. If the decayed waste is compacted, all labels visible in the compacted mass also must be defaced or removed.

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 Q provides a model procedure for disposal of radioactive waste by DIS, which incorporates the above guidelines.

Release into Sanitary Sewerage

Regulations in 10 CFR 20.2003, "Disposal by release into sanitary sewage," 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 that the licensee releases into the sewer each month averaged over the 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 released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radionuclides combined.

Licensees are responsible for demonstrating that licensed materials discharged into the public sewerage system are readily soluble in water. NRC IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 28, 1994, provides acceptable criteria for evaluating solubility of wastes released to the sewer. Careful consideration should be given to the possibility of reconcentration of radionuclides released into the sewer. 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 document.

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 Q 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 in 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 the appendix. Each person involved in the transfer for disposal and disposal of waste, including waste generator, waste collector, waste processor, and disposal facility operator, must comply with requirements specified in Section III 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

Some licensees do not have an LLW disposal facility available; therefore, they must use onsite interim storage until a facility becomes available. 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 RIS 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," 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 R 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 (1) decay-in-storage, or (2) disposal of liquids into sanitary sewerage) model waste procedures that are published in Appendix Q in NUREG-1556, Volume 7, Revision 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.'"

AND

If access to a radioactive waste burial site is unavailable, the applicant should request authorization for extended interim storage of waste. Applicant should use the references listed below for guidance and submit the required information with the application.

Note: 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.

Alternative responses will be reviewed using the criteria listed above.

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 20," January 1994.
- Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.303 (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 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.
- Policy and Guidance Directive PG 8-10, "Disposal of Incinerator Ash as Ordinary Waste," January 1997, ADAMS Accession Nos. ML003744979 and ML003752866 and Addendum, ADAMS Accession Nos. ML003744984 and ML003744988.
- NRC Regulatory Issue Summary 2004-17, "Revised Decay-in-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material," Revision 1, September 2005.

The next two items on NRC Form 313 should be completed on the form itself.

8.12 Item 12: License Fees

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

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

8.13 Item 13: Certification

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

Notes:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, those items become binding and are part of the license conditions and regulatory requirements

9. AMENDMENTS AND RENEWALS TO A LICENSE

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

Applicants for license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request.
- Submit either an 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 if many outdated documents are referenced or there have been significant changes in regulatory requirements, the NRC's guidance, the licensee's organization, or the licensee's radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

9.1 Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b)

Criteria: Licensees must provide full information and obtain the NRC's *prior, written consent* before transferring control of the license, or, as some licensees call it, "change of ownership" and/or "transferring the license."

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

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses or Agreement State licenses.
- Materials are properly handled and secured.
- Persons using these materials are competent and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material.

- 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, for more information about transfer of ownership.

10. APPLICATIONS FOR EXEMPTIONS

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

Criteria: Licensees may request exemptions from 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.

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

Exemptions are not intended to revise regulations or apply to large classes of licensees and are generally limited to unique situations. Exemption requests must be accompanied by descriptions of the following:

- Exemption requested basis, and justification for the requested exemption.
- Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested.
- Alternative methods for complying with the regulation and an explanation of why compliance with the existing regulation is not feasible.

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

11. TERMINATION OF ACTIVITIES

Regulations: 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36(d) and (k), 10 CFR 30.36(j)(1), 10 CFR 30.51(d), (e) and (f)

Criteria: The licensee must do the following:

- Notify the NRC, in writing, within 60 days of the occurrence of any of the following:
 - Expiration of its license.
 - A decision to permanently cease licensed activities at the entire site.
 - A decision to permanently cease licensed 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.
 - 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 to the appropriate NRC regional office a completed NRC Form 314, “Certificate of Disposition of Materials” (or equivalent information), and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final leak tests of sealed sources; final status surveys for facilities using unsealed materials).
- Before a license is terminated, send the records required by 10 CFR 30.51(f) to the appropriate NRC regional office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee in accordance with 10 CFR 30.35(g).

Discussion: Typically, an ARDL facility termination request will meet the above criteria if the licensee performs the following steps:

- Disposes of or transfers all licensed materials to an NRC or Agreement State licensee authorized to possess the materials and devices as described in Section 8.11, “Waste Management.”
- Submits results of a final status survey of the facility, demonstrating that the facility meets Subpart E, “Radiological Criteria for License Termination,” to 10 CFR Part 20. 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.” If the simplified methods cannot be used, other guidance in

NUREG-1757 may be applicable, as well as guidance in NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)."

- Submits copies of applicable decommissioning records as described in Section 8.5.2 "Financial Assurance and Recordkeeping for Decommissioning." Typically, these include transfer records of spills that may have resulted in residual contamination, drawings or diagrams of facilities where radioactive materials were used or stored, the list of designated restricted areas and areas where remediation may be needed, transfer records and final leak test records. See Section 8.5.2 for additional recordkeeping requirements if leaking sealed sources or other incidents that involve the spreading of contamination have occurred.
- Submits copies records of all applicable waste disposals (on-site burials, sewer disposal, incineration, and specific wastes) and records of results of surveys (measurements and calculations) of effluent releases.
- Submits a completed NRC Form 314 and a copy of the applicable decommissioning records to the appropriate NRC regional office.

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, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)."

APPENDIX A

LIST OF DOCUMENTS CONSIDERED IN DEVELOPMENT OF THIS NUREG

List of Documents Considered in Development of this NUREG

This document incorporates and updates the guidance previously found in the Regulatory Guides (RG) 10.2 and 10.7. In addition, it references other RGs, Policy and Guidance Directives (P&GD), Information Notices (IN), Inspection Procedure (IP), and other guidance documents used in its preparation. The guidance incorporated and referenced is listed in Table A.1. Documents marked with an asterisk are superseded by this NUREG.

Table A.1 List of Documents Considered in the Preparation of this Report

Document Identification	Title	Date
ANSI N13.1	Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities	2011
ANSI N42.18	Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents	1991
ANSI N323A	Radiation Protection Instrumentation Test and Calibration	1997
Enforcement Policy, Enforcement Guidance	http://www.nrc.gov/reading-rm/doc-collections/enforcement/ – Enforcement Policy at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html – Enforcement guidance (and Enforcement Manual) at http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html	
Federal Register 63 FR 64132	Decommissioning Guidance Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination, 63 FR 64132 (November 18, 1998) (building surfaces)	11/18/98
Federal Register 64 FR 68395	Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination, 64 FR 68395 (December 7, 1999) (soils)	12/7/99
Federal Register 65 FR 37186	Use of Screening Values to Demonstrate Compliance with the Final Rule on Radiological Criteria for License Termination, 65 FR 37186 (June 13, 2000)	6/13/00
IN 84-94	Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted under 10 CFR 20.303 (now 10 CFR 20.2003)	12/21/84
IN 89-25, Revision 1	Unauthorized Transfer of Ownership or Control of Licensed Activities	12/94

Document Identification	Title	Date
IN 90-09	Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees Updated by: Regulatory Issue Summary (RIS) 2008-12, Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees and RIS 2011-09, Available Resources Associated with Extended Storage of Low-Level Radioactive Waste, which refers to other helpful guidance documents	2/5/90 5/08 8/11
IN 94-07	Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR 20	1/28/94
IN 94-23	Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program	3/25/94
IN 96-28	Suggested Guidance Relating to Development and Implementation of Corrective Action	5/1/96
IN 97-30	Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises	6/3/97
IN 99-033	Management of Wastes Contaminated with Radioactive Materials	12/21/99
IN 00-16	Potential Hazards caused by Volatilization of Radionuclides	10/5/00
IN 01-01	The Importance of Accurate Inventory Controls To Prevent the Unauthorized Possession of Radioactive Material	3/26/01
IN 03-12	Problems Involved In Monitoring Dose to the Hands Resulting from the Handling of Radiopharmaceuticals	8/22/03
IN 09-07	Withholding of Proprietary Information from Public Disclosure	3/30/09
IN 09-30	Findings from the NRC Initiative To Assess Materials Licensees' Compliance with the NRC Decommissioning Requirements	11/6/09
IP 87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing	11/3/00
IP 87126	Industrial/Academic/Research Programs	9/28/05
NUREG-1400	Air Sampling in the Workplace	9/93
NUREG-1516	Management of Radioactive Material Safety Programs at Medical Facilities	4/97
NUREG-1549	Decision Methods for Dose Assessment To Comply with Radiological Criteria for License Termination	7/98
NUREG-1556, Vol. 15	Consolidated Guidance about Materials Licenses: Guidance about Changes of Control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses	11/00

Document Identification	Title	Date
NUREG-1757	Consolidated Decommissioning Guidance, – Vol. 1, “Decommissioning Process for Materials Licensees” (Revision 2), September 2006	9/06
	– Vol. 2, “Characterization, Survey, and Determination of Radiological Criteria” (Revision 1), September 2006	9/06
	– Vol. 3, “Financial Assurance, Recordkeeping, and Timeliness” Revision 1, February 2012	2/12
NUREG/CR-4884	Interpretation of Bioassay Measurements	7/87
NUREG/CR-5512, Vol. 3	Residual Radioactive Contamination from Decommissioning, Parameter Analysis	8/99
P&GD, PG 8-10	Disposal of Incinerator Ash as Ordinary Waste Policy and Guidance Directive PG 8-10, Disposal of Incinerator Ash as Ordinary Waste, dated January 1997, publicly available in the NRC’s Agencywide Documents Access and Management System (ADAMS) at Accession No. ;ML003744979 – Addendum to Draft PG 8-10, dated March 18, 1996, is publicly available in ADAMS at Accession No. ML003744984 – Generic Dose Assessment for Disposal of Incinerator Ash in a Landfill, September 1994, publicly available in ADAMS at Accession No. ML003752866 Technical Justification Addendum for PG 8-10, “Generic Dose Assessment for Disposal in a Landfill of Incinerator Ash Containing: S-35, Ca-45, Fe-59, P-32, and Tc-99m, using RESRAD and NUREG-1500 Methodology,” March 8, 1996; publicly available in ADAMS at Accession No. ML003744988	1/97
NCRP Commentary No. 3	Screening Techniques for Determining Compliance with Environmental Standards	1989/ Addendum (1989)
NCRP Report No. 48	Radiation Protection for Medical and Allied Health Personnel	1976
NCRP Report No. 127	Operational Radiation Safety Program	1998
NCRP Report No. 105	Radiation Protection for Medical and Allied Health Personnel	1989
NCRP Report No. 114	Maintaining Radiation Protection Records	1992

Document Identification	Title	Date
NCRP Report No. 157	Radiation Protection in Educational Institutions	2007
RG 4.20, Revision 1	Superseded by Regulatory Guide 4-20, Revision 1 "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors," April 2012	4/12
RG 8.7, Revision 2	RG 8.7 Revision 2, Instructions for Recording and Reporting Occupational Radiation Exposure Data, November 2005	11/05
RG 8.9	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program	7/1/93
RG 8.20 and DG-8050	Regulatory guide 8.20, Revision 1, "Applications of Bioassay for I-125 and I-131," September 1979 DG-8050, "Applications of Bioassay for I-125 And I-131" (ML102800439) September 2011 is also available on the NRC public web, Document Collections and in ADAMS	
RG 8.25, Revision 1	Air Sampling in the Workplace	6/92
RG 8.32	Criteria for Establishing a Tritium Bioassay Program	7/98
RG 8.34	Monitoring Criteria and Methods to Calculate Occupational Radiation Doses	7/92
RG 8.37	ALARA Levels for Effluents from Materials Facilities	7/93
RIS-05-031	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	12/22/05
RIS-07-004	Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission	3/9/07
RIS-08-012	Considerations for Extended Interim Storage Of Low-Level Radioactive Waste By Fuel Cycle And Materials Licensees	5/9/08
RIS-11-009	Available Resources Associated With Extended Storage Of Low-Level Radioactive Waste	8/16/11
SP-96-022	All Agreement States Letter	6/92
	"Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 9th edition	2001
	Handbook of Health Physics and Radiological Health, third edition, edited by Schlien, Slaback and Birky	1998

APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION FORM 313

United States 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 (03-2013) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120	EXPIRES: 05/31/2015 <small>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-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</small>		
 APPLICATION FOR MATERIALS LICENSE					
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.					
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS 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,		ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,			
SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713		SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511			
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.					
1. THIS IS AN APPLICATION FOR <i>(Check appropriate item)</i> <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 <i>(Include ZIP code)</i> _____ _____ _____			
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED _____ _____ _____		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION _____ BUSINESS TELEPHONE NUMBER _____ BUSINESS CELLULAR TELEPHONE NUMBER _____ BUSINESS EMAIL ADDRESS _____			
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.					
5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.		6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.			
8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.		7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.			
10. RADIATION SAFETY PROGRAM.		9. FACILITIES AND EQUIPMENT.			
12. LICENSE FEES <i>(Fees required only for new applications, with few exceptions*)</i> <i>(See 10 CFR 170 and Section 170.31)</i>		11. WASTE MANAGEMENT.			
FEE CATEGORY <input type="text"/>		AMOUNT ENCLOSED \$ <input type="text"/>			
13. CERTIFICATION. <i>(Must be completed by applicant)</i> 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, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.					
CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE		SIGNATURE	DATE		
FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY _____				DATE _____	

APPENDIX C

**SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED
IN ITEMS 5 THROUGH 11 OF NRC 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</p> <p>Unsealed or Sealed Sources</p> <ul style="list-style-type: none"> • For unsealed materials: <ul style="list-style-type: none"> – Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit. – For potentially volatile materials (e.g., I-125, I-131, H-3), 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 in each source. – Provide the manufacturer's (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. – Provide the activity per source and maximum activity in each device, and the maximum total number of sources and devices • Provide an Emergency Plan (if required). 	<p></p> <p>*</p> <p>*</p> <p></p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p></p>	<p>[]</p>
	<p>Financial Assurance and Recordkeeping for Decommissioning</p> <p>If FA or a DFP is required, submit the required documents as described in NUREG-1757, Volume 3.</p> <p>Records important to decommissioning and written materials documenting compliance with other financial assurance requirements will be examined during inspection.</p>	<p>*</p>	<p>[]</p>

Item No.	Suggested Response	Yes	Description Attached
6.	<p>PURPOSE 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>INDIVIDUALS 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, as 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>*</p>	<p>[]</p>
	<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. Also provide information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials. • Information should include, as 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) 	<p>*</p>	<p>[]</p>

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Radiation Monitoring Instruments</p> <p>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 J 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</p> <p>State that instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration.</p> <p style="text-align: center;">OR</p> <p>State that: "We will implement the model survey meter calibration program published in Appendix J 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>*</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>*</p>	<p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p>

Item No.	Suggested Response	Yes	Description Attached
	<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.” <p style="text-align: center;">AND</p> <p>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 shall be maintained for a period of 5 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer’s name and model numbers, and the date of the inventory.”</p>	<p>[]</p> <p>[]</p>	
10.	<p>RADIATION SAFETY PROGRAM (Cont’d)</p> <p>Occupational Dose</p> <p>State that: “We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20,” or “We will monitor individuals in accordance with the criteria in Section 8.10.4 entitled ‘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>Public Dose</p> <p>No response is required from the applicant in a license application but records and written materials documenting compliance will be examined during inspection.</p>	<p>[]</p> <p>N/A</p>	<p>N/A</p>

Item No.	Suggested Response	Yes	Description Attached
	<p>Safe Use of Radionuclides and Emergency Procedures</p> <p>Provide your procedures for safe use of radionuclides, security of materials and emergencies.</p> <p style="text-align: center;">AND</p> <p>If you want the option to make changes to the procedures, state that: "Procedures may be revised only if (1) the changes are reviewed and approved by the licensee management and the RSO in writing; (2) the licensee staff is provided training in the revised procedures before implementation; (3) the licensee management and the RSO review and approve the changes listed in (1) and (2) in writing."</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 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>State that: "We will develop, implement, and maintain procedures for safe use, security and emergencies."</p> <p>Emergency Response Plan</p> <p>If an emergency response plan is needed, submit it as a separate part of the application.</p>	<p>*</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>*</p>	<p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p>

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Surveys</p> <p>State that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix N in NUREG-1556, Volume 7, Revision 1, 'Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.'"</p> <p>Leak Testing</p> <p>Frequency</p> <p>State that: "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>Analysis</p> <p>State that: "Leak tests will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees or by using a leak test kit supplied by an organization that the NRC or an Agreement State has authorized to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions."</p> <p style="text-align: center;">OR</p> <p>State that: "As an alternative, we will implement the model leak test program published in Appendix O 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>Alternate survey and leak testing procedures are attached.</p>	<p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>*</p>	<p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p> <p>[]</p>

Item No.	Suggested Response	Yes	Description Attached
	<p>Transportation</p> <p>No response is needed from applicants during the licensing phase but records and written materials documenting compliance will be examined during inspection.</p>	N/A	N/A
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Security Program for Category 1 and Category 2 Materials In accordance with 10 CFR Part 37, licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material must establish, implement, and maintain an access authorization program and a security program to ensure physical protection of the radioactive material.</p>	N/A	N/A
11.	<p>WASTE MANAGEMENT</p> <p>State that: "We will use the model waste procedures published in Appendix Q 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 waste management.</p> <p style="text-align: center;">If applicable</p> <p>Submit waste disposal procedures for any method not covered in Appendix Q.</p> <p>If access to a radioactive waste burial site is unavailable, the applicant should submit procedures and request authorization for extended interim storage of waste.</p>	<p>[]</p> <p>*</p> <p>*</p> <p>*</p>	<p>[]</p> <p>[]</p> <p>[]</p>

APPENDIX D

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 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 radionuclide and proposed uses.

Regulations

Licensees are subject to all applicable provisions of the regulations in 10 CFR) Parts 20, 21, 30, 71, 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: Material to Be Possessed

- (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 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—Radiation Safety Officer

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 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.

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 shall 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.

Item 8: Training Provided to Other Users

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 shall 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.

The room, laboratory, or storage area where the device is located should be (1) accessible only to persons authorized to use the device and (2) 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.

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 I contains a suggested audit program that is acceptable to the NRC. All areas indicated in Appendix I may not be applicable to every licensee and may not need to be addressed during each audit.

10.2 Radiation Detection Instruments

A survey meter for routine uses of ECD/XRF is not required.

If maintenance and repair operations are proposed as described in Item 7, and the operations involve the sealed source, provide information about what surveys will be performed, what type of survey meter will 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 survey meter. For more information on survey meters, see “Radiation Safety Program–Instruments,” in Section 8.10.2 and Appendix J.

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 (see sample license, condition no. 16). 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 Personnel Monitoring Equipment

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 Leak Testing

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 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 Bq (0.005 μ Ci) 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 it to the kit supplier 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 "Radiation Safety Program—Surveys," in the main body of this NUREG.

10.6 Maintenance and Repair

If authorization has been requested to perform maintenance and repair operations as stated in Item 7, 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.

10.7 Transportation

If the application requests authorization to use ECDs or XRFs at a temporary jobsite, the applicant must take into consideration DOT regulations, particularly blocking and bracing the device containing licensed material. The applicant is not required to submit transportation information with the application.

10.8 Minimization of Contamination

Regulations in 10 CFR 20.1406 require new license applicants 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.

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.

Suggested Format for Providing Information Requested in Items 1 through 4 of NRC Form 313

D.1 ITEM 1: ACTION TYPE

ACTION TYPE: <input type="checkbox"/> New <input type="checkbox"/> Amendment <input type="checkbox"/> Renewal	ADMINISTRATIVE REVIEW: <input type="checkbox"/> Current Guidance Used <input type="checkbox"/> References in Application Based On Current Regulations <input type="checkbox"/> All Attachments Referenced Included <input type="checkbox"/> Signature on Application
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D.2 ITEM 2: LEGAL IDENTITY

NAME:	
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D.3 ITEMS 2 & 3: ADDRESS

STORAGE & LOCATION OF USE ADDRESS:	MAILING ADDRESS:
Temporary Job Sites <input type="checkbox"/> YES <input type="checkbox"/> NO	

D.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

CONTACT PERSON:	
TELEPHONE NUMBER:	

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

D.5 ITEMS 5 & 6: MATERIALS TO BE POSSESSED AND PROPOSED USES

Yes	No	Radionuclide	Mfg 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	Manufacturer name and model number		Measure physical properties of materials	<input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are:
		Iron-55	Manufacturer name and model number		Measure physical properties of materials	<input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are:
		Cobalt-57	Manufacturer name and model number		Measure physical properties of materials	<input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are:
		Nickel-63	Manufacturer name and model number		Measure physical properties of materials	<input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are:
		Americium-241	Manufacturer name and model number		Measure physical properties of materials	<input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are:
		Other (specify)				

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

D.6 ITEMS 7 THROUGH 11: TRAINING AND EXPERIENCE, FACILITIES AND EQUIPMENT, RADIATION SAFETY PROGRAM, AND WASTE DISPOSAL

Item No.	Title and Criteria	Yes	Description Attached
7	<p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE</p> <p>RSO</p> <p>Name: _____</p> <p>Before obtaining licensed materials, the proposed RSO will have successfully completed the training described in Appendix D, in NUREG-1556, Vol. 7.</p> <p style="text-align: center;">AND</p> <p>Before being named as the RSO, future RSOs will have successfully completed the training described in Appendix D, in NUREG-1556, Vol. 7.</p>	<p>[]</p> <p>[]</p>	
8	<p>TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS</p> <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>		N/A
9	<p>FACILITIES AND EQUIPMENT</p> <p>Describe the facilities where ECD/XRFs will be used and stored. 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

Item No.	Title and Criteria	Yes	Description Attached
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.</p>		N/A
	<p>Survey Instruments</p> <p>No survey instrument is required if proposed use does not involve the removal of sources from the device or any maintenance and repair of a device that involves the source.</p> <p style="text-align: center;">OR</p> <p>If the applicant proposes to perform operations that involve removal of sources from the device or maintenance and repair of a device that involves the source, state that: "we will possess or have access to a radiation survey meter that meets the requirements in the procedures for performing removal or repair of the sources."</p>	<p>[]</p> <p>[]</p>	
	<p>Material Receipt and Accountability</p> <p>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>Occupational Dosimetry</p> <p>No personnel monitoring is required if proposed use does not involve the removal of sources from the device or any maintenance and repair of a device that involves the source.</p> <p style="text-align: center;">OR</p> <p>If the applicant proposes to perform operations that involve the removal of sources from the device or maintenance and repair 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 "we will provide dosimetry processed and evaluated by an NVLAP-approved processor that is exchanged at a frequency recommended by the processor."</p>	<p>[]</p> <p>[]</p>	

Item No.	Title and Criteria	Yes	Description Attached
	<p>Public Dose</p> <p>The applicant is not required to submit a response to the public dose section during the licensing phase. This matter will be examined during an inspection.</p>		N/A
10	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Leak Test</p> <p>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>	[]	
	<p>Maintenance</p> <p>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</p> <p>The applicant is not required to submit its response to transportation during the licensing process; however, this issue will be reviewed during inspection.</p>		N/A
	<p>Minimization of Contamination</p> <p>The applicant is not required to submit a response to the minimization of contamination section if the applicant's responses meet the criteria for the following sections: "Radiation Safety Program–Leak Tests," "Facilities and Equipment," and "Waste Management."</p>		N/A

Item No.	Title and Criteria	Yes	Description Attached
11	<p>WASTE MANAGEMENT</p> <p>ECDs/XRFs Disposal and Transfer</p> <p>The applicant is not required to submit a response to waste management during the licensing process. The licensee should, however, develop, implement, and maintain ECD/XRF transfer and disposal procedures in its radiation safety program.</p>		N/A

APPENDIX E

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.

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 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. [NEW PARAGRAPH] 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 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 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 RSO or Authorized User (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 and Waste Handling

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 shall be secured to prevent unauthorized access to the animals. 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 the 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."

Animals that have been treated with certain compounds may require special facilities. For example, carbon-14 labeled compounds used in animals may be eliminated as carbon dioxide in the animals' breath, and require special facilities for controlling airborne contamination. Studies of fish with licensed materials may require separate water handling systems and testing of water for contamination before release of the water. Special precautions also may be needed for handling of animals and performing surveys if alpha-emitting radionuclides are used.

Disposal of animals that contain radioactive material may require special procedures. Animal carcasses that contain less than 1.85 kBq (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 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 (see Section 8.11, "Waste Management"). Animal carcasses containing other long-lived radioactive materials must be disposed of as radioactive waste.

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.**

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.

The NRC will authorize release of cats treated with I-131 when:

- cats are held not less than 4 complete days (96 hours) after administration AND
- the dose rate is less than 1 mR/hr at 6 inches (0.25 mR/hr 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 2 mrem in any one hour 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 2 millirem in any 1 hour, and 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 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 0.25 mR/hr 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 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 (1) the instructions pertaining to the extent and duration of contact permitted with the cat are easy for the owner to comply with, and (2) the potential dose would be well below 2 millirem in any 1 hour and 100 mrem in a year. Such proposals will be reviewed on a case-by-case basis. Additional consideration may be necessary when establishing the release date for release of a cat treated with I-131 to a home with small children.

For cats, release criteria above 0.5 mR/hr 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 2 millirem in any one hour, and less than 100 millirem 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 your 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, as a minimum, (1) waste handling, (2) contamination, and (3) 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 dispose of nonradioactive animal excreta in a landfill, radioactive waste may not be disposed of in this way. For animals treated with radioactive materials, instructions to caretakers should include storing animal excreta in a remote 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 sidewalk, parks, beaches, grooming salon)
- 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 (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:

1. Avoid public transportation; avoid staying in public accommodations (hotels). Transport your animal in its carrier as far from passengers as is reasonable and safe for the animal.
2. The animal should be kept inside or in his cage or stall following hospital discharge.
3. 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.
4. Pregnant women should avoid ANY contact with the animal or its urine and feces for at least ___ days after discharge.
5. 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.
6. Use a plastic litter pan liners and a scoopable litter (for cats).
7. Disposable gloves should be worn whenever handling animal waste, including changing the litter box for the next _____ days after discharge.
8. Wash hands after contact with the animal or the litter.
9. 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, avoid staying in public accommodations (hotels)
- Minimize time that children and pregnant women are with the animal.
- Do not hold or cuddle 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.

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. 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 kBq (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 Q for more information on waste disposal.

APPENDIX F

RADIATION SAFETY OFFICER DUTIES AND RESPONSIBILITIES

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license (see Figure 8.4). 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 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 21.6, "Posting requirements."
- Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements.
- Ensure that radiation exposures are "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 on waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.

- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radionuclides possessed under the license and limit the quantity to the amounts 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 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 personnel who use licensed material.
- 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 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.

Model Delegation of Authority to RSO

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

You, _____, have been appointed radiation safety officer and are responsible for ensuring the safe 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 G

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. 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 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. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable.
- K. Locations where the licensee has posted or made available: notices, copies of pertinent regulations, and copies of pertinent licenses, and license conditions (including applications and applicable correspondence), as required by 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. lost or replacement badges and dose assessment
 4. bioassay procedures
 5. records
- P. Instrumentation
1. 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, eating, smoking, and drinking in areas where licensed materials are used.

APPENDIX H

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 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.

Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, unsealed volatile licensed materials, and processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 10 CFR 20, Appendix B.

Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow, rather than by hand.

- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- To reduce radiation exposure from gamma-emitting radioactive materials, shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods, or in glove boxes.
- To reduce the exposure from high-energy beta-emitting materials, shielding of low atomic number material, such as high-density plastic, may be used.
- Shielded shipping containers frequently are used for continued storage after receipt of materials.
- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on the number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas and away from areas that personnel frequently occupy. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity.
- 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, you must follow the provisions of 10 CFR Part 20, Subpart H, "Respiratory protection and controls to restrict internal exposure in restricted areas."
- If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed per 10 CFR 20.1204

APPENDIX I

SAMPLE AUDIT PROGRAM

Sample Audit Program

An audit is conducted, in part, to fulfill the requirements of 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. It should also identify program weaknesses and allow licensees to take early corrective actions (before an 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. Check that radiation levels in areas adjacent to use are within regulatory limits and in accordance with 10 CFR 20.2103. Verify compliance with 10 CFR 20.1301. Records of surveys must be retained for 3 years after the record is made.

Section 10, Receipt and Transfer of Radioactive Material (Includes Waste Disposal). Verify that packages 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. Records of surveys, receipt, and transfer must be maintained in accordance with 10 CFR 20.2103 and 10 CFR 30.51.

Section 11, Transportation. Determine compliance with 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; 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, and 30. Ensure that the licensee is aware of the telephone number for NRC's Emergency Operations Center (301-816-5100).

Section 15, Posting and Labeling. Check for compliance with the posting and labeling requirements of 10 CFR 19.11, 20.1902, 20.1904, and 21.6.

Section 16, Recordkeeping for Decommissioning. Check to determine compliance with 10 CFR 30.35(g) and 20.1501(b).

Section 17, Bulletins and Information Notices. Check to determine if the licensee is receiving such documents as bulletins, information notices, and FSME newsletters from the NRC. Check whether the licensee took appropriate action in response to NRC mailings.

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: _____
(Signature)

Date:

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 20.502) Y N

5. Dose limits to embryo or fetus and declared pregnant women (10 CFR 20.1208) Y N

6. Procedures for opening packages (10 CFR 20.1906) Y N

Remarks:

4. INTERNAL AUDITS, REVIEWS, OR INSPECTIONS

A. Audits are conducted Y N

1. Audits conducted by _____

2. Frequency _____

B. Content and implementation of the radiation protection program reviewed annually (10 CFR 20.1101(c)) Y N

C. Records maintained [(0 CFR 20.2102) Y N

5. FACILITIES

A. Facilities as described in license application

B. 5. 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))
- 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 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) [] Y [] N [] N/A

- F. Records of receipt or transfer maintained (10 CFR 20.2103(a), 30.51) Y N
- G. Transfers within licensee's authorized users or locations performed as required (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 170-189) 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

B. 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

C. Shipping Papers N/A

1. Prepared and used (49 CFR 172.200(a)) Y N
2. Proper shipping name, hazard class, UN number, quantity, package type, nuclide, RQ, radioactive material, physical and chemical form, activity, category of label, T1, 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 177.718(e)) Y N

D. 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

E. 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. Adequate documentation of determination that unmonitored occupationally individuals are not likely to receive >10% 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 NVLAP-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 Y 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, 30.50) (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, 30.50) (theft or loss) Y N None
- C. Licensee in compliance with (10 CFR 20.2202, 30.50) (incidents) Y N None
- D. Licensee in compliance with (10 CFR 20.2203, 30.50) (overexposures and high radiation levels) Y N None
- E. Licensee aware of telephone number for NRC Emergency Operations Center (301-816-5100) Y N

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)) Y N

Remarks:

17. BULLETINS AND INFORMATION NOTICES

A. Receipt of NRC Bulletins, NRC Information Notices, NMSS newsletters Y N

B. Appropriate action taken in response to 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 (1) the requirement and (2) 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 radiation safety officer (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 J

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

Radiation Monitoring Instrument Specifications

The specifications in Table K.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 J.1 Typical Survey Instruments¹
(Instruments used to measure radiological conditions at licensed facilities.)

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-Ray	μR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
Nal Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (Nal)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

¹ Table from The Health Physics and Radiological Health Handbook, Revised Edition, edited by Bernard Shleien, 1992 (except for * items).

In addition to selecting an instrument that is appropriate for the radiation(s) of interest, it is important to know if the instrument is sufficiently sensitive so as to make measurements at the required level. This is particularly important for measurements such as for leak test samples,

bioassay measurement, and decommissioning of facilities or equipment. The “minimum detectable activity” (MDA) for your instrument should be a small fraction (10 to 50 percent) of the criteria you must meet.

Example 1: A sealed source is considered to be leaking if a removable contamination exceeds 185 becquerels (0.005 microcurie, or 11,100 disintegrations per minute (dpm)). The instrument used to measure wipe test samples should have an MDA of 10 percent of that limit, or 1,100 dpm for the radionuclide being tested; this is usually easy 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: You are closing a laboratory where uranyl acetate (generally licensed pursuant to 10 CFR 40.22, “Small quantities of source material”) was used. The total residual contamination screening value for uranium-238 is 101 dpm/100 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:

$$MDA = \frac{(3 + 4.65\sqrt{B})}{\epsilon t}$$

Where B = number of background counts

t = minutes of background count = minutes of sample count

ε = efficiency of instrument, determined using a calibration standard

$$\epsilon = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in dpm}} = \text{efficiency in c/d}$$

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

Example:

A gas-flow proportional counter is used in scalar mode to make 1-minute counts of samples.
sample count time = 1 minute = t

background count time = 1 minute = t
background counts = 300 counts
efficiency = 0.15 counts/disintegrations (c/d) = ϵ

$$\begin{aligned} \text{Then } MDA &= \frac{(3 + 4.65\sqrt{B})}{\epsilon t} = \frac{(3 + 4.65\sqrt{300 \text{ counts}})}{(0.15 \text{ c/d})(1 \text{ minute})} \\ &= 557 \text{ dpm} \end{aligned}$$

According to this calculation, you would be confident that 95 percent of the time, the instrument can reliably detect measurements as low as 557 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, you can determine the minimum detectable concentration (MDC) for your actual measurement conditions.

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

$$MDC = 557 \text{ dpm}/15 \text{ cm}^2 = 37 \text{ dpm}/\text{cm}^2 \text{ or } 3700 \text{ dpm}/100 \text{ cm}^2$$

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

Model Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

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
- mathematics and calculations basic to using and measuring radioactivity
- biological effects of radiation

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

- Observing authorized personnel performing survey instrument calibration.

- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment for Calibration of Dose Rate or Exposure Rate Instruments

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry.
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.
- The calibration source should be well-collimated, and the calibration area should be designed to minimize scatter of radiation, which could affect the calibration process.
- The calibration area should be appropriately controlled so that persons entering the area will be aware if a radiation source is in use. Posting as a radiation area also may be required.
- Depending on the type of calibrator or irradiator source used for calibration, the device and facilities may be regulated under 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators," and require interlocks and alarms. Review NUREG-1556, Volume 5, "Program-Specific Guidance about Self-Shielded Irradiator Licenses" and Volume 6 "Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses," for additional guidance.

Model Procedure for Calibrating Survey Instruments

Instruments should be calibrated before first use, and at least annually thereafter. Instruments also should be calibrated after any repair to the instrument.

A radioactive sealed source(s) used for calibrating survey instruments will:

- Approximate a point source
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified by the National Institutes of Standards and Technology (NIST)
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be used
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of cesium-137 or 7.8×10^2 megabecquerels (21 mCi) of cobalt-60]

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales shall 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 shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20 percent and 80 percent of full scale. The instrument's readings shall be within ± 15 percent of the conventionally true values for the lower point and ± 10 percent for the upper point.
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10 percent of the full decade value.
- Meters with a digital display device shall be calibrated the same as meters with a linear scale.
- Readings above 2.58×10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation.
- The inverse square and radioactive decay law should be used to correct changes in exposure rate because of changes in distance or source decay.

Surface Contamination Measurement Instruments¹

- Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.
- If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80 percent of full scale, and the reading at approximately 20 percent of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within 20 percent of the conventionally true value.

Model Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

A radioactive sealed source used for calibrating instruments will do the following:

- Approximate the geometry of the samples to be analyzed

¹ ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration."

- Have its apparent source activity traceable by documented measurements to a standard certified by the National Institutes of Standards and Technology (NIST)
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure

Calibration

- Calibration must produce readings within ± 20 percent of the actual values over the range of the instrument.
- Calibration of liquid scintillation counters will include quench correction.

Calibration Records

Calibration records, for all survey instruments, should indicate the procedure used and the data obtained. The description of the calibration should include:

- the owner or user of the 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
- for instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
- for instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument
- for 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 it was performed.

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

- for exposure rate meters, the source isotope used to calibrate the instrument (with correction factors) for each scale

- the efficiency of the instrument, for each isotope 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.

The publication entitled, "Air Sampling Instruments," found in the 9th edition, American Conference of Governmental Industrial Hygienists, 2001, provides guidance on total air sample volume calibration methods acceptable to NRC staff, as supplemented below.

Frequency of Calibration

- 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, "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. Primary standards are usually accurate to within ± 1 percent and secondary standards to within ± 2 percent.

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.)²
- 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 conditions (760 mm and 0° C)

V_1 = volume measured at conditions P_1 and T_1

T_1 = temperature of V_1 in °K

P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

The licensee should maintain records of all routine and special calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed, and

² The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factors to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20 percent, an additional error term should be included in the calculation above.

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: See the Notice of Availability on the inside front cover of this report to obtain a copy of:

- Regulatory Guide 8.25, "Air Sampling in the Workplace," Revision 1, June 1992.
- NUREG-1400, "Air Sampling in the Workplace," September 1993.
- *Handbook of Health Physics & Radiological Health*, Revised Ed., Edited by Bernard Shleien, Scinta, Inc., Silver Spring, MD, 1992.
- *Handbook of Health Physics & Radiological Health*, 3rd Ed., Edited by Bernard Shleien, Lester A. Slaback, Jr., and Brian Kent Birky, Lippincott Williams & Wilkins, 1998.
- ANSI N323A-1997, "American National Standard Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments," New York, NY, 1997, <http://www.ansi.org>.
- *Air Sampling Instruments*, 9th Ed., American Conference of Governmental Industrial Hygienists, 2001.

APPENDIX K

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 shall not exceed the maximum possession limit listed on the license. Therefore, the 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 10 CFR 30.51 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) shall 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 (RSO): _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

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

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

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

Name _____

Phone _____

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

Sample Procedure for Safely Opening Packages Containing Licensed Materials

For packages received under the specific license, authorized individuals shall 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 8.4, Section 13.14, Item 10.
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, so shipment 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). Again check that the shipment does not exceed license possession limits. If you find anything other than 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 carrier and the administrator of the appropriate NRC) Regional Office listed in Appendix D, "United States Nuclear Regulatory Commission Regional Offices," to 10 CFR Part 20, when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(l); 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 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, TLC or HPLC 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 or quarterly, or after each order, depending on the frequency of use and the amount of

materials on hand). Each AU should indicate if material possessed was disposed of or transferred from his or her responsibility (examples: waste in containers may be transferred to a common DIS storage 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 shall 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 shall 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, or U.S. Postal Service regulations, whichever is applicable. Before any transfer from the licensee, the RSO shall verify that the recipient is authorized to receive the licensed material, as required by 10 CFR 30.41.

Gifts

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

APPENDIX L

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.

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 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 and/or radioactive material released by a licensee • Sources of radiation under the control of a licensee • Air effluents from sources of licensed radioactive materials 	<p>DOES NOT INCLUDE doses from:</p> <ul style="list-style-type: none"> • Sanitary sewerage discharges from licensees • Natural background radiation • Medical administration of radioactive material • Voluntary participation in medical research

Typical unrestricted areas may include offices, shops, laboratories (where licensed material is not used or stored), areas outside buildings, property, and storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials, but the licensee may control access to these areas for other reasons, such as security.

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

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem)
- 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 of Appendix B to Part 20; and if an individual were continuously present in an unrestricted area the dose from external sources would not exceed 0.02 mSv (2 mrem) in 1 hour and 0.5 mSv (0.05 rem) in 1 year.
- Demonstrating that air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1 mSv (10 mrem) TEDE.

In order to perform a dose assessment, licensees should identify all potential sources of external and internal radiation exposure to members of the public and all locations of use, transport, and storage of radioactive material at their facilities. Licensees must then take radiation measurements or perform calculations to demonstrate compliance.

Measurements

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

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

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

Radioactivity releases may be determined by effluent monitoring or 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 at the boundary of the unrestricted area. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

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

If the calculation demonstrates that the public dose limit is exceeded with an occupancy factor of 1, then more realistic assumptions of the individual's occupancy at the points of highest internal and external exposures may be made. The licensee may use the occupancy factors in Table L.1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table L.1 Standard Occupancy Factors

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

Records

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

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

APPENDIX M

GENERAL TOPICS FOR SAFE USE OF RADIONUCLIDES AND MODEL EMERGENCY PROCEDURES

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 M.1).
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Store radioactive solutions in clearly labeled containers.

Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

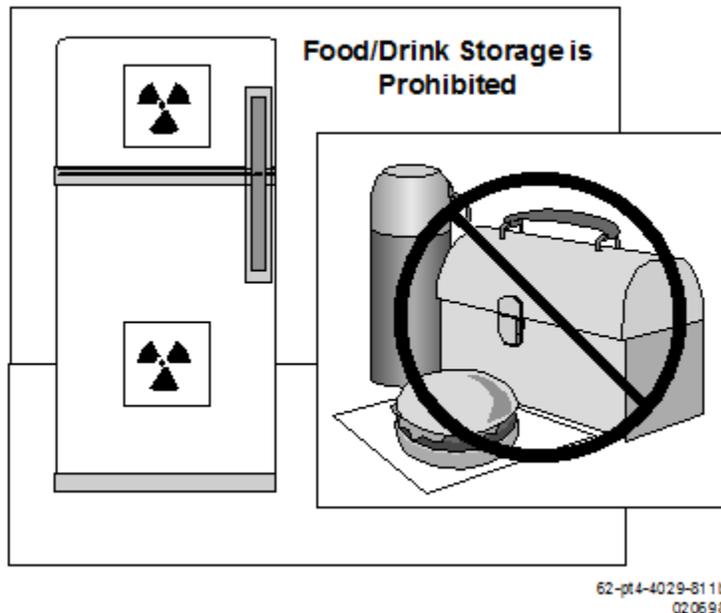


Figure M.1 Storage of Food and Drink

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. Examples of such procedures are included below.

Example 1:

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

- A mandatory radiation survey and wipe test for radioactive contamination after each use
- Bioassay procedures for individuals working with millicurie quantities of radioiodine
- The use of vented hoods for iodination and for storage of millicurie quantities of radioiodine
- A dry run before the performance of unfamiliar procedures, to preclude unexpected complications. In addition, it is recommended that the 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 low-density plastic shielding 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 1 millicurie or more
- A dry run before the performance of unfamiliar procedures to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures
- The use of eye protection for procedures that involve 10 millicuries or more

Sample Procedures for Handling Emergencies

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

General Safety Procedures to Handle Spills

- Name and telephone number of RSO or an alternate person(s) 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 survey instruments including batteries (for survey meters)

Minor Spills of Liquids and Solids

- Instructions to Workers
 - Notify persons in the area that a spill has occurred.
 - Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)
 - Clean up the spill, wearing disposable gloves and using absorbent paper.
 - Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
 - Survey the area with an appropriate low-range radiation detector 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 staff (e.g., investigation of root cause, provision of requested bioassay samples).
 - Follow the instructions of the RSO and RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).
- Reminders to RSO
 - Follow up on the decontamination activities and document the results.
 - As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
 - If necessary, notify the NRC.

Major Spills of Liquids and Solids

- Instructions to Workers
 - Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room.

- Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
- Shield the source only if it can be done without further contamination or significant increase in radiation exposure.
- Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
- Notify the RSO immediately.
- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with RSO and RSO staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and RSO 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.
- 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 radiation 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 staff (e.g., investigation of root cause, provision of requested bioassay samples).
- Follow the instructions of the RSO and RSO 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 may have been ingested, inhaled, or absorbed through the skin. Document incident.
 - If necessary, notify the NRC.

Minor Fires

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

– If necessary, notify 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.

APPENDIX N

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 RSO will ensure that he or she has sufficient training and experience to perform surveys independently.

Academic 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
- mathematics and calculations basic using and 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., cesium-137, cobalt-60).
- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements. See Appendix J.

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 (Sv) (2.5 millirem per hour (mrem/hr)) or more (50 millisieverts per year (mSv/year) divided by 2,000 hr/year).

- 10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in 1 year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any 1 hour.

The frequency of ambient surveys depends on the quantity and use of radioactive materials, as well as the specific protective 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 is required to ensure that the dose rate limits 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. The total contamination (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 should be performed:

- to evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
- after any spill or contamination event
- when procedures or processes have changed
- to evaluate 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. 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 N.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 N.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 N.2.

Table N.2 provides the maximum acceptable residual levels for equipment. 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 N.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 square centimeters (cm²) is acceptable to indicate levels of removable contamination.

Table N.2 Acceptable Surface Contamination Levels for Equipment

Nuclide^a	Average^{b, c}	Maximum^{b, d}	Removable^{b, e}
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)
I-126, I-131, I-133, Sr-90	16.7 Bq/100cm ² (1,000 dpm/100 cm ²)	50.0 Bq/100cm ² (3,000 dpm/100 cm ²)	3.3 Bq/100cm 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)

- ^a Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.
 - ^b As used in this table, dpm (disintegration per minute) 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.
 - ^c Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.
 - ^d The maximum contamination level applies to an area of not more than 100 cm².
 - ^e The 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.
- *1 Bq = 1 disintegration per second

Decommissioning Surveys for Release for Unrestricted Use

When a facility will be closed and released for unrestricted use, the values in Table N.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 (ALARA). Surveys should be conducted for both removable contamination (not to exceed 10 percent of the values in Table N.3) and for total residual contamination before the facilities or equipment are released from restricted to unrestricted use, to ensure that they meet the applicable limits.

Table N.3 Screening Values for Building Surface Contamination ¹

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

¹ 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.

Units are disintegrations per minute per 100 cm² (dpm/100 cm²). 1 dpm is equivalent to 0.0167 becquerel (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 N.3 was derived using the DandD screening code, Version 1, (DandD v1.0) and its default input parameters. Table N.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 N.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 N.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 N.3 does not include screening values for radionuclides that emit alpha particles, or for soil contamination. Screening values for radionuclides not listed above may be found in “Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination,” 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 FR68395 (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 ARDL licensees will be able to use the “Simple Approaches for Conducting Final Radiological Surveys” found in Appendix B of NUREG-1757, Volume 2. If the decommissioning of a facility is too complex to allow use one of the “simple approaches,” then a licensee may have to develop a more formal decommissioning plan.

Survey Record Requirements

Each survey record should include the following:

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

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.

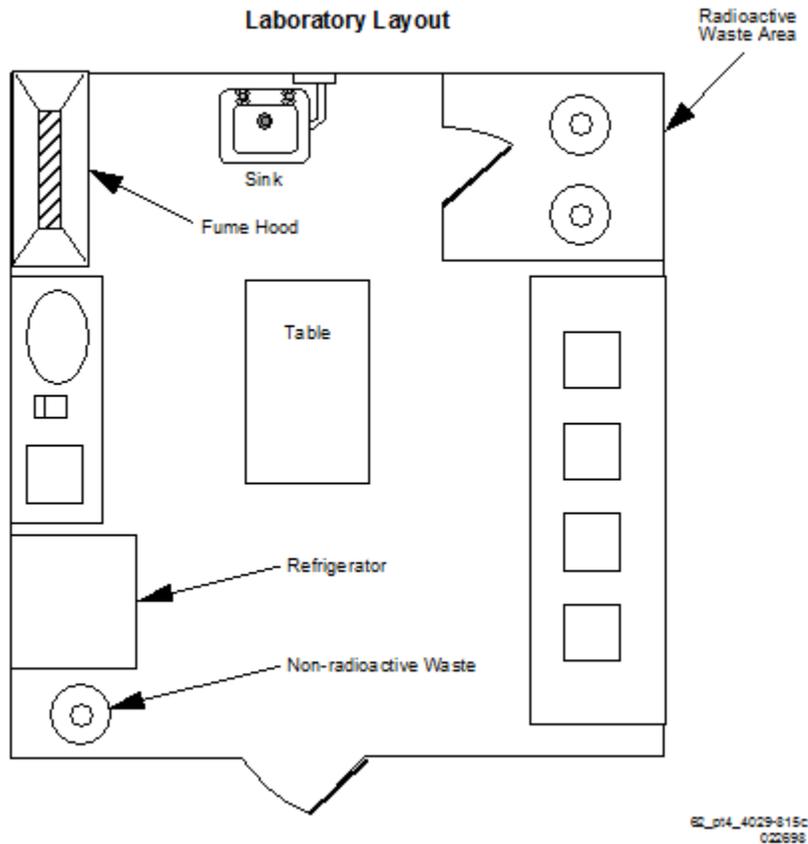


Figure N.1 Laboratory Layout

This is an example of a laboratory survey map.

Air Monitoring in the Workplace

Air sampling 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 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, for further

guidance on the air sampling. NUREG-1400 is available in ADAMS at Accession No. ML102371083.

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, issued 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," issued 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 (N13.1-2011), "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities," and ANSI N42.18-1991, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents."

Liquid Effluent Release Monitoring

- The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show that these releases meet the limits in 10 CFR 20.1301 and 20.2003, respectively.

The topic of sanitary sewerage releases is more fully discussed in Appendix Q.

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. Consider the following elements:

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

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

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

Routine 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 controls these radionuclides.

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

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

Special 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

References: The following reference documents may be found on the NRC's public web site under "Document Collections" or in the ADAMS Public Library using the Accession No.:

- NUREG-1549, "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)."
- 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-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, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees other than Power Reactors," Revision 1, April 2012.
- Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," Revision 1, July 1993.
- Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131, September 1979," (Note: DG-8050, "Applications of Bioassay for I-125 and I-131" (ADAMS Accession No. ML102800439)), Revision 1, September 2011, ADAMS at Accession No. ML102800439.)
- Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions," Revision 1, January 1981.
- Regulatory Guide 8.25, "Air Sampling in the Workplace," Revision 1, 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.
- NUREG-1400, "Air Sampling in the Workplace," September 1993, ADAMS Accession No. ML13051A671.
- ANSI N13.1 (N13.1-2011), "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities."
- ANSI N42.18 (N42.18-1991), "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents," 1991.

- NCRP Commentary No. 3, "Screening Techniques for Determining Compliance with Environmental Standards," published in January 1989, and the addendum published in October 1989.

APPENDIX O

MODEL LEAK TEST PROCEDURES

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 tests 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 tests

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:

$$MDA = 2.71 + 4.65 \sqrt{\frac{bkg \times t}{E}} = \text{Minimum Detectable Activity}$$

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: $bkg = 200$ counts per minute (cpm)
 $E = 0.1$ counts per disintegration (10% efficient)
 $t = 2$ minutes

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

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

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

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

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

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests shall be conducted every 6 months, or at the frequency specified in the respective SSD registration certificate.

Procedure for Performing Leak Testing and Analysis

For each source to be tested, list identifying information such as manufacturer, model number, serial number, radionuclides, and activity.

- If available, use a 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 (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 becquerels (Bq) (0.005 microcurie) of the radionuclides and ensure that its calibration is current.
- 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.

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

- Calculate efficiency.

For example: $[(\text{cpm from } \textit{std}) - (\text{cpm from } \textit{bkg})]$

activity of std in Bq

= efficiency in cpm/Bq

where: cpm = counts per minute

std = standard

bkg = background

Bq = becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in Bq (or millicuries).
For example: $[(\text{cpm from wipe sample}) - (\text{cpm from } \textit{bkg})]$
efficiency in cpm/Bq
= Bq on wipe sample
- Sign and date the list of sources, data, and calculations. Retain records for 3 years (as required by 10 CFR 20.2103(a)). If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO so that the source can be withdrawn from use and disposed of properly. Also notify the NRC.

APPENDIX P

TRANSPORTATION REQUIREMENTS

Note: The reference charts included at the end of this appendix are for reference only and are not a substitute for DOT and NRC transportation regulations.

The following are the major areas in U.S. Department of Transportation (DOT) regulations most relevant for shipping and transporting Type B quantities of radioactive material:

- A. Table of Hazardous Materials and Special Provisions—49 CFR 172.101
 - 1. Title 49 of the Code of Federal Regulations (49 CFR) 172.101—Purpose and Use of Hazardous Materials Table
- B. Shipping Papers
 - 1. 49 CFR 172.201—Preparation and Retention of Shipping Papers
 - 2. 49 CFR 172.202—Description of Hazardous Material on Shipping Papers
 - 3. 49 CFR 172.203—Additional Description Requirements
 - 4. 49 CFR 172.204—Shipper’s Certification (if applicable)
- C. Package Markings
 - 1. 49 CFR 172.301—General Marking Requirements for Non-Bulk Packages
 - 2. 49 CFR 172.304—Marking Requirements
 - 3. 49 CFR 172.310—Class 7 (radioactive) Materials
 - 4. 49 CFR 172.324—Hazardous Substances in Non-bulk Packaging (designation of “reportable quantities” with the letters “RQ”)
- D. Package Labeling
 - 1. 49 CFR 172.400(a)—General Labeling Requirements
 - 2. 49 CFR 172.403—Class 7 (radioactive) Material
 - 3. 49 CFR 172.406—Placement of Labels
- E. Placarding of Vehicles
 - 1. 49 CFR 172.504—General Placarding Requirements
 - 2. 49 CFR 172.516—Visibility and Display of Placards
 - 3. 49 CFR 172.556—RADIOACTIVE Placard
- F. Emergency Response Information
 - 1. 49 CFR 172.600—Applicability and General Requirements
 - 2. 49 CFR 172.602—Emergency Response Information
 - 3. 49 CFR 172.604—Emergency Response Telephone Number
- G. Training
 - 1. 49 CFR 172.702—Applicability and Responsibility for Training and Testing (for HAZMAT employees)
 - 2. 49 CFR 172.704—Training Requirements (includes types of training, when it must be conducted, need for refresher training every three years, recordkeeping)
- H. Safety and Security Plans
 - 1. 49 CFR 172.800—Purpose and Applicability
 - 2. 49 CFR 172.802—Components of a Security Program
 - I. Shippers—General Requirements for Shipments and Packaging

1. 49 CFR 173.25—Authorized Packaging and Overpacks
 2. 49 CFR 173.403—Definitions
 3. 49 CFR 173.413—Requirements for Type B Packages
 4. 49 CFR 173.416—Authorized Type B Packages (includes packaging certification requirements)
 5. 49 CFR 173.441—Radiation Level Limitations and Exclusive Use Provisions
 6. 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission approved packages
 7. 49 CFR 173.476—Approval of Special Form Class 7 (radioactive) Materials (includes requirement for documentation of special form status)
- J. Carriage by Public Highway
1. 49 CFR 177.817—Shipping Papers (location of shipping papers during transport)
 2. 49 CFR 177.842—Class 7 (radioactive) Material (includes requirement for blocking and bracing during transport)

Applicants should visit the U.S. Department of Transportation Web site for additional information on transportation requirements: <http://www.dot.gov/>.

1. Minimum Required Packaging for Class 7 (Radioactive) Material ^[1] (49 CFR 173 and 10 CFR 71) ^[4]					
These are basic reference charts; refer to current U.S. DOT & 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]		Excepted Quantities and Articles	Type A ^[4]	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 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 ^[9] 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 IP-3: liquids or gases/non-exclusive use	- IP-2: exclusive use IP-3: non-exclusive use	Unpackaged ^[9] IP-1 - -	- - IP-2 -
Alternative Provisions for Domestic only Transport ^[9]	Packaging shall meet the requirements of §§173.24, 24a, and 410 Transportation shall be an exclusive use shipment Activity per shipment must be less than an A ₂ quantity				

[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) materials greater than A₁ or A₂.
[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 m from the unshielded material or objects (see §173.427(a)(1)).
[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. 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 LSA material and SCO, transport of combustible solids, all liquids and all gases classified as LSA-II and LSA-III material, and transport of all SCO-I and SCO-II is limited to a maximum activity of 100 A₂ in a conveyance (see §173.427(a)(2)).
[8] Unless excepted by §§173.427(c) or (d), the material or object(s) shall be appropriately packaged in a Type IP, DOT-7A Type A or Type B package.
[9] Certain LSA-I and SCO-I may be transported unpackaged under the conditions specified in §173.427(c).

2. Radiation Level, TI and CSI Limits for Transportation by Road, Rail and Air ^[1] (49 CFR 172 - 177, and 10 CFR 71)				
Type of Transport	Non-exclusive use		Exclusive use	
Mode of Transport	Road, Rail, Vessel and Air		Vessel	Air (cargo only)
Radiation Level Limits ^[4]				
Package Surface ^[1]	2 mSv/h (200 mrem/h)		2 mSv/h (200 mrem/h): other than closed vehicles 10 mSv/h (1000 mrem/h): closed vehicles	None specified 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] 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): at any normally occupied area ^[6]	Requirement of §176.708 applies N/A
Transport Index (TI) Limits ^[4]				
Package ^[1,7]	3: passenger aircraft 10: road, rail, vessels and cargo aircraft		No limit	
Conveyance ^[4]	50: road, rail and passenger aircraft 50 to No limit: vessels ^[8] 200: cargo aircraft		No limit	
Overpack	N/A: for road, rail 50 to 200: vessels ^[8] 3: passenger aircraft; 10: cargo aircraft		N/A	No limit ^[8] N/A
Criticality Safety Index (CSI) Limit for fissile material ^[4]				
Package ^[1,7]	50		100	100
Conveyance ^[4]	50: for holds, compartments or defined deck areas of vessels ^[9] 200 to No limit: for a total vessel ^[9]		100	200 to No limit: for a total vessel ^[9] 100
Overpack	50: road, rail, vessels ^[9] and air		N/A	

[1] The limits in this table do not apply to excepted packages.
[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, also the sum of the CSIs.
[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.
[5] The outer surfaces (sides, top and underside) of vehicles are defined 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. Also, see CSI limits established by §71.59.
[8] For details on TI and CSI limits for transport by vessel, see §176.708.

**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 & 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 external surfaces of packages offered for transport must be kept as low as reasonable 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, gamma and low toxicity alpha emitters	4	10 ⁻⁴	220
All other alpha emitting radionuclides	0.4	10 ⁻⁵	22

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.

Provisions for Control of Contamination on Radioactive Material Packages Prior to Shipment

Prior to shipment, the non-fixed contamination on each package of radioactive material:

- must be kept as low as reasonable achievable; and
- may not exceed the limits set forth 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).
- Each transport vehicle used for transporting the radioactive material packages must be surveyed with appropriate radiation detection instruments after each use. If contamination values exceed acceptable levels, the transport vehicle may not be returned to service until 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 specified in §173.443(a), Table 9 (as shown above).

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

- The contamination levels must not exceed 10 times the levels prescribed in §173.443(a), Table 9 (as shown above).
- Each vehicle shall be stenciled 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.
- 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 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 & NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Shipping Paper Entries		
Always Required	Sometimes Required	Optional Entries
<p><u>Basic description (in sequence):</u></p> <ul style="list-style-type: none"> UN Identification number Proper Shipping Name Hazard Class (7) Total activity contained in each package in SI units (e.g. Bq, TBq, etc.), or in both SI and customary units (e.g. Ci, mCi, etc.) with customary units in parentheses following the SI units Number and type of packages <p><u>Additional description:</u></p> <ul style="list-style-type: none"> Name of each radionuclide^[1] Description of physical and chemical form (unless special form) Category of label used Transport index (TI) of each package bearing a Yellow-II or Yellow-III label <p><u>Additional entry requirements:</u></p> <ul style="list-style-type: none"> 24 hour emergency telephone number Shipper's Certification shall be provided by each person offering radioactive material for transportation^[2] Proper page numbering (e.g. Page 1 of 4) 	<p><u>Materials-based Requirements:</u></p> <ul style="list-style-type: none"> The criticality safety index (CSI) or "Fissile Excepted" for fissile material The words "Highway route controlled quantity" or the term "HRCQ" entered in the basic description for highway route controlled quantities The letters "RQ" entered on the shipping paper either before or after the basic description for each hazardous substance (see §171.8) Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required A hazardous waste manifest and the word "Waste" preceding the proper shipping name is required for radioactive material that is hazardous waste <p><u>Package-based Requirements:</u></p> <ul style="list-style-type: none"> The applicable DOE or NRC package approval identification marking for certified Type AF and Type B packages The International Atomic Energy Agency (IAEA) Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package <p><u>Shipment- and Administrative-based Requirements:</u></p> <ul style="list-style-type: none"> Specify "exclusive use shipment" as required Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use Specify the notation "DOT-SP" followed by the special permit number^[3] for a special permit shipment 	<ul style="list-style-type: none"> The weight in grams or kilograms of radionuclides 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 The words "RESIDUE: Last Contained * * *" may be included in association with the basic description of the hazardous material last contained in the packaging Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information
Special Considerations/Exceptions for Shipping Papers		
<ul style="list-style-type: none"> For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, <u>or</u> be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, <u>or</u> be designated by an "X" (or "RQ" if appropriate). Emergency response information consistent with §§172.600-606 shall be readily available on the transport vehicle. Shipments of limited quantities of radioactive material in excepted packages, under UN2908, 2909, 2910 and 2911, are excepted from shipping paper requirements if (a) the package does not contain fissile material unless excepted by §173.453, and (b) the limited quantity of radioactive material is not a hazardous substance or hazardous waste. 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. 		

[1] 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.

[2] The shipper's certification shall satisfy the requirements of either §172.204(a)(1) or 204(a)(2); or if transported by air of §172.204(c); but is not required if the shipper is a private carrier and the shipment is not reshipped or transferred from one carrier to another.

[3] Shipments made under an exemption or special permit issued prior to October 1, 2007 may bear the notation "DOT-E" followed by the number assigned.

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

These are basic reference charts; refer to current U.S. DOT & 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>Markings for Non-bulk Packagings:</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>Markings for Bulk Packagings:</p> <ul style="list-style-type: none"> • Identification number on orange rectangular panel: <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, or ▪ on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons), or ▪ on each side and end of motor vehicle carrying cylinders permanently installed on a tube trailer 	<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^[2] • Radiation (trefoil) symbol^[3] on outside of outermost receptacle of each Type B(U) or Type B(M) packaging design  • For NRC or DOE packaging, model number, serial number, gross weight, and package identification number for each certified package (Type AF, Type B(U), Type B(M), Type B(U)F, and Type B(M)F) • 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 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  • If a hazardous substance in non-bulk package, mark 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 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 C, Type CF, 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 align="center">Special Considerations for Marking Requirements</p> <ul style="list-style-type: none"> • All markings are to be (a) on the outside of each packaging, (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. 		

[1] Some exceptions exist as specified in §§172.301(a) and 302(a); and in §§173.421(a), 422(a).

[2] The international vehicle registration code for packages designed by a U.S. company or agency is the symbol "USA."

[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 that conform to the requirements of Appendix B to Part 172.

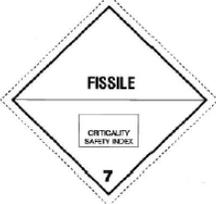
[4] The arrows must be either black or red on white or other suitable contrasting background and commensurate with the size of the package; depicting a rectangular border around the arrows is optional.

**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 & 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 containing a limited quantity of radioactive material; and (b) Low Specific Activity (LSA) material and Surface Contaminated Objects (SCO), packaged or unpackaged, when transported domestically and when material or object contains less than an A₂ quantity.
- Labeling is 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) un-obscured by markings or other attachments, and (f) representative of hazardous material content.
- Display duplicate labels on at least two opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material except as noted above for excepted packages, and packaged or unpackaged LSA material and SCO.

Radioactive Category Labels ^[3]			Other Labels ^[2]	
				
White-I	Yellow-II	Yellow-III	Fissile	Empty
Radiation Surface Level (RSL):				
mSv/h:	RSL ≤ 0.005	0.005 < RSL ≤ 0.5	0.5 < RSL ≤ 2 ^[4]	
mrem/h:	RSL ≤ 0.5	0.5 < RSL ≤ 50	50 < RSL ≤ 200 ^[4]	
Transport Index (TI):^[4]				
	TI = 0^[4]	0 ^[4] < TI ≤ 1	1 < TI ≤ 10 ^[4, 5]	
			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 shipments of empty Class 7 (radioactive) packages satisfying §173.428; and any previously-used labels cannot be visible

Contents on Labels

- Each radioactive category label must contain: (a) Except for LSA-I material, the names of the radionuclides in the package where, for mixtures of radionuclides, the names listed must be in accordance with the 95% rule specified in §172.433(g); and, for LSA-I material, the term "LSA-I"; (b) 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.
- Each fissile label must contain the relevant Criticality Safety Index (CSI).

[1] Additional labeling may be required if the radioactive material also meets the definition of one or more other hazard classes. See §§172.402 and 403 for details on label requirements. See §§172.403, 421 and 427 for details when labels are not required, and see §172.407 for details on label design, size, color, form identification, exceptions, etc.

[2] An additional "Cargo Aircraft Only" label is required for each package containing a hazardous material which is authorized for cargo aircraft only.

[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 radiation level 1 m from package surface; see definition for TI in §173.403 for details. If the measured TI is not greater than 0.05, the value may be considered to be zero.

[5] RSLs less than or equal to 10 mSv/h (1000 mrem/h), and TIs more than 10 are allowed for shipments under exclusive-use; see §§172.403(a) – 403(c). In addition; any package containing a Highway Route Controlled Quantity (HRCQ) must bear a YELLOW-III label.

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 & NRC regulations for complete requirements.

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

Conditions when Display of Radioactive Placards is Required [§§172.504, 507(a), 508 and 512(b)(2)]

- On bulk packages, road transport vehicles, rail cars, and freight containers, and on aircraft unit load devices having a capacity of 640 cubic feet or more^[1], on each side and each end when they contain either a package with a Radioactive Yellow-III label, or low specific activity (LSA) material or surface contaminated objects (SCO) being transported under exclusive use.
- On a square background on any motor vehicle used to transport a package containing Highway Route Controlled Quantity (HRCQ) Class 7 (radioactive) materials^[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 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 authorized words or identification number 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 background of contrasting color, or 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 for detailed requirements]

PLACARD FOR HRCQ



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

Special Considerations/Exceptions for Placarding

- Placards must conform to the specifications set forth in §172.519.
- A corrosive placard is required for more than 454 kg (1001 pounds) or more gross weight of fissile or low specific activity uranium hexafluoride.

[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 definition of Highway Route Controlled Quantity (HRCQ). A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels; see §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 and 49 CFR 172, Subparts G and H)

These are basic reference charts; refer to current U.S. DOT & 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 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 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

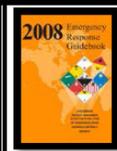
- Except for a road vehicle used solely for transporting Class 7 (radioactive) material, if radioactive material has been released in a road, rail, or air transport conveyance, the conveyance must be taken out of and remain out of service until the radiation dose rate at every accessible surface is less than 0.005 mSv/h (0.5 mrem/h) and the non-fixed radioactive surface contamination levels are below the values the limits in §173.443(a), Table 9 [see Chart 3].
- 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 [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) and 750(e), and §177.843(b)]

Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (§§171.15 and 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 specific or generic 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 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 Emergency Response Guidebook 2008 (ERG2008) is available at the following URL:
http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/erg2008_eng.pdf



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

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

Provisions for Training (49 CFR 172, Subpart H)

- For any person who is employed by an employer or is self-employed, and who directly affects radioactive 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\(d\)](#).

Provisions for Security (49 CFR 172, Subpart I and 49 CFR 173)

- 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\(b\)\(15\)](#));
 - (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\(b\)\(15\)](#)); 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 en route 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 Q

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.

Model Procedure for Disposal by Decay-in-Storage

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by decay-in-storage (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 must 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.
- 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 RSO for further instructions.
- If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (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 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 or 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 Appendix B to 10 CFR Part 20.

- 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, toilets, or release points.
- Discharge liquid waste slowly with water running from the faucet to dilute it.
- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.
- Before leaving the area, decontaminate all areas or surfaces, if found to be contaminated.
- Maintain records of each radionuclide and its quantity and concentration that is released into the sanitary sewer system.

Model Procedure for Compaction

The following information should be provided from licensees that propose to compact waste.

- (1) 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 (e.g., provide manufacturer's specifications, annotated sketches, photographs).
- (2) Describe the type, quantities, and concentrations of waste to be compacted.
- (3) Provide an analysis of the potential for airborne release of radioactive material during compaction activities.
- (4) State the location of the compactor(s) within the waste processing area(s), and provide a description of the ventilation and filtering systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange.
- (5) Discuss the methods used to monitor worker breathing zones and exhaust systems.
- (6) Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.
- (7) 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 R

INTERIM STAFF GUIDANCE ON CONSTRUCTION

**INTERIM STAFF GUIDANCE TO NUREG-1556 AND NUREG-1520:
COMMENCEMENT OF CONSTRUCTION AT EXISTING AND PROPOSED SOURCE,
BYPRODUCT, AND SPECIAL NUCLEAR MATERIAL FACILITIES AND IRRADIATORS WITH
SIGNIFICANT ENVIRONMENTAL IMPACTS**

PURPOSE AND SCOPE

This Interim Staff Guidance (ISG) provides guidance to U.S. Nuclear Regulatory Commission (NRC) staff on the new definition of construction and the consideration of activities that can be performed by materials license applicants and potential applicants (hereinafter collectively referred to as “applicants”), and licensees before the NRC staff has concluded its environmental review of the proposed licensing action.

This ISG applies to the review of licensing actions related to the receipt and possession of licensable source, byproduct, and special nuclear material (SNM) for the conduct of any activity which the NRC determines will significantly affect the quality of the environment. This ISG is intended to provide guidance to NRC staff but may also be instructive to all holders of operating licenses for source, byproduct, and SNM facilities and irradiators, and all persons that have submitted applications to construct source, byproduct, and SNM facilities or irradiators, or have submitted letters of intent to submit such applications under Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 36, 40, and 70.

This ISG applies to all Part 30, 36, 40 and 70 materials facilities other than uranium recovery facilities. Site preparation activities at uranium recovery facilities are addressed in Regulatory Issue Summary 2009-12, Uranium Recovery Policy Regarding Site Preparation Activities at Proposed, Unlicensed Uranium Recovery Facilities, September 23, 2009, ML092090353.

If a licensing action initiated pursuant to 10 CFR Parts 30, 40, or 70 meets any of the criteria in 10 CFR 51.20 or 51.21, then commencement of construction of a facility before the NRC staff has completed its environmental review process is grounds for denial of the license application, in accordance with 10 CFR 30.33(a)(5), 40.32(e), and 70.23(a)(7). However, if the licensing action meets the criteria in 10 CFR 51.22(c) for a categorical exclusion, and the NRC has not determined that an environmental assessment or an environmental impact statement is required in accordance with 10 CFR 51.22(b), then commencement of construction before the NRC staff concludes the environmental process should not be the sole basis for denial of the license application, as the NRC has already determined that this category of actions does not have a significant impact on the environment. In accordance with 10 CFR 36.15, commencement of construction of an irradiator will only be grounds for denial if the licensee or applicant has not submitted both an application and the requisite licensing fee.

BACKGROUND

The NRC amended its regulations in September 2011, by revising certain provisions applicable to the licensing and approval processes for byproduct, source and SNMs licenses, and irradiators in the final rule, “Licenses, Certifications, and Approvals for Materials Licensees” (76 FR 56951; September 15, 2011) (Material Licenses Construction Rule). The revisions contained in the Material Licenses Construction Rule revised the definitions of “construction” and “commencement of construction” with respect to materials licensing actions conducted

under the NRC's regulations. The NRC adopted these changes to further improve the effectiveness and efficiency of the licensing and approval processes for future materials license applications, as well as to eliminate certain inconsistencies that existed within the NRC's regulations with respect to the use and definition of the terms "construction" or "commencement of construction" for certain materials licensees for purposes of its environmental reviews.

The new definitions of "commencement of construction" in 10 CFR 30.4, 36.2, 40.4, and 70.4 are identical.

Commencement of construction means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this part that has a reasonable nexus to:

1. Radiological health and safety; or
2. Common defense and security.

In 10 CFR 150.31, *commencement of construction* means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this part that has a reasonable nexus to radiological health and safety. The regulations in 10 CFR 150.31 address the requirement for Agreement State regulation of byproduct material. Although Agreement State licensees may find this ISG informative, they should also communicate with the pertinent Agreement State agency for that agency's applicable requirements and guidance.

The new definitions of "construction" in 10 CFR 30.4, 36.2, and 70.4 are also identical.

Construction means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this part that are related to radiological safety or security. The term "construction" does not include:

- (1) Changes for temporary use of the land for public recreational purposes;
- (2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- (4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;
- (5) Excavation;
- (6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
- (7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

- (9) Taking any other action that has no reasonable nexus to:
 - (i) Radiological health and safety, or
 - (ii) Common defense and security.

“Construction,” as defined in 10 CFR 40.4, also includes the installation of wells associated with radiological operations (e.g., production, injection, or monitoring well networks associated with in-situ recovery or other facilities).

The Atomic Energy Act of 1954, as amended, expressly limits the NRC’s regulatory authority to matters concerning the radiological public health and safety or common defense and security and non-radiological hazards to the extent such hazards result from the actual processing of by-product material. The NRC has determined that this authority does not extend to site preparation activities that do not have a nexus to radiological health and safety or common defense and security.

This guidance provides criteria for NRC staff to use in evaluating whether a particular construction activity has a nexus to radiological health and safety, and thus falls under the jurisdiction of the NRC for licensing purposes. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a materials facility is operating, or will operate, in accordance with the NRC’s regulations and in a manner that protects the public health and safety or the common defense and security from radiological hazards. The revised definition of construction in 10 CFR 30.4, 36.2, 40.4, 70.4, and 150.31 list activities that are not considered “construction.” This guidance provides examples of activities that fall under each of the excepted activities that do not constitute construction. This guidance addresses some important considerations for materials licensees and applicants that were emphasized in the response to comments on the proposed Material Licenses Construction Rule. For example, site preparation activities that are not considered “construction,” while not under NRC jurisdiction may be subject to the regulatory authority of another Federal, State, or local agency which may require National Environmental Policy Act or state environmental review. NRC’s responsibilities under the National Historic Preservation Act of 1966, as amended (NHPA), must also be satisfied before a license is issued. Specifically, as noted in the SOC to the final Material Licenses Construction Rule, under certain circumstances the NRC may be required to deny a license application if the NRC determines that the applicant intentionally significantly adversely affected, or allowed to be affected, a historic property with intent to avoid the requirements of §106 of the NHPA.

DISCUSSION OF EXAMPLES

In addition to the background discussion provided above, the following examples clarify the delineation of site preparation activities and construction activities. It is important to recognize that the NRC may have regulatory authority over activities that can occur before construction begins, such as procurement of basic components as defined in 10 CFR Part 21, the process of dedicating commercial grade items or basic components, or procurement of items relied on for safety (IROFS) as defined in 10 CFR Part 70. It should also be noted that, while site preparation activities may not require prior NRC approval, various local, State, or other Federal permits may be required.

BYPRODUCT MATERIAL (10 CFR PART 30)

Prior to the conclusion of the environmental review process, applicants for byproduct material licenses or license amendments should not perform construction activities that have a nexus to radiological health and safety or the common defense and security. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a licensed materials facility is operating, or will operate, in accordance with the NRC's regulations and in a manner that

protects the public health and safety or the common defense and security from radiological hazards.

Installation of foundations or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to 10 CFR Part 30 that are related to radiological health and safety or common defense and security should not be performed prior to the conclusion of the environmental review of a license application or amendment. Byproduct material license applicants subject to 10 CFR Part 30 may perform those site preparation activities identified in revised 10 CFR 30.4 before the NRC has completed its environmental review of the license application.

Excavation and other site preparation activities that do not have a reasonable nexus to radiological public health and safety or common defense and security, whether permanent or temporary, are not "construction" activities. For example, piles driven to support the erection of a bridge for a temporary or permanent access road to a new facility would not be considered as construction and may be performed prior to the NRC staff concluding its environmental review of a proposed action.

The installation of a temporary feature within an excavation for a building in which materials license activities will be conducted and that will be removed during construction is a site preparation activity. Such features include retaining walls, dewatering systems, ramps, and other structures that will have no physical presence following construction.

Construction includes installation of the foundation, including soil compaction; the installation of permanent drainage systems and geofabric; the placement of backfill, concrete (e.g., mudmats), or other materials that will not be removed before placement of the foundation of a structure; the placement and compaction of a subbase; the installation of reinforcing bars to be incorporated into the foundation of the structure; the erection of concrete forms for the foundations that will remain in place permanently (even if nonstructural); and the placement of concrete or other material constituting the foundation of any safety-related feature.

The term "permanent" in this context includes anything that will exist in its final, in-place facility location after commencement of operations with licensed material. Construction also includes the "onsite, in-place" fabrication, erection, integration, or testing activities for any in-scope safety-related equipment. The terms "onsite, in place, fabrication, erection, integration, or testing" describe the process of constructing a facility in its final, onsite plant location, where components or modules are integrated into the final, in-plant location. The fabrication, assembly, and testing of components and modules in a shop building, warehouse, or laydown area, even if located onsite, is not construction. However, the installation or integration of the safety-related equipment into its final plant location is construction.

Construction also includes driving piles for safety-related equipment. Hence, an applicant must obtain a license before driving piles for safety-related equipment. However, driving piles that do not ensure the structural stability or integrity of a safety-related structure (e.g., piles driven to support the erection of a bridge for a temporary or permanent access road) is not construction; therefore, those piles may be driven prior to the NRC staff concluding its environmental review of a proposed action.

IRRADIATORS (10 CFR PART 36)

An applicant for a new irradiator license under 10 CFR Part 36 may perform the non-construction activities identified in revised 10 CFR 36.2 at any time. However, installation of foundations or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to 10 CFR Part 36 that have a reasonable nexus to radiological safety or security should not be performed prior to the submission of an application for a license and the fee required by 10 CFR 170.31. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a licensed materials facility is operating, or will operate, in accordance with the NRC's regulations and in a manner that protects the public health and safety or the common defense and security from radiological hazards. Activities that have a reasonable nexus to radiological health and safety or common defense and security include, but are not limited to, construction of systems subject to 10 CFR Part 36, Subpart C, and the following:

- Earthwork
- Pool excavation
- Footings and foundation for pool
- Irradiator foundations and walls
- Backfill pool
- Install pool liner
- Mechanical rough-in
- Electrical rough-in
- Shoring for roof
- Form and place roof
- Slab on grade

Subpart C of 10 CFR Part 36 currently lists the systems that have a nexus to radiological health and safety and defines the related engineering and safety concerns associated with each system:

- Access Control: Adequacy of access control systems using interlocks and radiation monitors to prevent inadvertent entry to areas where radiation sources are unshielded; to provide emergency exits; and to ensure compliance with all the requirements of 10 CFR 36.23. For computer-controlled access-control systems, licensing staff should consider expert evaluation of the software/system logic before operational testing.
- Site: Potential need for protection against flooding and earth slides.
- Base (soil, rock) for the Pool and Shielding Structures: Strength, settlement, liquefaction, ground water, soil compaction.

- Footers and Foundations for the Pool and Shielding Structures: Strength and reinforcement, alignment with pool and shielding structures.
- Pool and Shielding Structures: Strength and reinforcement, proper density of shielding materials, correct dimensions, minimization of voids in concrete or other shielding.
- Pool Liner: Contact with pool structure, penetrations in the liner, leak-tight welds.
- Pool Plumbing: Makeup water system; water cleanup system; effect of construction materials on pool-water chemistry; drainage system (potentially contaminated spilled water should flow into the pool); siphon breakers; radiation detection and alarm systems.
- Penetrations Through Shielding: Any significant effect on structural strength, shielding, or both.
- Source Rack Protection: If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.
- Source-Rack Mechanical Positioning System: Strength and stiffness of the rack and positioning cables or chains, source shroud will not interfere with source positioning, adequacy of motive power, potential for jamming.
- Source-Rack Movement and Position-Sensing System: Structural attachments for electrical and mechanical transducers, adequacy of transducers for interacting with the source-rack control system.
- Source-Rack Electrical Control System: Adequacy of the design of logistical and operational electrical circuitry and electromechanical components, to ensure unambiguous response of the system, which includes programmable controllers or computers and their interaction with operations, interlocks, doors, signals, and alarms.
- Source-Leak Detection: Adequacy of systems for detecting and isolating leaking sources.
- Hard Wiring: Adequacy of wire gauge and insulation to safely carry design currents and to withstand radiation and ozone damage if exposed; locating and attaching wiring to prevent fretting, wear, and exposure to potential fire hazards; accessibility to wiring for inspection and repair.
- Uninterruptable Electrical Power Supply: Adequate and reliable power capability to operate all electrical systems that are important to safety (including backup power sources); compatibility of the power supply with the electrical system.
- Fire Protection System: Adequacy to detect fire and smoke and to be manually as well as automatically initiated; must ensure that raised sources are immediately lowered into the pool.
- Emergency Systems for Returning an Up-stuck Source Rack to the Pool: Capability of the electrical control system to sense and signal the occurrence of an up-stuck source-rack; adequacy of mechanical or electrical means for personnel to safely release and lower the rack; need for, and adequacy of, a system to cool the source-rack until it can be released and lowered.
- Ozone Ventilation System: Capability of the system to be properly initiated and to provide adequate volume flow rate of air to protect personnel and components.
- System for Transferring Sources from and to Transport Vehicles: Adequately sized openings in the shield-structure roof if sources are roof-loaded; structural adequacy of the roof-shield plug and its supports for its removal and replacement; structural and

mechanical adequacy of systems for moving shipping containers into and out of the pool area.

URANIUM CONVERSION FACILITIES, ENRICHMENT FACILITIES, FUEL FABRICATION FACILITIES, AND URANIUM HEXAFLUORIDE (UF₆) DECONVERSION FACILITIES (10 CFR PART 40 and 10 CFR PART 70)

If any of the following actions are performed before the NRC staff has completed its environmental review process, then the NRC has grounds for denial of a license application, in accordance with 10 CFR 40.32(e), and 70.23(a)(7):

1. Procurement or construction of engineered items that are items relied on for safety (IROFS) required to meet the performance requirements of 10 CFR 70.61.
2. Construction of guard stations, fences, vehicle barriers, or other features that are, or will become, components of physical security systems required by regulations or orders.
3. Construction or installation of equipment whose purpose is the detection of radioactive material accidents or mitigation of the consequences of radioactive material accidents.
4. Installation of storage tanks that contain chemicals that could affect the safety of licensed material.
5. Construction of facilities or warehouses that will be used for operations involving licensed material.
6. Driving of piles; subsurface preparation; placement of backfill, concrete, or permanent retaining walls within an excavation; installation of foundations; or in-place assembly, erection, fabrication, or testing, which are for IROFS and on-site emergency facilities.
7. Erection of buildings, offices, construction trailers and warehouses that will become part of a Standard Practice Procedures Plan for Protection of Classified Information.

Construction includes the onsite, in-place fabrication, erection, integration, or testing activities for any safety related item. The terms "onsite, in place, fabrication, erection, integration, or testing" describe the process of constructing a fuel cycle facility in its final, onsite plant location, where components or modules are integrated into the final, in-plant location. Under the definition of "construction" applicants and existing licensees may be able to fabricate, assemble, and test components and modules in a shop building, warehouse, or laydown area, even if these facilities are located onsite. However, the installation or integration of that safety related equipment into its final plant location is a construction activity and should not be performed until after the NRC staff concludes its environmental review of the license application.

Excavation includes the removal of any soil, rock, gravel, or other material below the final ground elevation to the final parent material, and may be conducted prior to the conclusion of the NRC staff's environmental review. However, placing permanent, nonstructural dewatering materials, mudmats, or engineered backfill in advance of placing the foundation and associated permanent retaining walls for buildings or structures that will contain licensed materials are construction activities and should not be performed prior to the conclusion of the NRC staff's environmental review.

Construction includes driving piles for buildings or structures that will contain licensed materials. Hence the driving of piles for such buildings or structures should not be performed before the NRC staff concludes its environmental review. Driving piles that do not ensure the structural

stability or integrity of buildings or structures within the scope of the definition of “construction” (e.g., piles driven to support the erection of a bridge for a temporary or permanent access road) is not “construction”; therefore, those piles may be driven prior to the conclusion of the NRC staff’s environmental review.

In addition to 10 CFR 40.4, 51.4, and 70.4 criteria that are used to determine the scope of activities that fall within the definition of construction, construction includes the necessary excavation for safety related items. A necessary excavation is the portion of an excavation that provides sufficient construction access to the structures that are within the definition of construction. Applicants should ensure, and NRC staff will confirm, that these construction activities are separate from, and do not result in, adverse interactions with construction-related safety related item including influence on the stability (static and dynamic) analyses. Construction includes any change made to the parent material in which the excavation occurs (e.g., soil compaction, rock grouting); the driving of piles; the installation of foundations; the installation of permanent drainage systems and geofabric; the placement of backfill, concrete (e.g., mudmats) or other materials that will not be removed before placement of the foundation of a structure; the placement and compaction of a subbase; and the installation of reinforcing bars to be incorporated into the foundation of any safety related items that fall within the definition of construction. The foregoing items fall within the definition of construction because they have a rational, direct link to ensuring that a licensed materials facility is operating, or will operate, in accordance with the NRC’s regulations and in a manner that protects the public health and safety from radiological hazards.

ACTIVITIES WHICH HAVE NO REASONABLE NEXUS TO RADIOLOGICAL SAFETY OR SECURITY

The NRC has determined that, in general, the following activities at source, byproduct, and SNM facilities and irradiators listed in 10 CFR 30.4, 36.2, 40.4, and 70.4, do not have a reasonable nexus to radiological health and safety and the common defense and security may be performed by a licensee or applicant at any time. Note that in some circumstances, based on the specific licensing proposal, any of these activities could be determined to have a reasonable nexus to radiological health and safety or common defense and security and, based on that determination, these activities would be construction:

- (1) Changes for temporary use of the land for public recreational purposes;
- (2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- (3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- (4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to 10 CFR Parts 30, 36, 40, or 70;
- (5) Excavation;
- (6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

- (7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
- (8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
- (9) Taking any other action that has no reasonable nexus to:
 - (i) Radiological health and safety, or
 - (ii) Common defense and security.

While the above site preparation activities may not require prior NRC approval, other Federal, State, or Local permits may be required.

FINAL RESOLUTION

This interim staff guidance will be incorporated into the next revisions of NUREG-1556, and NUREG-1520.

APPLICABILITY

This ISG is applicable to all 10 CFR Parts 30, 36, 40, and 70 license applicants and existing licensees considering site preparation activities or construction activities at a facility that is subject to, or will be subject to, the licensing requirements of these parts.

REFERENCES

- 1) NUREG-1556, Volume 6, "Consolidated Guidance About Material Facilities: Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses," January 1999.
- 2) NUREG-1556, Volume 12, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Possession Licenses for Manufacturing and Distribution," December 2000.
- 3) NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, May 2010.
- 4) Regulatory Issue Summary 2009-12, Uranium Recovery Policy Regarding Site Preparation Activities at Proposed, Unlicensed Uranium Recovery Facilities, September 23, 2009, ML092090353.
- 5) NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with Materials Facilities," August 2003.
- 6) DC/COL-ISG-4, "Interim Staff Guidance on the Definition of Construction and on Limited Work Authorizations," February 9, 2009, ML082970729.
- 7) Inspection Manual Chapter 2815, "Construction and Preoperational Inspection of Panoramic Wet-Source-Storage Gamma Irradiators," March 27, 2001, ML010990225.
- 8) Docket No. 030-36974, Final Environmental Assessment Related to the Proposed Pa'ina Hawaii, LLC, Underwater Irradiator in Honolulu, Hawaii; August 10, 2007; ML071150121.
- 9) Docket No. 70-7015, Environmental Assessment for an Exemption to 10 CFR Parts 30, 40, and 70, Commencement of Construction Requirements, Areva Enrichment Services, Eagle Rock Enrichment Facility, Bonneville County, Idaho, February 28, 2010, ML093220528.

- 10) NUREG-1811, "Environmental Impact Statement for an Early Site Permit at the North Anna ESP Site," December 2006.
- 11) NUREG-1947, "Final Supplemental Environmental Impact Statement for Combined License (COLs) for Vogtle Electric Generating Plant Unit 3 and 4," March 2011.

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APPENDIX S

SAFETY CULTURE STATEMENT OF POLICY

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 NRC's 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.

BIBLIOGRAPHIC DATA SHEET

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11. ABSTRACT (200 words or less)

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 (ARLD). 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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