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

NUREG-1556
Volume 21, Rev. 1

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator

Draft Report for Comment

Office of Nuclear Material Safety and Safeguards

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Draft Report for Comment

Manuscript Completed: November 2016
Date Published: November 2016

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Office of Nuclear Material Safety and Safeguards

COMMENTS ON DRAFT REPORT

Any interested party may submit comments on this report for consideration by the U.S. Nuclear Regulatory Commission (NRC) staff. Comments may be accompanied by additional relevant information or supporting data. Please specify the report number NUREG1556, Volume 21, Revision 1, in your comments, and send them by the end of the comment period specified in the *Federal Register* notice announcing the availability of this report.

Addresses: You may submit comments by any one of the following methods. Please include Docket ID **NRC-2016-0158** in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site at http://www.regulations.gov.

Federal Rulemaking Website: Go to http://www.regulations.gov and search for documents filed under Docket ID **NRC-2016-0158**. Address questions about NRC dockets to Carol Gallagher at (301) 415-3463 or by e-mail at Carol.Gallagher@nrc.gov.

Mail comments to: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch, Division of Administrative Services, Office of Administration; Mail Stop: OWFN-12-H8, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For any questions about the material in this report, please contact: Robert MacDougall, Project Manager at 301 415-5175 or by e-mail at Robert.MacDougall@nrc.gov.

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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 the production of radioactive material using an accelerator. In particular, it describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

Paperwork Reduction Act Statement

This NUREG contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0014; 3150-0011; 3150-0021; 3150-0151; 3150-0155; 3150-0008; 3150-0002; and 3150-0093.

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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, NRC and Agreement State license reviewers, and other NRC personnel. The NUREG–1556 series currently includes the following volumes:

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

The current document, NUREG–1556, Volume 21, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator," 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 21, issued in October 2007.

This report takes a risk-informed, performance-based approach to licensing the production of radioactive materials using an accelerator. A team composed of staff from NRC Headquarters, NRC Regional Offices, and Agreement States prepared this document, drawing on their collective experience with radiation safety in general and specifically with using an accelerator to produce radioactive materials.

NUREG–1556, Volume 21, Revision 1, is not a substitute for NRC or Agreement State regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable if they include a basis for the staff to make the determinations needed to issue or continue a license.

Daniel S. Collins, Director
Division of Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards

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ACKNOWLEDGMENTS

The U.S. Nuclear Regulatory Commission (NRC) thanks the individuals listed below for assisting in the review and update of the report. All participants provided valuable insights, observations, and recommendations.

The working group would like to thank the staff in the regional offices of the NRC and all of the States who provided comments and technical information that assisted in the development of this report.

The working group also thanks Lisa Dimmick, Tomas Herrera, John O'Donnell, Monica Orendi, Tara Weidner, and Duane White for developing the formatting and language used in many parts of the report.

The Participants for this Revision

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ABBREVIATIONS

ADAMS	Agencywide Documents Access Management System
AEA	Atomic Energy Act
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANP	authorized nuclear pharmacist
ANSI	American National Standards Institute
bkg	background
Bq	becquerel
CFA	certification of financial assurance
CFR	*Code of Federal Regulations*
Ci	curie
cm^2	square centimeters
COC	certificate of compliance
cpm	counts per minute
DFP	decommissioning funding plan
DIS	decay in storage
DOT	U.S. Department of Transportation
dpm	disintegrations per minute
EPAct	Energy Policy Act of 2005
FDA	U.S. Food and Drug Administration
FR	*Federal Register*
FRN	*Federal Register Notice*
GBq	gigabecquerel
HAZMAT	hazardous material
hr	hour
IN	Information Notice
kBq	kilobecquerel
kg	kilogram
L/C	license condition
LLW	low-level radioactive waste
MBq	megabecquerel
mCi	millicurie
mGy	milliGray
MDA	minimum detectable activity
mR	milliroentgen
mrem	millirem
mSv	millisievert
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OMB	Office of Management and Budget
PET	positron emission tomography
PII	Personally Identifiable Information
PSE	Planned Special Exposures
Q	quality factor
QA	quality assurance
RG	Regulatory Guide
RIS	Regulatory Issue Summary

RQ	reportable quantity
RSO	radiation safety officer
SA	State Agreement
SI	International System of Units (abbreviated SI from the French, Le Système internationale d'unités)
SSD	Sealed source and device
std	standard
Sv	sievert
TBq	terabecquerel
TEDE	total effective dose equivalent
U.S.C.	United States Code
µC	microcoulomb
µCi	microcurie
µGy	microGray
UN	United Nations

1 PURPOSE OF REPORT

This NUREG provides guidance to applicants preparing a license application to produce radioactive materials using an accelerator(s). This NUREG also provides to the U.S. Nuclear Regulatory Commission (NRC) staff with the criteria for evaluating the license application. The body of this document contains the standard requirements and guidance for the possession and distribution of radioactive material (e.g., radiochemicals) that is produced by an accelerator(s) located at the applicant's facility. Additionally, this NUREG provides guidance to applicants applying for authorization to produce and distribute radioactive drugs noncommercially to medical use licensees for positron emission tomography (PET) in a consortium.

An applicant using this guidance to apply for a license to produce radioactive materials using an accelerator will also need to submit an application for a commercial radiopharmacy license if the applicant also plans to manufacture and commercially distribute radioactive drugs from the material made by the accelerator. NUREG–1556, Volume 13, provides guidance about submitting applications for commercial radiopharmacy licenses.

This NUREG was developed in accordance with the Energy Policy Act of 2005, which expanded the definition of byproduct material as defined in Section 11(e) of the Atomic Energy Act of 1954 placing under NRC regulatory authority accelerator-produced and naturally occurring radioactive material such as discrete sources of radium-226. Since NRC does not regulate the operation of accelerators, this NUREG does not provide guidance on accelerator operation.

This NUREG identifies the information needed to complete NRC Form 313, "Application for Material License," (Appendix A of this NUREG) for the possession and use of byproduct material. If the applicant requires any other type of license, such as a commercial radiopharmacy license or a broad-scope license, other applicable guidance documents in this NUREG–1556 series are applicable and available at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. The information collection requirements in Title 10 of the *Code of Federal Regulations* (10 CFR), Part 30, and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Numbers 3150-0017, 3150-0001, 3150-0020, 3150-0009, and 3150-0120, respectively.

As a guidance document intended to assist a wide variety of applicants, this NUREG contains a considerable amount of information about how licensees may choose to implement their programs to meet NRC regulatory requirements. The information in this document is not intended to impose any conditions beyond those required by the regulations in 10 CFR. This NUREG provides specific guidance on what information should be submitted in an application to satisfy NRC requirements.

Guidance and model procedures provided in this NUREG that are not required to be submitted are for illustrative purposes to guide licensees in developing their programs. Use of the word "should" implies "may" and is not intended to mean "must" or "shall;" the procedures provided in this guidance are intended to serve only as examples.

Chapters 1 through 7 of this document provide background information. Chapter 8, "Contents of an Application," of this NUREG identifies the information needed to complete NRC Form 313, "Application for Materials License" (see Appendix A of this NUREG), for the possession and use of radioactive materials produced in an accelerator. The Office of Management and Budget (OMB) has approved the information collection requirements in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and NRC Form 313 under

OMB Clearance Nos. 3150-0017 and 3150-0120, respectively. For each of these Items of technical information, the format is

- Regulations – references the regulations applicable to the item.
- Criteria – outlines the criteria used to judge the adequacy of the applicant's response.
- Discussion – provides additional information on the topic sufficient to meet the needs of most readers.
- Response from Applicant – provides suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

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

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 applications for possession and use of radioactive materials produced in an accelerator, Appendix B of this NUREG, "Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313," may be used to provide supporting information.

Appendices C through M of this NUREG contain additional information on various radiation safety topics. Appendix N provides guidance on preparing information for an authorization to produce and noncommercially distribute PET radioactive drugs to medical use licensees in a consortium. Appendix Q provides the NRC's policy statement on safety culture. Appendix P provides a checklist for requests to withhold proprietary information from public disclosure (under 10 CFR 2.390).

In this document, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent(TEDE), as defined in 10 CFR Part 20, "Standards for Protection against Radiation." 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 (or 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 equal to 1 rem. For alpha and neutron emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from an absorbed dose (rad) of alpha particles or neutrons requires the use of an appropriate quality factor (Q) value. These Q values are used to convert absorbed dose (rad) to dose equivalent (rem); Tables 1004(b)(1) and (2) in 10 CFR 20.1004, "Units of radiation dose," address the Q values for alpha particles and neutrons.

2 AGREEMENT STATES

2.1 Jurisdiction Determination

Certain States, called Agreement States (see Figure 2-1), have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass, which are used or possessed within their borders. Any applicant, other than a Federal entity, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with the NRC. In areas under exclusive Federal jurisdiction within an Agreement State, NRC continues to be the regulatory authority.

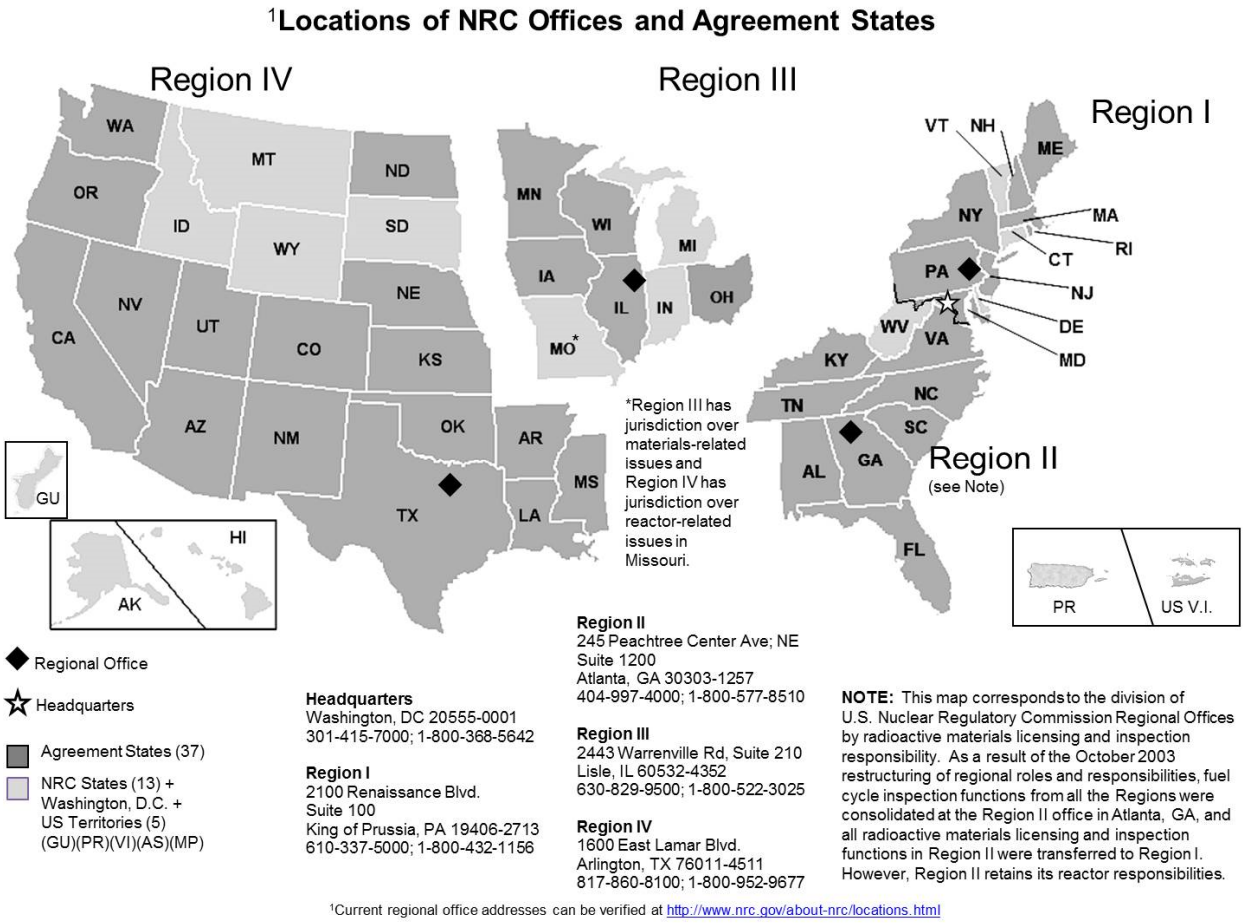


Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

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

State has regulatory authority. These areas can also include Tribal lands of federally recognized Indian Tribes.[2] The NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State may have jurisdiction over nonexclusive Federal jurisdiction land. Applicants are responsible for determining, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. Additional guidance on determining jurisdictional status is found in the Office of Nuclear Material Safety and Safeguards (NMSS) procedures in the State Agreement (SA) series, SA-500, "Jurisdiction Determination," which is available at https://scp.nrc.gov/. Once on the Web site, use the link for "NMSS Procedures" in the left-hand column under "Resources & Tools."

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

Table 2-1. Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency, regardless of location [except that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with Title 10 of the *Code of Federal Regulations* 10 CFR 30.12, "Persons using byproduct material under certain U.S. Department of Energy and U.S. Nuclear Regulatory Commission contracts"]	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory, or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or Tribal member on Indian Tribal land	NRC
Non-Federal entity on federally recognized Indian Tribal land	NRC[3]
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State	Agreement State
Non-Federal entity in Agreement State	Agreement State[4]
Non-Federal entity in Agreement State at federally controlled site **not** subject to exclusive Federal jurisdiction	Agreement State[4]

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

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

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

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	**Regulatory Agency**
Non-Federal entity in Agreement State at federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State conducting industrial radiography at a Part 50 or 52 reactor site, including construction, preoperational, and operational phases	Agreement State

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

2.2 Reciprocal Recognition of Specific Licenses

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

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

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

3 MANAGEMENT RESPONSIBILITY

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

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

3.1 Commitments and Responsibilities

Pursuant to Title 10 of the *Code of Federal Regulations* 10 CFR 30.32(c), each application must 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 who signed the application is duly authorized to act for and on the behalf of the applicant or licensee. The signature on an application acknowledges the 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 regulations, the licensee's operating, emergency, and security procedures, and NRC license commitments
- commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and compliance with regulations is maintained
- commitment to report defects, noncompliances, or reportable events, in accordance with regulations
- selection and assignment of a qualified individual to serve as the radiation safety officer (RSO) for licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities
- commitment to ensure that radiation workers have adequate training
- prevention of discrimination against 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, "Employee protection," and 10 CFR 30.10, "Deliberate misconduct"

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

- notification of the appropriate NRC regional administrator, in writing, immediately following the filing of a 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 NUREG

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of the NRC's Enforcement Policy and Inspection Procedures, available in the NRC's online library at 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).

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 a 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. But NRC's safety culture policy statement and traits are not incorporated into the regulations. Many of the safety culture traits may be inherent to an organization's existing radiation safety practices and programs. For

instance, manual removal of accelerator-irradiated target materials, if done improperly, can cause high doses to extremities and high contamination levels. An individual performing this task must review it carefully beforehand, observing ambient radiation levels and any interferences, such as cables, unnecessary shielding, and cyclotron componentry, that could pose a trip hazard or otherwise impede the ready removal of the material and its undelayed insertion into a shielded container. The need to evaluate the safety of existing conditions, survey if necessary, review the procedure, and reposition as many interferences as possible before attempting to remove targets 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). Licensees should be aware that this is just an example, however, and should consider reviewing their radiation safety programs in order to develop and implement a safety culture commensurate with the nature and complexity of their organizations and functions.

Refer to Appendix Q of this NUREG for the NRC's safety culture policy statement. More information on NRC activities relating to safety culture can be found at http://www.nrc.gov/about-nrc/safety-culture.html.

Table 3-1. Traits of a Positive Safety Culture

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

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of Title 10 of the *Code of Federal Regulations* (10 CFR contain U.S. Nuclear Regulatory Commission (NRC) regulations applicable to possession of radioactive material produced in an accelerator. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

The current versions of these parts can be found under the "Basic References" link at the NRC's online library at http://www.nrc.gov/reading-rm/doc-collections/cfr/; 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 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 Publishing Office Customer Contact Center toll-free at 866-512-1800, in Washington, DC; calling 202-512-1800; or ordering online at http://bookstore.gpo.gov.

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

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

5 HOW TO FILE

5.1 Application Preparation

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete NRC Form 313 (Appendix A of this NUREG), Items 1 through 4, 12, and 13, on the form itself. A link to the form is available at http://www.nrc.gov/reading-rm/doc-collections/forms/.
- Complete NRC Form 313, Items 5 through 11, on supplementary pages or use Appendix B of this NUREG.
- Provide sufficient detail for the NRC to determine that the equipment, facilities, training, experience, and radiation safety program are adequate to protect health and safety and minimize danger to life and property.
- For each separate sheet, other than NRC Form 313 and Appendix B pages, as applicable, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Avoid submitting proprietary information and personally identifiable information. If submitted, proprietary, personal privacy, security-related, and other sensitive information should be clearly identified according to 10 CFR 2.390, "Public inspections, exemptions, requests for withholding" (see Chapter 6, "Identifying and Protecting Sensitive Information").

5.2 Where to File

Applicants wishing to possess or use licensed material in any State, U.S. territory, or U.S. possession subject to NRC jurisdiction must file an application with the NRC regional office for the locale in which the material will be possessed or used. Figure 2-1 identifies the NRC's four regional offices and their respective areas for licensing purposes and the Agreement States. Note that all materials applications are submitted to Regions I, III, or IV. All applicants for materials licenses located in the Region II geographical area should send their applications to Region I.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State and not with the NRC. However, if work will be conducted at federally controlled sites or federally recognized Indian Tribal lands in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether the NRC or the Agreement State has regulatory authority. See Chapter 2, "Agreement States," for additional information.

5.3 Paper Applications

Paper applications received by the NRC are scanned through an optical character reader and converted to an electronic format. To ensure a smooth transfer to an electronic format, applicants should do the following:

- Submit all documents, typed, on 8½ × 11-inch or legal-sized paper that will feed easily into a document scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura.
- Use an 11-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

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

5.4 Electronic Applications

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

6 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

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

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

- Proprietary Information and Trade Secrets: If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Appendix P of this NUREG provides a checklist for requests for withholding information from public disclosure.

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

- Security-Related Information: Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive, unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities and associated security measures are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information and the top of every page of a document that contains such information should be clearly marked: "Security Related—Withhold under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 22, 2005, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Additional information on procedures and any updates is available at http://www.nrc.gov/reading-rm/sensitive-info.html.

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

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

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

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

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

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

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

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

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

7 APPLICATION AND LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to 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. NRC will not issue a license until the fee is received. Consult 10 CFR 170.11, "Exemptions," for information on exemptions from these fees. Once the technical review of an application has begun, no fees will be refunded. Application fees will be charged regardless of the NRC's disposition of an application or the withdrawal of an application.

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

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

8 CONTENTS OF AN APPLICATION

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

All items in the application should be completed in enough detail for the NRC to determine whether the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect public health and safety and minimize danger to life and property. Consideration should be given, when developing the application, to the concepts of keeping exposures 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 on 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, Revision 2, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," discusses the ALARA concept and philosophy. The application should document ALARA considerations, including establishing administrative action levels and monitoring programs.

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

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

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

8.1 Item 1: License Action Type

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

Type of Action	License No.
[ ] A. New License	Not Applicable
[ ] B. Amendment	XX-XXXXX-XX
[ ] C. Renewal	XX-XXXXX-XX

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

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

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

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

8.2 Item 2: Name and Mailing Address of Applicant

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

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

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

8.2.1 Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h)

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

Response from Applicant: Licensees must immediately notify the NRC, in writing, following the filing of a voluntary or involuntary petition for bankruptcy by or against the licensee. The notification requirement of 10 CFR 30.34(h) does not apply to applicants for a new license.

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

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

Specify the street address, city, and State or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility 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, for each facility where licensed materials will be stored or used.

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

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

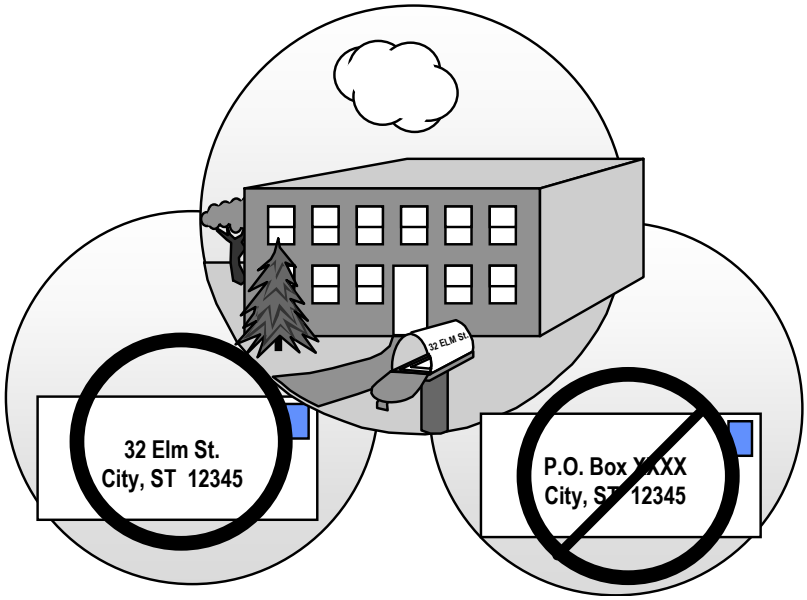
A license amendment is required before receiving, using, or storing licensed material at an address or location not already listed on the license.

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

If an applicant submits documents that give the exact location of use and storage for any amount of radioactive materials, 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.

Response from Applicant:

- Provide the specific address of each location where an accelerator will be used to produce radioactive material. If applicable, describe the locations or use of the properties outside of the location where accelerator operations will be conducted.



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

Figure 8-1. Location of Use or Possession

Note: As discussed in Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning," licensees must maintain permanent records that describe where licensed material was used or stored while the license was in effect. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches, written descriptions of the specific locations or room numbers where licensed material is used or stored and any records of leaking radioactive sources, or other unusual occurrences involving the possible spread of contamination in or around the licensee's facilities.

8.4 Item 4: Person To Be Contacted about This Application

Identify the individual who can answer questions about the application, and include a telephone number where the individual may be contacted. Also include business cell phone numbers and e-mail addresses. This individual, usually the radiation safety officer (RSO), will serve as the point of contact during the review of the application. If this individual is not a full-time employee of the licensed entity, his or her position and relationship to the licensee should be specified. The NRC should be notified if the person assigned to this function changes or if his or her telephone number, cell phone number, or e-mail address changes. Notification of a contact change is only to provide information and would not be considered an application for license amendment, unless the notification involves a change in the contact person who is also the RSO.

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

8.5 Item 5: Radioactive Material

8.5.1 Unsealed and Sealed Byproduct Material

Regulations: 10 CFR 30.4, 10 CFR 30.6, 10 CFR 30.9, 10 CFR 30.11, 10 CFR 30.32, 10 CFR 30.33, 10 CFR 30.34, 10 CFR 30.36, 10 CFR 30.37, 10 CFR 30.38, 10 CFR 32.19, 10 CFR 32.210, 10 CFR Part 51.

Criteria: A specific license is required, describing and authorizing the production and distribution of radioactive materials to persons specifically licensed. Applicants must submit information specifying each radionuclide that will be produced, the form of the radionuclide, and the maximum activity to be possessed at any one time. The list of radionuclides should also include incidentally activated radionuclides that are produced during production of the primary radionuclide(s).

Discussion: For incidentally activated radionuclides, the applicant could request authorization to possess and use byproduct material with atomic numbers from 1 through 83. The applicant should indicate the total cumulative quantity for all radionuclides to be possessed at any one time, and the total cumulative possession should be commensurate with the applicant's needs, facilities, procedures, and demonstrated experience. If certain incidentally activated radionuclides will be produced in much larger quantities than described in the atomic number 1-83 request and the radionuclides have a half-life greater than 120 days, the applicant should list these separately, rather than increase the possession limit for all radionuclides.

Similarly, if it is known that specific high-risk, incidentally activated radionuclides are produced in smaller quantities, they should also be listed separately. Note that it is important to select carefully the type of material used in the equipment (e.g., accelerator), shielding, and accelerator facility in order to minimize the amount and type of incidentally activated radionuclides.

If needed, an applicant may request authorization to possess byproduct materials with atomic numbers greater than 83 (e.g., atomic numbers 84 through 96). For this request, the applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. Note that authorization to possess byproduct materials with atomic numbers 84 through 96 does not authorize the possession of uranium, thorium, or plutonium because, even though these elements have atomic numbers within the range of 84 through 96, these materials are either source material or special nuclear material and not byproduct material. Each authorized radionuclide is listed on an NRC license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit).

Applicants and licensees should also determine whether they possess or will possess sealed sources or devices, including check, calibration, transmission, and reference sources, or unsealed radioactive materials containing these naturally occurring radionuclides such as radium-226 or accelerator-produced radionuclides made subject to NRC regulatory authority under the Energy Policy Act of 2005 (EPAct). (See 10 CFR 30.4, "Definitions," for a complete definition of byproduct material under the EPAct).

Applicants must request authorization to possess specifically-licensed sealed source(s) or device(s), in accordance with 10 CFR 30.32(g). If the manufacturer and distributor are no longer in service, a copy of the Sealed Source and Device (SSD) registration certificate may be requested from the NRC or the issuing Agreement State. Sealed sources and devices that were produced before October 23, 2012, may not have received radiation safety evaluations and/or may not have been registered by the NRC or Agreement State. If the applicant possesses these types of sources or devices, the applicant must submit all available information identified in 10 CFR 32.210(c) concerning the source, and if applicable, the device, and sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a leak test. For calibration and reference sources of less than 1 millicurie beta/gamma and less than 10 microcuries alpha, the applicant need only submit the manufacturer, model number, radionuclide, and quantity.

The NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in an SSD registration certificate. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining NRC's prior permission in a license amendment. For additional guidance relating to sealed sources and devices, see also NUREG–1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration."

The applicant should list each requested radionuclide by its element name and its mass number in Item 5 on NRC Form 313, specifying 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 generally required.

For unsealed radioactive material, applicants should specify whether the radionuclides produced will be in volatile or nonvolatile form, since additional safety precautions are required when handling volatile material. Also, if the facility possesses discrete sources of radium-226, the discrete source should be described, since additional precautions may need to be taken if the source is compromised. Applicants requesting discrete sources of radium-226 and authorization to manipulate volatile radioactive material must describe appropriate facilities and engineering controls, as described in Section 8.9, "Facilities and Equipment," and radiation safety procedures for handling of such material, in specific responses to Section 8.10.4, "Occupational Dose;" Section 8.10.5, "Public Dose;" Section 8.10.6, "Safe Operating and Emergency Procedures;" and Section 8.10.7, "Surveys and Leak Tests."

The anticipated possession limit for each radionuclide should also be specified in becquerels(Bq), although the curie (Ci)value may be provided in addition. Possession limits must include 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. Under 10 CFR 30.9(a), "Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations … shall be complete and accurate in all material respects." This effectively requires an applicant to specify the total anticipated inventory of radionuclides, including those in storage and possessed as waste. Under 10 CFR 30.34(c), each person licensed under parts 30 through 36 and 39 "shall confine his [sic] possession and use of the byproduct material to the locations and purposes authorized in the license. The applicant's needs for the radioactive material and proposed facilities for their safe handling should be commensurate with these purposes.

Applicants should also review the requirements in 10 CFR 30.35, "Financial Assurance and Recordkeeping for Decommissioning," for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radionuclide with a half-life greater than 120 days. These requirements are discussed in Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

Response from Applicant:

For unsealed materials:

- Provide an element name with mass number, chemical and/or physical form, and a maximum requested possession limit for each radionuclide produced.

- Identify the largest quantity of each radionuclide to be possessed at one time under the license, including produced, stored, and waste materials.

Note: For incidentally activated radionuclides, the applicant may request authorization to possess and use any form of byproduct material with atomic numbers 1 through 83, and indicate the total cumulative quantity for these radionuclides to be possessed at any one time.

For potentially volatile materials (e.g., I-123):

- Specify whether the material will be volatile or nonvolatile and the requested possession limit for each form.

For sealed radioactive materials and discrete sources of radium-226:

- 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, device, or source/device combination requested. If the manufacturer and distributor are no longer in service, a copy of the SSD registration certificate may be requested from the NRC or the issuing Agreement State.

- Confirm that each sealed source, device, or source/device combination is registered as an approved sealed source, device, or discrete source by NRC or an Agreement State.

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

If the sealed source, device, or source/device combination is not registered and was manufactured before October 23, 2012, provide all available information identified in 10 CFR 32.210(c) concerning the source, and if applicable, the device, and sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. In accordance with 10 CFR 32.210(c), such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience with the source, device, or source/device combination, and the results of a leak test.

For calibration and reference sources with less than 1 millicurie beta/gamma and 10 microcuries alpha, provide the manufacturer, model number, radionuclide, and quantity.

***Notes**:*

- Licensees who request a possession limit in excess of the quantities specified in 10 CFR 30.72, "Schedule C—Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must submit an emergency plan, as specified in 10 CFR 30.32(i).

- When responding to this Section, licensees should follow the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," to determine if their response includes sensitive security-related information that needs to be marked accordingly.

8.5.2 Financial Assurance and Recordkeeping for Decommissioning

Regulations: 10 CFR 20.2108; 10 CFR 30.34(b), 10 CFR 30.35, 10 CFR 30.51(f)

Criteria: A licensee authorized to possess radioactive material in excess of the limits specified in 10 CFR 30.35 must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (CFA) for decommissioning. Even if a DFP or CFA is not required, licensees are required under 10 CFR 30.35(g) to maintain, in an identified location until the site is released for unrestricted use, decommissioning records related to leaking sources and structures, equipment, and the site where radioactive materials are used or stored. Also, before

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

Discussion: The NRC wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. Most accelerator facilities that produce radioactive materials will be required to comply with the financial assurance requirements because of the incidentally activated materials produced during operation.

NRC regulations requiring a DFP or CFA are designed to provide reasonable assurance that the decommissioning of licensed facilities will be accomplished in a safe and timely manner, and that licensees will provide adequate funds to cover all costs associated with decommissioning in accordance with 10 CFR 30.35. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee, through a third party, that funds will be available to decommission and release the site for unrestricted use. Applicants are required to submit a DFP or CFA when they possess radioactive material with a half-life ($T_{1/2}$) greater than 120 days that exceeds certain limits. Regulations in 10 CFR 30.35 set forth criteria for determining whether an applicant is required to submit a DFP or has an option to submit either a DFP or CFA (or neither).

A DFP contains a site-specific cost estimate and a certification by the licensee that it has provided financial assurance in the amount of the cost estimate for decommissioning. The DFP must also contain a signed original of this financial instrument, which must satisfy the requirements of 10 CFR 30.35(f). Subsection (f) establishes the methods by which any financial assurance instrument, such as a prepayment, surety bond, insurance, or sinking fund, must be provided. As an alternative to developing a DFP, some licensees may be eligible under 10 CFR 30.35(b)(2) to submit a CFA in an amount corresponding to the table of possession limits set forth in 10 CFR 30.35(d). Note that a CFA financial assurance instrument must meet the same 10 CFR 30.35(f) requirements as a DFP.

NUREG–1757, Vol. 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," provides guidance acceptable to NRC staff on the information to be provided for establishing financial assurance for decommissioning and a standard format for presenting the information. (See Figure 8-2 for some acceptable forms of financial assurance.)

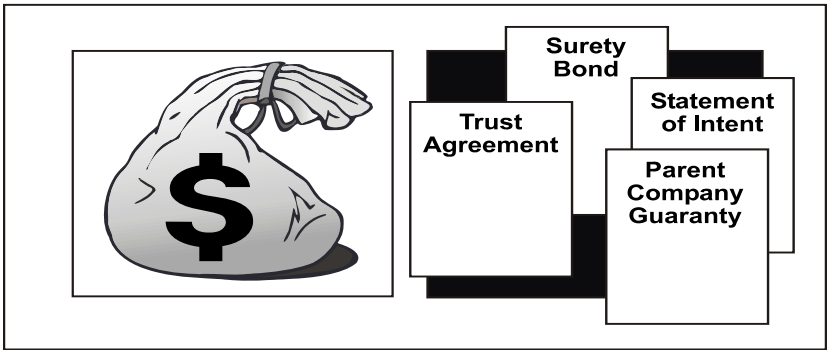


Figure 8-2. Financial Assurance for Decommissioning

Licensees that possess and operate an accelerator will likely need to provide financial assurance for decommissioning, because of the accumulation of longer-lived incidentally activated radionuclides. Large accelerator operators may need one of several approved financial mechanisms.

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in 10 CFR 30.35(g). These requirements also apply to licensees that are not required to submit a DFP or CFA. Under this provision, "records important to decommissioning" include

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information identifying involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination, such as buried pipes, that may be subject to contamination. If drawings are not available, the licensee must substitute appropriate records of available information concerning these areas and locations.

(3) Except for areas containing only sealed sources (provided the sources have not leaked, or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

(i) all areas designated and formerly designated restricted areas as defined in 10 CFR 20.1003, "Definitions." (For requirements before January 1, 1994, see 10 CFR 20.3, as contained in the CFR edition revised as of January 1, 1993.)

(ii) all areas outside of restricted areas that require documentation under 10 CFR 30.35(g)(1)

(iii) all areas outside of restricted areas where current and previous wastes have been buried as documented under 10 CFR 20.2108

(iv) all areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 10 CFR Part 20, Subpart E, "Radiological Criteria for License Termination," or apply for approval for disposal under 10 CFR 20.2002, "Method for Obtaining Approval of Proposed Disposal Procedures"

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

It is also important to note that under 10 CFR 30.35(e)(2), the DFP must be updated at the time of license renewal and at intervals not to exceed 3 years, to account for changes in costs and the extent of contamination. The updated DFP must also specifically consider the decommissioning cost impacts of

(i) spills of radioactive material producing additional residual radioactivity in onsite subsurface material

(ii) waste inventory increasing above the amount previously estimated

(iii) waste disposal costs increasing above the amount previously estimated

(iv) facility modifications

(v) changes in authorized possession limits

(vi) actual remediation costs that exceed the previous cost estimate

(vii) onsite disposal

The regulations in 10 CFR 30.35(g) also require that licensees maintain records important to decommissioning in an identified location. In accordance with 10 CFR 30.35(g), licensees must transfer records important to decommissioning to any new proposed licensee before licensed activities can be transferred or assigned according to 10 CFR 30.34(b). Furthermore, under 10 CFR 30.51(f), before license termination, each licensee shall forward the records required by 10 CFR 30.35(g) to the appropriate regional office. Recipients of existing licenses in accordance with 10 CFR 30.34(b) are also responsible for maintaining these records until the license is terminated or transferred to another party. Careful recordkeeping of radionuclides possessed and used, including their form, amount, and the size of the area(s) where they have been used, will facilitate license termination and release of the area(s) for unrestricted use.

Response from Applicants:

- State the following: "Pursuant to 10 CFR 30.35(g), we shall maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b). 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 or assign the records to the appropriate NRC regional office before the license is terminated."

AND

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

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

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

Regulations: 10 CFR 30.4, 10 CFR 30.32(j), 10 CFR 30.33(a)(1)

Criteria: An application for a license will be approved if the proposed activity is authorized by the Atomic Energy Act of 1954, as amended, and devices will be used only for the purposes for which they were designed and according to the manufacturer's recommendations for use, as specified in an approved SSD registration certificate. For this license, the materials will be produced by an accelerator and transferred or distributed to another licensee for use. The radioactive material produced will be possessed and stored as necessary. Also, activated products will be handled during maintenance, repair, and disposal activities.

Discussion: Applicants should specify that the accelerator-produced radioactive material requested in Item 5 will be possessed and stored incident to production, in accordance with NRC regulations. Applicants may use the format given in Table 8-1 to provide the requested information. Once the radioactive material is produced, it may be used under a separate license held by the same entity or distributed to another licensee. The produced radioactive material may be transferred or distributed to any licensee authorized to receive it, including holders of

- manufacturing and distribution licensees
- commercial radiopharmacy licensees
- broad-scope licensees
- limited-scope licensees
- medical use licensees

For more information on applying for these types of licenses, refer to the following NUREG–1556 guidance reports:

- For a manufacturing and distribution license, refer to NUREG–1556, Vol. 12, "Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution."

- For a commercial radiopharmacy license, refer to NUREG–1556, Vol. 13, "Program-Specific Guidance About Commercial Radiopharmacy Licenses."

- For a broad-scope license, refer to NUREG–1556, Vol. 11, "Program-Specific Guidance About Licenses of Broad Scope."

- For a limited-scope license, refer to NUREG–1556, Vol. 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers."

- For a medical use license, refer to NUREG–1556, Vol. 9, "Program-Specific Guidance About Medical Use Licenses."

As defined in 10 CFR 30.4, a consortium is an association of medical use licensees and a positron emission tomography (PET) radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. Furthermore, the PET radionuclide production facility within the consortium must be located at

an educational institution, Federal facility, or medical facility. Although members of a consortium hold licenses to use PET radionuclides under 10 CFR 30.32(j), at least one member of the consortium must be specifically licensed to produce and distribute PET radioactive drugs to medical use licensees noncommercially (i.e., within the consortium and not to an independent third party). Specific guidance for applicants requesting authorization for the production and noncommercial distribution of PET radioactive drugs to medical use licensees in a consortium can be found in Appendix N of this NUREG.

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

Radionuclide	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
Any byproduct material with atomic numbers 1 through 83	Incidentally Activated Products	Not to exceed 20 millicuries per radionuclide and 1 curie total, except as noted	Possession and storage incident to production activities
Fluorine-18	Any	20 curies	Production and possession of a radiochemical for transfer or distribution to authorized licensees.
Manganese-54	Incidentally Activated Products	100 millicuries	Possession and storage incident to production activities
Cobalt-60	Incidentally Activated Products	50 millicuries	Possession and storage incident to production activities
Germanium-68	Sealed source, Mfg. name & model	10 millicuries per source and 50 millicuries total	Calibration and check of instruments
Palladium-103	Any	50 curies	Production and possession of a sealed source for transfer or distribution to authorized licensees.
Cadmium-109	Incidentally Activated Products	100 millicuries	Possession and storage incident to production activities
Indium-111	Any	1 curie	Production and possession of a radiochemical for transfer or distribution to authorized licensees.

Table 8-1. Sample Format for Providing Information About Requested Radionuclides			
Radionuclide	**Chemical/ Physical Form**	**Maximum Possession Limit**	**Proposed Use**
Iodine-123	Volatile	100 millicuries	Production and possession of a radiochemical for transfer or distribution to authorized licensees.
Thallium-201	Any	1 curie	Production and possession of a radiochemical for transfer or distribution to authorized licensees.

Response from Applicant: For accelerator-produced radionuclides, applicants should state that radioactive materials will be possessed and stored in accordance with NRC regulations. For all other material that is not accelerator-produced, specify its proposed use (e.g., calibration of instruments). Using the format in Table 8-1 will facilitate the review of the application.

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

Regulation: 10 CFR 30.33(a)(3).

Criteria: Radiation safety officers RSOs and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures must have adequate training and experience.

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

Each program in which radioactive materials are possessed and used under an NRC license will have someone responsible for radiation safety and compliance with NRC's regulations. The individual's training and experience must be commensurate with his or her duties and responsibilities. For additional guidance on radiation safety training, see Appendix O. Supporting staff should be provided, as appropriate, for the size and scope of the program. A radiation safety program for a radioactive materials production facility may consist of some or all of the following characteristics:

- the need for accurate detection, identification, and measurement of radioactivity in various types of effluents (gas, liquid, solid) containing varying amounts of different radionuclides and for evaluation of these effluents against NRC regulatory requirements and limitations

- the need for radioactive effluent treatment by filtration, absorption, adsorption, holdup for decay

- the need for the selection, evaluation, design, maintenance, and use of radioactive effluent treatment systems

- the need for the selection, evaluation, and maintenance of radiation measurement and analysis equipment

- a potential for the contamination of facilities, equipment, and personnel, accompanied by the need to control such contamination (including airborne contamination); decontaminate personnel and equipment; and evaluate possible internal dose (including determination of the need for bioassays and interpretation of bioassay results)

The NRC holds the licensee responsible for the radiation safety program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted safely. As discussed later in this guide, senior management will delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NRC regulations and license provisions and to terminate unsafe activities involving byproduct material. Other responsibilities will be delegated to other individuals. Such delegations should be clearly communicated to all parties. While these delegations are important to the operation of the program, the licensee's senior management maintains the ultimate responsibility for the safety of licensed activities.

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

8.7.1 Radiation Safety Officer

Regulation: 10 CFR 30.33(a)(3).

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 safety program is the RSO. The RSO is the key to overseeing and ensuring safe operation of the licensee's radiation protection program. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO should have independent authority to stop operations that he or she considers unsafe. He or she should have sufficient time and commitment from management to fulfill his or her duties and responsibilities to ensure that (i) radioactive materials are possessed and used in a safe manner, (ii) approved radiation safety procedures are being implemented, and (iii) the required records of licensed activities are maintained. This management support includes resource allocation.

Typical RSO duties are illustrated in Figure 8-3 and described in Appendix C of this NUREG. The NRC requires the name of the RSO to be listed 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.

The RSO may delegate certain day-to-day tasks of the radiation protection program to other responsible individuals (potential designees). Appendix C of this NUREG also provides a model Delegation of Authority, which should be used to further emphasize the agreement by

management and the designated RSO on duties and responsibilities of the RSO. Licensees may also appoint ”alternate RSOs” who may “step in” as an emergency contact when the RSO is unavailable. Such “alternate RSOs” or “site RSOs” do not need to meet all RSO qualifications, but these individuals should be qualified, experienced authorized users who have adequate knowledge of the activities to which they are assigned. Designees should have the same management support and decision-making authority as the RSO necessary to accomplish the tasks to which they have been assigned. Please note that only the primary RSO is named on an NRC license. Applicants do not have to identify other responsible individuals if day-to-day tasks will not be delegated.

To demonstrate adequate training and experience at a radioactive materials production facility, it is recommended that the RSO have (i) at a minimum, a college degree at the Bachelor level or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (ii) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection instrumentation
- biological hazards of exposure to radiation (appropriate to types and forms of licensed material to be possessed and used)
- NRC regulatory requirements and standards
- handling of radioactive materials in relation to production activities (e.g., maintenance and repair of the accelerator)

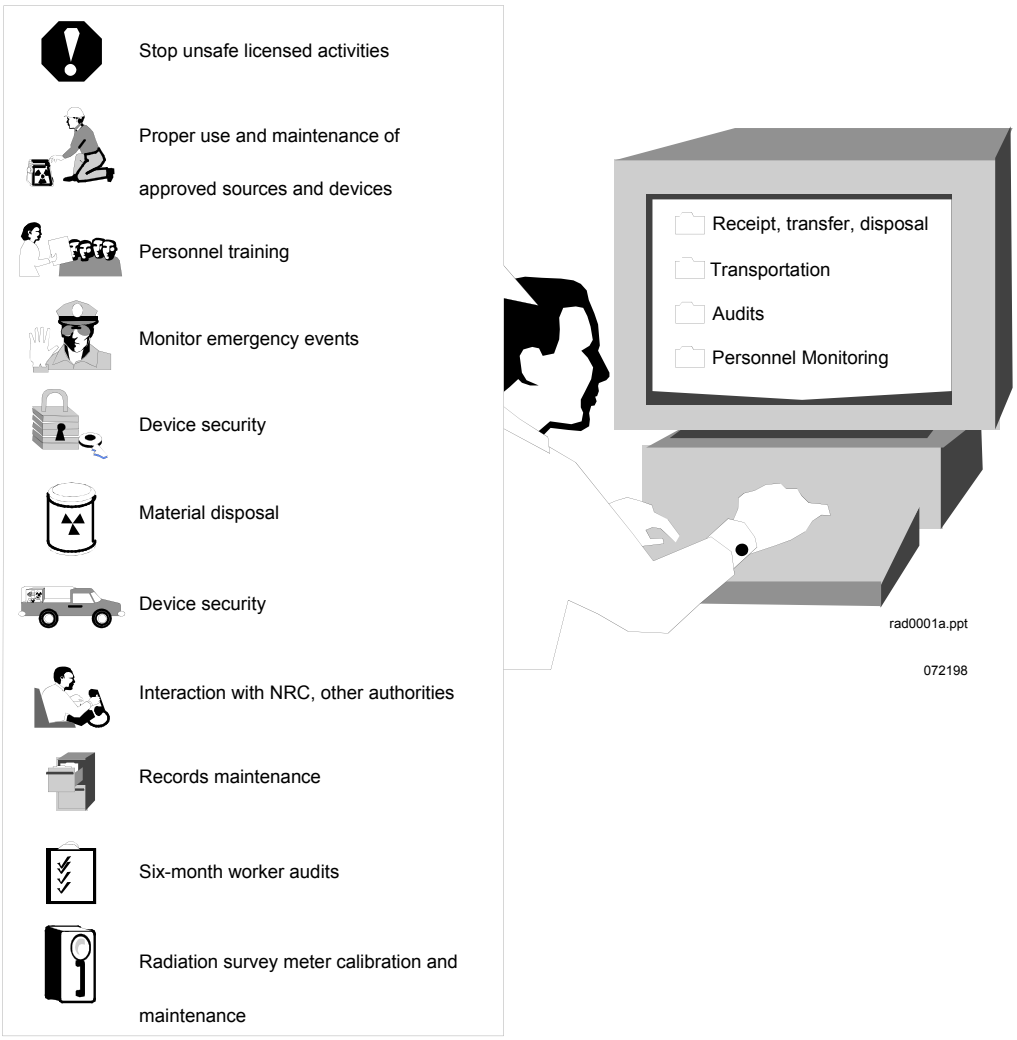


Figure 8-3. RSO Responsibilities. *Typical duties and responsibilities of RSOs.*

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 accelerator facilities where workers may handle curie quantities of radioactive material should be specialists in the field of radiation protection and may need at least 40 hours of radiation safety training specific to their job duties, as well as a year of experience with similar types, forms, quantities, and uses of radioactive material before they are qualified to be an RSO. The proposed RSO's training and experience must be sufficient to identify and control the anticipated radiation hazards. For example, the RSO should have experience planning and conducting evaluations, surveys, and measurements similar to those required by the licensee's radiation safety program. 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 professional organization of radiation protection experts.

Response from Applicant: Provide the following:

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

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

Applicants should provide information about the proposed RSO's training and experience with the licensed material and uses requested in the application. Do not include private, personal information (e.g., home address, home telephone number, Social Security number, date of birth, and radiation dose information). Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, and personal private information. Submittal of unrelated material may delay the review process.

Note: It is important to notify the NRC and obtain a license amendment before making changes in the designation of the RSO listed on the license. The name and qualifications of the replacement RSO should be submitted to the NRC as part of an amendment request.

8.7.2 Individuals Authorized To Handle Licensed Material

Regulations: 10 CFR 19.12, 10 CFR 20.1101(b), 10 CFR 30.33(a)(3).

Criteria: Individuals authorized to handle licensed material must have adequate training and experience with the types and quantities of licensed material that they propose to possess and handle.

Discussion: Applicants must name at least one individual who is qualified to handle the requested licensed materials. For a production license, handling of licensed materials includes, for example, the processing of produced radiochemicals and the handling or manipulation of activated targets and/or components (e.g., maintenance and/or repair of the accelerator). An individual who is authorized to handle licensed material is a person whose training and experience have been reviewed and approved by the NRC or an Agreement State, who is named on the license, and who uses or directly supervises the use of licensed material. This individual's primary responsibility is to ensure that radioactive materials are handled safely and according to regulatory requirements. The individual is also responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

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

To demonstrate adequate training and experience at an accelerator facility, the authorized individual should have (i) a college degree at the Bachelor level or equivalent training and experience in physical, chemical, or biological sciences or in engineering; and (ii) training and experience commensurate with the scope of proposed activities, such as handling of activated

targets and activated products associated with accelerator 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)
- handling of radioactive materials relevant to accelerator activities

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 or equivalent experience, an authorized individual at a radioactive materials production facility who may use curie quantities of radioactive material should have at least 40 hours of radiation safety training specific to his or her job duties, as well as a minimum of 6 months of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be authorized to handle licensed material. In general, authorized individuals should demonstrate training and experience with the type and quantity of material they propose to handle. For example, an individual with training and experience only with sealed radioactive sources might not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities of radioactive materials 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 low-energy beta emitters may not have appropriate experience for high-energy gamma emitters. Individuals named on an Agreement State license for authorization to produce and/or handle licensed material may provide a copy of the Agreement State license to the NRC to demonstrate appropriate training and experience for the uses requested in a license application to NRC. Conversely, an individual named on an equivalent NRC materials license may provide a copy of that license to an Agreement State agency to demonstrate appropriate training and experience for the uses requested in a license application to that Agreement State.

An individual who is authorized to handle licensed material is considered to be supervising the handling of radioactive materials when he or she directs personnel in activities involving licensed material. Although the authorized individual may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), the authorized individual is responsible for the safe handling of radioactive material.

Note that accelerator manufacturers or companies that provide repair or maintenance service to licensed accelerator facilities may need an NRC service provider license or equivalent Agreement State license. In particular, this would be required when individuals (e.g., service engineers) perform certain maintenance and/or repair activities that involve the handling of radioactive materials (e.g., activated targets or components) during the accelerator maintenance and repair activities. If an NRC service provider license or equivalent Agreement State license is not obtained, individuals must be authorized under the facility's production license to handle

licensed material or must work under the supervision of an individual authorized to handle materials under the facility's production license. For guidance on how to apply for an NRC service provider license, see NUREG–1556, Vol. 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses." For guidance on how to work under an Agreement State license while under NRC jurisdiction, refer to NUREG–1556, Vol. 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)."

Response from Applicant: Provide the following:

- name of each proposed individual with the types and quantities of licensed material, including the activated targets and activated products, to be possessed and handled

- information demonstrating that each proposed individual is qualified by training and experience to possess and handle the requested licensed materials

Applicants should provide information about the proposed authorized individual's training and experience relative to the licensed material and uses requested in the application. Do not include private, personal information (e.g., home address, home telephone number, Social Security number, date of birth, and radiation dose information). Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, and personal privacy information. Submittal of unrelated material may delay the review process.

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

8.8 Item 8: Training for Individuals Working in or Frequenting Restricted Areas

Regulations: 10 CFR 19.12, 10 CFR 30.33(a)(3).

Criteria: Individuals whose assigned duties involve exposure to radiation and/or radioactive material (from both licensed and unlicensed sources) and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 millisievert (mSv) [100 millirem (mrem)], whether from all external sources, all internal sources, or any combination, must receive instruction commensurate with potential radiological health protection problems present in the work place, as required by 10 CFR 19.12, "Instruction to Workers."

Discussion: Before beginning work with licensed material, individuals should receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training at no more than 12-month intervals. Training should also be performed whenever there is a significant change in hazards, duties, procedures, regulations, or terms of the license.

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

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 lectures, demonstrations, recorded media, or self-study, and it should emphasize practical subjects important to the safe possession and use of licensed material. If training is not conducted by an instructor, a method should be adopted whereby a trainee can ask questions and discuss topics relating to occupational radiation exposure. The program should consider all topics pertinent for each group of workers as well as the method and frequency of training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. This assessment may be performed by a written test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

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

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 2.390, 10 CFR 20.1101(b), 10 CFR 20.1301, 10 CFR 20.1406, 10 CFR 30.33(a)(2), 10 CFR 30.35(g), 10 CFR 30.36.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. Under 10 CFR 20.1101(b) and 10 CFR 20.1406, the licensee must keep exposures to workers and the public ALARA and minimize the introduction of residual radioactivity into the site.

Discussion: Applicants must demonstrate that, together with any proposed administrative measures, their facilities and equipment provide sufficient engineered 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 to 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.

Under 10 CFR 30.35(g), licensees must keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Applicants are reminded that records important to decommissioning include:

- 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 or transfer lines that may be subject to contamination

- records of spills and unusual occurrences that may result in contamination of the facility or site

Under 10 CFR 30.36(k), facilities are required to meet NRC decommissioning requirements before termination of the license and release of the site. Therefore, careful facility design is important to prevent contamination, facilitate decontamination, and reduce the costs of decommissioning. For further information, see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

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

***Note**:* For further information on facility design, see Chapter 4 of NCRP Report No. 127, "Operational Radiation Safety Program."

Response from Applicant: Describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed, and/or used (see Appendix D of this NUREG for topics to consider). The application should also include:

- A description of the areas assigned for the production, transfer, storage, preparation, shipping, security, and measurement of radioactive materials.

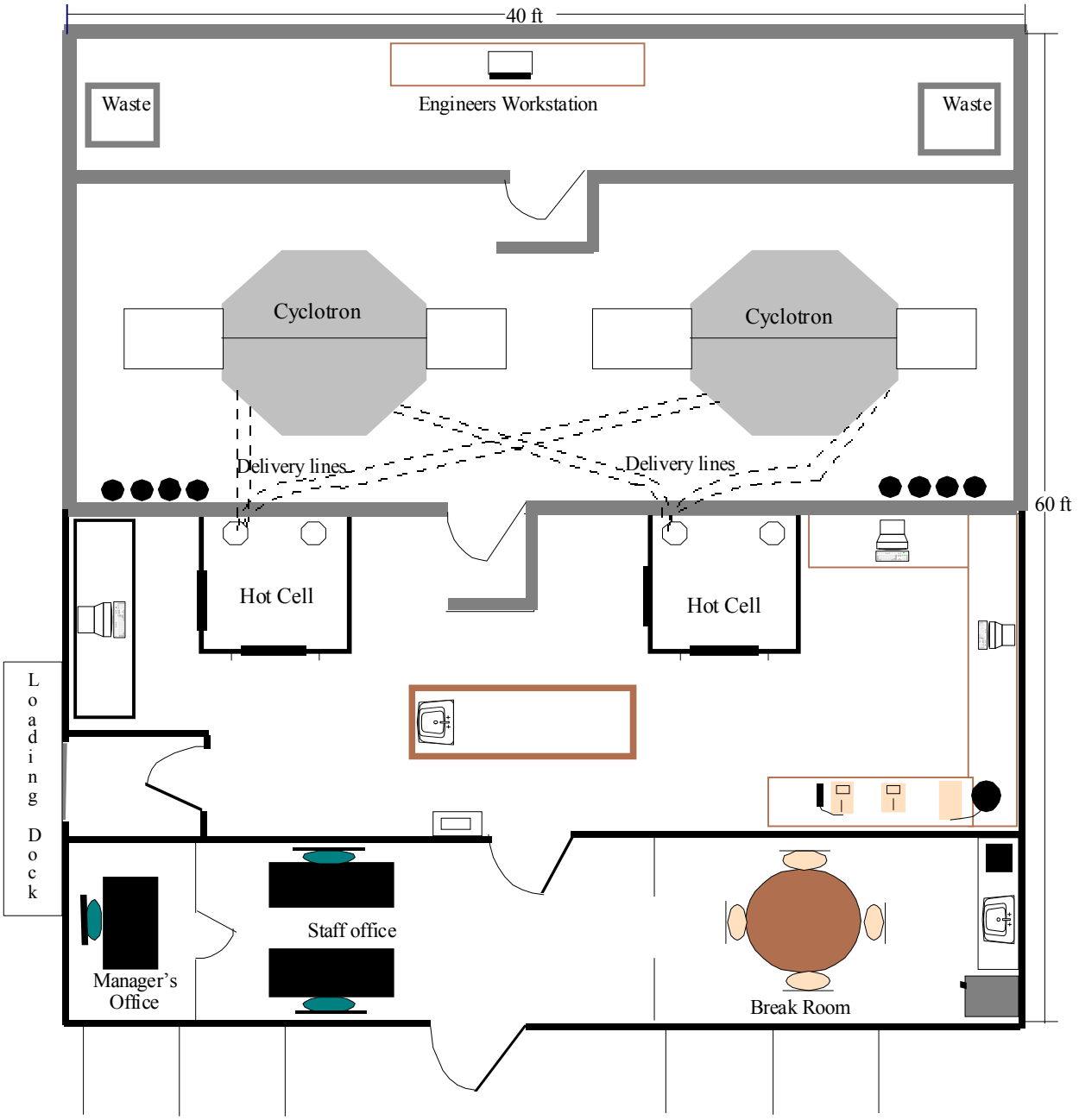
- A description and diagrams showing the locations of delivery lines, shielded areas and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety (see Figure 8-4). The licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. An example of such sensitive information could be a room number specifically identifying the location of the accelerator and related safety equipment. License applications containing sensitive information should be marked as indicated below, in accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," before the information is submitted to the NRC. If the application must contain proprietary information or trade secrets, the applicant should 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.

- A description and diagram of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne.

- Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions under 10 CFR 20.1101(d). For guidance on methods that are acceptable to the NRC, see Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors."

Note: Mark drawings and diagrams that provide the exact location of materials or depict the specific location of safety or security equipment as "Security-Related Information—Withhold Under 10 CFR 2.390." See generic Figure 8-4 below.

SECURITY-RELATED INFORMATION—WITHHOLD UNDER 10 CFR 2.390*



*For the purposes of this NUREG, this diagram is marked appropriately for an application. This particular diagram does not contain real security-related information.

Figure 8-4. Facility Diagram for a Radioactive Materials Production Facility

8.10 Item 10: Radiation Safety Program

8.10.1 Audit Program

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

Criteria: Licensees must review the content and implementation of their radiation safety programs at least annually [10 CFR 20.1101(c)].

Discussion: It is in the best interest of licensees to have a strong audit program to ensure that:

- licensees comply with NRC and U.S. Department of Transportation (DOT) regulations and the terms and conditions of the license
- occupational doses and doses to members of the public are ALARA (10 CFR 20.1101) and dose reduction efforts have been considered
- operating procedures are in place for activities that could potentially affect radioactive material or occupational dose [10 CFR 20.1101(a)]

Records of audits and other reviews of program content are maintained for 3 years after the record is made.

Appendix E of this NUREG contains a suggested audit program that is specific to the use of accelerator-produced radioactive materials and is acceptable to the NRC. Since all areas indicated in Appendix E may not be applicable to every licensee and all items may not need to be addressed during each audit, licensees may wish to develop a program-specific audit checklist.

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

It is essential that when problems are identified, comprehensive corrective actions are taken in a timely manner. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. The NRC routinely reviews licensee's records to verify whether appropriate corrective actions were implemented in a timely manner to 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. 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. For examples of the NRC's use of discretion in issuing a notice of violation, refer to the most recent version of NRC's enforcement documents at http://www.nrc.gov/reading-rm/doc-collections/enforcement/.

With regard to audit records, 10 CFR 20.2102(a) requires, in part, that licensees maintain records of "audits and other reviews of program content and implementation" for 3 years after

the record is made. The NRC has found that audit records containing the following information are acceptable:

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

References: The current version of the NRC's Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement.html.

IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, can be found on the NRC's Generic Communications Web site under Information Notices at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

Audit Objectives. The NRC holds the licensee responsible for the radiation safety program. It is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Audits may be used by licensees to self-assess the adequacy of the licensed program, identify program weaknesses, and allow licensees to take early corrective actions (before an NRC inspection). The objectives of the audit should include an evaluation of the licensee's:

- efforts to maintain doses ALARA
- compliance with NRC requirements
- ability to identify and correct deficiencies in its radiation safety program
- management of the radiation safety program, including the roles and responsibilities of senior management and the RSO
- implementation of the radiation safety program

Scope of Audit. Audits should cover both the management of the radiation safety program and the details of its implementation in the areas chosen for review. Mechanisms used by senior management to ensure that adequate oversight of the program is exercised should be included in the scope of the audit.

Auditor Qualifications. Auditors should have training and experience similar to that of an individual authorized for the types, forms, uses, and quantities of radioactive material used in the areas audited. Auditors should not be selected from the staff or management of areas to be audited. Ideally, auditors are third parties, from independent organizations.

Audit Frequency. Audits should be conducted at least once every 12 months, but if the licensee's activities involve high-activity materials or frequent handling of intermediate activity materials, applicants should consider developing survey and audit schedules based on activity and use (e.g., high-use/activity areas may be audited monthly, moderate-use/activity areas may be audited quarterly). More frequent audits should be considered if the potential for overexposures exists.

Audit Techniques. While any audit of a radiation safety program should review documentation, emphasis should be placed on actual observations of work in progress. Licensees and applicants for license amendments should consider performing unannounced audits of radioactive material users to observe work in progress and determine if, for example, operating and emergency procedures are available and being followed. Radiation safety audits should include activities conducted during all shifts. Some details of typical audit techniques follow:

- **Audit History**. Note the date of the last audit, whether any deficiencies were identified, and whether actions were taken to correct the deficiencies.

- **Organization and Scope of Program Area Audited**. Give a brief description of the licensee's organizational structure, noting any changes in personnel. Describe the scope of licensed activities at the audited location. Check whether the RSO is the person identified in the license and fulfills the duties specified in the license.

- **Training, Retraining, and Instructions to Workers**. Ensure that workers have received the training required by 10 CFR 19.12. Be sure that before being permitted to use byproduct material, the user has received training and has a copy of the licensee's operating and emergency procedures. Note whether refresher training is conducted in accordance with licensee commitments and whether all shift workers are included. By interview and/or observation of selected workers, ensure that each worker has a copy of the licensee's procedures and can implement them properly. Special attention should be directed to the adequacy of training and observation of new employees performing their radioactive material duties.

- **Facilities**. Verify that the facilities are as described in the license documents.

- **Materials**. Verify that the license authorizes the quantities and types of byproduct material that the licensee possesses.

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

- **Inventories**. Verify that inventories are conducted at least once every 6 months to account for all sources. Inventory records should be maintained.

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

- **Production Activities**. Verify that used accelerator parts (e.g., targets and O-rings) and other activated products are properly stored and shielded. Also, verify that maintenance and repair logs are maintained, accurate, and up-to-date.

- **Transfer of Radioactive Material (Including Waste Disposal)**. Ensure that transfers are performed in accordance with 10 CFR 30.41. Records of surveys, receipts, and transfers must be maintained in accordance with 10 CFR 20. 2103 and 10 CFR 30.51.

- **Transportation**. Determine compliance with DOT requirements. Verify that radioactive packages are prepared, marked, and labeled in accordance with 49 CFR Parts 172 and 173 requirements. Verify that shipping papers are prepared, contain all needed information, and are readily accessible during transport (49 CFR 172.200, 172.201, 172.202, 172.203, and 172.204).

- **Personnel Radiation Protection**. Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits. Alternatively, 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. The licensee is also responsible for ensuring that dosimetry results are assigned accurately and should consider that the assigned deep-dose equivalent and shallow-dose equivalent must be for the part of the body receiving the highest exposure. Therefore, if possible, whole body and extremity dosimeters should be placed in the areas that receive the highest exposure. An evaluation should be performed to determine if the maximum dose to a part of the whole body or an extremity may be substantially higher than the dose measured by the dosimeter. If the evaluation indicates that the maximum dose to a part of the whole body or extremity is higher than that measured by the dosimeter, the higher dose will be used as the dose of record (see Section 8.10.4). If any worker declared her pregnancy in writing, evaluate compliance with 10 CFR 20.1208, "Dose Equivalent to an Embryo/Fetus." Check whether records are maintained as required by 10 CFR 20.2101, 20.2102, 20. 2103, 20.2104, and 20.2106.

- **Independent Measurements**. Make independent survey measurements and compare the results with those made or used by the licensee. Survey measurements should include engineer's workstation, waste/storage locations, and other shielded locations/equipment.

- **Notification and Reports**. Check for compliance with the notification and reporting requirements in 10 CFR Parts 19, 20, 21, and 30. Ensure that the licensee is aware of the telephone number for NRC's Emergency Operations Center: 301-816-5100.

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

- **Recordkeeping for Decommissioning**. Check to determine compliance with 10 CFR 30.35(g).

- **Bulletins and Information Notices**. Check to determine whether such notifications as bulletins, information notices, and newsletters are received from the NRC. Check whether appropriate actions were taken in response to NRC mailings.

- **Special License Conditions or Issues**. Verify compliance with any special conditions in the license. If there are any unusual aspects of work, review and evaluate compliance with regulatory requirements.

- **Recommendations**. List any recommendations to improve the overall efficiency and effectiveness of the audit and radiation safety program.

- **Evaluation of Other Factors**. Evaluate management's involvement with the radiation safety program, whether the RSO has sufficient time to perform his/her duties, and whether there is sufficient staff to handle the workload and maintain compliance with regulatory requirements.

Problems or Deficiencies Noted: The licensee should have a process for correcting violations and deficiencies during and after the audit. The licensee should identify the safety significance of each violation to set priorities and identify resources to correct these violations. Results of the audit program reviews should be reported to senior management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with NRC regulations and licensee conditions. IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," 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 NRC for guidance if they are uncertain about a reporting requirement. All audit findings and corresponding corrective actions, whether from internal, State, or Federal audit findings, should be communicated to the staff for review and added to new and refresher radiation safety training sessions. If the findings represent a significant safety impact on the staff, special training sessions may be appropriate.

Records to be Maintained: Under 10 CFR 30.9, licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. Audit records should contain 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 follow-up. These records must be maintained for inspection by the NRC. Appendix E of this NUREG contains a sample audit program that can be used to document the annual audit of the radiation protection program.

Response from Applicant: No response is required. The licensee's program for auditing its radiation safety program will be reviewed during inspection.

8.10.2 Radiation Monitoring Instruments

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

Criteria: Licensees must possess radiation monitoring instruments to evaluate radiation hazards that may be present [10 CFR 20.1501(a)]. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured [10 CFR 20.1501(b)]. Each licensee must maintain records showing the results of surveys and calibrations required by §§ 20.1501 and retain these records for 3 years after the record is made [10 CFR 20.21031(a)].

Discussion: Licensees must possess calibrated radiation detection/measurement instruments to perform, as necessary:

- dose rate surveys
- personnel and facility contamination measurements
- sealed-source leak tests
- air sampling measurements

- bioassay measurements
- effluent release measurements
- package surveys

For the purposes of this document, radiation monitoring instruments are defined as any device used to measure the radiological conditions, which include licensed and nonlicensed activities (e.g., accelerator operation) at a licensed facility. Some of the instruments that may be used to perform the above functions include:

- portable or stationary count rate meters
- portable or stationary dose rate or exposure rate meters
- single or multichannel analyzers
- liquid scintillation counters
- gamma counters
- proportional counters
- stack monitors
- solid state detectors
- neutron detectors
- hand and foot contamination monitors

The choice of instrument should be appropriate for the type of radiation to be measured and for the type of measurement to be taken (e.g., count rate, dose rate). Figure 8-5 illustrates some common radiation survey instruments used for contamination surveys. Applications should include descriptions of the instrumentation available for use and the instrumentation that applicants intend to purchase before starting licensed activities. The description should include the type of instrument and probe and the instrument's intended purpose.

Instruments used for qualitative surveys are only intended to detect contamination in the laboratory. Such instruments should be checked for operational response with an appropriate check source containing radioactive material and can be calibrated with an electronic pulser instead of a radioactive source. However, these instruments cannot be used for measurement of surface contamination or radiation levels without performing a calibration with appropriate radioactive sources, as described in Appendix F of this NUREG, "Radiation Monitoring Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program."

Instrument calibrations should be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform radiation survey instrument calibrations should submit procedures for review. Appendix F provides information about instrument specifications and model calibration procedures. Applicants should be aware that calibrations often require possession and use of a calibration source or device. Instruments for counting smear wipes to detect contamination and leakage need calibration sources that may be listed on the production license. Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts an authorized firm to perform calibrations, the licensee must retain calibration records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made, in accordance with 10 CFR 20.2103(a).

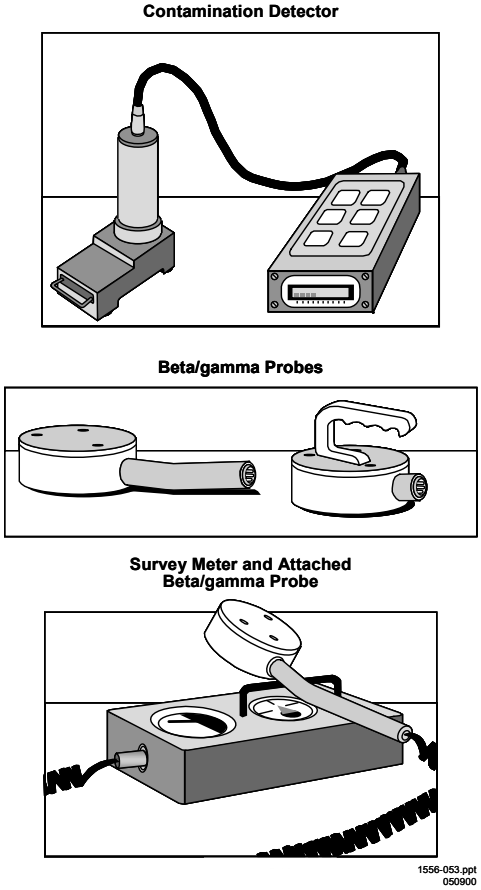


Figure 8-5. Examples of Portable Instruments Used in Laboratory Settings

Response from Applicant: Provide one of the following:

A description of the instrumentation, including the type of instrument and probe, and the instrument's intended purpose that will be used to perform required surveys and a statement: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F in the current version of NUREG–1556, Vol. 21, 'Program-Specific Guidance About Possession License for Production of Radioactive Materials Using an Accelerator.'"

OR

A description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration of radiation survey equipment will be performed at the required frequency. Calibrations may be performed by licensees specifically authorized to provide this service. It is not necessary to have a copy of the instrument manufacturer's license, but calibration vendors other than the instrument manufacturer should be verified to ensure they have authorization to calibrate instruments for others.

AND

A description of the instruments that will be used to quantitatively measure the radioactivity in the products, processes, and effluents. Include the calibration procedures that will be followed to ensure the accuracy of those measurements.

AND

A description of method(s) that may be used to determine the concentration of radioactive air effluents that are released in order to demonstrate compliance with the 10 CFR 20.1101(d) constraint on air emissions. For real-time monitoring of radioactive air effluents, provide a description of the detector and the methodology that will be used to calculate the air effluent release concentrations.

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

8.10.3 Material Security and Accountability

Regulations: 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 20.2001, 10 CFR 20.2102, 10 CFR 20.2201, 10 CFR 30.35(g), 10 CFR 30.41, 10 CFR 30.51

Criteria: Licensees must ensure the security and accountability of licensed material (10 CFR 20.1801 and 10 CFR 20.1802). Licensees must make arrangements to take possession of a package containing more than a Type A quantity of radioactive material expeditiously (10 CFR 20.1906). Licensees must report any lost, stolen, or missing licensed material in an aggregate quantity exceeding specified limits (10 CFR 20.2201).

Discussion: Licensees must secure and control licensed material and should have a means of promptly detecting losses of licensed material. Regulations in 10 CFR 20.1801 and 20.1802 require licensees to secure radioactive materials from unauthorized removal or access while in storage in controlled and unrestricted areas and to control and maintain constant surveillance over licensed material that is in a controlled or unrestricted area and not in storage.

Security: To meet 10 CFR 20.1801, all licensed materials stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who are not knowledgeable about radioactive materials cannot be exposed to or contaminated by the material and cannot take the material. When any licensed material is used or handled in controlled or unrestricted areas, it must be under constant surveillance to prevent others from becoming contaminated by or exposed to the material, or to prevent persons from removing the material from the area. Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include: (i) storage and use of licensed materials only in restricted areas, (ii) limiting access to an entire facility or building or portion of the building only to radiation workers, (iii) providing storage areas that can be locked to prevent access to the material, and (iv) implementing procedures that require a radiation worker to be within “line of sight” of the materials whenever licensed materials are in use. Applicants should develop procedures that clearly state acceptable methods to secure licensed material at their facility. Particular attention may need to be paid to security procedures at facilities that may have unusual needs due to the activities performed.

Material Accountability: To meet 10 CFR 20.1801 requirements to “secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas,” (and applicable recordkeeping requirements under 10 CFR 30.51), licensees should: track their licensed material from production to disposal in order to ensure accountability; identify when

licensed material could be lost, stolen, or misplaced; and ensure that possession limits listed on the license are not exceeded. Licensees may exercise control and accountability over licensed material by:

- conducting physical inventories of sealed sources at intervals not to exceed 6 months (or some other interval justified by the applicant and approved by the NRC) to account for all sealed sources, in accordance with license conditions
- maintaining material inventories within license possession limits
- maintaining up-to-date records of transferred and distributed materials
- maintaining up-to-date records of disposed materials (e.g., waste records)

Licenses will normally contain specific conditions requiring the licensee to perform inventories and leak tests of sealed sources every 6 months. Since the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program. Sealed Sources must be leak tested and inventoried as required by license conditions.

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

With regard to incidentally activated products, licensees should develop procedures for assessing volumetric contamination of such equipment and materials to ensure that possession limits are not exceeded.

Receipt, inventory, transfer, and disposal records must be maintained for the times specified in Table 8-2. Typically, these records contain the following types of information:

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

Table 8-2 lists the types and retention times for the records the applicant must maintain of production, use, transfer, and disposal (as waste) of all licensed material (10 CFR 30.51). Other records, such as transfer records, could be linked to radioactive material inventory records.

Table 8-2. Record Maintenance	
Type of Record	**How Long Record Must Be Maintained**
Receipt	For as long as the material is possessed and for 3 years following the transfer or disposal of the material
Inventory	For 5 years from the date of the inventory
Transfer	For 3 years after each transfer, unless a specific requirement dictates otherwise
Disposal	Until the NRC terminates the license
Important to Decommissioning*	Until the site is released for unrestricted use
* See Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning," for more details.	

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

Information about locations where licensed material is used or stored are among the records important to decommissioning and required by subsection (g) of 10 CFR 30.35, "Financial Assurance and Recordkeeping for Decommissioning."

Response from Applicant: Provide the following statements:

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

AND

"We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months."

8.10.4 Occupational Dose

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

Criteria: Applicants must do either of the following:

- Perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a), and maintain a record of this evaluation for inspection by the NRC.

OR

- Provide and require the use of individual monitoring devices (dosimetry) that is exchanged at a frequency recommended by the processor. (All personnel dosimeters that require processing to determine the radiation dose must be processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor.)

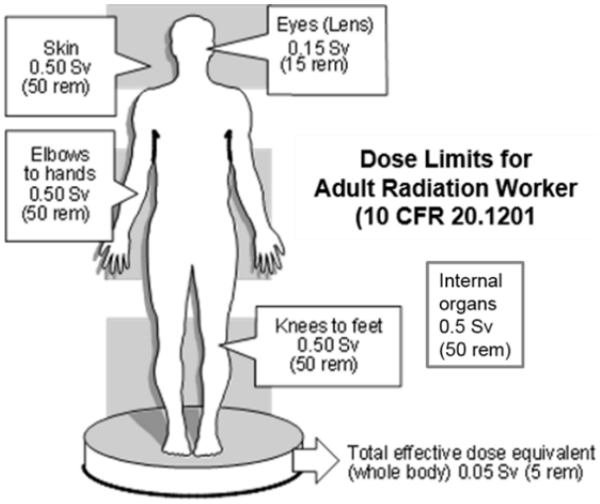
Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure.

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

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

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

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



TOTAL EFFECTIVE DOSE EQUIVALENT (TEDE) = DEEP DOSE FROM EXTERNAL EXPOSURE + DOSE FROM INTERNALLY DEPOSITED RADIONUCLIDES

Figure 8-6. Annual Dose Limits for Adult Radiation Workers

Discussion: Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure. The licensee should perform a prospective evaluation of the dose that the individual is likely to receive from licensed and unlicensed activities (e.g., accelerator operation), before allowing the individual to receive the dose. When performing the prospective evaluation, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. Prospective doses may be based on any combination of work location, radiation monitoring, radiation survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received. For individuals who have received doses at other facilities in the current year, these previous doses need not be considered in the prospective evaluation if monitoring was not required at the other facilities. Only dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring, and therefore, recordkeeping and reporting requirements. Prospective dose evaluations need not be made for every individual, but may be made for employees with similar job functions or work areas. Further guidance on evaluating the need to provide monitoring is provided in Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses."

If the prospective evaluation shows that an individual's dose is not likely to exceed 10 percent of any applicable regulatory limit, the individual is not required to be monitored for radiation exposure, and there are no recordkeeping or reporting requirements for doses received by that individual. If it was determined that monitoring was not required and a subsequent evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received.

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

If the prospective dose evaluation shows that the individual is likely to exceed 10 percent of an applicable limit, monitoring and reporting of the results of monitoring performed—regardless of the actual dose received—is required (10 CFR 20.1502; see Figure 8-6 for annual dose limits for adults). If air sampling or bioassay is required, discussion of air sampling or bioassay should provide enough detail so that the NRC staff is assured that appropriate steps will be taken to manage and monitor such exposure. Licensees must provide individual radiation exposure data to each worker as required by 10 CFR 19.13.

Authorized individuals and other radiation workers at an accelerator facility are generally likely to receive 10 percent or more of the limit for an occupational dose. When working at an NRC-licensed facility, in addition to exposure to NRC-regulated material, a worker may be exposed to radiation (e.g., emitted by accelerators) regulated by the State in which the facility is located. With respect to NRC regulation of activities at the facility, State regulated sources of radiation and radioactive material are considered unlicensed. An occupational dose includes the dose received by individuals in the course of their employment (10 CFR 20.1003), including exposure to radiation and radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other individuals.

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

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

Note that, in accordance with 10 CFR 20.1207, the annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers. Also, 10 CFR 20.1208 requires the licensee to ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem [5 mSv].

Most licensees use either film badges, thermoluminescent dosimeters (TLDs), or optically stimulated luminescence dosimeters that are supplied by an NVLAP-approved processor to monitor for external exposure. Applicants should verify that the processor is NVLAP-approved (10 CFR 20.1501, "General," Subpart F, "Surveys and Monitoring: General"). Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use. If

monitoring is required, then the licensee must maintain records of the monitoring, regardless of the actual dose received (10 CFR 20.2106, Subpart L, "Records: Records of Individual Monitoring Results"). For individuals who handle licensed material at production facilities, extremity and whole body dosimeters should be worn. Workers who handle targets, filters, and work on the cyclotron unit and product delivery lines should be equipped with self-reading pocket dosimeters or alarming-rate dosimeters. It is recommended that extremity and whole body dosimeters be exchanged at least monthly. Also, for individuals who will handle PET radionuclides or other radionuclides that emit high-energy gammas/photons, it is recommended that extremity dosimeters be exchanged at least biweekly, and a pocket or alarming dosimeter that provides a real-time dose estimate should be used in addition to the individual's personal whole body dosimeter.

Workers are typically monitored for a year or more to determine an 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 there are changes in the licensee's program, such as changes in procedures, frequency of use, quantity of licensed material used, or isotopes used. The licensee should also consider a more frequent exchange of dosimeters when employees start a new job function so that their doses can be more accurately monitored when they are performing unfamiliar tasks. In addition, see Appendix J of this NUREG, "Radiation Safety Survey Topics," for information on bioassay monitoring for internal exposure assessment. Routine bioassays should be performed when volatile radioactive material (e.g., I-123) is produced and/or handled. For guidance about methodologies for determination of internal occupational dose and summation of occupational dose, refer to Table 8-3.

Table 8-3. Documents That May Contain Applicable Guidance on Personnel Monitoring and Bioassay

Regulatory Guide 8.7	Instructions for Recording and Reporting Occupational Radiation Exposure Data
Regulatory Guide 8.9	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program
Regulatory Guide 8.20	Applications of Bioassay for Radioiodine
Regulatory Guide 8.21	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
Regulatory Guide 8.23	Radiation Safety Surveys at Medical Institutions
Regulatory Guide 8.25	Air Sampling in the Workplace
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Radiation Doses
Regulatory Guide 8.35	Planned Special Exposures
Regulatory Guide 8.36	Radiation Dose to the Embryo/Fetus
Regulatory Guide 8.37	ALARA Levels for Effluents from Materials Facilities
ANSI N13.30-2011	"Performance Criteria for Radiobioassay," dated 1996
Information Notice 2000-10	Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits

Additional Reference for Further Reading:

U.S. Department of Energy G 441.1 1C, "Radiation Protection Programs Guide," May 19, 2008

Response from Applicant: Provide the following statement:

"We have developed and will implement and maintain written procedures for monitoring occupational doses that meet the requirements in 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, and 10 CFR 20.2106, as applicable."

AND

Provide the criteria for issuing extremity dosimeters, self-reading dosimeters, and alarming dosimeters.

AND

Describe how internal doses would be evaluated in a timely fashion if an accidental airborne release were to occur.

AND

Provide one of the following statements:

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

OR

- "We will provide and require the use of individual monitoring devices (dosimetry). All personnel dosimeters that require processing to determine the radiation dose will be processed and evaluated by an NVLAP-approved processor."

OR, IN LIEU OF THESE STATEMENTS,

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

In addition, licensees or applicants that want the flexibility to revise their personnel monitoring program without amendment of the license, as discussed in Chapter 1, "Purpose of Report" of this NUREG, should describe the process they will use to revise and implement their submitted personnel monitoring program.

***Notes**:*

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

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

8.10.5 Public Dose

Regulations: 10 CFR 20.1101(d), 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2107, 10 CFR 20.2203

Criteria: Under the 10 CFR regulations below, 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] TEDE] in a year from licensed activities [10 CFR 20.1301(a)(1)].

- Ensure that air emissions of radioactive material to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv [10 mrem] (TEDE) in a year from those emissions [10 CFR 20.1101(d)].

- Ensure that the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour, from licensed operations [10 CFR 20.1301(a)(2)].

- Prevent unauthorized access, removal, or use of licensed material (10 CFR 20.1801, 10 CFR 20.1802).

Discussion: "Member of the public" is defined in 10 CFR 20.1003 as "any individual except when that individual is receiving an occupational dose." "Public dose" is also defined in this section as "the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes 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. For guidance about accepted methodologies for determining dose to members of the public, refer to Appendix G of this NUREG, "Methodology for Determining Public Dose."

Figure 8-7 shows the steps to calculate the annual dose to an individual member of the public.

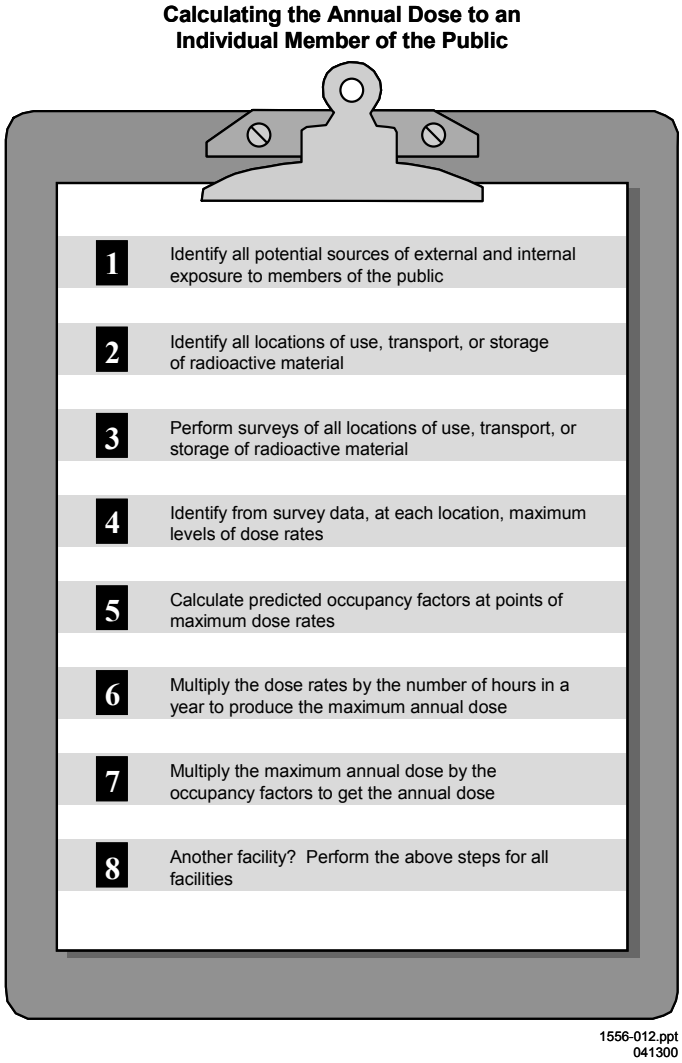


Figure 8-7. Calculating Public Dose. *Steps to calculate the annual dose to an individual member of the public (see Appendix G of this NUREG for more information about occupancy factors).*

Many possible internal dose pathways may contribute to the TEDE, but it can be broken down into three major dose pathway groups:

- airborne radioactive material
- waterborne radioactive material
- external radiation exposure

The licensee should review these major pathways and decide which are applicable to its operations. The licensee must ensure that the TEDE from all exposure pathways arising from licensed activities does not exceed 1.0 mSv [100 mrem] to the maximally exposed member of the public [10 CFR 20.1301(c)(1)]. In addition, the licensee must control air emissions such that the individual member of the public likely to receive the highest TEDE does not exceed the constraint level of 0.1 mSv [10 mrem] per year from those emissions [10 CFR 20.1101(d)]. If

exceeded, the licensee must report this in accordance with 10 CFR 20.2203 and take prompt actions to ensure against recurrence.

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1101(d) and 20.1302(b). The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to the Section entitled, "Radiation Safety Program—Surveys and Leak Tests."

During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit and the dose constraint [10 CFR 20.1302(b) and 10 CFR 20.2107].

The application will be evaluated and the license reviewer will determine if enough information is present to assure compliance with the limiting exposure to a member of the public. Additional responses may be required when there is insufficient information to assure that a member of the public will not receive a total exposure exceeding 0.1 mSv [100 mrem]. 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 [10 CFR 20.1302(b)]. See Appendix G of this NUREG for examples of methods to demonstrate compliance.

Response from Applicant: Provide the following:

Submit a description of the effluent monitoring program and the means to detect and evaluate concentrations of radioactive materials released to the environment. Provide a schematic of the effluent ventilation system and note any filters used and their location. Provide the criteria for changing out any high-efficiency particulate-air (HEPA) and charcoal filters.

8.10.6 Safe Operating and Emergency Procedures

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1902, 10 CFR 20.1903, 10 CFR 20.1904, 10 CFR 20.1905, 10 CFR 20.2201, 10 CFR 20.2202, 10 CFR 20.2203, 10 CFR 21.21, 10 CFR 30.32(i), 10 CFR 30.50, 10 CFR 30.72

Criteria: Operating procedures for activities that can potentially impact radioactive material or occupational dose must be developed, documented, implemented, and maintained to comply with 10 CFR 20.1101, "Radiation Protection Programs," including the requirement to maintain

doses ALARA under normal and emergency operating conditions.[1] Under 10 CFR 21.21, licensees must also adopt procedures to "identify defects and failures to comply with associated substantial safety hazards as soon as practicable." Such procedures should identify as soon as practicable failures to comply arising from substantial safety hazards associated with emergency conditions.

Discussion: Licensees are responsible for the security and safe possession and use of all licensed material from the time it is produced at the facility until its use, transfer/delivery, and/or disposal. Licensees must develop written procedures to ensure safe possession and use of licensed material, and the procedures should also include operational and administrative guidelines. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public.

General Safety Procedures

The written procedures should include the following elements:

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

[1] 10 CFR 20.1101(b) requires the licensee to "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)." This requirement makes no distinction between normal and emergency operating procedures for achieving ALARA doses, and in the May 21 *Federal Register Notice (FRN)* for the final Part 20 rule, the Commission noted that both types of measures should be available when necessary to minimize exposures to workers, the public, and the environment. Explaining the addition of a new sentence to the new "Purposes" section, 20.1001, that "nothing in this Part shall be construed as limiting actions that may be necessary to protect health and safety," the *FRN* said "[i]t is the Commission's intent that the regulations be observed to the extent practicable during emergencies, but that conformance with the regulations should not hinder any actions that are necessary to protect public health and safety such as lifesaving or maintaining confinement of radioactive materials. ... The Commission believes that the dose limits for normal operation should remain the primary guidelines in emergencies. However, the Commission also recognizes that, in an emergency, operations that do not conform to the regulations may have to be carried out to achieve the high-priority tasks of worker, public, and facility protection. The purpose of the addition to this section is to assure licensees that their first priority should be to carry out those actions … necessary to protect workers and the public from radiation exposure, to perform lifesaving activities, to prevent or limit the spread of radioactive contamination or the release of radioactive materials to the environment, and to preserve an adequate margin of safety." (56 FR 23365.) Thus, both normal and emergency operating procedures are considered to serve the same adequate protection purposes, and so long as both types of measures are based on sound radiation protection principles, neither should be ruled out as "procedures … to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable."

These procedures should include policies for:

- frequency of personnel monitoring
- use of appropriate shielding
- frequent change of gloves to minimize exposure to the individual and to avoid spread of contamination in the facility

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

Licensees should determine whether they have areas that require posting in accordance with 10 CFR 20.1902, unless they meet the exemptions listed in 10 CFR 20.1903. Also, containers of licensed material (including radioactive waste) must be labeled in accordance with 10 CFR 20.1904, unless they meet the exemptions in 10 CFR 20.1905, "Exemptions to Labeling Requirements."

Emergency Procedures

Accidents and emergencies can happen during any operation with radionuclides, including their transportation, use, production processes, transfer, and disposal. Such incidents can result in contamination or release of material to the environment, and unintended radiation exposure to workers and members of the public. In addition, such incidents as loss or theft of licensed material, sabotage, fires, and floods can jeopardize the safety of personnel and members of the public. It may, therefore, be necessary to develop written procedures to minimize, as much as possible, the impact of these incidents on personnel, members of the public, and the environment. Applicants who plan to possess quantities of material in excess of the applicable amounts 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") may also 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 intervention by outside emergency response personnel. For accelerator facilities, written procedures should be included for specific accident scenarios such as target failures, spills or releases outside a containment enclosure, delivery line failures, malfunction of air supply or exhaust systems, and high radiation levels in exhaust monitors or systems. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee staff should have a clear understanding of their limitations in an emergency, along with step-by-step instructions and clear guidelines for whom to contact.

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

includes model emergency procedures. Applicants may adopt these procedures or develop their own, incorporating the safety features included in these model procedures.

Response from Applicant: The applicant should state that:

"Procedures for safe handling of radionuclides and emergencies will be developed and documented before production of licensed material."

AND

"Operating and emergency procedures will be implemented and maintained.

AND

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

If an "Emergency Response Plan" is required for a license under 10 CFR 30.32(i) the applicant should submit it as a separate part of the application.

8.10.7 Surveys and Leak Tests

Regulations: 10 CFR 20.1501, 10 CFR 20.2103, 10 CFR 30.34(j)(2)(ii), 10 CFR 30.53, 10 CFR 32.59, 10 CFR 32.72(c)

Criteria: Licensees are required by 10 CFR 20.1501 to make surveys of potential radiological hazards in their workplace. The NRC requires testing to measure the radioactivity in doses of radiopharmaceuticals [10 CFR 30.34(j)(2)(ii) and 10 CFR 32.72(c)] and to determine whether there is any radioactive leakage from sealed sources (10 CFR 30.53 and 10 CFR 32.59). Licensees must maintain records of leak test results in accordance with license conditions or, if applicable, NRC regulations. [10 CFR 20.2103(a)].

Discussion: Surveys are evaluations of radiological conditions and potential hazards (see Figure 8-8). These evaluations may be measurements (e.g., radiation levels measured with radiation survey instruments or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions for both licensed and unlicensed (e.g., accelerator operation) activities and the licensed facility. 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. Licensees must also maintain records of leak-test results in accordance with license conditions, or, if applicable, NRC regulations.

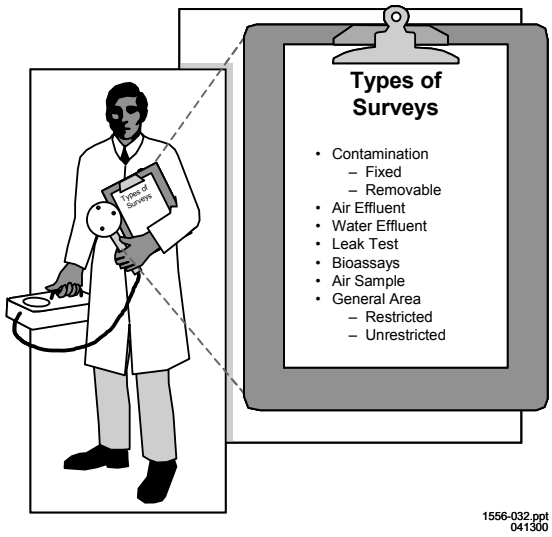


Figure 8-8. Types of Surveys. *There are many different types of surveys performed by production licensees.*

Radiation surveys are used to detect and evaluate contamination of:

- facilities
- equipment
- personnel (during production, use, possession, transfer, or disposal of licensed material, see Figure 8-9)
- restricted and unrestricted areas
- packages
- products produced

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

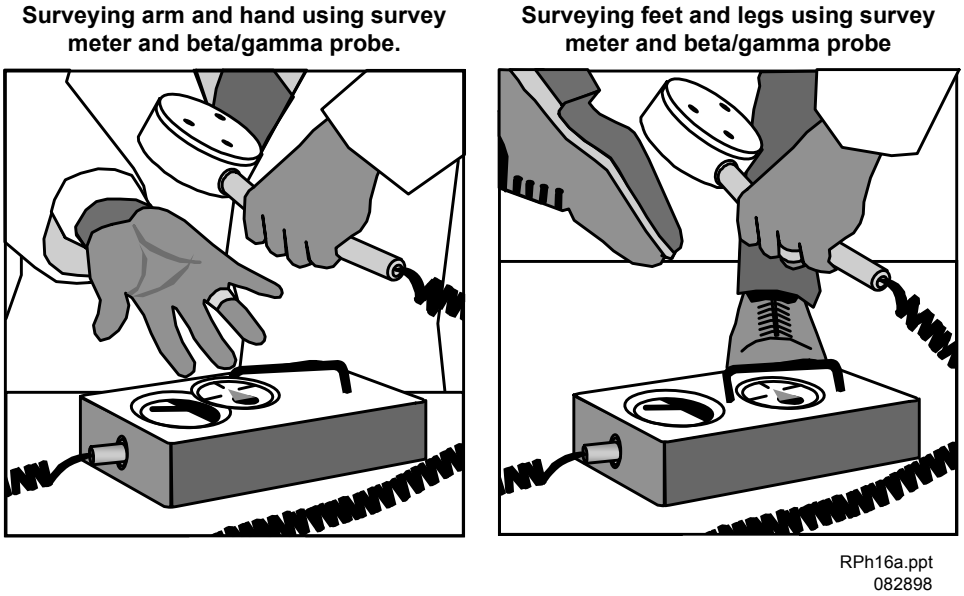


Figure 8-9. Personnel Surveys. *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the restricted area(s) of the facility*.

Under 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 due to the particular use of licensed materials. The most important are

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

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

- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer.

- Bioassays to determine the kinds, quantities, or concentration, and in some cases, the location of radioactive material in the human body. A bioassay can be made by direct measurement *(in vivo* counting), or by analysis and evaluation of material excreted or removed from the human body (*in vitro* counting).

- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

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

Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any radiation safety program. Table F–1 in Appendix F of this NUREG contains radiation monitoring and survey instruments and calibration programs that are acceptable to the NRC.

No limits for surface contamination are specified in 10 CFR Part 20, "Standards for Protection Against Radiation." Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area. Contamination checks are required before distributing licensed material. Table J–2 in Appendix J of this NUREG contains contamination limits that are acceptable to the NRC.

Sealed Source and Plated Foil Leak Tests

When issued, a license will require performance of leak tests of sealed/plated foil sources at intervals approved by the 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 microcuries (μCi)] of radioactivity.

Manufacturers, distributors, consultants, and other organizations may be authorized by the NRC or an Agreement State to either perform the entire leak-test sequence on behalf of licensees or provide leak-test kits to licensees. In the latter case, the licensee takes the leak-test sample, according to the manufacturer's and/or the kit supplier's instructions, and returns it to the leak-test service provider for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. The NRC or an Agreement State may, in a license condition, specifically authorize licensees using radioactive materials produced in an accelerator to conduct the entire leak-test sequence themselves.

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

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

For more information regarding leak tests, see Appendix K of this NUREG, "Model Leak Test Program and Procedures."

Response from Applicant: Do one of the following:

State: "We will survey our facility and maintain contamination levels in accordance with the radiation survey frequencies and contamination levels published in Appendix J in the current version of NUREG–1556, Vol. 21." If applicable, state: "We will perform contamination checks on all manufactured sealed sources before distribution. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees. Alternatively, we may perform leak tests using a leak-test kit supplied by an organization authorized by NRC or an Agreement State to provide leak-test kits to other licensees according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative to either of these leak test implementation methods, we will implement the model leak-test program published in Appendix K in the current version of NUREG–1556, Vol. 21, 'Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator.'"

OR

Submit a description of alternative equipment and/or procedures to evaluate a radiological hazard and determine whether there is radioactive leakage from sealed sources or plated foils.

***Notes**:*

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

8.10.8 Maintenance

Regulation: 10 CFR 20.1101

Criteria: Facilities and equipment for the production and use of radioactive materials (e.g., accelerators and chemistry synthesis units) should be maintained. Maintenance should be planned and carried out as frequently as needed, using ALARA principles. Individuals performing maintenance should be trained in the procedures they implement. Procedures should be written to account for the skills of the implementing personnel. Ordinarily, individuals handling unshielded materials should have up to 40 hours of classroom and on-the-job training in radiation safety. Instructors should be more extensively qualified than the staff they teach.

Discussion: Maintenance of equipment and facilities is necessary to produce a quality product safely and efficiently and to ensure a safe environment for staff and the public. Producing radioactive materials is an additional hazard, requiring attention to detail when incorporating maintenance information into procedures. Licensee staff should ensure that materials in the process stream are properly shielded/located/protected to minimize the hazard to maintenance staff. Maintenance staff should be aware of the hazards and the procedures to minimize their exposure to radioactive materials used to control the production process. As examples: (i) the staff should survey the accelerator working area before entering the accelerator vault or after opening accelerator self-shields, and (ii) a maintenance procedure should direct the shutdown

and lockout of the accelerator before beginning work in the area. Maintenance procedures should be prepared with the use of engineering controls first, using ALARA principles and administrative controls as needed.

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

8.10.9 Transportation

Regulations: 10 CFR 30.41; 10 CFR 30.51; 10 CFR 71.5; 10 CFR 71.14; 10 CFR 71.17; 10 CFR 71.19; 10 CFR 71.20; 10 CFR 71.47; 10 CFR 71, Appendix G; 10 CFR 71, Appendix H; 49 CFR 107; 49 CFR 171, 172, 173, 174, 175, 176, 177, 178, 179, and 180; 49 CFR 390, 391, 392, 393, 395, 396, and 397.

Criteria: A licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport. Therefore, applicants who will package, transport, or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material to ensure compliance with NRC and DOT regulations.

Discussion: In accordance with a Memorandum of Understanding between DOT and the NRC, the NRC inspects and enforces DOT's regulations governing the transport of radioactive materials by NRC's licensees. Appendix L of this NUREG provides an overview of the transportation requirements that commonly affect NRC licensees

Licensees should consider the safety of all individuals who may handle or come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that 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, "External Radiation Standards for All Packages," but are ALARA. The DOT regulations require that individuals who perform functions related to the packaging and shipment of radioactive material packages receive training specific to those functions. The training must include a general awareness of DOT requirements, function-specific training for the individuals' duties, safety training, and security awareness training. The DOT regulations also specify the frequency of the training and a record-retention requirement for training.

The types and quantities of radioactive materials shipped by production licensees generally meet the criteria for shipment in a "Type A" package, as defined by DOT. The requirements for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling, and radiation and contamination level limits. For licensees who transport their own packages, the packages must be blocked and braced, and shipping papers must be stored in the driver's compartment, as described in 49 CFR 177.817, "Shipping Papers."

All domestic shipping paper and label information must be stated in the International System of Units (SI) only **OR** must be in SI units first, with English units in parenthesis.

The general license in 10 CFR 71.17, "General License: NRC-Approved Package," provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material, and specifies certain conditions. Transporting licensed materials originating at some facilities involves quantities of radioactive material that require a Type B package. The manufacturer (or service licensee) who is subject to the provisions of 10 CFR 71.17, "General license: NRC-approved package," or 10 CFR 71.19, "Previously approved package," as appropriate, is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

If a licensee plans to make shipments of licensed materials in Type B packages on its own, the licensee must be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, two of the requirements under the 10 CFR 71.17 general license. For information about QA plans, see Revision 2 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated March 2005.

Licensees should also 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.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials on its own using Type B packages, a licensee needs to have registered with the NRC as a user of the package and obtained NRC's approval of its QA program. Transportation activities will be reviewed during inspection.

8.10.10 Minimization of Contamination

Regulation: 10 CFR 20.1406.

Criteria: Applicants for new licenses 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 fullest extent practicable, the generation of radioactive waste.

Discussion: When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination/decontamination during operation and during decommissioning efforts, and how to minimize radioactive waste generation during all phases of the facility life cycle.

For accelerator production facilities, it is important to consider the types of materials used for the construction of the facility and for the shielding of the accelerator. Due to the neutron activation that generally takes place during the operation of the accelerator, it is important to carefully characterize all of the materials used in the accelerator (e.g., target material), the shielding of the accelerator, and the accelerator facility to minimize the amount of activated products that are produced.

Customers may also request the licensee of the radioactive materials production facility to provide recovery and shipping services for unwanted, damaged, and replacement materials/sources. As such, the licensee should consider the designs of shipping and recovery containers to meet transportation requirements. Procedures should be developed to enable

these activities to be carried out with minimal impact on the radiological condition of the facility, decommissioning in the future, and employee external and internal radiation exposure.

When submitting new applications, applicants should also 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
- air flows appropriate to the work being conducted
- use of appropriate plumbing materials with minimal pipe lengths and traps
- minimization of the number of disposal sites (sinks) where liquid waste is disposed of if there is a sanitary sewer system

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

Response from Applicant: The applicant does not need to provide a response to this item under the following condition: The NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: Section 8.5.1, "Radioactive Material–Unsealed and Sealed Byproduct Material;" Section 8.9, "Facilities and Equipment;" Section 8.10.6, "Radiation Safety Program–Safe Operating and Emergency Procedures;" Section 8.10.7, "Radiation Safety Program–Surveys and Leak Tests;" and Section 8.11, "Waste Management."

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1101, 10 CFR 20.1302, 10 CFR 20.1904, 10 CFR 20.1906, 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 generated as part of the production and distribution process must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained. Waste materials (such as gloves, rags, and tools) may not be received from others unless recipients are specifically licensed to receive them. Licensed materials that were distributed (such as decayed sources or devices at end of useful life) may be received from others and sent for proper disposal.

Discussion: The applicant should discuss the methods for management and disposal of radioactive waste. The program should include procedures for waste minimization, waste characterization, waste handling, safe and secure storage, and waste disposal. Appropriate training should be provided to waste handlers. U.S. Environmental Protection Agency guidance for developing a comprehensive program to reduce hazardous waste was transmitted to licensees by the NRC in IN 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program," dated March 1994. The application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (e.g., radioactive from nonradioactive, short from long half-life, liquid from solid waste).

The following methods of waste disposal may be considered and should be addressed in the application, as appropriate.

Transfer to an Authorized Recipient

Waste may be transferred to a recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste, in accordance with 10 CFR 20.2001(a). Each shipment must comply with all applicable NRC and DOT requirements.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage (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, members of the public, and the environment. Safety procedures should be implemented to address these concerns.

Decay-in-Storage

The NRC has concluded that materials with half-lives of less than or equal to 120 days are appropriate for decay-in-storage (DIS). The holding time of the waste should be based on the radionuclide(s), half life, and the activity present when the waste was placed into storage. Such waste may be disposed of as ordinary trash if radiation surveys of the waste indicate that radiation levels are indistinguishable from background. The surveys should be performed with an appropriate radiation detection meter set on its most sensitive scale in a low background area and without any interposed shielding. In accordance with 10 CFR 20.1904(b), all radiation

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

Applicants should ensure that adequate space and facilities are available for the storage of such waste, and care should be taken to ensure that the waste form does not degrade or interact adversely with the waste container. Procedures for management of waste by DIS should include methods of segregation, surveys before disposal, and maintenance of records of disposal.

Licensees can minimize the need for storage space if radioactive waste is segregated according to physical half-life. Segregation of waste is accomplished by depositing radionuclides of shorter physical half-lives in containers separate from those used to store radioactive waste with longer physical half-lives. Radioactive waste with shorter half-lives will take less time to decay and, thus, may be disposed of in shorter time periods, freeing storage space. 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.

The NRC does not consider storage as a substitute for final disposal of radioactive wastes. Other than storage for radioactive decay, LLW should be stored only when disposal capacity is unavailable, and for no longer than necessary. The NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

A model procedure for DIS is contained in Appendix M of this NUREG, "Model Waste Management Procedures."

Release into Air and Water

Release of radioactive material into air and water must conform to the requirements described in 10 CFR 20.1302(b)(2) (See Figure 8-10). The applicant should discuss the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the "constraint" on air emissions of radioactive material required by 10 CFR 20.1101(d), which effectively reduces the limits specified in 10 CFR 20.1302(b)(2) for release of gaseous effluents by a factor of 10. Applicants considering release of radioactive material into air and water should review Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," on the application of ALARA in controlling gaseous and liquid effluents and references documents with acceptable methods of effluent monitoring.

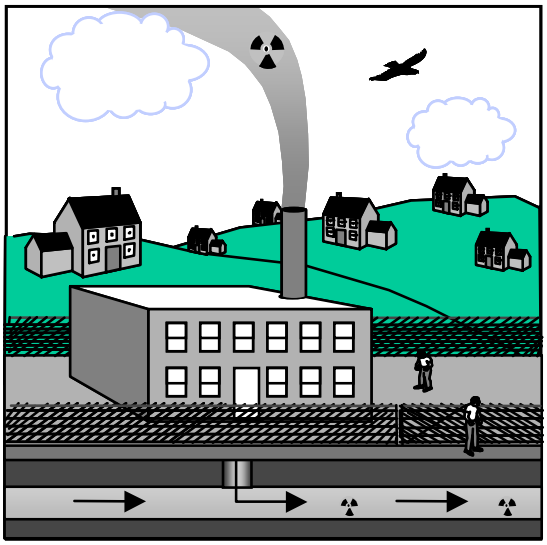


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Figure 8-10. Air and Water Effluents from a Radioactive Materials Production Facility. *Also note the fence, creating a "controlled area."*

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of 10 CFR 20.2003. Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are readily soluble or biologically readily dispersible in water. In NRC IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," criteria are provided for evaluating the solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be readily dispersible. Licensees should carefully consider the possibility of reconcentration of radionuclides that are released into the sewage system. The NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewage systems in NRC IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted Under 10 CFR 20.303 [now 10 CFR 20.2003]."

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage system meet 10 CFR 20.2003 criteria and do not exceed the monthly and annual limits specified in the regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage system. A model procedure for disposal of radioactive waste via a sanitary sewer is described in Appendix M.

If liquid releases are made to a private sewerage treatment system, septic system, or leach field, the sludges or other solids from these systems may become contaminated with radioactive material. Applicants should describe the monitoring planned for these systems in Item 8.10.7 of the application. Contaminated sludges should be disposed of as radioactive waste using one of the methods described in this Section. Applicants may obtain approval of alternative disposal methods through application to the NRC, as described in 10 CFR 20.2002.

Incineration

Applicants who wish to treat or dispose of licensed material by incineration must comply with the requirements of 10 CFR 20.2004. A model procedure for waste incineration is described in Appendix M of this NUREG. Applicants considering disposal of radioactive material by incineration should review Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities." Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring.

Waste Volume Reduction

Waste volume reduction operations (e.g., compaction) that could create a radiological hazard to licensee employees or the general public should be described in detail in the application. A model procedure for waste compaction is described in Appendix M of this NUREG.

Other Methods Specifically Approved by NRC Under 10 CFR 20.2002

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and describe 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, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits. If implementation of the alternative disposal method could affect additional governmental jurisdictions, the licensee should refer to State and Tribal Communication Letter FSME 12-025, dated March 13, 2012, "Clarification of the Authorization for Alternative Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR" (ADAMS Accession No. ML12065A038).

Additional Considerations

Some licensees do not have an LLW disposal facility available to them and therefore may wish to use onsite interim storage until such 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, since protection of workers and the public is enhanced by disposal rather than storage of waste. Licensees may also find it more economical to dispose of radioactive waste than to store it onsite because, as the available capacity decreases, the cost of disposal of radioactive waste may continue to increase. LLW should be stored only when disposal capacity is unavailable and for no longer than is necessary. NRC IN 90-09 provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

The application should describe the considerations given to ALARA before disposal of radioactive materials and discuss the potential for unmonitored or unanticipated release of radioactive materials from likely release points (e.g., hoods and incinerator stacks) to work areas. To be in compliance with the ALARA philosophy stated in 10 CFR 20.1101, "Radiation Protection Programs," radioactive material waste stream concentrations should be a fraction (generally 10 percent to 20 percent) of the limits specified in 10 CFR Part 20, Appendix B, Table II. Furthermore, due to the variability of inventory control programs for monitoring disposal and releases of licensed material possessed, or possessed and in use, a program for

physically measuring releases should be in place whenever releases exceed the specified point at which expected doses might warrant additional review to ensure that they remain ALARA.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan their disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement. Sealed source manufacturers and suppliers that accept the return of sealed sources should consider this when developing their waste management programs.

***Note**:* Before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), if licensees are authorized to possess byproduct material with a half-life greater than 120 days in an unsealed form, the licensees must, in accordance with 10 CFR 30.51(e) transfer the following records to the new licensee:

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

Response from Applicant:

Unless the applicant intends to submit its own or an alternative NRC method for demonstrating compliance, the applicant should state that: "We will use the model waste procedures and guidelines published in Appendix M to NUREG–1556, Vol. 21 'Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator.'"

If the applicant does not intend to submit its own alternative compliance demonstration method, nor to use the model waste procedures and guidelines published in Appendix M, but wishes instead to use only selected model procedures and guidelines, the applicant should state that "We will use the [specify either (i) decay-in-storage, or (ii) disposal of liquids into sanitary sewerage] model waste procedures that are published in Appendix M to NUREG–1556, Vol. 21, 'Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator.'"

If the applicant wishes to compact or incinerate radioactive waste, the applicant should provide the requested information concerning these activities in Appendix M to NUREG–1556, Vol. 21, "Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator."

If access to a radioactive waste burial site is unavailable, the applicant should request authorization for extended interim storage of waste. The applicant should refer to NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials

Licensees," dated February 1990, for guidance and submit the required information with the application.

***Note**:* 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 Minimization Program," dated March 1994
- Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994
- Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984
- Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990
- Regulatory Issue Summary 2008-12, "Considerations For Extended Interim Storage Of Low-Level Radioactive Waste By Fuel Cycle And Materials Licensees"
- Regulatory Issue Summary 2011-09, "Available Resources Associated With Extended Storage Of Low-Level Radioactive Waste"
- Policy and Guidance Directive (PG) 8-10, "Disposal of Incineration Ash as Ordinary Waste," January 1997, ADAMS Accession Nos. ML003744979 and ML003752866 and Addendum, ADAMS Accession Nos. ML003744984 and ML003744988.
- NRC Regulatory Issue Summary 2004-17, Revision 1, Revised Decay-In-Storage Provisions For The Storage Of Radioactive Waste Containing Byproduct Material, September 2005
- State and Tribal Communication Letter FSME 12-025 dated March 13, 2012 "Clarification of the Authorization for Alternative Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR" (ADAMS Accession No. ML12065A038)
- Division of Waste Management and Environmental Protection, Environmental and Performance Assessment Directorate, Operating Procedures, EPPAD 3.5 (Draft for Interim Use), "Review, Approval, and Documentation of Low-Activity Waste Disposals in Accordance with 10 CFR 20.2002 and 10 CFR 40.13(a)," dated August 2009
- Regulatory Issue Summary 2016-11, "Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002" dated November 13, 2016

8.12 Item 12: License Fees

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

Direct all questions about the NRC's fees or completion of Item 12 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 for fees questions is Fees.Resource@nrc.gov.

8.13 Item 13: Certification

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

***Notes**:*

- It is a criminal offense to knowingly and willfully make a false statement or representation on applications or correspondence (18 U.S.C. 1001).

- When an application references commitments, those items will be incorporated into the license and, therefore, will become binding regulatory requirements.

9 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee should submit an application for a license amendment before the change takes place. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date [Title 10 of the *Code of Federal Regulations* (10 CFR) 2.109, "Effect of Timely Renewal Application," and 10 CFR 30.36(a)].

Applicants for license amendment or renewal should

- Use the most recent guidance in preparing an amendment or renewal request.
- Submit either U.S. Nuclear Regulatory Commission (NRC) Form 313 or a letter requesting amendment or renewal.
- Provide the license number and docket number.
- For renewals, provide a complete and up-to-date application, including all required program elements outlined in Appendix B of this NUREG. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application.

9.1 Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b)

Criteria: Licensees must provide all supporting information and obtain the NRC's prior written consent before transferring control of the license, also referred to as a "change of ownership" 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 capable, competent, and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material.
- Public health and safety are not compromised by the use of such materials.
- Adequate financial assurance is provided for compliance with the applicable NRC requirements, if required.

For further information, see Regulatory Issue Summary (RIS) 2014-08, Revision 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licensees," dated May 5, 2016, (ADAMS Accessions No. ML15181A223). This RIS can also be found on the NRC's Generic Communications webpage under "Regulatory Issue Summaries:" http://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

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

10 APPLICATIONS FOR EXEMPTIONS

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

Criteria: Licensees may request exemptions from NRC regulations. The licensee must demonstrate that the exemption is authorized by law; will not endanger life, property, or the common defense and security; and is otherwise in the public interest. Licensees may also use existing specific exemptions outlined in Title 10 of the *Code of Federal Regulations* (10 CFR regulations) if they meet the established criteria.

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

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

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

11 TERMINATION OF ACTIVITIES

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

Criteria: The licensee must

- Notify the U.S. Nuclear Regulatory Commission (NRC), in writing within 60 days of the occurrence of any of the following:
  - — the expiration of its license
  - — a decision to permanently cease licensed activities at the entire site.
  - — a decision to permanently cease principal activities[1] 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[1] under the license have been conducted for a period of 24 months
  - — no principal activities[1] have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements
- Submit a decommissioning plan, if required by Title 10 of the *Code of Federal Regulations* (10 CFR) 30.36(g).
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j).
- Submit, to the appropriate NRC regional office, completed NRC Form 314, "Certificate of Disposition of Materials," (or equivalent information) and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final surveys and results of leak tests of sealed sources).
- Before a license is terminated, send 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: To comply with the above criteria, before a licensee can decide whether it must notify the NRC under 10 CFR 30.36(d), the licensee must determine whether residual radioactivity is present and, if so, whether the levels make the building or outdoor area

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

unsuitable for release, according to NRC requirements. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

The permanent cessation of principal activities[1] in an individual room or laboratory may require the licensee to notify the NRC if no other licensed activities are being performed in the building.

The current regulatory guidance concerning decommissioning of facilities and termination of licenses is found in NUREG–1757, "Consolidated Decommissioning Guidance." Appendix B of the handbook contains a comprehensive list of the NRC's decommissioning regulations and guidance. Applicants are encouraged to consult NRC staff about updates of decommissioning guidance, due to ongoing revisions. Licensees who have large facilities to decommission should review NUREG–1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," and NUREG–1575 Supplement 1, "Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)."

Supplemental information on the implementation of the final rule on radiological criteria for license termination was published in the *Federal Register* (63 FR 64132) on November 18, 1998. Supplemental information on the implementation of the final rule on radiological criteria for license termination also was published in the *Federal Register* on December 7, 1999 (64 FR 68395), which addresses screening values in soils for the most common radionuclides, and in the *Federal Register* on June 13, 2000 (65 FR 37186), for screening values for building surfaces and soils contaminated with radionuclides not addressed in the prior *Federal Register* notices.

The computer code "DandD" offers an acceptable method for calculating screening values to demonstrate compliance with the unrestricted dose limits. Table H–1 of NUREG–1757 provides acceptable license termination screening values of common beta/gamma radionuclides for building surface contamination, and Appendix J of this NUREG discusses methods for conducting site-specific dose assessments for facilities with contamination levels above those in the table.

For information about requirements that apply to the timeliness of decommissioning, see Regulatory Issue Summary (RIS) 2015-19, Revision 1, "Decommissioning Timeliness Rule Implementation and Associated Regulatory Relief," dated September 27, 2016, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": http://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

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 as summarized in the "Criteria" above.

References: NRC Form 314 is available at http://www.nrc.gov/reading-rm/doc-collections/forms.

APPENDIX A

U. S. NUCLEAR REGULATORY COMMISSION FORM 313

U. S. Nuclear Regulatory Commission Form 313

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

NRC FORM 313 (06-2016) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40 — **U.S. NUCLEAR REGULATORY COMMISSION**

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 06/30/2019**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

SEND APPLICATIONS TO:

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

IF YOU ARE LOCATED IN:

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

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

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

SEND APPLICATIONS TO:

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

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

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- ☐ A. NEW LICENSE
- ☐ B. AMENDMENT TO LICENSE NUMBER _____
- ☐ C. RENEWAL OF LICENSE NUMBER _____

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

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

BUSINESS TELEPHONE NUMBER | BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

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

5. RADIOACTIVE MATERIAL

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

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

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

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

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

FOR NRC USE ONLY

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

NRC FORM 313 (06-2016)

APPENDIX B

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

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

The table below is designed to help applicants develop their applications. Checking a box (❒) in the "Agree to Use" or "Description Attached" column indicates, respectively, that the applicant will agree to use a model procedure for the indicated activity or (if not using a model procedure) will describe and submit its alternative procedure for the same activity. ("N/A" indicates that no model procedure applies, and the applicant must submit a description of its individual procedure.)

Item No.	Suggested Response	Agree to Use	Description Attached
5.	**RADIOACTIVE MATERIAL**		
	Unsealed and Sealed Byproduct Material		
	• For unsealed materials:	N/A	
	— Provide an element name with mass number, chemical and/or physical form, and a maximum requested possession limit for each radionuclide produced.		❒
	— Identify the largest quantity of each radionuclide to be possessed at one time under the license, including produced, stored, and waste materials.		❒
	Note: For incidentally activated radionuclides, the applicant may request authorization to possess and use any form of byproduct material with atomic numbers 1 through 83. However, the applicant should indicate the total cumulative quantity for all radionuclides to be possessed at any one time.		
	• For potentially volatile materials (e.g., I-123):	N/A	
	— Specify whether the materials will be free (volatile) or bound (nonvolatile) and the requested possession limit for each form.		❒
	• For sealed radioactive materials and discrete sources of radium-226:	N/A	
	— 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, device, or source/device combination requested. If the manufacturer and distributor are no longer in service, a copy of the SSD registration certificate may be requested from the NRC or the issuing Agreement State.		❒

Item No.	Suggested Response	Agree to Use	Description Attached
5.	**RADIOACTIVE MATERIAL (Continued)**		
	Unsealed and Sealed Byproduct Material (Continued)	N/A	
	— Confirm that each sealed source, device, or source/device combination is registered as an approved sealed source or device by the NRC or an Agreement State and — Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by the NRC or by an Agreement State. — If the sealed source, device, or source/device combination is not registered and was manufactured before October 23, 2012, provide all available information identified in 10 CFR 32.210(c) concerning the source, and if applicable, the device, and sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience with the source, device, or source/device combination, and the results of a leak test. — For calibration and reference sources with less than 1 millicurie beta/gamma and 10 microcuries alpha, provide the manufacturer, model number, radionuclide, and quantity.		

Item No.	Suggested Response	Agree to Use	Description Attached
5.	**RADIOACTIVE MATERIAL (Continued)**		
	Unsealed and Sealed Byproduct Material (Continued)		
	— When responding to this Section, licensees should follow the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," to determine if their response includes sensitive security-related information and needs to be marked accordingly. ***Note**:* Licensees who request a possession limit in excess of the quantities specified in 10 CFR 30.72, "Schedule C—Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must submit an emergency plan, as specified in 10 CFR 30.32(i).		
	Financial Assurance and Recordkeeping for Decommissioning State the following: "Pursuant to 10 CFR 30.35(g), we shall maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b). 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 or assign the records to the appropriate NRC regional office before the license is terminated." **AND** If financial assurance is required, submit evidence of financial assurance following the guidance of NUREG–1757, Volume 3. **Reference**: NUREG–1757, Volume 3, "Consolidated Decommissioning Guidance—Financial Assurance, Recordkeeping and Timeliness."	N/A ❒	❒

Item No.	Suggested Response	Agree to Use	Description Attached
6.	**PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED** For accelerator-produced radionuclides, applicants should state that radioactive materials will be possessed and stored in accordance with NRC regulations. For all other material that is not accelerator-produced, specify its proposed use (e.g., calibration of instruments). Using the format in Table 8-1 will facilitate the review of the application.	❒	❒
7.	**INDIVIDUALS RESPONSIBLE FOR THE RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE**		
	Applicants should submit an organizational chart describing the management structure, reporting paths, and flow of authority between executive management and the RSO. Refer to the subsequent sections specific to the individuals described above. **RSO** Provide the following: • the name of the proposed RSO who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures • information demonstrating that the proposed RSO is qualified by training and experience	N/A	❒ ❒ ❒

Item No.	Suggested Response	Agree to Use	Description Attached
7.	**INDIVIDUALS RESPONSIBLE FOR THE RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Continued)**		
	Applicants should provide information about the proposed RSO's training and experience with the licensed material and uses requested in the application. Do not include private, personal information (e.g., home address, home telephone number, Social Security number, date of birth, and radiation dose information). Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, and personal private information. Submittal of unrelated material may delay the review process. ***Note**:* It is important to notify the NRC and obtain a license amendment before making changes in the designation of the RSO responsible for the radiation safety program. The name and qualifications of the replacement RSO should be submitted to the NRC as part of an amendment request.	N/A	❒
	Provide the following: • name of each proposed individual with the types and quantities of licensed material, including the activated targets and activated products, to be possessed and handled • information demonstrating that each proposed individual is qualified by training and experience to possess and handle the requested licensed materials	N/A	❒ ❒

Item No.	Suggested Response	Agree to Use	Description Attached
7.	**INDIVIDUALS RESPONSIBLE FOR THE RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE (Continued)**		
	Individuals Authorized to Handle Licensed Material		
	Applicants should provide information about the proposed authorized individual's training and experience relative to the licensed material and uses requested in the application. Do not include private, personal information (e.g., home address, home telephone number, Social Security number, date of birth, and radiation dose information). Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, and personal privacy information. Submittal of unrelated material may delay the review process. ***Note**:* Applicants for broad-scope programs should refer to NUREG–1556, Vol. 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope." Broad-scope programs may be permitted to name authorized individuals without amending the license.	N/A	❒
8.	**TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Occupationally Exposed Individuals and Ancillary Personnel)**		
	Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.	N/A	❒

Item No.	Suggested Response	Agree to Use	Description Attached
9.	**FACILITIES AND EQUIPMENT**		
	Describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed, and/or used (see Appendix D of this NUREG for topics to consider). The application should also include	N/A	❒
	• a description of the areas assigned for the production, transfer, storage, preparation, shipping, security, and measurement of radioactive material		❒
	• a description and diagrams showing the locations of delivery lines, shielded areas and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety (see Figure 8-4). The licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. An example of such sensitive information could be a room number specifically identifying the location of the accelerator and related safety equipment. License applications containing sensitive information should be marked as indicated below in accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," before the information is submitted to the NRC. If the application must contain proprietary information or trade secrets, the applicant should 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.		❒
	• a description and diagram of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne.		❒

Item No.	Suggested Response	Agree to Use	Description Attached
9.	**FACILITIES AND EQUIPMENT (Continued)**		
	Describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed, and/or used (see Appendix D of this NUREG for topics to consider). The application should also include:	N/A	
	verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions under 10 CFR 20.1101(d). For guidance on methods that are acceptable to the NRC, see Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors." ***Note**:* Mark drawings and diagrams that provide the exact location of materials or depict the specific location of safety or security equipment as: "Security-Related Information—Withhold Under 10 CFR 2.390."		❒
10.	**RADIATION SAFETY PROGRAM**		
	Audit Program		
	No response is required. The license's program for auditing its radiation safety program will be reviewed during inspection	N/A	N/A
	Radiation Monitoring Instruments		
	Provide one of the following: A description of the instrumentation, including the type of instrument and probe and the instrument's intended use in performing required surveys, together with a statement that: "We will use instruments that meet the radiation-monitoring instrument specifications published in Appendix F in the current version of NUREG–1556, Vol. 21, 'Program-Specific Guidance About Possession License for Production of Radioactive Materials Using an Accelerator.'" **OR**		❒

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM (Continued)**		
	Radiation Monitoring Instruments		
	A description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration of radiation survey equipment will be performed at the required frequency. Calibrations may be performed by licensees specifically authorized to provide this service. It is not necessary to have a copy of the instrument manufacturer's license, but calibration vendors other than the instrument manufacturer should be verified to ensure they have authorization to calibrate instruments for others. If the applicant chooses the second alternative above, the applicant should provide: A description of the instruments that will be used to quantitatively measure the radioactivity in the products, process, and effluents. Include the calibration procedures that will be followed to ensure the accuracy of those measurements. **AND** A description of method(s) that may be used to determine the concentration of radioactive air effluents that are released in order to demonstrate compliance with the 10 CFR 20.1101(d) constraint on air emissions. For real time monitoring of radioactive air effluents, provide a description of the detector and the methodology that will be used to calculate the air effluent release concentrations. ***Note**:* Alternative responses will be reviewed using the criteria listed above*.*		❒ ❒ ❒

10.	**RADIATION SAFETY PROGRAM (Continued)**		
	Material Security and Accountability		
	Provide the following statements: "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times." **AND** "We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months."		
	Occupational Dose	❒	N/A
	Provide the following statement: "We have developed and will implement and maintain written procedures for monitoring occupational doses that meet the requirements in 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1203, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, and 10 CFR 20.2106, as applicable." **AND** Provide the criteria for issuing extremity dosimeters, self-reading dosimeters, and alarming dosimeters. **AND** Describe how internal doses would be evaluated in a timely fashion if an accidental airborne release were to occur.		

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM (Continued)**		
	Occupational Dose	❒	N/A
	***Notes**:* Alternative responses will be evaluated using the criteria listed above. Some licensees choose to monitor their workers for reasons other than compliance with NRC requirements (e.g., in response to worker requests). **Reference**: The National Institute of Standards and Technology (NIST) maintains a directory of laboratories that are NVLAP-approved at http://ts.nist.gov/standards/scopes/dosim.htm.		
	Public Dose	N/A	
	Provide the following: Submit a description of the effluent monitoring program and the means to detect and evaluate concentrations of radioactive materials released to the environment. Provide a schematic of the effluent ventilation system and note any filters used and their location. Provide the criteria for changing out any HEPA and charcoal filters.		❒
	Safe Operating and Emergency Procedures	❒	N/A
	The applicant should state that procedures for safe handling of radionuclides and emergencies will be developed and documented before production of licensed material. In addition, the applicant should state that operating and emergency procedures will be implemented and maintained. The applicant should submit a statement that "Procedures will be revised only if (i) the changes are reviewed and approved by the licensee management and the RSO in writing; (ii) the licensee staff is provided training in the revised procedures before implementation; (iii) the changes are in compliance with NRC regulations and the license; and (iv) the changes do not degrade the effectiveness of the program."		

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM (Continued)**		
	Safe Operating and Emergency Procedures (Continued)	❒	N/A
	If an "Emergency Response Plan" is required for a license under 10 CFR 30.32(i), the applicant should submit it as a separate part of the application.	❒	N/A
	Survey and Leak Tests	❒	
	Do one of the following: State: "We will survey our facility and maintain contamination levels in accordance with the radiation survey frequencies and contamination levels published in Appendix J in the current version of NUREG 1556, Vol. 21, 'Program-Specific Guidance About Possession License for Production of Radioactive Materials Using an Accelerator.'" If applicable, state: "We will perform contamination checks on all manufactured sealed sources before distribution. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate.		
	Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees. Alternatively, we may perform leak tests using a leak-test kit supplied by an organization authorized by NRC or an Agreement State to provide leak-test kits to other licensees according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative to either of these leak test implementation methods, we will implement the model leak-test program published in Appendix K in the current version of NUREG 1556, Vol. 21." **OR** Submit a description of alternative equipment and/or procedures to evaluate a radiological hazard, and determine whether there is radioactive leakage from sealed sources or plated foils.		❒

Item No.	Suggested Response	Agree to Use	Description Attached
10.	**RADIATION SAFETY PROGRAM (Continued)**		
	Survey and Leak Tests	❒	
	***Notes**:* Alternative responses will be reviewed using the criteria listed above. If a sealed source or plated foil is added to an existing license, that license might already authorize the licensee to perform the entire leak-test sequence. In this case, the licensee may perform the leak testing on the sealed source or plated foil according to the procedures previously approved on its license.		
	Maintenance		
	No response is required in the application process. The results of actions taken during the maintenance and repair of facilities and equipment will be reviewed during inspection.	N/A	N/A
	Transportation		
	No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials on its own using Type B packages, a licensee needs to have registered with the NRC as a user of the package and obtained NRC's approval of its QA program. Transportation activities will be reviewed during inspection.	N/A	N/A
	Minimization of Contamination		
	The applicant does not need to provide a response to this item under the following condition: The NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: Section 8.5.1, "Radioactive Material–Unsealed and Sealed Byproduct Material;" Section 8.9, "Facilities and Equipment;" Section 8.10.6, "Radiation Safety Program–Safe Operating and Emergency Procedures;" Section 8.10.7, "Radiation Safety Program–Surveys and Leak Tests;" and Section 8.11, "Waste Management."	N/A	N/A

Item No.	Suggested Response	Agree to Use	Description Attached
11.	**WASTE MANAGEMENT** Provide procedures for waste collection, storage, and disposal by any of the authorized methods described in Section 8.11, "Waste Management." Applicants should contact the appropriate NRC Regional Office for guidance and obtain advance approval of any method(s) of waste disposal other than those discussed in Section 8.11. ***Note**:* Alternative responses will be reviewed using the criteria listed above.	N/A	❒

APPENDIX C

TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

Typical Duties and Responsibilities of the Radiation Safety Officer

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

- stopping activities that the RSO considers unsafe
- keeping exposures as low as is reasonably achievable
- developing, maintaining, distributing, and implementing up-to-date operating and emergency procedures
- ensuring that individuals associated with accelerator operations are properly trained and evaluated
- ensuring that nonroutine operations for accelerators (see Appendix H of this NUREG) are consistent with the limitations in the license, registration certificate(s) for the sealed source or device, and the manufacturer's written recommendations and instructions
- analyzing potential safety consequences of nonroutine operations before conducting any such activities that have not been previously analyzed
- ensuring nonroutine operations are performed by the manufacturer or person specifically authorized by the NRC or an Agreement State to perform those operations
- ensuring that personnel monitoring devices are used and exchanged at the proper intervals and that records of the results of such monitoring are maintained by the licensee
- either (i) providing personal monitoring devices or (ii) maintaining documentation showing that unmonitored individuals are not likely to receive, in a year, a radiation dose in excess of 10 percent of the allowable limits
- notifying proper authorities of incidents such as damage to or malfunction of accelerators, fire, loss, or theft of licensed materials (see Appendix I)
- investigating emergencies and abnormal events involving the accelerators (e.g., malfunctions or damage), identifying their cause(s), and implementing appropriate and timely corrective action(s)
- performing radiation safety program audits at least every 12 months and developing, implementing, and documenting timely corrective actions
- ensuring transport of licensed material according to all applicable U.S. Department of Transportation requirements
- ensuring proper disposal of licensed material
- maintaining appropriate records associated with accelerator operations

- maintaining an up-to-date license and timely submission of amendment and renewal requests

- ensuring that when the licensee identifies violations of regulations or license conditions or program weaknesses, corrective actions are developed, implemented, and documented

Model Delegation of Authority

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

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

_____ _____
Signature of Management Representative Date

I accept the above responsibilities,

_____ _____
Signature of Radiation Safety Officer Date

cc: Affected department heads

APPENDIX D

FACILITIES AND EQUIPMENT CONSIDERATIONS

Facilities and Equipment Considerations

Below is a list of topics that should be considered when developing a description of the facilities and equipment that a licensee will use or otherwise have available. Not every application will need to address each topic.

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Applicants should submit scaled floorplan drawings and sketches 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, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Applicants should use trays or absorbent surface covers to catch and retain spilled liquids 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 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 [as needed for as low as is reasonably achievable (ALARA) compliance] 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, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream, unless monitoring or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 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 Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection against Radiation.”

Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for containment during the storage and use of liquids and solids that can release 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 buildup. This buildup 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 should be used on benchtops, 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, should be used.

- Shielded shipping containers are frequently 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, and should be placed near the waste-generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials inside.

- For ALARA exposure, remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials. In addition, shielded handling devices, such as shielded syringes, should 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 in such a way that, in the event of an accident, they can be shut down and isolated to contain radioactivity.

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

- Areas with the lowest possible background radiation levels should be designated for personnel dosimetry storage when the dosimeters are 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 with mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or with 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, applicants should follow the provisions of 10 CFR Part 20, Subpart H.

APPENDIX E

SAMPLE AUDIT PROGRAM

Sample Audit Program

Licensees may use the following audit form to self-assess the adequacy of the licensed program, identify program weaknesses, and allow licensees to take corrective actions before an inspection by the U.S. Nuclear Regulatory Commission (NRC). This form is not intended to be all-inclusive. During an audit, the auditor needs to keep in mind not only the requirements of NRC regulations, but also the licensee's commitments in its applications and other correspondence with the NRC. Licensees are encouraged to modify the audit form as needed to include items specific to their licensed program. The auditor should also evaluate whether the licensee is keeping exposures of workers and the general public to radiation as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement. This audit form includes references at the end.

Radiation Safety Program Audit [20.1101(c)]
Annual Radiation Protection Audit

Date of this Audit _____ Date of Last Audit _____

Next Audit Date _____

Auditor _____ Date _____

(Signature)

Management Review _____ Date _____

(Signature)

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

Organization and Scope of Program

A. Organizational structure (specify any changes)

1. Matches license requirements? [L/C[1]]
2. Multiple authorized locations of use and/or field sites authorized?
3. List of location(s) inspected—attached for reference?
4. Brief description of scope of activities, including types of equipment, types and quantities of use involving byproduct material, frequency of use, staff size, etc.?

[1]L/C refers to license condition.

B. Radiation safety officer (RSO)

1. Named on license? [L/C]

2. Fulfills duties as RSO?

3. Meets requirements?

4. Potential RSO designee(s) identified, if applicable?

Training, Retraining, and Instructions to Workers

A. Instructions to workers [19.12]

B. Parts 19, 20, 21, 30; the license; and operating and emergency procedures are furnished to all licensee personnel who will be possessing radioactive targets?

C. Training program description the same as that submitted with license application or as amended? [L/C]

1. Individual authorized to prepare positron emission tomography drugs meets requirements for authorized nuclear pharmacist? [30.32(j)(3)]

2. Dosimeters processed by an accredited individual? [20.1501(d)]

2. Records maintained? [30.34(e)(4)]

D. Part 20. Workers cognizant of requirements for

1. Radiation Safety Program? [20.1101]

a. Occupational exposure annual limits? [20.1201; 20.1202]

b. Public annual dose limits? [20.1301; 20.1302]

2. NRC Forms 4 and 5?

3. 10 percent monitoring threshold? [20.1502]

4. Dose limits to embryo/fetus and declared pregnant worker? [20.1208]

5. Procedures for opening packages? [20.1906]

Operating and Emergency Procedures

A. Procedures current? [20.1101, 20.1906]

B. Procedures contain information specified in license?

C. Procedures submitted to the NRC? [30.32(i)(3)(x)]

Internal Audits or Inspections

A. Audits/inspections conducted at least annually and as appropriate? [20.1101(c); L/C]

B. Instrument check before use each day? [32.72(c)(2)]

C. Instrument inspection and maintenance performed at scheduled intervals? [32.72(c)(1)]

D. Records maintained? [20.2102]

Facilities

A. High-radiation area posted? [20.1601(a); 20.1902(b)]

B. Entrance controls are as described? [20.1601(a); L/C]

1. Visible and audible radiation signals?
2. Visible signal actuates if entry is attempted when irradiated target is exposed?
3. Audible signal actuates if entry is attempted when irradiated target is exposed?
4. Records maintained for at least 3 years? [30.51]

C. Temporary high-radiation area entry controlled? [20.1601(b)]

D. Storage area

1. Storage facilities as described in license? [20.1801; L/C]
2. Licensee maintains instructions/procedures for constant control and surveillance of material not in storage? [20.1802; L/C]

E. Isotope production conducted at location identified on license? [32.72(a); L/C]

Equipment

A. Licensee possesses and uses instrumentation to measure the radioactivity of radioactive drugs? [32.72(c)]

B. Licensee has procedures for use of the instrumentation? [32.72(c)]

C. Licensee can document that it performs tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and makes adjustments when necessary? [32.72(c)(1)]

D. Equipment exempted by specific license condition is used in accordance with license commitments and authorization? [L/C]

Materials

A. Isotope, chemical/physical form, quantity, and use as authorized? [L/C]

Instrumentation

A. Describe the radiation survey instruments possessed:

Model No. _____ Range: _____

B. Each instrument tested for accuracy, linearity, and geometry dependence, as appropriate, before initial use, periodically, and following repair? [32.72(c)(1)]

C. Each instrument checked for constancy and proper operation at the beginning of each day of use? [32.72(c)(1)]

D Records maintained for 3 years? [20.2102]

Radiation Surveys

A. Area or facility radiation surveys conducted to show compliance with 20.1301 and 20.1302(a) (dose limits to individual members of the public) in accordance with 20.1501(a)? [20.1501(a)]

B. Records maintained? [20.2103]

C. Protection of members of the public? [20.1301 and 20.1302]

1. Verify that adequate radiation surveys are made to demonstrate

   a. The total effective dose equivalent to the individual likely to receive the highest dose does not exceed 0.1 millisievert (mSv) [100 millirem (mrem)] in a year. [20.1301(a)(1)]

OR

   b. For an individual continuously present in an unrestricted area, the external dose would not exceed 0.02 mSv [2 mrem] in an hour and 0.5 mSv [50 mrem] in a year. [20.1302(b)(2)]

2. Unrestricted area radiation levels do not exceed 0.02 mSv [2 mrem] in any one hour? [20.1301(a)(2)]

3. Records maintained? [20.2103, 20.2107]

Personnel Radiation Protection

A. Dosimetry

1. Workers, including minors and declared pregnant women, monitored as required? [20.1502(a); L/C]

2. Exchange Frequency_____Supplier_____

Type of Dosimeter

3. Verify supplier is approved by the National Voluntary Laboratory Accreditation Program [20.1501(d)]

4. Dosimeters calibrated at required frequency? [20.1501(c); L/C]

5. Dosimetry records maintained? [20.2106]

B. Pocket Dosimeters and Electronic Personal Dosimeters

1. Model No. _ Range _____

Model No. _ Range _____

2. Dosimetry records maintained? [20.2106]

C. Alarm Ratemeters

1. Model No._____Range_____

2. Documented procedures in place to check periodically that alarm functions properly? [20.1601(a)(2)]

3. Records maintained? [20.2102]

D. Dosimetry Reports

1. Reviewed by_____Frequency_____

2. Reviewed personnel monitoring records for interval (from to)

3. Maximum exposures: total effective dose equivalent____extremity_____

other_____

4. NRC Forms (or equivalent) [20.2104(d); 20.2106(c)]

a. NRC Form 4—occupational exposure history

b. NRC Form 5—current occupational exposure

5. Maximum exposures in compliance with annual limits? [20.1201]

6. Fetal and pregnant worker exposure? [20.2106(e)]

a. Worker declared pregnancy in writing during the audit interval?

b. If yes, licensee in compliance? Records maintained?

7. Dosimetry records maintained? [20.2106]

E. Radiation Protection Program

1. Program includes provisions for keeping dose ALARA? [20.1101]

2. Procedures and engineering controls used to achieve ALARA doses? [20.1101(b)]

3. Content and implementation reviewed annually by licensee? [20.1101(c)]

4. Records of program reviews maintained? [20.2102 (a)(2)]

F. Planned Special Exposures (PSE) [20.1206]

1. PSEs performed?_____

2. If so, when, where, and why?_____

3. Records maintained? [20.2105; 20.2106; 20.2204]

Receipt and Transfer of Radioactive Material

A. Procedures established and followed for picking up, receiving, and opening packages? [20.1906 (e)]

B. Incoming packages surveyed? [20.1906 (b)(2); L/C]

C. Shipment of sources since last inspection?

1. Used container authorized by license or certificate of compliance (COC)? [L/C; COC]

2. Transfers? [30.41]

3. All sources surveyed before shipment and transfer? [20.1501(a); 49 CFR 173.475(i); L/C]

D. Records of radiation surveys and receipt/transfer/disposal maintained? [20.2103 (a); 30.51]

E. Transactions entered into the National Source Tracking System, including annual reconciliation? [20.2207]

Transportation [10 CFR 71.5(a) and 49 CFR 170–189]

A. Shipments are

1. Delivered to common carriers?

2. Transported in company's private vehicle?

3. Both?

4. No shipments since last audit?

B. Hazardous materials (HAZMAT) training? [49 CFR 172.700, 172.701, 172.702, 172.703, and 172.704]

C. Packages

1. Authorized packages used? [49 CFR 173.415; 173.416]

2. Performance test records on file?

a. Special form sources? [49 CFR 173.476(a)]

b. U.S. Department of Transportation (DOT)-7A packages? [49 CFR 173.415(a)]

3. COCs on file with the NRC for Type B? [71.17(c)(1)]

4. Two labels with Transport Index, Nuclide, and Hazard Class? [49 CFR 172.403; 172.441]

5. Properly marked? [Shipping name, United Nations (UN) number[2], Package type, Reportable quantity (RQ), Name and address of consignee] [49 CFR 172.101; 172.301; 172.310; 172.324]

6. Closed and sealed during transport? [49 CFR 173.475(f)]

D. Shipping papers

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

2. Proper? (Shipping name, Hazard class, UN number, Quantity, Package type, Nuclide, RQ, Radioactive material, Physical and chemical form, Category of label, Transport Index, Shipper's name, Certification and signature, Emergency response phone number, "Limited Quantity," "Cargo Aircraft Only" if applicable) [49 CFR 172.200, 172.201, 172.202, 172.203, and 172.204; 175.700]

3. Readily accessible during transport?

E. Vehicles

1. Placarded? [49 CFR 172.504]

2. Cargo blocked and braced? [49 CFR 177.842(d)]

3. Proper overpacks? (Shipping name, UN number label, Statement of inner packaging complies with specification packaging) [49 CFR 173.25]

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[2]The UN number identifies the hazardous substance. The UN number is universally recognized and assigned by the United Nations.

F. Any transportation incidents reported to DOT National Response Center? [49 CFR 171.15; 171.16]

Auditor's Independent Measurements

A. Survey Instrument_____
Serial No._____
Last Calibration_____

B. Auditor's measurements were compared with audited person's measurement?

C. Describe the type, location, and results of measurements; attach a diagram/survey sheet and refer to this section

Notifications and Reports

A. Reports to individuals, public and occupational, monitored to show compliance with Part 20? [19.13; 30.50]

B. Theft or loss? [20.2201; 30.50]

C. Incidents? [20.2202; 30.50]

D. Overexposures and high-radiation levels? [20.2203; 30.50]

E. Annual reports furnished to the NRC? [20.2206(b), (c)]

F. Reporting of defects and noncompliance? [21.21]

Posting and Labeling

A. Radiation areas? [20.1902(a)]

B. High-radiation areas? [20.1902(b)]

C. Use or storage areas? [20.1902(e)]

D. Containers or devices labeled? [20.1904(a)]

E. NRC Form 3? [19.11]

F. Parts 19, 20, 21 (Section 206 of Energy Reorganization Act) OR notification of location of required documents? [19.11; 21.6]

G. Other posting and labeling? [20.1902; 20.1904]

Recordkeeping for Decommissioning

A. Decommissioning records in independent and identifiable location? [30.35(g)]

B. Decommissioning records include all required data? [30.35(g)]

Generic Communications and Newsletters

A. Communications received and reviewed?

B. Appropriate response to bulletin, generic letters, etc.?

Special License Conditions or Issues

Evaluate special license conditions for data, actions.

Performance Evaluation Factors

These indicators may signify the status of the Radiation Safety Program as perceived by management:

A. Lack of senior management involvement with the Radiation Safety Program and/or RSO oversight?

B. RSO too busy with assignments other than radiation safety?

C. Insufficient staffing?

D. Inadequate consulting service or inadequate audits?

APPENDIX F

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

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

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

Table F–1. Typical Survey Instruments* (Instruments Used to Measure Radiological Conditions at Licensed Facilities)

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detector Type	**Radiation Detected**	**Energy Range**	**Efficiency**
REM Meter	Neutron	Rem to mrem	Low
Exposure Rate Meters	Gamma, X-ray	microroentgen to roentgen	N/A
Count Rate Meters:			
Zinc Sulfide	Alpha	All energies	High
Geiger-Mueller	Beta	All energies (depends on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (depends on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (depends on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detector Type	**Radiation Detected**	**Energy Range**	**Efficiency**
Liquid Scintillation Counter*	Alpha	All energies	Moderate
	Beta	All energies	Moderate
Gamma Counter (NaI)*	Gamma	All energies	Moderate
Gas Proportional	Alpha	All energies	High
Plastic Scintillator	Beta	C-14 or higher (depends on window thickness)	Moderate
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

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

Model Instrument Calibration Program

Training

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

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:
  - — principles and practices of radiation protection
  - — radioactivity measurements, monitoring techniques, and the use of radiation detection instruments

- mathematics related to the use and measurement of radioactivity
- biological effects of radiation

- On-the-job training will consist of the following:
  - observing authorized personnel performing radiation survey instrument calibration
  - conducting radiation survey meter calibrations under the supervision and in the physical presence of an individual already authorized to perform calibrations

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

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

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

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

Evaluate posting of the calibration area with appropriate radiation warning signs, as required by Subpart J of 10 CFR 20.

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

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

Frequency of Calibration of Radiation Measurement Instruments and Equipment

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

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

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

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

Calibration Sources for Dose and Dose Rate Measuring Instruments

A radioactive sealed source(s) will be used for calibrating dose and dose rate measuring radiation survey instruments, and this source will have the following characteristics:

- The source should approximate a point source.

- Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 microgray/hour (µGy/h) [0.1 millirad/hour (mrad/h)] and 10 percent for dose rates less than 1.0 µGy/h [0.1 mrad/h].

- The source should contain a radionuclide that emits radiation of identical or similar type and energy as the environment in which the calibrated device will be used.

- The source should be strong enough to give an exposure rate of at least 7.7 microcoulomb per kilogram per hour [30 milliroentgen per hour] at 100 centimeters {e.g., 3.1 gigabecquerels [(85 mCi (millicuries)] of cesium-137 or 780 megabecquerels [21 mCi] of cobalt-60}.

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

Calibration of Dose or Dose Rate Measuring Instruments

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

- **Linear readout instruments** with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on each scale. After adjustment, check the response of the instrument at approximately 20 percent and 80 percent of full scale. Instrument readings should be within ±x of the conventionally true value for the following ranges:

  — Background to 10 µGy/h [1.0 mrad/h]; ±x = ±30%
  — 10 µGy/h [1.0 mrad/h] to 1.0 mGy/h [100 mrad/h]; ±x = ±20%
  — mGy/h [100 mrad/h] to 10 Gy/h [1,000 Rad/h]; ±x = ±10%

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

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

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

Calibration of Surface Contamination Measurement Instruments

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

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

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

- alpha measurement

  0.01 Bq/cm^2 to 2.0 Bq/cm^2 [60 to 12,000 dpm/100 cm^2]; ±x = ±20%

  2.0 Bq/cm^2 to 200 Bq/cm^2 [12,000 to 1,200,000 dpm/100 cm^2]; ±x = ±10%

- beta measurement

  0.05 Bq/cm^2 to 2.0 Bq/cm^2 [300 to 12,000 dpm/100 cm^2]; ±x = ±20%

  2.0 Bq/cm^2 to 200 Bq/cm^2 [12,000 to 1,200,000 dpm/100 cm^2]; ±x = ±10%

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

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

As with calibration of other radiation measurement instruments, calibration of analytical instruments use a radioactive sealed source(s). These should be suitable for the geometry of the sample(s) to be analyzed. The calibration source(s) should have a known activity(ies) and be of similar type and energy as the radioactive materials to be analyzed. The analysis should be sensitive enough to detect the lowest levels of radioactivity desired. Correction of results for

quenching, self-absorption, and other factors may be required, depending on the analytical instrument, the samples type, and other environmental conditions.

Calibration Records

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

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

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

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

- the date of calibration and the next calibration due date

- the apparent exposure rate or count rate from the check source, if used

Air Sampler Calibration

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

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

Frequency of Calibration of Air Sampling Equipment

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually (Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace").

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

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

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

Error Limit for Measurement of Air Sample Volume

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

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

E_C: The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)[1]

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

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

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

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

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

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

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

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

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

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

Documentation of Calibration of Air Metering Devices

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

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

estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration and should include the appropriate correction factors to be used.

References:

- Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," June 1992
- NUREG–1400, "Air Sampling in the Workplace," September 1993 (available at the ADAMS Accession No. ML102371083)
- Health Physics and Radiological Health, 4th Edition. Edited by Thomas E. Johnson and Brian Kent Birky, 2012
- American National Standards Institute (ANSI) N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments"

"Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 9th Edition, 2001

Additional References:

- The Health Physics and Radiological Health Handbook, 3rd Edition. Edited by Bernard Shleien, Lester A. Slaback, Jr., and Brian Kent Birky, 1998.
- Detailed information about portable radiation survey instrument calibration may be obtained by referring to ANSI N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered online at http://www.ansi.org.
- "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 9th Edition, 2001.
- ANSI N13.10-1974 and ANSI N42.18-2004, "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents."
- NRC Regulatory Guide 4.15, Revisions 1 and 2, "Quality Assurance for Radiological Monitoring Programs – Effluent Streams and the Environment."
- NRC Regulatory Guide 1.21, Revisions 1 and 2, "Measuring, Evaluating and Reporting Radioactivity in Solid Wastes and Releases of Radioactive Material in Liquid and Gaseous Effluents from Light Water Cooled Nuclear Power Plants."
- NRC Health Physics Positions Database (NUREG/CR–5569, Revision 1), HPPOS Number 040, "Effluent Radiation Monitor Calibrations."
- NRC Information Notice 2013-13, "Deficiencies with Effluent Radiation Monitoring System Instrumentation."

APPENDIX G

METHODOLOGY FOR DETERMINING PUBLIC DOSE

Methodology for Determining 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 one calendar year resulting from the licensee's possession and/or use of licensed materials.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv [2 mrem] in any one hour.

- Air emissions of radioactive materials do not result in a total effective dose equivalent (TEDE) in excess of 10 mrem [0.1 mSv] per year. As required in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1101(d), if the licensee exceeds this 10 mrem per year air emission dose constraint, the licensee shall report the exceedance as provided in 10 CFR 20.2203, and promptly take appropriate corrective action to ensure against recurrence.

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

Doses to Members of the Public	
INCLUDE doses from • 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 • Licensed material in transportation or storage at the licensee's facility	DO NOT INCLUDE doses from • Sanitary sewerage discharges from licensee activities done in accordance with 10 CFR 20.2003, "Disposal by Release into Sanitary Sewerage" • Natural background radiation • Medical administration of radioactive material including patients released under 10 CFR 35.75 • Voluntary participation in medical research

Unrestricted areas are areas, access to which is neither limited nor controlled by the licensee as defined by 10 CFR 20.1003. Typical unrestricted areas may include offices, shops, areas outside buildings, property, and storage areas for nonradioactive materials, and other facilities or laboratories where licensed material is not used or stored. Although the licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials, the licensee may control access to these areas for other reasons, such as security, and these areas are still considered unrestricted for radiological purposes.

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] in a year.

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

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

Measurements

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

- dose rate surveys for radiation exposures from external radiation sources
- measurements of radionuclides in air and water effluent
- use of environmental dosimeters in unrestricted areas

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

Radioactivity releases may be determined by effluent monitoring or by effluent sampling and analysis. Airborne effluents may be discharged during accelerator operation. Due to the uncertainty of this type of discharge, it may be important to perform effluent monitoring continuously or at least during the operation of the accelerator. 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 might 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. An extremely conservative calculation would assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see Table G–1). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, there is no need for further evaluation. Also, see Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," for more information on calculating public dose.

If, however, the licensee would rather choose a more realistic assumption of the individual's occupancy at the points of highest internal and external exposures, then the licensee may use the occupancy factors in Table G–1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table G–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, 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

In accordance with 10 CFR 20.2107, "Records of Dose to Individual Members of the Public," 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, radiation 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 H

GENERAL TOPICS FOR SAFE USE OF RADIONUCLIDES AND MODEL EMERGENCY PROCEDURES

General Topics for Safe Use of Radionuclides and Model Emergency Procedures

General Topics for Safe Use of Radionuclides

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

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used.
- Wear disposable gloves at all times when handling licensed materials.
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area.
- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Do not store food, drink, or personal effects in areas where licensed material is stored or used.
- 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).

Radionuclide-Specific Procedures

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

Example 1:

If requesting more than 37 megabecquerel (MBq) [1 millicurie (mCi)] of unbound ("free") iodine-125 or iodine-131, special safety instructions should be provided to users and should include

- a mandatory radiation survey and wipe test for radioactive contamination after each use
- bioassay procedures for individuals working with millicurie quantities of unbound radioiodine or volatile compounds labeled with radioiodine
- the use of vented hoods for iodination procedures and for the storage of millicurie quantities of potentially volatile forms radioiodine
- a dry run before performing unfamiliar procedures to preclude unexpected complications; in addition, the U.S. Nuclear Regulatory Commission (NRC) recommends that the radiation safety officer (RSO) be present during the first performance of 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 and should include

- the use of low-density plastic shielding to minimize bremsstrahlung radiation
- a mandatory radiation survey and wipe test for radioactive contamination after each use
- the use of extremity monitors for procedures that involve 1 mCi or more
- a dry run before performing unfamiliar procedures to preclude unexpected complications; in addition, the NRC recommends that the RSO be present during the first performance of new procedures
- The use of eye protection for procedures that involve 370 MBq (10 mCi) or more

Model Procedures for Handling Emergencies

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

General Safety Procedures to Handle Spills

- The name and telephone number of the RSO or an alternate person(s) should be posted conspicuously in areas of use and be readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include

  - 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
  - prestrung “radioactive material” labeling tags
  - box of wipes
  - instructions for emergency procedures
  - clipboard with copy of the radioactive spill report form for the facility
  - pencil
  - appropriate radiation survey instruments, including batteries (for survey meters)

A decision to implement a major spill procedure instead of a minor spill procedure would depend on many incident-specific variables, such as the number of individuals affected, other hazards present, the likelihood of spreading contamination, the types of surfaces contaminated, and the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be to restrict access, pending complete decay. The applicant should establish criteria for determining when to use the major spill procedure versus the minor spill procedure.

Minor Spills of Liquids or 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.

- — Promptly report the incident to the RSO.

- — Allow no one to return to work in the area unless approved by the RSO.

- — Cooperate with the RSO and the RSO's staff (e.g., in the investigation of root cause(s) and provision of requested bioassay samples).

- — Follow the instructions of the RSO and the RSO's staff (e.g., in performing decontamination techniques, radiation surveys, and bioassay sampling and handling, or in providing 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.

  - — Determine whether any immediate or 24-hour NRC notifications are required by Subpart M, "Reports," of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection Against Radiation," or by 10 CFR 30.50, "Reporting Requirements." See Appendix I of this NUREG, "Typical Notification and Reporting Requirements."

Major Spills of Liquids or 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 a sign on the entrance to the room 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 the RSO and/or the RSO's staff (e.g., in the investigation of root cause(s) and provision of requested bioassay samples).

— Follow the instructions of the RSO and/or the RSO's staff (e.g., in performing decontamination techniques, radiation surveys, and bioassay sampling and handling, or 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 that was released by perspiration.

— Supervise decontamination activities and document the results. Documentation should include the location of radiation surveys and decontamination results.

— Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin.

— Determine whether any immediate or 24-hour NRC notifications are required by Subpart M of 10 CFR 20 or by 10 CFR 30.50. See Appendix I of this NUREG.

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 possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.

— Vacate the room. Seal the area, if possible.

— Notify the RSO immediately.

— Ensure that all access doors to the area are closed and posted with radiation warning signs, or post trained guards at all access doors to prevent accidental opening of the doors or entry to the area.

— Survey all persons who could possibly have 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 and/or supervised by the RSO.

— Allow no one to return to work in the area unless approved by the RSO.

— Cooperate with the RSO and/or the RSO's staff (e.g., in the investigation of root cause(s) and provision of requested bioassay samples).

— Follow the instructions of the RSO and/or the RSO's staff (e.g., in performing decontamination techniques, radiation surveys, and bioassay sampling and handling, or 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 exams and/or whole body counts before permitting involved individuals to return to work with licensed material.

— Determine the cause(s) of the incident and corrective actions needed; consider the need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document the incident.

— Determine whether any immediate or 24-hour NRC notifications are required by Subpart M of 10 CFR Part 20 or by 10 CFR 30.50. See Appendix I of this NUREG.

Minor Fires

- Instructions to Workers

— Immediately attempt to put out the fire by approved methods (e.g., using a 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. Call the fire department if instructed to do so by RSO.

— When the fire is out, isolate the area to prevent the possible spread of 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 radiation survey equipment necessary to decontaminate the area.

— Allow no one to return to work in the area unless approved by the RSO.

— Cooperate with the RSO and/or the RSO's staff (e.g., in the investigation of root cause(s) and provision of requested bioassay samples).

— Follow the instructions of the RSO and/or the RSO's staff (e.g., in performing decontamination techniques, radiation surveys, and bioassay sampling and handling, or 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 affected area again to remove any contamination that was released by the perspiration.

— Consult with fire-safety officials to ensure that there is no possibility of another fire starting.

— Determine the cause(s) of the incident and needed corrective actions; consider the need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document the incident.

— Determine whether any immediate or 24-hour NRC notifications are required by Subpart M of 10 CFR 20 or by 10 CFR 30.50. See Appendix I of this NUREG.

Larger 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.

— Allow no one to return to work in the area until approved by the RSO.

— Cooperate with the RSO and/or the RSO's staff (e.g., in the investigation of root cause(s) and provision of requested bioassay samples).

- — Follow the instructions of the RSO and/or the RSO's staff (e.g., in performing decontamination techniques, radiation surveys, and bioassay sampling and handling, or requested documentation).

- Reminders to RSO

  - — Coordinate activities with the facility's industrial hygienist or environmental health and safety office and with the local fire department.

  - — Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished.

  - — Once the fire is extinguished, advise firefighters not to enter potentially contaminated areas where radioactive sources may be present or radiation areas until a thorough evaluation and radiation survey are performed to determine the extent of the damage to the licensed material's 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 is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document the incident.

  - — Determine whether any immediate or 24-hour NRC notifications are required by Subpart M of 10 CFR 20 or by 10 CFR 30.50. See Appendix I of this NUREG.

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

Procedures for Collecting Bioassay Samples

In an emergency in which an individual may become contaminated or take radioactive material into the body through skin absorption or other means, or an individual is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. The following items should be considered in developing your procedures:

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

APPENDIX I

TYPICAL NOTIFICATION AND REPORTING REQUIREMENTS

Typical Notification and Reporting Requirements

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

Table I–1. Typical NRC Notification and Reporting Requirements for Incidents

Event	Telephone Notification	Written Report	Regulatory Requirement
Package received with removable radioactive surface contamination exceeding the limits of 10 CFR 71.87(i) or external radiation levels exceeding the limits of 10 CFR 71.47	immediate [U.S. Nuclear Regulatory Commission (NRC) and final delivery carrier must be notified]	none	20.1906(d)
Theft or loss of licensed material	immediate	30 days	10 CFR 20.2201(a)(1)(i) 10 CFR 20.2201(b)(1)
Whole body dose greater than 0.25 Sieverts (Sv) [25 rems]	immediate	30 days	10 CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Gray [250 rads]	immediate	30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 0.5 Sv [50 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems]	none	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 millisievert [0.1 rem]	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i) & (ii)
Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a) & (c)(2)

Table I–1. Typical NRC Notification and Reporting Requirements for Incidents			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4) & (c)(2); 40.60(b)(4) & (c)(2); and 70.50(b)(4) & (c)(2)
Unplanned contamination event that requires restricted access for more than 24 hours and involves a quantity of material greater than five times the lowest annual limit on intake for the material as specified in Appendix B of 10 CFR Part 20 and requires the area to be restricted for a reason other than to allow radionuclides with half-lives less than 24 hours to decay	24 hours	30 days	10 CFR 30.50(b)(1) & (c)(2); 40.60(b)(1) & (c)(2); and 70.50(b)(1) & (c)(2)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2) & (c)(2); 40.60(b)(2) & (c)(2); and 70.50(b)(2) & (c)(2)

***Note**:* Telephone notifications must be made to the NRC Operations Center at 301-816-5100 or by facsimile to 301-951-0550, except as noted. The Center is staffed 24 hours a day and accepts collect calls.

APPENDIX J

RADIATION SAFETY SURVEY TOPICS

Radiation Safety Survey Topics

This Appendix provides applicants and licensees with additional information on radiation surveys, including training requirements, survey frequency, contamination limits, and bioassays. Note that the U.S. Nuclear Regulatory Commission (NRC) does not regulate the operation of accelerators and, therefore, does not regulate radiation surveys performed on an accelerator during its operation. This Appendix refers to radiation surveys performed because of the use, handling, and/or storage of the radioactive materials that have been produced by an accelerator.

Training

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

Classroom training may be in the form of a lecture, video recording, or self-study and should cover the following subject areas:

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

Appropriate on-the-job training should consist of the following:

- observing authorized personnel using radiation survey equipment, collecting samples, and analyzing samples

- using radiation 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 the required sensitivity of radiation measurements is achieved, survey samples should 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 or cobalt-60).

- A liquid scintillation counting (LSC) system can be used to count samples containing most beta-emitters and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements). The LSC is the most common instrument used for measurement of tritium (H-3) contamination and other low-energy beta-emitters commonly used in laboratory research and development, such as carbon-14, sulfur-35, and phosphorus-32.

- Licensees may use a gas-flow proportional counting system to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits or where an individual is working in a dose rate of 0.025 millisievert (mSv) [2.5 millirem/hour (mrem/h)] or more (50 mSv/year divided by 2,000 h/year). It is also recommended that area monitors be used in areas where high-energy gamma/photon-emitting radioactive materials or radiation are produced and handled.

- 10 CFR 20.1301, "Dose Limits for Individual Members of the Public," requires that the total effective dose equivalent to an individual member of the public from the licensed operation must not exceed 1 millisievert (mSv) [0.1 rem] in a year, and the dose in any unrestricted area from external sources should not exceed 0.02 mSv [2 millirem] in any one hour.

Contamination Surveys

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

- to evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, work benches, and equipment

- after any spill or contamination event

- when procedures or processes have changed

- to evaluate contamination of users and the immediate work area, at the end of the day, or before leaving the area of use, when licensed material is used

- in unrestricted areas at frequencies consistent with the types and quantities of materials in use, but 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 in an amount greater than or equal to 10 percent of the smallest annual limit on intake (ALI), either for inhalation or ingestion listed for that radionuclide in Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," of 10 CFR Part 20, "Standards for Protection Against Radiation." These radiation surveys should be done at a frequency appropriate to the types and quantities of radioactive

materials in use, but no less often than quarterly. If amounts used are greater than or equal to the smallest ALI listed for that radionuclide in 10 CFR Part 20, detailed and documented radiation surveys should be performed at least daily and records retained in accordance with 10 CFR 20.2103.

Table J–1 contains the suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material "in use" at any one time at any particular location. If licensed material has not been used for a period of time greater than the required survey frequency, then it is considered to be "not in use."

Table J–1. Suggested Frequency of Contamination Surveys From Regulatory Guide 8.23

	< 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 J–2, taken from the NRC Policy and Guidance Directive FC 83-23, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material" (August 1987) (ADAMS Accession No. ML030590504). Note that, for the purposes of release of facilities for unrestricted use or termination of the license, these values have been superseded by 10 CFR 20, Subpart E, "Radiological Criteria for License Termination," and cannot be used for that purpose. In particular, the acceptable contamination levels listed below for most alpha emitters exceed the levels which will meet the 10 CFR 20, Subpart E criteria. Table J–2 levels can continue to be used for release of equipment and material from licensed material facilities during operational activities prior to license termination. (63 FR 64134; November 18, 1998)

Table J–2. Acceptable Surface Contamination Levels

Nuclide*	Average†‡	Maximum†§	Removable†‖
I-123, 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/100 cm^2 [3,000 dpm/100 cm^2]	3.3 Bq/100 cm^2 [200 dpm/100 cm^2]
Transuranics, Ra-226, Ra-228, Th-230, Th- 228, Pa-231, Ac-227, I-125, I-129	1.7 Bq/100 cm^2 (100 dpm/100 cm^2)	5.0 Bq/100 cm^2 (300 dpm/100 cm^2)	0.3 Bq/100 cm^2 (20 dpm/100 cm^2)
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133	16.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)	50.0 Bq/100 cm^2 (3,000 dpm/100 $cm^{2)}$	3.3 Bq/100 cm^2 (200 dpm/100 cm^2)
U-nat, U-235, U-238, and associated decay products	83.3 Bq/100 cm^2 (5,000 dpm/100 cm^2)	250 Bq/100 cm^2 (15,000 dpm/100 cm^2)	16.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)

Table J–2. Acceptable Surface Contamination Levels

Nuclide*	Average†‡	Maximum†§	Removable†‖
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)

*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.
†As used in this table, dpm (disintegrations 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.
‡Measurements of average contamination should not be averaged over more than 100 cm^2 (15.5 in^2). For objects of less surface area, the average should be derived for each such object.
§The maximum contamination level applies to an area of not more than 100 cm^2.
‖The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with a filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.
¶Bq = becquerel
#cm^2 = square centimeters
**dpm = disintegrations per minute

When potentially contaminated equipment or facilities are to be released for unrestricted use, the above table provides the maximum acceptable residual radioactivity levels. It is appropriate to decontaminate to below these levels to the extent practicable. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use, to ensure that they meet these limits. 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 J–2 values also may be acceptable criteria for contamination in facilities during facilities in operation.

A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm^2 (15.5 in^2) is acceptable to indicate levels of removable contamination.

Decommissioning Surveys for Release for Unrestricted Use

When a facility will be closed and released for unrestricted use, the values in Table J–3 provide acceptable residual contamination levels, known as "screening values" for building surfaces. To the extent practicable facilities should be decontaminated to below these levels [as low as is reasonably achievable (ALARA)]. Surveys should be conducted for both removable contamination (not to exceed 10 percent of the values in Table J–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 J–3. Screening Values for Building Surface Contamination*		
Radionuclide	**Symbol**	**Screening levels for unrestricted release (dpm/100 cm^2)**
Hydrogen-3 (Tritium)	H-3	1.2×10^8
Carbon-14	C-14	3.7×10^6
Sodium-22	Na-22	9.5×10^3
Sulfur-35	S-35	1.3×10^7
Chlorine-36	Cl-36	5.0×10^5
Manganese-54	Mn-54	3.2×10^4
Iron-55	Fe-55	4.5×10^6
Cobalt-57	Co-57	2.1×10^5
Cobalt-60	Co-60	7.1×10^3
Nickel-63	Ni-63	1.8×10^6
Zinc-65	Zn-65	4.8×10^4
Strontium-90	Sr-90	8.7×10^3
Technetium-99	Tc-99	1.3×10^6
Iodine-129	I-129	3.5×10^4
Cesium-137	Cs-137	2.8×10^4
Europium-152	Eu-152	1.3×10^4
Tungsten-181	W-181	1.1×10^6
Iridium-192	Ir-192	7.4×10^4

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

Units are disintegrations per minute per 100 cm^2 (dpm/100 cm^2). One dpm is equivalent to 0.0167 Bq. The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv [25 mrem] in a year unrestricted release dose limit in 10 CFR 20.1402, "Radiological criteria for unrestricted use." For radionuclides in a mixture, the "sum of fractions" rule applies; see 10 CFR Part 20, Appendix B, Note 4 for an example of the "sum of fractions" calculation. Refer to NUREG–1757, "Consolidated Decommissioning Guidance," for further information on application of the values in this table.

Table J–3 was derived using the DandD screening code, Version 1, (DandD, v1.0) and its default input parameters. Table J–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 J–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 J–3, additional site-specific dose assessments may be necessary, and licensees should refer to NUREG–1757 regarding acceptable methods for conducting the appropriate dose assessment, such as using the current version of DandD to develop site-specific screening criteria. The most recent version of the DandD code can be installed by downloading the self-extracting program file, setup.exe, accessed through the Web site: http://www.marssim.com/Dose_Modeling.htm. Links to other useful software and guidance documents are also found at that Web site.

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

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

Survey Record Requirements

Each radiation survey record should include the following:

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

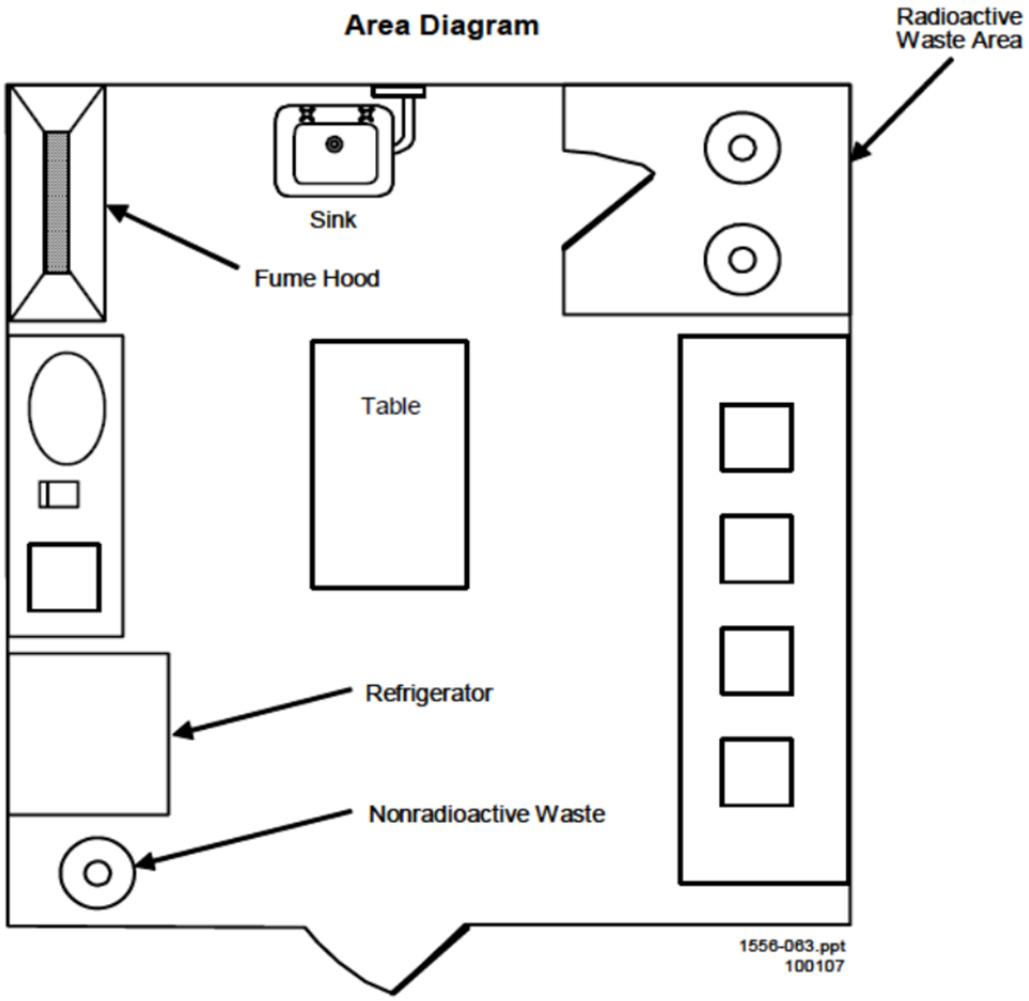

Figure J–1. Area Diagram. *This is an example of a laboratory survey map.*

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

Air Monitoring in the Workplace

Air monitoring may 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 can eliminate the need for bioassays.

Refer to Regulatory Guide 8.25, "Air Sampling in the Workplace," and NUREG–1400, "Air Sampling in the Workplace," for further guidance on air sampling.

Airborne Effluent Release Monitoring

When practicable, airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, or vents) in order 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, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," 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," provides guidance on designing an acceptable program for establishing and maintaining as low as is reasonably achievable (ALARA) levels of gaseous and liquid effluents at materials facilities.

For release points for which monitoring is not practicable, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur 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 in Column 1 of Table 2 in 10 CFR Part 20, Appendix B, whichever is greater.

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

Liquid Effluent Release Monitoring

The licensee 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 20.1302, "Compliance with dose limits for individual members of the public," and 20.2003, "Disposal by release into sanitary sewerage," respectively.

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

Bioassay Monitoring

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends on the exposure potential and the physical and chemical characteristics of the radioactive material, as well as the route of entry to the body. Consider the following factors:

- potential exposure of the individual
- retention and excretion characteristics of the radionuclide
- 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 that 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 Measurements

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

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

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity since the most recent bioassay measurement is > 0.02 ALI (40 derived air concentration hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours should be excluded from the evaluation, because 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 a change in employment status, bioassay measurement should be terminated, when practicable, to ensure that any unknown intakes are quantified.

Collection of Emergency Bioassay Samples

In the event of an emergency in which an individual becomes contaminated and has ingested or is suspected of having inhaled radioactive material or ingested it through skin absorption or other means, the licensee should estimate the amount of material taken into the body. Frequently, this estimate is made by performing a bioassay of the individual. Bioassays may be performed through direct methods, such as whole body counting or thyroid counting, using appropriate instruments, or indirect methods, such as sampling urine or other excreta from the body. This would allow the licensee to calculate 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 and/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 licensee's radiation safety program should include procedures and equipment for appropriate sample collection in an emergency. The following items should be considered in developing your procedures:

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

Special Monitoring

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

- the presence of unusually high levels of facial and/or nasal contamination
- entry into airborne radioactivity areas without appropriate exposure controls
- operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity)

- known or suspected incidents of a worker ingesting radioactive material
- incidents that result in contamination of wounds or other skin absorption
- evidence of damage to or failure of a respiratory protective device

References:

- Regulatory Guide 4.20,"Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors"
- Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"
- Regulatory Guide 8.20, Revision 2, "Applications of Bioassay for Radioiodine"
- Regulatory Guide 8.23, Revision 1, "Radiation Safety Surveys at Medical Institutions"
- Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace"
- Regulatory Guide 8.32, "Criteria for Establishing a Tritium Bioassay Program"
- Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities"
- NUREG–1400, "Air Sampling in the Workplace"
- NUREG–1549, Draft Report for Comment, "Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination" July 1998, ADAMS Accession No. ML993250291
- NUREG–1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)" Revision 1, August 2000
- NUREG–1575, Supplement 1, "Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)" January 2009
- NUREG–1757, "Consolidated Decommissioning Guidance"

  Volume 1, Decommissioning Process for Materials Licensees
  Volume 2, Characterization, Survey, and Determination of Radiological Criteria
- NUREG/CR-4884, "Interpretation of Bioassay Measurements"
- NUREG/CR-5512, Volume 2, "Residual Radioactive Contamination from Decommissioning: User's Manual DandD Version 2.1," April 2001, ADAMS Accession No. ML010940257
- NUREG/CR–5512, Volume 3, "Residual Radioactive Contamination from Decommissioning, Parameter Analysis, Draft Report for Comment," October 1999 [containing Tables 5.19 (surface contamination) and 6.91 (surface soil)], ADAMS Accession No. ML082460902

- *Federal Register:* "Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination," 63 FR 67132-34, November 18, 1998

- *Federal Register: "Supplemental* Information on the Implementation of the Final Rule on Radiological Criteria for License Termination," 64 FR 68395–96, December 7, 1999

- *Federal Register:* "Use of Screening Values to Demonstrate Compliance With the Final Rule on Radiological Criteria for License Termination," 65 FR 37186, June 13, 2000

- ANSI N13.1-2011, "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities"

- ANSI N13.30-2011, "Performance Criteria for Radiobioassay"

- ANSI N42.18-2004, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents," 2004

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

- U.S. Department of Energy, DOE G 441.1-1C, Admin Chg 1, "Radiation Protection Programs Guide for Use with Title 10, Code of Federal Regulations, Part 835, Occupational Radiation Protection"

APPENDIX K

MODEL LEAK TEST PROGRAM AND PROCEDURES

Model Leak Test Program and Procedures

Model Leak-Test Program

Training

Before allowing an individual to perform leak testing and sample analysis, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak testing and sample analysis independently, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.33(a)(3).

Classroom training may be in the form of lecture, online, video recording, 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

- observing authorized personnel collecting and analyzing leak-test samples
- collecting and analyzing leak-test samples under the supervision and in the physical presence of an individual authorized to perform leak testing and sample analysis

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, analyze leak tests in a low-background area.
- Use a calibrated and operable radiation survey instrument to check leak-test samples for gross contamination before they are analyzed.
- Analyze the leak-test sample using an instrument that is appropriate for the type of radiation to be measured [e.g., NaI (Tl) well-counter system for gamma emitters, liquid scintillation for beta-emitters, gas-flow proportional counters for alpha-emitters].
- If the sensitivity of the counting system is unknown, determine the minimum detectable activity (MDA). The MDA may be determined using the following formula:

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

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

For example:

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

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

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

= 478.55 disintegrations/minute
Bq = 1 disintegration/second

$$\text{Bq} = \frac{478.55\ \text{disintegrations}}{\text{minute}} \times \frac{1\ \text{minute}}{60\ \text{seconds}} = 7.976\ \text{Bq}$$

For example:

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

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

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

= 478.55 disintegrations/minute
1 becquerel (Bq) = 1 disintegration/second
Bq = 478.55 disintegrations × 1 minute = 7.976 Bq/minute (60 seconds)

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

Frequency for Conducting Leak Tests of Sealed Sources

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

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.

Procedure for Performing Leak Testing and Analysis

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

- Either use a leak-test kit, or, for each sealed source to be tested, list identifying information such as the manufacturer's name, model number, serial number, radionuclide, and activity of the sealed source.
- Use a radiation survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area (but not directly from the surface of a plated or foil source) where contamination would accumulate if the sealed source were leaking (see manufacturer's instructions).
- Select an instrument that is sensitive enough to detect 185 Bq [0.005 millicurie (mCi)] of the radionuclide and ensure that its calibration is current.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. The calibration source should be in the same configuration as the sample. Accuracy of standards should be within ±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 of the detector. A sample calculation is shown in the next box

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

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

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in Bq (orµCi).

For example: $\frac{\text{[(cpm from wipe sample) - (cpm from bkg)]}}{\text{efficiency in cpm/Bq}}$ = Bq on wipe sample

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

- If the wipe-test activity is 185 Bq [0.005 mCi] or greater, notify the radiation safety officer, so that the source can be withdrawn from use and disposed of properly.

- Also notify the U.S. Nuclear Regulatory Commission.

Reference: See NUREG–1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," if the applicant wants to provide leak testing and sample analysis as a commercial service provider.

APPENDIX L

APPLICABLE U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS

Applicable U.S. Department of Transportation Regulations

Note: The following list of U.S. Department of Transportation (DOT) regulations is provided to inform licensees about typical requirements that apply to the transportation of licensed material including the preparation of shipments of licensed material. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, transportation requirements change; therefore, licensees should consult the regulations for definitive information about current requirements. Additional information on transportation requirements may be found at the DOT Web site: http://www.dot.gov/.

- 49 CFR Part 172, "Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans"

(1) Table of Hazardous Materials and Special Provisions (Subpart B)

— Purpose and use of hazardous materials table (49 CFR 172.101)

— List of Hazardous Substances and Reportable Quantities for radionuclides (49 CFR 172.101, Table 2 to Appendix A), Radionuclides

(2) Shipping Papers (Subpart C)

— Preparation and retention of shipping papers (49 CFR 172.201)
— Description of hazardous material on shipping papers (49 CFR 172.202)
— Additional description requirements (49 CFR 172.203)
— Shipper's certification (49 CFR 172.204)

(3) Marking (Subpart D)

— Applicability (49 CFR 172.300)
— General marking requirements for non-bulk packagings (49 CFR 172.301)
— Prohibited marking (49 CFR 172.303)
— Marking requirements (49 CFR 172.304)
— Class 7 (radioactive) materials (49 CFR 172.310)
— Hazardous substances in non-bulk packagings (49 CFR 172.324)

(4) Labeling (Subpart E)

— General labeling requirements (49 CFR 172.400)
— Exceptions from labeling (49 CFR 172.400a)
— Prohibited labeling (49 CFR 172.401)
— Class 7 (radioactive) material (49 CFR 172.403)
— Placement of labels (49 CFR 172.406)
— Label specifications (49 CFR 172.407)
— RADIOACTIVE WHITE-I label (49 CFR 172.436)
— RADIOACTIVE YELLOW-II label (49 CFR 172.438)
— RADIOACTIVE YELLOW-III label (49 CFR 172.440)

(5) Emergency Response Information (Subpart G)

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

(6) Training (Subpart H)

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

- 49 CFR Part 173, "Shippers – General Requirements for Shipments and Packagings," Class 7 (Radioactive) Materials (Subpart I)

— Authorized packagings and overpacks (49 CFR 173.25)

— Definitions (49 CFR 173.403)

— General design requirements (49 CFR 173.410)

— Industrial packages (49 CFR 173.411)

— Additional design requirements for Type A packages (49 CFR 173.412)

— Authorized Type A packages (49 CFR 173.415)

— Requirements for determining basic radionuclide values, and for the listing of radionuclides on shipping papers and labels (49 CFR 173.433)

— Table of A_1 and A_2 values for radionuclides (49 CFR 173.435)

— Radiation level limitations and exclusive use provisions (49 CFR 173.441)

— Requirements for U.S. Nuclear Regulatory Commission approved packages (49 CFR 173.471)

— Quality control requirements prior to each shipment of Class 7 (radioactive) materials (49 CFR 173.475)

— Approval of special form Class 7 (radioactive) materials (49 CFR 173.476)

- 49 CFR Part 177, "Carriage by Public Highway"

— General Information and Regulations (Subpart A)
— Driver training (49 CFR 177.816)
— Shipping papers (49 CFR 177.817)

(1) Loading and Unloading (Subpart B)

— General requirements (49 CFR 177.834)
— Packages secured in a motor vehicle [49 CFR 177.834(a)]
— Class 7 (radioactive) material (49 CFR 177.842)

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

These are basic reference charts; refer to current U.S. DOT & 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 A_1 or A_2.
[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 A_2 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	Road and Rail	Vessel	Air (cargo only)
Radiation Level Limits[2]				
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]	N/A	N/A
		0.1 mSv/h (10 mrem/h): at any point two (2) m (6.6 ft) from sides of the vehicle[5]	N/A	N/A
Occupied position	N/A	0.02 mSv/h (2 mrem/h): at any normally occupied area[6]	Requirement of §176.708 applies	N/A
Transport Index (TI) Limits[2]				
Package[1,7]	3: passenger aircraft 10: road, rail, vessels and cargo aircraft	No limit		10
Conveyance[4]	50: road, rail and passenger aircraft 50 to No limit: vessels[8] 200: cargo aircraft	No limit		200
Overpack	N/A: for road, rail 50 to 200: vessels[8] 3: passenger aircraft; 10: cargo aircraft	N/A	No limit[8]	N/A
Criticality Safety Index (CSI) Limit for fissile material[2]				
Package[1,7]	50	100	100	100
Conveyance[4]	50: road, rail and air 50: for holds, compartments or defined deck areas of vessels[8] 200 to No limit: for a total vessel[8]	100	200 to No limit: for a total vessel[8]	100
Overpack	50: road, rail, vessels[8] and air	N/A		

[1] 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 cm^2 in size;
(c) measuring the activity on each single wiping material and dividing that value by the surface area wiped and the efficiency of the wipe procedure, where an actual wipe efficiency may be used, or it may be assumed to be 0.10.

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

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 **a**bove).

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 **a**bove).
- The internal contamination of an empty package must not exceed 100 times the limits in §173.443(a), Table 9 (as shown **a**bove).

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 **a**bove).
- 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 **a**bove).

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 **a**bove).
- 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 A_2 quantity and intended for air shipment has been tested to show that it will not leak under an ambient atmospheric pressure of not more than 25 kPa, absolute (3.6 psia), where the test must be conducted on the entire containment system, or on any receptacle or vessel within the containment system, to determine compliance with this requirement;
  (h) the internal pressure of the containment system will not exceed the design pressure during transportation; and
  (i) the external radiation and contamination levels are within the allowable limits specified in §173.441 and 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
Basic description (in sequence): • **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** Additional description: • **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 Additional entry requirements: • 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)	Materials-based Requirements: • 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 Package-based Requirements: • 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 Shipment- and Administrative-based Requirements: • Specify "exclusive use shipment" as required • Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use • Specify the notation "DOT–SP" followed by the special permit number[3] for a special permit shipment	• 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

- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, or be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, or be designated by an "X" (or "RQ" if appropriate).
- Emergency response information consistent with §§172.600-606 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]

Markings for Non-bulk Packagings:

- Proper shipping name
- Identification number (preceded by "UN" or "NA," as appropriate)
- Name and address of consignor or consignee, unless the package is:
  - highway only and no motor carrier transfers; or
  - part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee

Markings for Bulk Packages:

- Identification number on orange rectangular panel:
  - 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

Additional Markings Sometimes Required

Package-based marking requirements:

- Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 lb)
- Package type as appropriate, i.e., "TYPE IP–1," "TYPE IP–2," "TYPE IP–3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"[1]
- Marked with international vehicle registration code of country of origin for IP–1, IP–2, IP–3 or Type A package design [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.

Materials-based requirements:

- 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

Administrative-based requirements:

- For each Type B(U), Type B(M) or fissile material package destined for export shipment, mark "USA" in conjunction with specification marking, or certificate identification; and package identification indicated in 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

Optional Markings

- Both the name and address of consignor and consignee is recommended.
- Other markings on packages such as advertising are permitted, but must be located away from required markings and labeling.

Special Considerations for Marking Requirements

- 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 A_2 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):			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
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]		

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-us; 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)	PLACARD FOR HRCQ
	
White triangular background color in the lower portion with yellow triangle in the upper portion; trefoil symbol, text, class number and inner and outer borders in black. [see §172.556 for detailed requirements]	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 ≥ 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 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 current Emergency Response Guidebook is available at the following URL:
  http://www.phmsa.dot.gov/hazmat/library/erg

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 M

MODEL WASTE MANAGEMENT PROCEDURES

Model Waste Management Procedures

General Discussion

1. All radioactivity labels must be defaced or removed from containers and packages before their disposal into nonradioactive waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind workers that nonradioactive waste, such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.

3. 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.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.

5. The waste management program should include waste-handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.

6. Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or radiation.

7. A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, Appendix G, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests."

Model Procedure for Decay-In-Storage (DIS)

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

1. Only waste with a physical half-life of 120 days or less may be disposed of by DIS.

2. Short-lived wastes should be segregated from long-lived wastes.

3. Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.

4. Liquid and solid wastes should be stored separately.

5. Filled containers should be sealed. Sealed containers should be identified with labels affixed or attached to them.

6. The identification label should include the date when the container was sealed, the longest-lived radionuclide in the container, total activity, and the initials of the individual who sealed the container. The container may then be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after several half-lives, so persons performing radiation surveys should be aware of the potential for measurable radiation.

7. 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.

8. Before disposal as ordinary trash, each container should be monitored with an appropriate radiation detection instrument, on the lowest setting, as follows:

    a. Check the radiation-detection survey meter for proper operation with a radiation source.

    b. Survey the contents of each container in a low-background area.

    c. Remove any shielding from around the container.

    d. Monitor all surfaces of the container.

    e. 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 readings).

    f. If the surveys indicate residual radioactivity, return the container to the DIS area and contact the radiation safety officer for further instructions.

    g. If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, the type of waste (e.g., used or unused material, gloves), the radiation survey instrument used, and the name of the individual performing surveys and disposing of the waste.

***Note**:* All radiation labels should be defaced or removed from containers and packages before their disposal as ordinary trash.

Model Procedure for Disposal of Liquids Into Sanitary Sewerage

1. Confirm that the sewer system is a public system, not a private sanitary sewer, septic system, or leach field.

2. Confirm that the liquid waste being discharged is readily soluble (or is biological material that is easily dispersible) in water.

3. Calculate the amount of each radionuclide that can be discharged by using the information from prior similar discharges and the information in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, Appendix B, ”Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.”

4. Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR Part 20, Appendix B, Table 3, "Releases to Sewers."

5. If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 must not exceed unity.

6. Confirm that the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 gigabecquerels (GBq) [5 curies (Ci)] of H-3 (tritium), 37 GBq [1 Ci] of C-14, and 37 GBq [1 Ci] of all other radionuclides combined.

7. 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.

8. Liquid waste approved for disposal in sanitary sewer systems should be discharged only into designated sinks or toilets or other designated sewerage receptacles.

9. Discharge liquid waste slowly to minimize splashing, with water running to dilute it and to ensure that the material moves out of the sink into the sewer system.

10. Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remains in the sink or on work surfaces. Decontaminate as appropriate.

11. Before leaving the area, decontaminate any areas or surfaces found to be contaminated.

12. Maintain records of releases of licensed material to the sanitary sewer system. These records should include, for each release, the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the initials of the individual discharging the waste. For the licensed facility as a whole, records should be maintained of the quantity and concentration of radionuclides that are released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Model Procedure for Incineration

These guidelines apply to noncommercial incineration by a licensee of its own waste. Specific U.S. Nuclear Regulatory Commission (NRC) approval is not necessary in order to incinerate certain categories of radioactive waste. For example, 10 CFR 20.2005, "Disposal of Specific Wastes," provides that animal tissue and low concentrations of tritium and carbon-14 in liquid scintillation media may be disposed of without regard to radioactivity. After reviewing the disposal program and confirming the existence of waste that requires specific NRC approval for incineration, provide the following information in the license application.

1. Describe the training and experience of the person who will be responsible for the onsite and day-to-day supervision of incinerator operations.

2. Describe the waste proposed to be incinerated, including the chemical and/or physical form of the waste containing licensed material, and describe how the waste is segregated, packaged, and labeled for transfer from the generation site to the incinerator. Provide the name of the radionuclide, the concentration of radioactivity

averaged over the weight of the material to be incinerated (microcurie per gram of waste medium) for each isotope to be incinerated, the total radioactivity of each isotope per burn, and the total number of burns per year. Describe procedures for ensuring that these frequencies and activities will not be exceeded.

3. Describe the procedures for packaging, handling, securing, and monitoring waste to prevent contamination and/or unnecessary exposure of personnel or property during the waste's life cycle.

4. Describe the method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe the procedures for collection, handling, and disposal of the ash residue.

5. Describe the recordkeeping procedures for the waste-incineration program. Records should be adequate to document all receipts, incineration, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records should use the same units of measurement as the applicable regulations.

6. Describe the characteristics of the incinerator and site location, including: height of the stack, rated air flow (in cubic feet per hour or similar units), proximity of the stack or other discharge to occupied areas (e.g., residences, schools, or hospitals), and distance to the nearest air-intake ducts of adjacent buildings. Describe any scrubbers, filters, or air-cleaning equipment that are present.

7. State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined. Describe any planned stack monitoring.

8. Provide a copy of the written safety analysis that demonstrates that the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in 10 CFR Part 20.

9. Provide a written commitment that the applicant has coordinated with appropriate State and local authorities and that such permits and other authorizations as may be necessary have been obtained.

10. Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations, and for monitoring all effluent generated by the incineration process. The procedures should ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant should describe disposal procedures for any generated ash that exceeds regulatory limits.

Model Procedure for Compaction

The following information should be provided by licensees who propose to compact waste:

1. Describe the compactor to show that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations. Provide manufacturer's specifications, annotated sketches or photographs, and other information about the compactor design.

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 describe the ventilation and filtering systems used in conjunction with the compactor(s) and 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 radiation surveys that will be performed for contamination control in the compactor area.

7. Discuss the instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method(s) of handling uncompacted waste, and examination of containers for defects.

APPENDIX N

PRODUCTION AND NONCOMMERCIAL DISTRIBUTION OF PET RADIOACTIVE DRUGS TO CONSORTIUM MEMBERS

Production and Noncommercial Distribution of PET Radioactive Drugs to Consortium Members

Purpose of Appendix

The purpose of this Appendix is to provide guidance to the educational institution, medical facility, or Federal facility applicant with a positron emission tomography (PET) radionuclide production facility that is a member of a "consortium," as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 30.4 and is requesting authorization under 10 CFR 30.32(j) for the production and noncommercial distribution of PET radioactive drugs to medical use licensees within the consortium. This Appendix also provides guidance to an applicant for authorization to receive and possess such radioactive drugs from a consortium member licensed to produce them. The information required in this Appendix is specific to this authorization, and supplements information required for other uses of byproduct material covered under the applicant's byproduct materials license application.

As defined in 10 CFR 30.4, "[c]onsortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility." Note that medical-use applicants/licensees may also refer to Volume 9, "Program-Specific Guidance About Medical Use Licenses," of NUREG–1556, "Consolidated Guidance About Materials Licenses," for similar guidance on the production and commercial distribution of PET radioactive drugs to consortium members.

The regulatory requirements for educational institutions, Federal facilities, and medical facilities to receive authorization for producing PET radioactive drugs for noncommercial distribution to licensees in a consortium are in 10 CFR 30.32(j). Regulatory requirements for licensees with this specific authorization are in 10 CFR 30.34(j). The noncommercial distribution of PET radioactive drugs may be requested as an additional authorization on a current byproduct material possession license (e.g., by an educational institution, medical facility, or Federal facility broad-scope or limited specific licensee). The information associated with the radiation safety program specifically needed for producing PET radioactive drugs is in the current version of NUREG–1556, Volume 13, "Program-Specific Guidance About Commercial Radiopharmacy Licenses." To avoid duplication, many sections in this Appendix refer the applicant to the appropriate sections in NUREG–1556, Volume 13.

It should be noted that under 10 CFR 30.34(j)(1), the authorization to produce PET radioactive drugs for noncommercial distribution to medical use licensees in a consortium does not relieve the applicant or licensee from complying with applicable U.S. Food and Drug Administration (FDA) requirements, or other Federal or State requirements, governing radioactive drugs.

Consortium Criteria

In accordance with 10 CFR 30.32(j), only an applicant from a medical facility, educational institution, or Federal facility can produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 10 CFR Part 35, "Medical Use of Byproduct Material," or compatible Agreement State requirements. Therefore, the U.S. Nuclear Regulatory Commission (NRC) must have sufficient information to make the necessary

determination that the licensee is a member of a consortium that meets the definition in 10 CFR 30.4, and that the applicant will distribute the PET radioactive drugs only to medical use licensees in its consortium. To assist the NRC in making this determination, the applicant should describe this consortium. Because the medical use consortium members are authorized by 10 CFR 35.100(a), 35.200(a), or 35.300(a) to receive the PET radioactive drugs, the applicant does not have to identify the medical use members of the consortium specifically if the application describes the criteria for consortium membership. This description should focus on regulatory requirements and include a description of the geographical area where the members are located. Even if it provides the names of the individual consortium members, the applicant should also document the joint ownership or sharing of the PET radionuclide production facility's operating and maintenance costs. This documentation should include, but might not be limited to, signed agreements or contracts indicating roles and responsibilities of all of the individuals/entities involved.

The applicant is required by 10 CFR 30.32(j)(1) to either request authorization for the production of PET radionuclides (if the applicant possesses or will possess the PET radionuclide production facility but does not hold a license to operate the facility), or provide evidence of an existing license issued under 10 CFR Part 30 or compatible Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

Response from the Applicant:

- Identify the medical use members of the consortium or provide a description of the criteria for consortium membership.

- Describe the geographical area in which the members are located.

- Provide documentation of the terms of the association demonstrating the joint ownership of the PET radionuclide production facility or sharing of its operating and maintenance costs.

- Request authorization for the production of PET radionuclides if the applicant has the PET radionuclide production facility but does not have a license for it.

***Note**:* If the applicant intends only to receive, and not produce, the PET radioactive drugs, the applicant need only be licensed to possess and use these drugs.

Qualified To Produce PET Radioactive Drugs

Regulations in 10 CFR 30.32(j)(2) require that the applicant be qualified to produce PET radioactive drugs for medical use by meeting one of the following criteria:

- being registered with the FDA as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a)

- being registered or licensed by a State agency as a drug manufacturer

- being licensed as a pharmacy by a State Board of Pharmacy

- operating as a nuclear pharmacy within a Federal medical institution
- being a PET drug production facility registered with a State agency

Response from the Applicant:

- Provide documentation of registration with the FDA as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a); or
- Provide a copy of the applicant's State agency registration or license as a drug manufacturer; or
- Provide a copy of the applicant's State Board of Pharmacy license; or
- Provide evidence of operation as a nuclear pharmacy within a Federal medical institution; or
- Provide a copy of the applicant's State agency registration as a PET drug production facility.

Radioactive Materials and Uses

Under 10 CFR 30.32(j)(4), which references the information requirements of 10 CFR 32.72(c), the applicant is required to provide information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs to for which the applicant is requesting authorization to produce and noncommercially transfer to members of its consortium. Because applicants are only authorized for production and noncommercial distribution of these PET radioactive drugs, the applicant should request authorization to receive potentially contaminated "empty" radiation transport shields back from consortium members. It is the responsibility of the medical use consortium licensees under 10 CFR 20.2001 to dispose of licensed materials properly. These would include unused dosages and residual radioactivity remaining in syringes and vials that were received from the licensee authorized to produce and transfer PET radioactive drugs to consortium members.

Response from the Applicant:

- Identify the radionuclide; its chemical and physical form; and the maximum activity per vial, syringe, generator, or other container for each PET radioactive drug produced under this authorization.
- Request authorization to receive potentially contaminated containers, and estimate the maximum activity per vial, syringe, generator, or other container of the radioactive drug.

Individuals Responsible for Radiation Safety Programs and Their Training and Experience

Individuals responsible for the radiation safety program for the production of PET radioactive drugs and their transfer are the applicant's (or licensee's) radiation safety officer (RSO) and the

authorized individual(s) responsible during the production process for turning the PET radionuclides into radioactive drugs. The applicant's RSO and authorized individuals must meet the requirements in 10 CFR 30.33(a)(3). If these individuals are already identified for other materials and uses, they may already be authorized for the quantities, materials, and radiation safety considerations associated with the PET radioactive drug production process. To demonstrate that these individuals are qualified by their training and experience to use these materials for the purpose requested, as required by 10 CFR 30.33(a)(3), applicants should describe their additional training and experience for materials, quantities, and radiation-safety considerations that differ substantially from the current authorization(s).

Under 10 CFR 35.24, "Authority and Responsibilities for the Radiation Protection Program," a licensee's management must approve, in writing, an Authorized Nuclear Pharmacist (ANP) before allowing that individual to produce PET radioactive drugs. For guidance on the minimum training and experience requirements for an ANP, and the optional use of NRC Form 313A (ANP) to document the ANP's training and experience, the applicant should refer to the current version of NUREG–1556, Vol. 13, "Program-Specific Guidance About Commercial Radiopharmacy Licenses."

A licensee that produces PET radioactive drugs in a pharmacy under a 10 CFR 30.32(j) authorization is permitted to allow an individual to produce PET radioactive drugs if the individual is an ANP who meets the requirements in 10 CFR 32.72(b)(2) or is under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.27. Note that the licensee is required to notify the NRC within 30 days from the date the individual began work and must provide the specified information in accordance with 10 CFR 35.14.

Response from the Applicant:

Identify the individuals responsible for the radiation safety program and describe their training and experience using similar quantities, materials, and uses of radioactive materials.

- Describe the RSO's additional training and experience if the quantities, materials, and radiation safety considerations differ substantially from existing authorizations.

- Describe the authorized individuals' additional training and experience if the quantities, materials, and radiation safety considerations differ substantially from existing authorizations.

- If the applicant will be producing the PET radioactive drugs in a pharmacy, identify at least one individual who meets the requirements of an ANP. The applicant must also document that this individual's training and experience meets the requirements in 10 CFR 35.55 for a new ANP or 10 CFR 35.57 for an experienced ANP. Use NRC Form 313A (ANP) to document this information for new ANPs.

Training for Individuals Working in or Frequenting Restricted Areas

Individuals working with licensed material must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. In addition, those individuals who are likely to receive in a year a dose in excess of 100 millirem (mrem) [1 millisievert (mSv)] during their employment must be instructed according to 10 CFR 19.12.

An applicant should already have provided the training information for individuals working in or frequenting restricted areas as part of the radionuclide possession license application. In addition to this training information, applicants must also ensure that individuals involved in the preparation and transportation of PET radioactive drugs meet the training requirements of 49 CFR 172.704 for the transportation of hazardous materials. Sections 8.8.2 and Section 8.8.3 of the current version of NUREG–1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," provides guidance on training requirements for individuals involved in the preparation and transport of hazardous materials packages and the supervised individuals who prepare radioactive drugs.

Response from the Applicant:

- For personnel involved in the preparation and transport of hazardous materials, the applicant should submit the following statement:

  "We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.704."

- For supervised individuals preparing radioactive drugs, the applicant does not need to provide a response. Supervision will be reviewed during inspection.

Facilities and Equipment

Applicants should have already provided information regarding the facilities and equipment used for the radionuclide facility. In addition to this information, in order to demonstrate that the facilities and equipment are adequate to protect public health and safety, as required by 10 CFR 30.33(a)(2), the applicant must provide a description of the facilities and equipment used for the production of PET radioactive drugs and the noncommercial distribution to consortium members. Section 8.9.2, "Facilities and Equipment for PET Radiopharmacies," of the current version of NUREG–1556, Vol. 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," provides guidance on the information that should be provided regarding PET radioactive drug production and the distribution facility/area.

Response from the Applicant:

Describe the facilities and equipment to be made available at each location where radioactive materials will be used, including the method used to physically transfer licensed material to the different processes (e.g., chemical synthesis or dispensing). A diagram should be submitted showing the applicant's entire facility and identifying activities conducted in all contiguous areas surrounding the facility (See Figure 8-4). Diagrams should be drawn to a specified scale, or dimensions should be indicated. Include the following information:

- descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive drugs and the location(s) for radioactive waste storage.

- sufficient detail in the diagram to indicate locations of shielding and/or shielding equipment (e.g., hot cells for positron-emitting radionuclides); the proximity of radiation

sources to unrestricted areas; and other items related to radiation safety, such as remote handling equipment and area monitors.

- a general description of the ventilation system, including representative equipment such as glove boxes or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the production, use, or storage of radioactive drugs; and verification that ventilation systems ensure that effluents are as low as is reasonably achievable (ALARA), are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d).

- an explanation of how radiation levels in unrestricted areas will be maintained at less than 1 mSv [100 mrem] per year.

- a description of the visible-audible signal system or entrance control system and its locations.

Radiation Safety Program

The majority of information regarding the radiation safety program may have already been provided to NRC as part of a radionuclide production/possession license application. The applicant should review its authorization to determine whether supplementary information should be submitted about its radiation safety program. Section 8.10 of this guidance document (in Item 10: "Radiation Safety Program") provides guidance regarding an acceptable radiation safety program for a radionuclide production facility. This guidance also applies to the production of PET radioactive drugs. However, in addition to the radiation safety guidance mentioned in this document, applicants that will produce and noncommercially distribute PET radioactive drugs to their consortium members under 10 CFR 30.32(j) and must adhere to the following:

Audit Program

The applicant is not required to, and should not, submit its audit program to the NRC for review during the licensing phase. (See Appendix E of this NUREG for a sample radiation safety program audit). Audits will be reviewed during inspections to determine compliance with NRC regulations.

Dosage Measurement System

Among other things, 10 CFR 30.33(a)(2) requires that the applicant's proposed equipment be adequate to protect public health. In 10 CFR 30.34(j)(2)(ii), a licensee is required to possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and have procedures for use of the instrumentation. In addition, 10 CFR 30.34 (j)(2)(ii) requires licensees to measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs before transfer for commercial distribution. The licensee must also perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; make adjustments when necessary; and check each instrument for constancy and proper operation at the beginning of each day of use.

Therefore, the licensee shall have procedures for the use of instrumentation. In addition, the licensee shall measure, by direct measurement or a combination of direct measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs before noncommercial distribution.

The licensee must also ensure that the dose calibrator or other dose-measurement systems function properly. This is accomplished by performing periodic checks and tests before first use (followed by checks at specified intervals) and after repairs that could affect system performance. Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated for the applicable radionuclide being measured. For photon emitters such as PET radionuclides, activity measurement is a fairly straightforward determination. Generally, PET radionuclides can be measured using direct measurement only and do not require calculations, which are often required for beta-emitting radionuclides.

For each dose-measurement system, specific periodic tests must be performed, as appropriate to the system, to ensure correct operation. Typically, all systems must be checked each day of use for constancy, to ensure continued proper operation of the system. In addition, other appropriate tests may include accuracy (for the range of energies to be measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and product containers). Licensees should assay patient dosages in the same type of vial or syringe and geometry as used to determine the correct dose calibrator settings. The use of vials or syringes other than those used for geometry dependence may result in measurement errors. Also, the applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair or calibration.

Response from the Applicant:

- Describe instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of the consortium.

- Describe the types of systems (measurement or combination of measurement and calculation) intended for the measurement of PET radioactive drugs.

- For each dose-measurement system used to measure the amount of radioactivity in PET radioactive drugs, state: "We have developed, and will implement and maintain a written procedure for the performance of dose-measurement system checks and tests that meets the requirements in 10 CFR 30.34(j)(2)(ii).

Radioactive Drug Labeling for Distribution

Section 30.34(j)(2)(i) of 10 CFR Part 30 requires the licensee for the noncommercial transfer of PET radioactive drugs to satisfy the same labeling requirements in Section 32.72(a)(4) for commercial transfers of these drugs. Section 32.72(a)(4) requires that to transfer a radioactive drug, the licensee must affix a label to its transport radiation shield.[1] The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER,

[1]The term "transport radiation shield" refers to the primary shield for the radioactive drug, which may include the syringe, the vial, or the shield of the syringe or vial. To comply with 10 CFR 32. 72(a)(3), the transport radiation shield should be constructed of material appropriate for the isotope to be transferred for noncommercial distribution.

RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. (For radioactive drugs with a half-life greater than 100 days, the time may be omitted.) The radiation symbol referred to in Section 32.72(a)(4) is described in 10 CFR 20.1901).

Section 32.72(a)(4), as applied by Section 30.34(j)(2)(i), also requires the licensee to affix a label to each syringe, vial, or other container (e.g., generator) used to hold a radioactive drug to be transferred for noncommercial distribution. As with the label for the transport radiation shield, this label must include the radiation symbol with the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," but in addition, it must have an identifier ensuring that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label. Identifiers may include the prescription number, the name of the radioactive drug or its abbreviation, the name of the patient, or the clinical procedure.

Response from the Applicant:

- Describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g., on the transport radiation shield or the container used to hold the radioactive drug).

- Confirm that the required labels will be affixed to all transport radiation shields and to each container used to hold the radioactive drugs.

Radioactive Drug Shielding for Noncommercial Transfer

Among other things, 10 CFR 30.33(a)(2) requires that the applicant's equipment be adequate to protect public health. Under 10 CFR 30.34(j)(4), the shielding provided for each radioactive drug to be noncommercially distributed is required to be appropriate for safe handling and storage by the consortium members. The applicant must provide appropriate transport radiation shields for the primary container of each PET radioactive drug that it intends to distribute. The shielding must be adequate for the types and quantities of radioactive materials that the applicant intends to transfer. Typically, transport radiation shields used to carry radioactive drugs include two-piece, shielded syringe and vial containers (or "pigs"). Facilities have used lead and tungsten shields for gamma-/photon-emitting materials. The applicant should select appropriate shielding materials and dimensions to ensure not only that occupational doses are ALARA, but also that the transport radiation shield can be easily handled.

Response from the Applicant: For each PET radioactive drug to be noncommercially distributed:

- Indicate the radionuclide and the maximum activity for each type of container (e.g., vial or syringe).

- Describe the type and thickness of the transport radiation shield provided for each type of container.

- Indicate the maximum radiation level to be expected at the surface of each transport radiation shield when the radioactive drug container is filled with the maximum activity.

***Note**:* With respect to the transport radiation shield, it is not acceptable to state that the applicant will comply with U.S. Department of Transportation (DOT) regulations. The dose rate

limits that DOT imposes apply to the surface of the package, not the surface of the transport radiation shield.

Transportation

For the transportation of PET radioactive drugs to consortium members, refer to Section 8.10.9, (Transportation) of this document for guidance. The required transportation information should be consistent with the information provided for the production and distribution of accelerator-produced radionuclides.

Waste Management

Radioactive waste generated as part of the production of PET radioactive drugs for noncommercial distribution to consortium members must be disposed of in accordance with regulatory requirements and license conditions. In order to comply with the regulations in 10 CFR Part 20 and 10 CFR 30.51, appropriate records of waste disposal must be maintained. Section 8.11 Item 11, Waste Management") of this document provides guidance on the information required for handling waste.

Return Waste

It is the responsibility of the other medical use consortium licensees to dispose of unused dosages, empty syringes, and vials received from the licensee who is authorized to produce and transfer PET radioactive drugs to its consortium members. Under 10 CFR Part 20, these consortium members can only send radioactive waste to individuals authorized to receive it. The licensee authorized to produce and transfer PET radioactive drugs to consortium members will not be authorized to receive returned used or unused radioactive drugs from consortium members. Therefore, only "empty" radiation transport shield packages can be returned to the PET radionuclide production facility.

APPENDIX O

RADIATION SAFETY TRAINING

Radiation Safety Training

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

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

Frequency of Training

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

General Information

A. Radiation safety

1. radiation vs. contamination
2. internal vs. external exposure
3. biological effects of radiation
4. as low as is reasonably achievable (ALARA) concept
5. use of time, distance, and shielding to minimize exposure
6. contact dose rates and dose rates at a distance from high-activity sources
7. dose reduction responsibilities

B. Regulatory requirements

1. radiation safety officer (RSO)
2. material control and accountability
3. personnel dosimetry
4. radiation safety program audits
5. transfer and disposal
6. recordkeeping
7. radiation surveys
8. postings
9. labeling of containers
10. handling and reporting of incidents or events
11. licensing and inspection by the U.S. Nuclear Regulatory Commission (NRC)
12. need for complete and accurate information
13. employee protection
14. deliberate misconduct

Licensee-Specific Program Elements

A. authorized individuals and supervised individuals

B. worker-specific production activities (e.g., maintenance of the accelerator)

C. shipping

D. moving/transferring radionuclides to different areas or licensees

E. applicable regulations and license conditions

F. areas where radioactive material is used or stored

G. potential hazards associated with radioactive material in each area where the individuals will work

H. appropriate radiation safety procedures

I. licensee's in-house work rules (for instructions on laboratory safety and uses of radionuclides, see Appendix H of this NUREG)

J. each individual's obligation to report unsafe conditions to the RSO

K. appropriate response to spills, emergencies, or other unsafe conditions

L. worker's right to be informed of occupational radiation exposure and bioassay results, if applicable

M. Locations where the licensee has posted or made available: notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 19

N. Emergency procedures

1. RSO name and telephone number
2. immediate steps to prevent or control spread of contamination
3. clean-up instructions, decontamination

O. Survey program

1. radiation survey instrument accessibility
2. who is responsible
3. types, contamination, and areas
4. frequency
5. levels of contamination
6. personnel, hands, shoes
7. records

P. Waste

1. liquids
2. solids
3. air effluents from accelerator operation
4. sanitary sewer
5. burial (transfer to low-level waste repository)
6. storage
7. decay-in-storage
8. waste storage radiation surveys
9. incineration
10. records

Q. Dosimetry

1. whole body
2. extremities
3. lost or replacement badges and dose assessment
4. bioassay procedures
5. records

R. Instrumentation

1. radiation survey meters – use, calibration frequency, use of check sources
2. analytical instruments – gas-flow counters, liquid scintillation counters

S. Procedures for receiving packages containing radioactive materials (if applicable)

1. normal
2. off-duty
3. notification of user and RSO
4. securit
5. exposure levels
6. possession limit
7. receipt of damaged packages

T. Sealed sources

1. leak-test requirements
2. inventory requirements
3. exempt quantities
4. records

U. NRC/State/Licensee audit findings

V. Other topics

W. Question and answer period

For Laboratory Safety and Use of Radionuclides

A. Control procedures for obtaining permission to possess or possess and use radioactive materials at the facility; give limitations on quantity to be handled per user, or allowed per experiment.

B. Protective clothing and what laboratory apparel to wear and what equipment to use.

C. Limitations and conditions relative to handling unsealed licensed material and what laboratory equipment to use when working with such material. For example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or glove boxes. Explain what shielding or remote handling equipment is to be used when beta- and/or gamma-emitting licensed materials are handled.

D. Routine radiation survey and monitoring procedures to be followed for contamination control. Include where and how contaminated articles and glassware are to be handled and stored.

E. Emergency procedures concerning spills, fires, release of material, and/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 possessed or possessed and used.

I. Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.

J. Waste disposal procedures to follow, limitations for disposal of liquid or solid wastes, and procedures to use for waste storage. If the program involves experiments with animals, procedures for cleaning animal quarters and handling animal excreta and carcasses for disposal.

K. Records to be maintained on possession, use, and disposal of licensed materials.

L. Prohibitions of pipetting by mouth, eating, smoking, and drinking in areas where licensed materials are possessed or possessed and used.

APPENDIX P

CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)

Checklist for Requests to Withhold Proprietary Information From Public Disclosure (Under 10 CFR 2.390)

In order to request that the U.S. Nuclear Regulatory Commission (NRC) withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:	
☐	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
☐	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should **not** be marked as proprietary.
☐	An affidavit that:
☐	Is signed under oath and affirmation (notarization may suffice).
☐	Clearly identifies (such as by name or title and date) the document to be withheld.
☐	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information the organization is seeking to withhold and is authorized to apply for withholding on behalf of the organization.
☐	States that the organization submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
☐	Provides a rational basis for holding the information in confidence.
☐	Fully addresses the following issues:
☐	Is the information submitted to, and received by, the NRC in confidence? Provide details.
☐	To the best of the applicant's knowledge, is the information currently available in public sources?
☐	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
☐	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your organization, the amount of effort or money expended in developing the information, and the ease or difficulty for others to acquire the information.

APPENDIX Q

SAFETY CULTURE STATEMENT OF POLICY

Safety Culture Statement of Policy

Safety Culture

The Safety Culture Policy Statement, published in the *Federal Register* (76 FR 34773) on June 14, 2011, can be found at: http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf. It is also posted in the U.S. Nuclear Regulatory Commission (NRC) Agencywide Documents Access and Management System 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 that might result in error or inappropriate action, and continuously challenge existing conditions and activities in order to identify discrepancies.

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.

NRC FORM 335
(12-2010)
NRCMD 3.7

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER
(Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)
NUREG 1556, Volume 21, Revision 1 -- Draft Report for Comment

2. TITLE AND SUBTITLE
Consolidated Guidance About Materials Licenses -- Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator (NUREG 1556, Volume 21, Revision 1) -- Draft Report for Comment

3. DATE REPORT PUBLISHED

MONTH	YEAR
November	2016

4. FIN OR GRANT NUMBER

5. AUTHOR(S)
Dennis Lawyer, Robert MacDougall, Kevin Null, Lizette Roldan-Otero, and Karl Von Ahn

6. TYPE OF REPORT
Technical

7. PERIOD COVERED (Inclusive Dates)
October 2007 to November 2016

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)
Division of Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
11545 Rockville Pike
Rockville, MD 20852

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above", if contractor, provide NRC Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address.)
Same as above

10. SUPPLEMENTARY NOTES

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 licenses to possess radioactive materials produced in an accelerator. 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 implementi9ng the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)
NUREG-1556
Volume 21
Accelerator
Cyclotron
License
Radiodiagnostic
Radiopharmaceutical

13. AVAILABILITY STATEMENT
unlimited

14. SECURITY CLASSIFICATION
(This Page)
unclassified
(This Report)
unclassified

15. NUMBER OF PAGES

16. PRICE

Federal Recycling Program

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

OFFICIAL BUSINESS

NUREG-1556, Vol. 21
Revision 1, Draft

Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator

November 2016