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

NUREG-1556
Volume 13, Rev. 2

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Commercial Radiopharmacy Licenses

Final Report

Office of Nuclear Material Safety and Safeguards

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Manuscript Completed: March 2019
Date Published: March 2019

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ABSTRACT

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

Paperwork Reduction Act Statement

This NUREG contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0044; 3150-0014; 3150-0035; 3150-0017; 3150-0016; 3150-0001; 3150-0010; 3150-0214; 3150-0020; 3150-0009; 3150-0008; 3150-0120; and 3150-0028, respectively. Send comments regarding this information collection to the Information Services Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0044; 3150-0014; 3150-0035; 3150-0017; 3150-0016; 3150-0001; 3150-0010; 3150-0214; 3150-0020; 3150-0009; 3150-0008; 3150-0120; and 3150-0028) Office of Management and Budget, Washington, DC 20503.

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FOREWORD

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

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

The current document, NUREG–1556, Volume 13, Revision 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," is intended for use by applicants, licensees, and NRC staff. This revision provides a general update to the previous information contained in NUREG–1556, Volume 13, Revision 1, issued November 2007.

This report takes a risk-informed, performance-based approach to licensing the use of byproduct material in commercial radiopharmacy. A team composed of staff from NRC Headquarters, NRC regional offices, and Agreement States prepared this document, drawing on their collective experience in radiation safety in general and as specifically applied to commercial radiopharmacy.

NUREG–1556, Volume 13, Revision 2, is not a substitute for NRC or Agreement State regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable if they include a basis for the staff to make the determinations needed to issue or renew a license.

The comments received during the public comment period for NUREG–1556, Volume 13, Revision 2, were summarized and addressed in a document that can be located on the NRC's Agencywide Documents and Management System (ADAMS) under ML18305B303. Access to ADAMS is available on the public Web site at: https://www.nrc.gov/reading-rm/adams.html. The comments received by NRC included general text and formatting corrections, requests for additional information on activity measurements and surveys for alpha-emitting radioisotopes, and recommendations for routine and non-routine surveys and survey levels.

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ACKNOWLEDGMENTS

The working group would like to thank the staff in the Headquarters and regional offices of the U.S. Nuclear Regulatory Commission (NRC) and all of the States who provided comments and technical information that assisted in the development of this report.

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ABBREVIATIONS

ACMUI	Advisory Committee on the Medical Uses of Isotopes
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
AU	Authorized User
Bq	becquerel
CEDE	Committed Effective Dose Equivalent
CFR	*Code of Federal Regulations*
Ci	curie
cm	centimeter
Co-57	cobalt-57
cpm	counts per minute
Cs-137	cesium-137
DDE	Deep Dose Equivalent
DIS	Decay-In-Storage
DFP	decommissioning funding plan
DOT	U.S. Department of Transportation
dpm	disintegrations per minute
DU	depleted uranium
EPAct	Energy Policy Act of 2005
FA	Financial Assurance
FDA	U.S. Food and Drug Administration
FR	Federal Register
GM	Geiger Mueller
GBq	Gigabecquerel
h	hour
I-131	iodine-131
IN	Information Notice
IP	Inspection Procedure
kg	kilograms
LLEA	Local Law Enforcement Agency
LLW	low-level radioactive waste
LSC	Liquid Scintillation Counter
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
mCi	millicurie
mGy	milligray
MDA	Minimum Detectable Activity
Mo-99	molybdenum-99
mrad	millirads
mrem	millirem
mSv	millisievert
NaI	sodium iodide
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission

NSTS	National Source Tracking System
NSTTR	National Source Tracking Transaction Reports
NVLAP	National Voluntary Laboratory Accreditation Program
OJT	on the job training
OMB	Office of Management and Budget
PET	Positron Emission Tomography
PII	Personally Identifiable Information
Ra-226	radium-226
RIS	Regulatory Issue Summary
RQ	Reportable Quantity
RSO	Radiation Safety Officer
SDE	Shallow Dose Equivalent
SI	International System Of Units (abbreviated SI from the French, Le Système Internationale d'Unités)
SSD	Sealed Source and Device
Sv	sievert
Tc-99m	technetium-99m macroaggregated albumin
TEDE	Total Effective Dose Equivalent
TI	Transportation Index
TLD	Thermoluminescent Dosimeters
U.S.C.	United States Code

1 PURPOSE OF REPORT

This report provides guidance to an applicant applying for a commercial radiopharmacy license, and provides the U.S. Nuclear Regulatory Commission (NRC) staff with the criteria for evaluating such applications. Within this document, the terms "byproduct material," "licensed material," and "radioactive material" are used interchangeably.

Commercial radiopharmacy licenses are those licenses issued by the NRC, pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR 32.72, "Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35." Within this document, preparation includes the making of radiopharmaceuticals from reagent kits (e.g., technetium (Tc)-99m macroaggregated albumin) and from raw materials (e.g., the compounding of radioiodine capsules for diagnostic and therapeutic medical use or the compounding of Positron Emission Tomography (PET) radiopharmaceuticals for medical use). Commercial radiopharmacies may also be authorized to transfer for commercial distribution *in vitro* test kits described in 10 CFR 31.11, "General license for use of byproduct material for certain in vitro clinical or laboratory testing," radiopharmaceuticals to licensees authorized to possess them for other than human medical use (e.g., veterinary medicine and research licensees), and radiochemicals to those licensees authorized to possess them, pursuant to 10 CFR Part 30. In addition, 10 CFR Part 30 authorizes radiopharmacies to redistribute (transfer) sealed sources for calibration and medical use initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use."

Specific guidance for applicants requesting the production of radioactive material using an accelerator (e.g., PET radiopharmacies) is included in NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator." The activities related to producing radiochemicals with a cyclotron require a specific NRC authorization and must be included on a specific license under 10 CFR Part 30 that is separate from the commercial radiopharmacy license.

Note that this NUREG should be used for the activities that take place after the radiochemical is produced, such as compounding a radiochemical to a pharmaceutical, resulting in a radiopharmaceutical. Also, specific guidance for applicants requesting authorization to manufacture and initially distribute molybdenum-99/Tc-99m generators, *in vitro* kits, radiochemicals, and sealed sources is included in NUREG-1556, Volume 12, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution," and is not within the scope of this guidance for commercial radiopharmacies. These activities require specific NRC or Agreement State authorization and must be included on a specific license under 10 CFR Parts 30 and 32.

Furthermore, specific guidance for applicants requesting authorization to manufacture, distribute, and redistribute radioactive drugs to persons exempt from licensing (e.g., carbon-14 tagged urea) is included in NUREG–1556, Volume 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses," and also is not within the scope of this guidance. These activities require specific NRC authorization and require the issuance of a separate license for exempt distribution under 10 CFR Part 32.

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

Chapter 8, "Contents of an Application," of this NUREG identifies the information needed to complete NRC Form 313, "Application for Materials License" (see Appendix A of this NUREG), for the use of byproduct materials in commercial radiopharmacies. 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 the OMB Clearance Nos. 3150-0017 and 3150-0120, respectively.

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

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

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

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11, as indicated on the form. Applicants should address those items on separate sheets of paper and submit them along with the completed NRC Form 313. For the convenience and streamlined handling of applications for commercial radiopharmacy licenses in the new materials licensing process, 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 O contain additional information on various radiation safety topics, including model procedures. Appendix P of this NUREG includes a table (Table P–1) of NRC incident notification and reporting requirements applicable to commercial radiopharmacies.

In this NUREG, "dose" or "radiation dose" means either absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent (CEDE), or total effective dose equivalent (TEDE), as defined in 10 CFR Part 20, "Standards for Protection Against Radiation." Roentgen equivalent man (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 (Sv), rather than rad (Gray). When the radioactive material emits beta and gamma rays, 1 roentgen is assumed to equal 1 rad, which is assumed to equal 1 rem. For alpha and neutron-emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from

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

2 AGREEMENT STATES

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

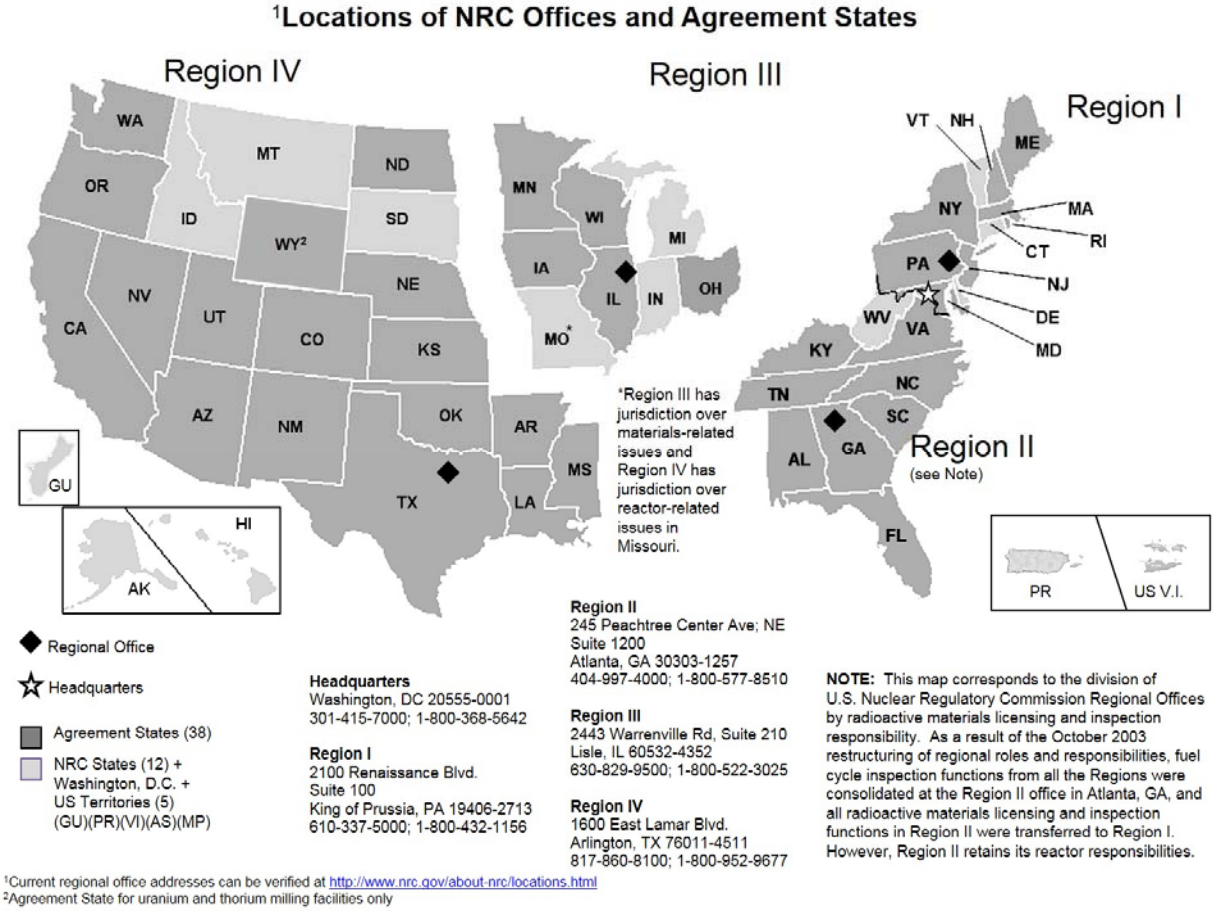


Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

In the special situation of work at federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement State has regulatory authority. These areas can also include Tribal lands of federally recognized Indian Tribes.[3]

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

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

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 10 CFR 30.12, "Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts;" also, see 10 CFR 40.11.	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[4]
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State.	Agreement State

[3]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.

[4]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.

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	**Regulatory Agency**
Non-Federal entity in Agreement State	Agreement State[5]
Non-Federal entity in Agreement State at federally controlled site **not** subject to exclusive Federal jurisdiction	Agreement State[5]
Non-Federal entity in Agreement State at federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	NRC
Non-Federal entity in Agreement State using radioactive materials **not** directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	Agreement State[5]

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

[5]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.

3 MANAGEMENT RESPONSIBILITY

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

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

3.1 Commitments and Responsibilities

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

- to ensure 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 and 40.9, "Completeness and accuracy of information")
- knowledge about the contents of the license and application
- compliance with current NRC and U.S. Department of Transportation (DOT) regulations, 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
- to report defects, noncompliances, or reportable events in accordance with regulations
- selection and assignment of a qualified individual to serve as the radiation safety officer (RSO) for licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities
- commitment to ensure that radiation workers have adequate training

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

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

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

- notification of the appropriate NRC regional administrator, in writing, immediately following the filing of petition for voluntary or involuntary bankruptcy [10 CFR 30.34(h) and 40.41(f)], as discussed further in Section 8.2.1, "Notification of Bankruptcy Proceedings," of this NUREG.

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

3.2 Safety Culture

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

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

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

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

Refer to Appendix R of this NUREG for the NRC's Safety Culture Policy Statement. More information on NRC activities relating to safety culture can be found at https://www.nrc.gov/about-nrc/safety-culture.html.

Table 3-1. Traits of a Positive Safety Culture

Leadership Safety Values and Actions	**Problem Identification and Resolution**	**Personal Accountability**
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.	All individuals take personal responsibility for safety.
Work Processes	**Continuous Learning**	**Environment for Raising Concerns**
The process of planning and controlling work activities is implemented so that safety is maintained.	Opportunities to learn about ways to ensure safety are sought out and implemented.	A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.

Table 3-1. Traits of a Positive Safety Culture		
Effective Safety Communications	**Respectful Work Environment**	**Questioning Attitude**
Communications maintain a focus on safety.	Trust and respect permeate the organization.	Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

4 APPLICABLE REGULATIONS

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

The current versions of these 10 CFR regulations can be found under the "Basic References" link at the NRC's online library at https://www.nrc.gov/reading-rm.html. For viewing in a browser, the following list includes direct links to the rules:

- 10 CFR Part 2 "Agency Rules of Practice and Procedure"
- 10 CFR Part 19 "Notices, Instructions, and Reports to Workers: Inspection and Investigations"
- 10 CFR Part 20 "Standards for Protection Against Radiation"
- 10 CFR Part 21 "Reporting of Defects and Noncompliance"
- 10 CFR Part 30 "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 31 "General Domestic Licenses for Byproduct Material"
- 10 CFR Part 32 "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 35 "Medical Use of Byproduct Material"
- 10 CFR Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- 10 CFR Part 40 "Domestic Licensing of Source Material"
- 10 CFR Part 71 "Packaging and Transportation of Radioactive Material"
- 10 CFR Part 110 "Export and Import of Nuclear Equipment and Material"
- 10 CFR Part 170 "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"
- 10 CFR Part 171 "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC"

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

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

The U.S. Nuclear Regulatory Commission (NRC) regulations can also be accessed from the "NRC Library" link on the NRC's public Web site at https://www.nrc.gov. Regulations are periodically amended, and the NRC (as well as all other Federal agencies) is required to publish notice of such amendments in the *Federal Register*.

5 HOW TO FILE

5.1 Application Preparation

Applicants for a materials license should do the following:

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

5.2 Where to File

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

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

5.3 Paper Applications

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

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

Applications must be signed by the applicant, licensee, or a person duly authorized, as required by 10 CFR 30.32(c) and 40.31(b) (see Section 8.13, "Certification").

5.4 Electronic Applications

Applications may be submitted in electronic form via the NRC's Electronic Information Exchange or CD-ROM. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at https://www.nrc.gov/site-help/e-submittals.html. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of 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 U.S. Nuclear Regulatory Commission (NRC) Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit www.nrc.gov.

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

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

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

- Security-Related Information: Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information and the top of every page of a document that contains such information should be clearly marked: "Security Related Information—Withhold under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, Rev. 1, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 26, 2017, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at https://www.nrc.gov/reading-rm/doc-collections/gen-

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

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

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

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

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

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

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

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

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

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

7 APPLICATION AND LICENSE FEES

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

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16, "Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC." Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities." Note that in order to pay reduced fees, 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 U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix A of this NUREG).

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

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

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

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. Also note that an initial on-site security review may be conducted in accordance with NRC Inspection Manual chapter 2800, "Materials Inspection Program," before issuance of the license.

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

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

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

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

8.2.1 Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h), 10 CFR 40.41(f)(1)

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

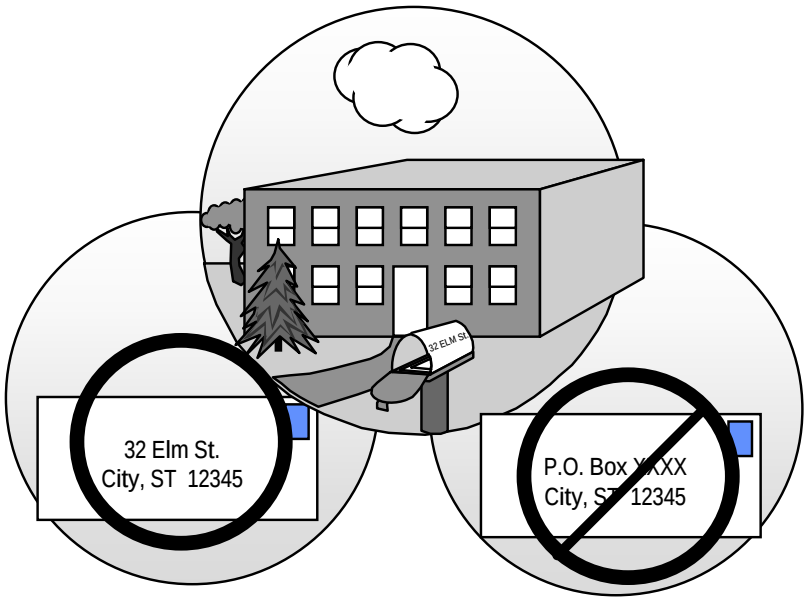
Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains subject to all applicable NRC regulatory requirements. The NRC must be notified when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled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

Response from Applicant: No response is required at the time of application for a new license. Licensees must immediately notify the NRC, in writing, following the filing of a voluntary or involuntary petition for bankruptcy by or against the licensee.

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

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

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



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

Figure 8-1. Location of Use

appropriate, for each permanent storage or use facility and field station located in a remote area.

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

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

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

Response from Applicant:

- Provide the specific address of each location of use.

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

8.4 Item 4: Person to Be Contacted About This Application

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

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

8.5 Item 5: Radioactive Material

8.5.1 Sealed and/or Unsealed Byproduct Material

Regulations: 10 CFR 30.4, 10 CFR 30.32(g), 10 CFR 30.32(i), 10 CFR 30.33, 10 CFR 30.72, 10 CFR 32.72(a)(3), 10 CFR 32.210, 10 CFR Part 37, 10 CFR 40.31, 10 CFR 40.32

Criteria: Applicants must submit information specifying each radionuclide requested, the form, and the maximum activity to be possessed at any one time. For sealed sources, the applicant must also submit the manufacturer and model number of each requested sealed source. Licensees must also protect aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5, from theft, diversion, and sabotage.

Requests to license naturally occurring radioactive material (NORM) should be made to the appropriate regulatory agency. As a result of the Energy Policy Act of 2005 (EPAct), the NRC and Agreement States through their agreements with the NRC, regulate discrete sources of radium (Ra)-226, accelerator-produced radioactive materials, and other discrete sources of NORM that pose a threat similar to that of a discrete source of Ra-226, as described in the definition of byproduct material in 10 CFR 30.4. Notwithstanding the EPAct, most NORM continues to be regulated by the States. The NRC will only license NORM if it is a discrete source and meets the criteria above. Applicants and licensees should determine whether they possess or will possess sealed sources or devices containing byproduct material as defined in the Atomic Energy Act, which would include check, calibration, and reference sources that are not generally licensed or exempt from licensing. Applicants will have to request authorization for possession of these sealed source(s) or device(s).

Note that naturally occurring and accelerator-produced radioactive material sealed sources and devices that were manufactured before November 30, 2007, may not have been registered by the NRC in accordance with 10 CFR 32.210(c) or an Agreement State. If the applicant possesses unregistered sources and/or devices and is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant must submit the information required by 10 CFR 30.32(g)(2), (3), or (4).

Discussion: 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). For each Ra-226 sealed source and device and discrete source of Ra-226 requested, provide the activity per source and the maximum possession limit [e.g., 1 millicurie (mCi) per source with a maximum possession limit of 3 mCi].

The applicant should list each requested radionuclide by its element name and its mass number (e.g., technetium (Tc)-99m, indium-111, and fluorine-18) in Item 5. Alternatively, provide the requested information using the Checklist in Appendix B [e.g., Any byproduct material listed in 10 CFR 31.11(a) (e.g., for redistribution)], any byproduct material authorized under 10 CFR 35.65 (e.g., redistribution of a cobalt-57 sheet source for gamma camera quality control tests), and cesium-137 for instrument calibration. The NRC provides broad authorization to permit commercial radiopharmacy licensees flexibility to prepare and distribute a range of radionuclides as new radioactive drugs are developed. It is necessary to specify whether the material will be acquired and used in unsealed or sealed form or in the case of Ra-226, in the form of a discrete source. The name of the specific chemical compound that contains the radionuclide is not generally required.

For unsealed radioactive material, it is also necessary to specify whether requested radionuclides will be handled in volatile or nonvolatile form, because additional safety precautions are required when handling and using material in a volatile form. For example, when requesting authorization to possess and distribute iodine (I)-131, specify whether the material will be manipulated at the commercial radiopharmacy in a volatile form (e.g., compounding of I-131 capsules) or received in the form in which it will be distributed (e.g., redistribution of sealed, unopened vials of I-131 capsules). Also, if the commercial radiopharmacy possesses discrete sources of Ra-226, the discrete source should be described, because additional precautions may need to be taken if the source is compromised. Applicants requesting discrete sources of Ra-226 and authorization to manipulate volatile radioactive material must describe appropriate facilities and engineering controls in response to Section 8.9, “Facilities and Equipment,” and radiation safety procedures for handling such material in specific responses to Section 8.10.4, “Occupational Dose;” Section 8.10.5, “Public Dose;” Section 8.10.6, “Safe Use of Radionuclides and Emergency Procedures;” and Section 8.10.7, “Surveys.”

The anticipated possession limit in becquerels (Bq) or curies (Ci) for each radionuclide should also be specified. 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. Applicants should review the requirements for submitting a certification for financial assurance (FA) 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.”

Applicants that produce radionuclides using an accelerator [e.g., Positron Emission Tomography (PET) cyclotron] would list only those radionuclides produced for use in the commercial radiopharmacy (e.g., fluorine-18). All other radionuclides associated with PET radionuclide production (e.g., activation products) should be provided with the application submitted in accordance with NUREG–1556, Volume 21, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator.”

A safety evaluation of sealed sources and devices is performed by the NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) registration certificate. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that the NRC can verify that they have been evaluated in an SSD registration certificate or specifically approved on a license.

A commercial radiopharmacy possessing a sealed source containing byproduct material that does not have an SSD registration certificate must provide the information required under 10 CFR 30.32(g). As noted earlier, some sealed sources that contain accelerator-produced radioactive materials or Ra-226 may not have existing safety evaluations. A commercial radiopharmacy that intends to manufacture, distribute, or redistribute such a source must request a safety evaluation by the NRC or an Agreement State.

Applicants should consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the sealed source and device designations registered with the NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective SSD registration certificates, without obtaining NRC's prior permission in a license amendment. To ensure that applicants use sources and devices according to the certificates, they should obtain copies of the certificates and review them or discuss them with the manufacturer.

To obtain copies of the SSD registration certificate, applicants should contact the manufacturer or distributor of the device. If the manufacturer or distributor are no longer in service, a copy of the SSD registration certificate may be requested from the NRC or the issuing Agreement State. For additional guidance relating to sealed sources and devices, see also NUREG–1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

The applicant must also request authorization to possess depleted uranium (DU) if it will be used as shielding for molybdenum (Mo)-99/Tc-99m generators or as other shielding. DU is frequently used as shielding for generators when the Mo-99 activity is greater than 148 gigabecquerels (GBq) [4 Ci]. In accordance with 10 CFR 40.13(c)(6), DU is exempt from the requirements for a specific or general 10 CFR Part 40 license, to the extent that the material is used as a shipping container, such as when Mo-99/Tc-99m generators are in transit from their manufacturer to the pharmacy; however, a specific license or authorization from NRC is needed to possess and use the DU as a shield during the time that the pharmacy uses or stores the generator at its facility. The applicant must specify the total amount of DU, in kilograms (kg), that will be needed.

Applicants who plan to possess radioactive materials in excess of the quantities listed in 10 CFR 30.72, "Schedule C–Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release," must, in accordance with 10 CFR 30.32(i), provide with the application either: (i) an evaluation showing that the maximum offsite dose because of a release of radioactive materials would not exceed 1 rem [0.01 Sievert (Sv)] effective dose equivalent or 5 rem [0.05 Sv] to the thyroid, or (ii) an emergency plan for responding to a release in accordance with the criteria listed in 10 CFR 30.32(i)(3). Refer to Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," Revision 1, issued April 2011, for

additional information on emergency plans. For radiopharmacies, I-131 is the radionuclide most likely to trigger the need for an emergency plan due to its Schedule C quantity of 10 Ci.

Licensees must submit a license amendment and receive NRC authorization before they may make changes in the types, forms, and quantities of materials possessed.

The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated "Category 1 quantity of radioactive material" or "Category 2 quantity of radioactive material." These terms are defined in 10 CFR 37.5, and the radionuclides referenced in these 10 CFR 37.5 definitions are listed in Appendix A to 10 CFR Part 37. See Section 8.10.14, "Security Program for Category 1 and Category 2 Radioactive Material," of this NUREG for more information on the applicability and requirements of 10 CFR Part 37.

Response from Applicant:

- For unsealed materials
  - — Identify each radionuclide (element name and mass number) that will be used, and the maximum requested possession limit, or provide the requested information using the checklist in Appendix B of this NUREG.
  - — For potentially volatile materials (e.g., iodine-123, I-131), specify whether the materials will be manipulated at the commercial radiopharmacy and if so, specify where manipulation occurs (i.e., a hood or a hot cell).
- For sealed sources and discrete sources of Ra-226
  - — Identify each radionuclide (element name and mass number) that will be used in each source, the activity per source, and the maximum requested possession limit, or provide the requested information using the checklist in Appendix B of this NUREG.
  - — Provide the manufacturer's or distributor's name and model number for each sealed source and device and discrete source of Ra-226 requested.
  - — Confirm that each sealed source, device, source/device combination, and discrete source of Ra-226 is registered as an approved sealed source, device, or discrete source by the NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available.
    - o For each sealed source, device, and source and device combination that is not registered, provide the applicable information, as described in 10 CFR 30.32(g) and 32.210.
  - — 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 above information cannot be provided for the discrete source of Ra-226, describe the discrete source and its physical boundaries.

- For depleted uranium, specify the total amount (in kilograms).

- Provide an emergency plan, if required by 10 CFR 30.32(i) and 10 CFR 30.72

***Note**:* See B.5 "Item 5: Materials to be Possessed" in Appendix B of this NUREG for a listing of the various radionuclides and other information to be addressed by the applicant when responding to this section.

8.5.2 Financial Assurance and Recordkeeping for Decommissioning

Regulations: 10 CFR 30.34(b), 10 CFR 30.35, 10 CFR 30.51(f), 10 CFR 40.36(f), 10 CFR 40.46, 10 CFR 40.61(f)

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35 titled "Financial Assurance and Recordkeeping for Decommissioning"—must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (FA) for decommissioning.

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

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

Licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where devices are used or stored, as well as records related to leaking sources. Furthermore, pursuant to 10 CFR 30.51(f) and/or 10 CFR 40.61(f) prior to license termination, each licensee must forward the records required by 10 CFR 30.35(g) and/or 10 CFR 40.36(f), respectively, to the appropriate NRC regional office.

Discussion: The requirements for FA for decommissioning are specific to the types and quantities of byproduct material authorized on a license. Most commercial radiopharmacy applicants and licensees do not need to take any action to comply with the FA requirements, because the vast majority of radioactive materials they possess and redistribute do not have half-lives greater than 120 days and the total inventory of licensed materials with half-lives greater than 120 days does not exceed the thresholds in 10 CFR 30.35(b) and (d).

Applicants requesting more than one radionuclide may determine whether FA for decommissioning is required by calculating, for each radionuclide with a half-life greater than 120 days possessed, the ratio between the activity possessed, in curies, and the radionuclide's threshold activity requiring FA, in curies. If the sum of such ratios for all of the radionuclides possessed exceeds "1" (i.e., "unity"), applicants must submit evidence of FA for decommissioning.

The regulations in 10 CFR 30.35(g) and 10 CFR 40.36(f) require that licensees maintain records important to decommissioning in an identified location. All commercial radiopharmacy licensees

need to maintain records of structures and equipment where radioactive material was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees must substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the specific areas and locations. If no records exist regarding structures and equipment where radioactive materials were used or stored, licensees shall make all reasonable efforts to create such records based upon historical information (e.g., employee recollections). In addition, if commercial radiopharmacy licensees have experienced unusual occurrences (e.g., incidents that involve spread of contamination, leaking sources), they should also maintain records about contamination that remains after cleanup or contamination that may have spread to inaccessible areas. Leak test records are part of the decommissioning records.

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

DFP for Possession of Germanium-68 (Ge-68)/Gallium-68 (Ga-68) generators

In accordance with 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning," applicants must have a DFP to obtain a license to possess Ge-68/Ga-68 generators. In a NRC Memorandum dated July 13, 2017, "Revision of Technical Basis for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators," (Agencywide Documents Access and Management Accession No. ML17075A487), the Director of the NRC Office of Nuclear Material Safety and Safeguards delegated to the NRC Regional Administrators the authority to grant an exemption to the DFP requirements in 10 CFR 30.35(a)(1) for the possession and use of Ge-68/Ga-68 generators when certain conditions are met. If an applicant or licensee requests an exemption from the requirements in 10 CFR 30.35(a)(1) for the possession and use of Ge-68/Ga-68 generators, the applicant or licensee would still need to provide FA. The total amount of FA would vary depending on the number of generators that the applicant is requesting be authorized or the licensee is authorized to possess. Additionally, in order to be granted an exemption from 10 CFR 30.35(a)(1) for the possession and use of Ge-68/Ga-68 generators, the applicant or licensee must have a legally binding agreement in place with the manufacturer or distributor of the generators that addresses the return of expired generators. Applicants and licensees that request and are granted the exemption will have a specific license condition placed on their license addressing the exemption. Applicants and licensees who wish to request such an exemption to the DFP requirements in 10 CFR 30.35(a)(1) for the possession and use of Ge-68/Ga-68 generators should refer to the July 13, 2017, Memorandum for additional information. For commercial radiopharmacy licensees whose contamination incidents did not involve radioactive materials with half-lives exceeding 120 days and whose sealed sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where radioactive material was used or stored.

Response from Applicant: No response is needed from most applicants. If a DFP or FA is required, submit the documentation required under 10 CFR 30.35 and 10 CFR 40.36, as appropriate.

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

8.6 Item 6: Purposes For Which Licensed Material Will Be Used

The distribution of radioactive materials by commercial radiopharmacies is authorized by several distinct regulations. The appropriate regulation to refer to depends on the nature of the material, the purpose(s) for which it will be used, and to whom it is sent. See narrative description below and the Discussion in Section 8.6.1.

Description of Commercial Radiopharmacy Activities and Applicable Requirements	
Activities	**Authorized By**
Possession and Use of Byproduct Material	10 CFR 30.33
Provide Leak Test, Instrument Calibration, or Other Services to Other Licensees	License Condition
Transfer of Radiochemicals and Radioactive Drugs to Veterinarians, Laboratories, and Other Radiopharmacies	10 CFR 30.41
Transfer of Radiochemicals to Medical Use Licensees Authorized Under 10 CFR Part 35	
Manufacture, Prepare, and Transfer Radioactive Drugs to Medical Use Licensees Authorized Under 10 CFR Part 35	10 CFR 32.72
Distribute Sealed Sources or Devices to Medical Use Licensees Authorized Under 10 CFR Part 35	10 CFR 32.74
Distribute Byproduct Material for In Vitro Clinical or Laboratory Testing under a 10 CFR 31.11 General License	10 CFR 32.71
Manufacture, Prepare, or Transfer for Commercial Distribution Carbon-14 Urea Capsules for *in vivo* Human Diagnostic Use to Persons Exempt from Licensing under 10 CFR 30.21	10 CFR 32.21
Receive Commercial Radiopharmacy-Originated Radioactive Waste from Customers	License Condition

Applicants who are requesting authorization for the possession of sealed sources or devices containing sealed sources should note that an application for a license will be approved if the proposed activity is authorized by the Atomic Energy Act of 1954, as amended, and devices will be used only for the purposes for which they were designed and according to the manufacturer's and distributor's recommendations for use, as specified in an approved SSD registration certificate, unless otherwise authorized in the license.

8.6.1 Distribution and Redistribution of Sealed and Unsealed Materials

Regulations: 10 CFR 30.41, 10 CFR 32.71, 10 CFR 32.72, 10 CFR 32.74, 10 CFR 40.51

Criteria: The applicant must specify the radioactive material it intends to distribute and redistribute.

Discussion: Radiochemicals are those materials that either require further manipulation to be suitable for human use or are not intended for human use. Examples include raw materials received from a supplier (chemical grade materials). Radioactive drugs are those materials suitable for human use and include radiobiologics (e.g., monoclonal antibodies and Tc-99m-tagged red blood cells) and radiopharmaceuticals. However, the terms

"radiopharmaceutical" and "radioactive drug" will be used interchangeably in this guidance document, and reference to one is not meant to exclude the other.

In licensing, distribution activities are normally classified as either "distribution" or "redistribution." "Distribution" applies to the transfer of those radioactive drugs and radiochemicals initially prepared by the commercial radiopharmacy. "Redistribution" refers to the transfer of those materials received from another person authorized pursuant to either 10 CFR 32.71, "Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license;" 10 CFR 32.72, "Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35;" or 10 CFR 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," depending on the product distributed (i.e., *in vitro* kits, other radiopharmaceuticals, or sealed sources for medical use, respectively).

The distribution of radioactive materials to other persons requires specific approval from the NRC, either by NRC regulation or by a license authorizing the activity. The initial distribution of radioactive drugs for medical use must be performed by a person licensed pursuant to 10 CFR 32.72. The redistribution of *in vitro* kits and sealed sources containing byproduct material for medical use is authorized pursuant to 10 CFR 32.71 and 10 CFR 32.74, respectively, provided that the materials are not repackaged and the labels are not altered. The *in vitro* kits and sealed sources for medical use intended for redistribution must be initially distributed by a person licensed pursuant to 10 CFR 32.71 or 10 CFR 32.74, respectively. The transfer of radioactive materials including radiochemicals, and sealed calibration and reference sources, is authorized pursuant to 10 CFR 30.41, "Transfer of byproduct material."

All radioactive material listed above shall be distributed only to persons authorized by an NRC or Agreement State license to receive such materials, or by a general license (10 CFR 31.11, or equivalent Agreement State regulation) to receive *in vitro* test materials.

Initial distribution of unsealed byproduct material in the form of radiopharmaceuticals intended for human diagnostic and therapeutic use by medical licensees comprises the bulk of commercial radiopharmacy activities. Before the transfer, distribution, or redistribution of any licensed material, the commercial radiopharmacy must verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. Five methods that can be used to meet the license verification requirement are listed in 10 CFR 30.41(d). The commercial radiopharmacy shall verify that the address to which radioactive materials are delivered is an authorized location of use listed on the customer's license. Radiopharmacies that plan to transfer, distribute, or redistribute licensed material to a mobile medical licensee's mobile van or coach where there is no permanent structure for byproduct material storage should describe procedures to ensure that licensed material is securely and safely provided to the mobile medical licensee.

Response From Applicant:

For all transferred, distributed, and redistributed sealed and unsealed materials:

- Provide a statement that, "We have developed and will implement and maintain written procedures to meet the license verification requirements specified in 10 CFR 30.41(d)."

AND

- Describe procedures to ensure that sealed and unsealed materials are securely and safely provided to mobile medical licensees if they are transferred, distributed, or redistributed to a mobile medical licensee's mobile van or coach where there is no permanent structure for byproduct material storage. For example, procedures should ensure that delivery directly to the van or coach will only occur if the van or coach is occupied by mobile medical licensee personnel at the time of delivery.

AND

Provide the following, as applicable:

For radiopharmaceuticals:

- Confirm that radiopharmaceuticals will be prepared under the supervision of an authorized nuclear pharmacist (ANP) or will be obtained from a supplier authorized pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements.

- Describe all licensed material to be distributed or redistributed.

For generators:

- Confirm that the generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements.

- Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

For redistribution of used generators:

- Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.

- Confirm that the manufacturer's packaging and labeling will not be altered.

- Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.

- Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.

- Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

***Note**:* Although redistribution of used generators may be authorized by the NRC, NRC approval does not relieve the licensee from complying with applicable U.S. Food and Drug Administration (FDA) or other Federal and State requirements.

For redistribution of sealed sources for brachytherapy or diagnosis:

- Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74, or under equivalent Agreement State requirements.

- Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of calibration and reference sealed sources:

- Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements, to initially distribute such sources.

- Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of prepackaged units for *in vitro* tests:

- Confirm that the prepackaged units for *in vitro* tests to be redistributed will be obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to 10 CFR 32.71, or under an equivalent license of an Agreement State.

For redistribution of prepackaged units for in vitro tests to general licensees (10 CFR 32.71):

- Confirm that the manufacturer's packaging and labeling of the prepackaged units for *in vitro* tests will not be altered in any way.

- Confirm that each redistributed prepackaged unit for *in vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

For redistribution of prepackaged units for *in vitro* tests to specific licensees:

- Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for *in vitro* tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11).

- Confirm that the labeling on redistributed prepackaged units for *in vitro* tests will conform to the requirements of 10 CFR 20.1901, "Caution signs," and 20.1904, "Labeling containers."

For redistribution of discrete sources of Ra-226:

- Confirm that the discrete sources of Ra-226 will be obtained by a manufacturer authorized to distribute it.

- Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing sources.

***Note**:* If the above cannot be confirmed, contact the appropriate NRC regional office for assistance.

8.6.2 Preparation of Radiopharmaceuticals

Regulation: 10 CFR 32.72(b)

Criteria: The preparation of radiopharmaceuticals for commercial distribution to medical users requires specific authorization.

Discussion: The bulk of commercial radiopharmacy activities involve the preparation of radiopharmaceuticals for commercial distribution to medical users.

Response from Applicant: Indicate the types of radiopharmaceutical preparation activities the applicant intends to perform (e.g., compounding of I-131 capsules, radioiodination, chemical synthesis of PET radiopharmaceuticals, and Tc-99m kit preparation).

8.6.3 Sealed Sources for Calibration and Checks and Possession of Discrete Sources of Radium-226 and Depleted Uranium

Regulations: 10 CFR 30.32(g), 10 CFR 30.33, 10 CFR 32.210

Criteria: The applicant must specify the uses for discrete sources of Ra-226, sealed sources for reference and calibration, and DU for shielding.

Discussion: The applicant should describe the intended use of discrete sources of Ra-226 and sealed sources. This will normally be for calibration and checks performed only on the applicant's instruments and equipment. Any sources intended for use in a specific instrument calibration device should be identified, along with the manufacturer and model number of the device. The use of DU for shielding (e.g., incorporated into Mo-99/Tc-99m generators) should also be specified, if applicable.

Response from Applicant: Supply specific information concerning the use of discrete sources of Ra-226, sealed sources for reference and calibration, and DU for shielding.

8.6.4 Service Activities

Regulation: 10 CFR 30.33(a)(1)

Criteria: The applicant must specify the radiation protection services it intends to provide to other licensees (e.g., customers), if the service involves the applicant's possession of licensed material (e.g., calibration sources and leak test samples).

Discussion: If the applicant intends to provide radiation protection services to customers, the services must be described. Typically these services include instrument calibration, sealed source leak testing, or other specified services. Specific guidance regarding requests to provide service activities is included in NUREG–1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

Response from Applicant: Specify the customer radiation protection services involving licensed material that will be provided and include the information described in NUREG–1556, Volume 18, as applicable.

Note: Examples of customer radiation protection services that may be provided include sealed source leak testing, instrument calibration, or other specified services.

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

Regulations: 10 CFR 30.33(a)(3), 10 CFR 32.72(b), 10 CFR 35.55, 10 CFR 40.32(b)

Criteria: The RSO, Authorized Users (AUs), and Authorized Nuclear Pharmacists (ANPs) must have adequate training and experience.

Discussion: Individuals responsible for the Radiation Protection Program are licensee senior management, the RSO, ANPs, and AUs. NRC regulations require that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Specific criteria are given in 10 CFR 35.55 and 10 CFR 32.72(b) for acceptable training and experience for ANPs. The minimum training and experience criteria for RSOs and AUs, although not specifically described in the NRC's regulations for commercial radiopharmacy licensees, should include a Bachelor's degree in a physical science, or equivalent, and previous experience handling and supervising similar activities. Applicants should note that a résumé or curriculum vitae does not usually supply all the information needed to evaluate an individual's training and experience.

The licensee is responsible for its Radiation Protection Program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Senior management should delegate to the RSO, in writing, 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 radioactive material. The licensee maintains the ultimate responsibility, nevertheless, for the conduct of licensed activities.

Response from Applicant: Applicants should submit an organizational chart describing the management structure, reporting paths, and the 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

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

Criteria: The RSO must have adequate training and experience.

Discussion: The person responsible for the radiation protection program is the RSO. The RSO is the key to overseeing and ensuring safe and secure 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 to be unsafe. He or she should have sufficient time, support, and commitment from management to fulfill his or her duties and responsibilities to ensure that radioactive materials are used in a safe manner, approved radiation safety procedures are being implemented, and the required records of licensed activities are maintained. Typical duties and responsibilities of a commercial radiopharmacy RSO are included in Appendix D of this NUREG. The NRC adds the name of the RSO on the license, as provided by the applicant or licensee, to ensure that the licensee management always has a responsible, qualified person identified and that the named individual knows of his or her designation as RSO.

The RSO needs a level of basic technical knowledge sufficient to understand the work to be performed with byproduct materials at the commercial radiopharmacy and to be qualified by training and experience to perform the duties required for that position. Any individual who has sufficient training and experience to be named as an ANP is also considered qualified to serve as the facility RSO. The same is true for an AU who has had adequate training and experience in the radiation safety aspects associated with the use of similar types of byproduct material.

The training and experience requirements for the RSO may be met by any of the following:

- qualification as an ANP
- identification as an AU on the license and experience in the use of the types and quantities of licensed material for which the individual has RSO responsibilities
- didactic training and work experience

In order to demonstrate adequate training and experience, the RSO should have (i) at a minimum, a college degree at the Bachelor level or equivalent training and experience in physical, chemical, or biological sciences, or engineering; and (ii) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities

- radiation detection and measurement instrumentation

- biological hazards of exposure to radiation (appropriate to types and forms of byproduct material to be used)

- NRC regulatory requirements and standards commensurate with the uses proposed by the applicant

- hands-on use of radioactive materials commensurate with the uses proposed by the applicant

The length of training and experience will depend upon the type, form, quantity, and proposed use of the licensed material requested. The proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. The requisite training may be obtained from online and formal courses consisting of lectures and laboratories designed for RSOs presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

Classroom training normally does not include on-the-job training (OJT), since OJT may not include all topics of a formal training course. Supervised OJT may be used to document hands-on training components. A "formal" training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to the NRC upon request.

- A detailed description of how the sponsoring institution examined the student's knowledge of the course content (e.g., include a final grade or percentile), which is maintained on file at the institution and can be made available to NRC upon request; and

- A permanent record that the student successfully completed the course is kept at the institution.

The qualifications described above only apply to an RSO for a commercial radiopharmacy that prepares radioactive drugs or redistributes other products. NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator" provides training and experience guidance for individuals that will be RSOs at radionuclide production facilities.

Response from Applicant: Provide the following:

- name of the proposed RSO

AND

- a copy of the license (NRC or Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, ANP, or AU

OR

- description of the training and experience demonstrating that the proposed RSO is qualified by training and experience applicable to commercial nuclear pharmacies

Note: See Tables C–1 and C–2 in Appendix C of this NUREG for convenient formats to use for documenting hours of training in basic radionuclide handling techniques and hours of experience using radionuclides.

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

8.7.2 Authorized Nuclear Pharmacist (ANP)

Regulations: 10 CFR 32.72 (b)(2), (4), and (5); 10 CFR 35.2; 10 CFR 35.55(a) and (b); 10 CFR 35.59

Criteria: The ANP must be a State-licensed or State-registered pharmacist with adequate training and experience.

Discussion: Each commercial radiopharmacy must have an ANP to prepare or supervise the preparation of radioactive drugs for medical use. An individual who is not qualified to be an ANP may work under the supervision of an ANP.

The requisite training may be obtained from online and formal courses consisting of lectures and laboratories designed for ANPs presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. The criteria for a pharmacist to work as an ANP at a commercial radiopharmacy are described in 10 CFR 32.72(b)(2) and (4). This section of the regulation essentially provides the training requirements for an ANP. Individuals can meet the ANP training requirements in two ways: the board certification pathway or the alternate pathway. The board certification pathway is provided in 10 CFR 35.55(a) and specified in the definition of ANP in 10 CFR 35.2. The alternate pathway is described in 10 CFR 35.55(b). All ANPs, no matter the pathway they use to meet the training requirements, must also meet the recentness of training criteria in 10 CFR 35.59, “Recentness of training,” which requires the successful completion of training within 7 years preceding the date of the application. Additional training and experience may be necessary if the time interval is greater than 7 years.

The applicant must document that the nuclear pharmacist meets the criteria in 10 CFR 32.72(b). Applicants may find it convenient to present documentation of the ANP’s training using NRC Form 313A (ANP) in Appendix C of this NUREG. Each hour of training may be listed only once and under the most applicable category.

Classroom training normally does not include OJT, since OJT may not include all topics of a formal training course. Supervised OJT may be used to document hands-on training components. A “formal” training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to the NRC upon request.

- A detailed description of how the sponsoring institution examined the student’s knowledge of the course content (e.g., include a final grade or percentile) which is maintained on file at the institution and can be made available to NRC upon request; and

- A permanent record that the student successfully completed the course is kept at the institution.

Response from Applicant: For each proposed ANP, provide the following:

- name of the proposed ANP

AND

- pharmacist's license number and issuing entity

AND

For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial radiopharmacy that has been authorized to identify ANPs [10 CFR 32.72(b)(2)(i)]:

- previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Material License broad scope permittee on which the individual was named as an ANP or a copy of an authorization as an ANP from a commercial radiopharmacy that has been authorized to identify ANPs

OR

For an individual qualifying under 10 CFR 32.72(b)(4):

- documentation that the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material

AND

- documentation that the individual practiced at a pharmacy at a Government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC

OR

For an individual qualifying under 10 CFR 35.55(a):

- copy of the certification(s) of the specialty board whose certification process has been recognized[1] under 10 CFR 35.55(a) **(Written attestation, signed by a preceptor ANP, <u>is not required</u>)**

AND

[1]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web page at https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.

- if applicable, description of recent related continuing education and experience as required by 10 CFR 35.59

For an individual qualifying under 10 CFR 32.72(b)(2)(ii):

- description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience

AND

- written attestation, signed by a preceptor ANP, that the individual has satisfactorily completed the requirements in 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an ANP

AND

- if applicable, description of recent related continuing education and experience as required by 10 CFR 35.59

***Notes**:*

- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.55(a) or (b). NRC Form 313A (ANP) is provided in Appendix C of this NUREG.

- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR 32.72(b)(2) are met. If the training and experience do not appear to meet these criteria, the NRC may request additional information from the applicant or may request the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) in evaluating such training and experience.

8.7.3 Authorized Users (AU)

Regulation: 10 CFR 30.33(a)(3), 10 CFR 40.32

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

Discussion: If the applicant intends to perform functions other than the preparation and distribution of radioactive drugs, the applicant may request that an individual other than an ANP perform and/or supervise those functions. This individual, if approved, would be designated on the license as an AU. These other functions may include leak testing of sealed sources, instrument calibration services for the commercial radiopharmacy and its customers, or serving as the radiopharmacy RSO. However, the term Authorized User, as used in this document, should not be confused with the definition of an "Authorized User" contained in 10 CFR 35.2 for medical use.

In order to demonstrate adequate training and experience, the proposed AU should have:
(1) at a minimum, a college degree at the bachelor level, or equivalent training and experience

in physical, chemical, or biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

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

The length of training and experience listed above will depend upon the type, form, quantity, and proposed use of the licensed material requested. The proposed AU's training and experience should be sufficient to identify and control the anticipated radiation hazards. The above training may be obtained from online and formal radiation safety courses consisting of lectures and laboratories presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

Classroom training normally does not include OJT, since OJT may not include all topics of a formal training course. Supervised OJT may be used to document hands-on training components. A "formal" training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to the NRC upon request.
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to the NRC upon request. The evidence of the student's overall competency in the course material should include a final grade or percentile.
- A permanent record that the student successfully completed the course is kept at the institution.
- The AU must demonstrate training and experience with the type and quantity of material that is to be used at the commercial radiopharmacy. For example, someone with training and experience limited to gamma-emitters may not be qualified to use or supervise the use of high-energy beta emitters.

Note that for applicants that produce radioactive material using an accelerator, the individual who handles byproduct materials during the maintenance and repair of an accelerator or other related equipment should also be considered an AU. However, training and experience

documentation for these individuals should be submitted with the license application for radionuclide production as specified in NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator."

Response from Applicant: For each proposed AU, provide the following:

- name of the proposed AU

AND

- types, quantities, and proposed uses of licensed material

AND

- a copy of the license (NRC or Agreement State) on which the individual was specifically named as an AU for the types, quantities, and proposed uses of licensed materials

OR

- a copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials

OR

- a description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed materials.

***Note**:* The applicant may find it convenient to describe this training and experience using a format similar to Table C–1 and C–2 in Appendix C of this NUREG.

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

8.8.1 Occupationally Exposed Workers and Ancillary Personnel

Regulations: 10 CFR 19.12, 10 CFR 20.1101(a), 10 CFR 30.33(a)(3), 10 CFR 37.43, 10 CFR 40.32(b)

Criteria: 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, in the course of employment, are likely to receive in a year an occupational dose in excess of 100 millirem (mrem) [1 mSv] must be instructed according to 10 CFR 19.12, "Instruction to workers." Any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material (as defined in 10 CFR 37.5) must implement a training program for those individuals implementing the security program.

Discussion: Under 10 CFR 20.1101(a), each licensee is required to develop, document, and implement a Radiation Protection Program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with 10 CFR Part 20. Each individual working with

radioactive material must be trained in the radiation safety procedures applicable to his or her job before beginning work with licensed materials. Licensees should not assume that safety instruction has been adequately covered by prior employment or training. Practical, site-specific training should be provided for all individuals before beginning work with, or in the vicinity of, licensed material. Training should also be performed whenever there is a significant change in duties, procedures, regulations, or terms of the license. Each individual should also receive periodic refresher training at least annually to ensure that all staff remain adequately trained.

Additional training is required if an individual is likely to receive a dose in excess of 100 millirem (mrem) [1 mSv] in a year. ANPs and others involved in the preparation of radiopharmaceuticals are most likely to receive doses in excess of 100 millirem (mrem) [1 mSv] in a year; however, potential radiation doses received by all employees must also be evaluated. The evaluation must include consideration of assigned activities during both normal and abnormal situations involving exposure to radiation and radioactive material that can reasonably be expected to occur during licensed activities.

If individuals making deliveries of radioactive material at the licensee's facility are likely to receive a dose in excess of 100 millirem (mrem) [1 mSv] in a year from the licensee's activities, the licensee is responsible for ensuring that the person has received the training specified in 10 CFR Part 19 regardless of whether that person is an employee of the licensee. If the training has been provided by someone else (such as the shipper or another licensee), the licensee does not have to provide training except for instruction in site-specific radiation hazards. This issue is discussed in NRC Generic Letter 95-09, "Monitoring and Training of Shippers and Carriers of Radioactive Materials," dated November 3, 1995.

Training may be in the form of lectures, demonstrations, video presentations, and self-study, and should emphasize practical subjects important to the safe use of licensed material. A method for asking questions should be provided for individuals receiving instructions and training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual (e.g., RSO, ANP, AU, or radiation safety professional familiar with the licensee's program).

Licensee personnel who work in the vicinity of, but do not handle radioactive materials (ancillary staff), are not required to have radiation safety training as long as they are not likely to receive 100 millirem (mrem) [1 mSv] in a year; however, to minimize potential radiation exposure when ancillary staff are working in the vicinity of radioactive material, it is prudent for them to work under the supervision and in the physical presence of an ANP/AU or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the radioactive material and the meaning of the radiation symbol, and should be instructed not to handle radioactive material and to keep away from it as much as their work permits.

Some ancillary staff, although not likely to receive doses over 100 millirem (mrem) [1 mSv], should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their assignments in the vicinity of the radioactive material to ensure the control and security of the material.

The guidance in Appendix J of this NUREG, "Model Personnel Training Program," may be used by the applicant to develop a training program.

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

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

Response from Applicant: Provide a statement that, "We have developed and will implement and maintain written procedures for a training program for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."

Reference: NRC Generic Letter 95-09, "Monitoring and Training of Shippers and Carriers of Radioactive Materials," dated November 3, 1995.

8.8.2 Personnel Involved in Hazardous Materials Package Preparation and Transport

Regulation: 49 CFR 172.700, 49 CFR 172.702, 49 CFR 172.704

Criteria: Applicants must train personnel involved in the preparation and transport of hazardous material packages in accordance with the applicable DOT regulations.

Discussion: Licensees who prepare packages of radioactive materials or who transport their own packages must provide training to their employees who perform those functions. The training must include

- general awareness and familiarization training designed to provide familiarity with DOT regulations to ensure that the employees recognize and identify hazardous materials

- function-specific training concerning the DOT regulations that are specifically applicable to the functions the employee performs (e.g., if the employee's duties require affixing DOT radioactive labels to packages, the employee must receive training in DOT's regulations governing package labeling)

- safety training concerning emergency response information; measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed in the workplace; and methods and procedures

for avoiding accidents, such as the proper procedures for handling packages containing hazardous materials

- security awareness training: training regarding awareness of security risks associated with hazardous materials transportation and methods designed to enhance transportation security

The training must be provided initially and at least once every 3 years thereafter. Records of training must be maintained.

***Note**:* The licensee is not responsible for providing DOT-required hazardous materials training to common carriers to which the commercial radiopharmacy offers radioactive materials packages for transport.

Response from Applicant: Submit the following statement: "We have developed and will implement and maintain records and written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704, as applicable."

8.8.3 Instruction for Supervised Individuals Preparing Radiopharmaceuticals

Regulations: 10 CFR 19.12, 10 CFR 30.33(a)(3), 32.72(b)(1), 10 CFR 35.27(b)

Criteria: Individuals who prepare byproduct material for medical use under the supervision of an ANP must be instructed in the preparation of byproduct material for medical use, the principles of radiation safety, and the licensee's procedures for the use of byproduct material; must follow the instructions given; and have their work, and records kept to reflect their work, periodically reviewed by the supervising ANP.

Discussion: The applicant must instruct supervised individuals in the preparation of byproduct material for medical use and require those individuals to follow their instructions, the written Radiation Protection Program, license conditions, and NRC regulations. The supervising ANP must review the work of supervised individuals in the preparation of byproduct material for medical use and should keep the records to reflect that work. If an ANP is always physically present when radioactive drugs are prepared, supervision may be fulfilled by the day-to-day instruction and review of the supervised individual by the ANP.

An ANP is considered to be supervising the use of radioactive materials when directing personnel in the conduct of operations involving licensed materials. The ANP need not be present at all times during the use of such materials; however, the supervising ANP is responsible for ensuring that personnel under supervision have been properly trained and instructed. The supervising ANP is, therefore, responsible for the supervision of operations involving the use of radioactive materials, whether or not he or she is present.

The NRC regulations do not relieve the licensee from complying with applicable U.S. Department of Health and Human Services, FDA, or other Federal and State requirements governing radioactive drugs. From an NRC perspective, if the supervision requirements are met, it is permissible for the licensee to allow the supervised individual to prepare radiopharmaceuticals without the presence of the ANP; however, some States require that a pharmacist be physically present during the preparation and dispensing of pharmaceuticals,

including radioactive drugs. It is the licensee's responsibility to ensure that its practices comply with any additional State requirements concerning this issue.

Response from Applicant: No response from the applicant is necessary. Supervision will be reviewed during inspection.

8.9 Item 9: Facilities and Equipment

8.9.1 Facilities and Equipment for Radiopharmacies

Regulations: 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1406, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.33(a)(2), 10 CFR 30.35(g), 10 CFR 32.72(a)(2), 10 CFR 37.5, 10 CFR 37.49, 10 CFR 37.53, 10 CFR 40.32(c)

Criteria: A commercial radiopharmacy must demonstrate that it is a commercial radiopharmacy. Facilities and equipment must be adequate to protect health and minimize danger to life or property, minimize the likelihood of contamination and keep exposures to workers and the public ALARA. Facilities and equipment must also provide enhanced physical protection of aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5. In addition, licensed materials must be secured from unauthorized access and removal.

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

- implement the physical protection requirements in 10 CFR Part 37 for material in use and storage, at permanent jobsites; and
- in accordance with 10 CFR 37.49, be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones, including those surrounding mobile devices, and immediately detect any unauthorized removal of Category 1 quantities of radioactive material from the security zone. (Monitoring and detection systems may include, among other methods, monitored video surveillance systems and electronic devices for intrusion detection alarms.)
- for mobile devices containing Category 1 or Category 2 quantities of radioactive material, have two independent physical controls to secure the material from unauthorized removal when the device is not under direct control and constant surveillance in accordance with 10 CFR 37.53. "Mobile device" is defined in 10 CFR 37.5.

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

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

Discussion: An applicant must demonstrate that it is a pharmacy by submitting evidence of at least one of the following:

- licensure as a pharmacy by a State Board of Pharmacy, or
- operation as a nuclear pharmacy within a Federal medical institution

If the registration or license has not been issued by the State Board of Pharmacy at the time of application, the applicant may provide it at a later date, but before license issuance from the NRC.

Applicants must provide the NRC with documentation demonstrating that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees. The facilities and equipment must also keep exposures to radiation and radioactive materials ALARA and minimize the risks from the uses of the types and quantities of radioactive materials. The applicant should provide clear delineations between its restricted and unrestricted areas through the use of barriers, postings, and worker instructions.

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

It is important to note that applicants who plan to amend their license to add the use and distribution of high-energy gamma-/photon-emitting radionuclides, such as PET radionuclides, to their operations should ensure their facilities and equipment are adequate to handle the higher energy radiation. Most likely, applicants will need to add and/or replace shielding, modify ventilation and air filtration systems, and possibly modify the facility's design to accommodate the higher energy radionuclides.

Applicants are reminded that records important to decommissioning must be maintained in an identifiable location. For further information, see Section 8.5.2, "Financial Assurance And Recordkeeping For Decommissioning."

Response from Applicant: Provide the following:

- Copies of their registration or license from a State Board of Pharmacy as a licensed pharmacy, or evidence that the facility is operating as a nuclear pharmacy within a Federal medical institution.

***Note**:* If the applicant's particular activities are not recognized as the practice of commercial radiopharmacy, the applicant must submit evidence that it is registered or licensed with the State or FDA as a drug manufacturer. Refer to NUREG–1556, Volume 12, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution" for guidance on drug manufacturer requirements.

AND

- A description of the facilities and equipment at each location where radioactive material will be used, which includes the method and shielding used to physically transfer

licensed material (e.g., transfer lines) to the different processes (e.g., chemical synthesis, dispensing).

***Note**:* Diagram(s) should be submitted showing the applicant's entire facility and identifying activities conducted in all contiguous areas surrounding the facility (see Figure 8-2). Diagrams should be drawn to a specified scale, or dimensions that are indicated.

AND

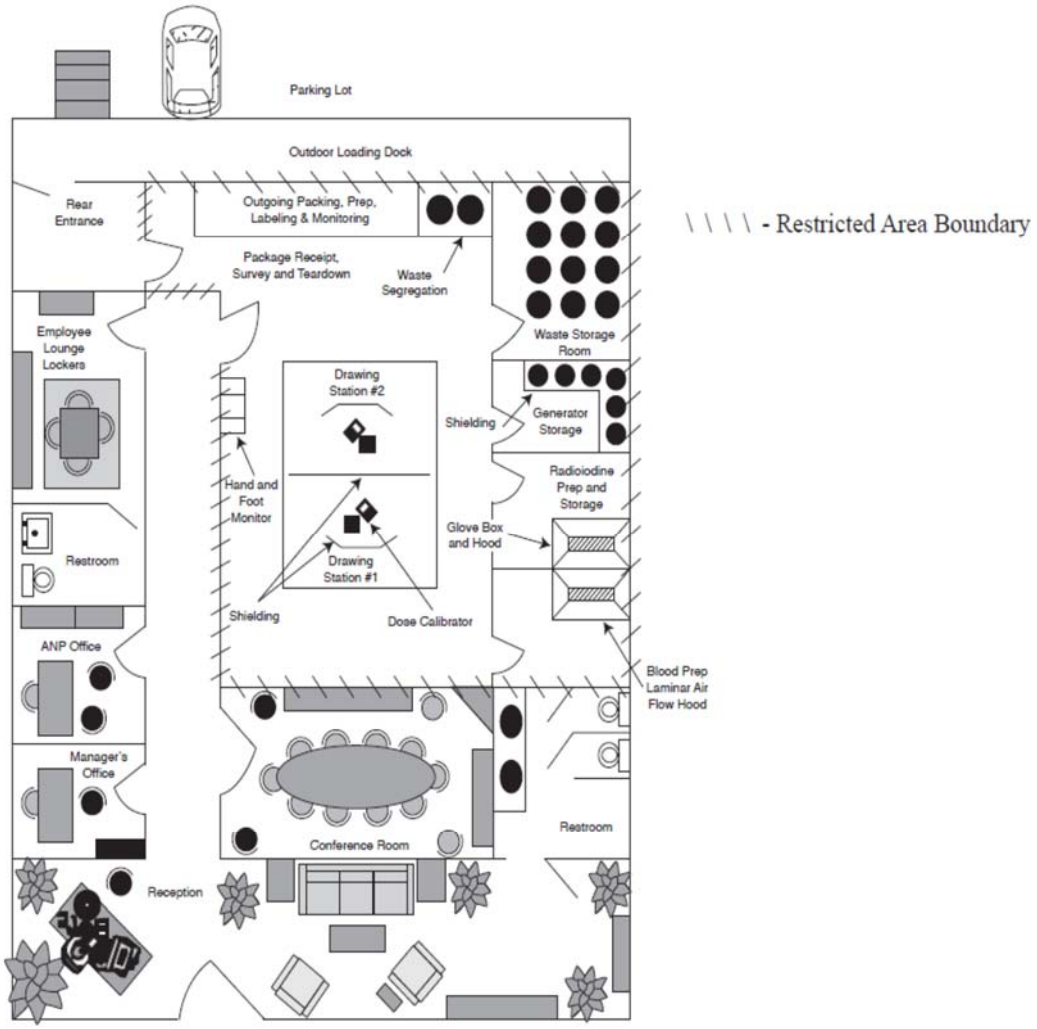
- The diagram(s) should also include: (1) descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials and the location(s) for radioactive waste storage; (2) sufficient detail in the diagram to indicate locations of shielding, the shielding thickness, and the materials used for shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety; (3) a general description of any ventilation system that is used when handling radionuclides, including representative equipment such as glove boxes or fume hoods ; (4) confirmation that such ventilation systems will be employed for the use or storage of radioactive materials likely to become airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions; and (5) 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 established under 10 CFR 20.1101(d).

***Notes**:* Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved.

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

Reference: For further information on facility design, see Chapter 4 of National Council on Radiation Protection and Measurements (NCRP) Report No. 127, "Operational Radiation Safety Program."

SECURITY-RELATED INFORMATION - WITHHOLD UNDER 10 CFR 2.390*



SECURITY-RELATED INFORMATION - WITHHOLD UNDER 10 CFR 2.390*

*For the purposes of this NUREG, this diagram has markings regarding security-related information that are appropriate for an application. This particular diagram is an example only. It is not drawn to scale, does not contain a specified scale or dimensions, and does not contain real security-related information.

Figure 8-2. Typical Commercial Radiopharmacy Diagram

8.9.2 Facilities and Equipment for PET Radiopharmacies

Regulations: 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1406, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.33(a)(2), 10 CFR 30.35(g)

Criteria: PET radiopharmacies must demonstrate that they are registered with a State agency, are licensed as a pharmacy by the State's Board of Pharmacy, or operate as a nuclear pharmacy within a Federal medical institution. Facilities and equipment must be adequate to protect health and minimize danger to life or property, minimize the likelihood of contamination, and keep exposures to workers and the public ALARA.

Discussion: In addition to the information required for a radiopharmacy, PET radiopharmacy applicants should describe the equipment and/or method and shielding used to physically transfer (e.g., transfer lines) PET radiochemicals to the chemical synthesis equipment for radiopharmaceutical manufacturing and then to the dispensing area. The description should also include shielding used for chemical synthesis and/or dispensing radiopharmaceuticals. Also, the type of remote handling equipment used for handling the PET radionuclides and drugs should be described.

PET radiopharmacies should implement proper engineering controls due to the potential for radioactive air effluents produced during the chemical synthesis process. Examples of some engineering controls that should be used include exhaust filtration (e.g., high efficiency particulate air and carbon filters) and/or containment systems for decay of effluents. In addition, a continuous "real-time" effluent (stack) monitor should be installed at the facility. Appendix N of this NUREG provides guidance on effluent monitoring.

Response from Applicant: Provide the following:

- Copies of the registration or license from a State Board of Pharmacy as a pharmacy, or provide evidence that the facility is operating as a nuclear pharmacy within a Federal medical institution.

***Note**:* If the applicant's particular activities are not recognized as the practice of commercial radiopharmacy, the applicant must submit evidence that it is registered or licensed with the State or FDA as a drug manufacturer. Refer to NUREG–1556, Volume 12, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution" for guidance on drug manufacturer requirements.

AND

- Description of the facilities and equipment at each location where radioactive material will be used, which includes the method and shielding used to physically transfer licensed material (e.g., transfer lines) to the different processes (e.g., chemical synthesis, dispensing).

***Note**:* A diagram should be submitted that shows the applicant's entire facility and identifies activities conducted in all contiguous areas surrounding the facility (see Figure 8-3). Diagrams should be drawn to a specified scale, or dimensions that are indicated. Diagrams should include locations of shielding, such as shielding for hot cells and transfer lines.

AND

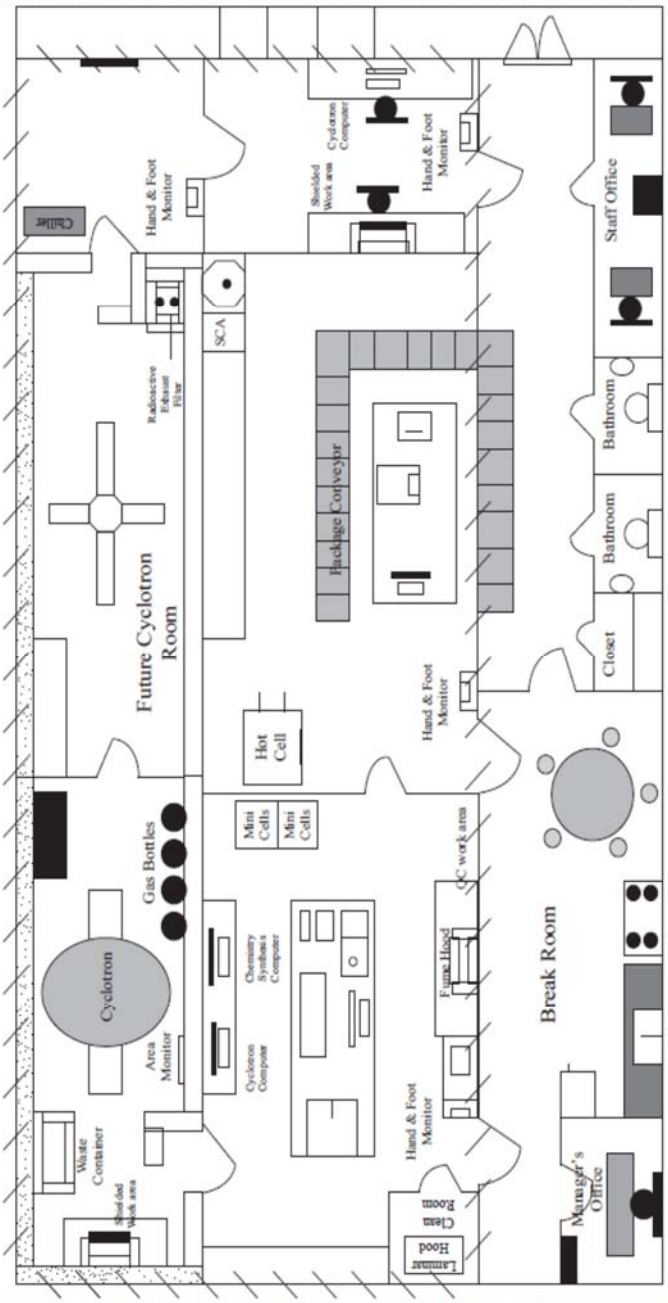
- The diagram(s) should also include: (1) descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials and the location(s) for radioactive waste storage; (2) locations of shielding, the shielding thickness, the materials used for shielding, and the locations of hot cells for positron emitting radionuclides; (3) the proximity of radiation sources to unrestricted areas and other items related to radiation safety such as remote handling equipment and area monitors (4) a general description of any ventilation system that is used when handling radionuclides, including representative equipment, such as glove boxes or fume hoods; (5) confirmation that such ventilation systems will be employed for the use or storage of radioactive material likely to become airborne; and (6) 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 established under 10 CFR 20.1101(d).

***Notes**:* Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved.

Mark drawings, diagrams, and descriptions that provide the exact location of materials or depict specific locations of security equipment as, “Security-Related Information—Withhold under 10 CFR 2.390”

SECURITY-RELATED INFORMATION - WITHHOLD UNDER 10 CFR 2.390*



\ \ \ \ - Restricted Area Boundary

SECURITY-RELATED INFORMATION - WITHHOLD UNDER 10 CFR 2.390*

*For the purposes of this NUREG, this diagram has markings regarding security-related information that are appropriate for an application. This particular diagram is an example only. It is not drawn to scale, does not contain a specified scale or dimensions, and does not contain real security-related information.

Figure 8-3. Typical PET Commercial Radiopharmacy Diagram

8.10 Item 10: Radiation Safety Program

8.10.1 Audit and Review of Program

Regulations: 10 CFR 20.1101, 10 CFR Part 20.2101, 10 CFR 20.2102, 10 CFR 37.33, 10 CFR 37.55

Criteria: Licensees must review the content and implementation of their Radiation Protection Programs annually to ensure the following:

- compliance with NRC and DOT regulations (as applicable) and the terms and conditions of the license
- occupational doses and doses to members of the public are ALARA (10 CFR 20.1101, "Radiation protection programs")
- records of audits and other reviews of program content are maintained for 3 years after the record is made

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

Discussion: Appendix E of this NUREG contains an audit and review of program that is specific to commercial radiopharmacies and is acceptable to the NRC. All areas indicated in Appendix E of this NUREG may not be applicable to every licensee and may not need to be addressed during each audit.

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 and review of the program, licensees should 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 https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The Enforcement Manual may be found online at https://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html. For examples of the NRC's use of discretion in issuing a notice of violation, refer to the most recent version of NRC's enforcement documents at https://www.nrc.gov/reading-rm/doc-collections/enforcement/.

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

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

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

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

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

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

Response from Applicant: No response is required. The licensee's program for auditing its Radiation Safety Program may be reviewed during inspection.

References:

Inspection Procedure (IP) 87127 "Radiopharmacy Programs" July 2008

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

8.10.2 Radiation Monitoring Instruments

Regulations: 10 CFR 20.1101, 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2), 10 CFR 40.32(c)

Criteria: Licensees must possess radiation monitoring instruments for the evaluation, detection, and measurement of possible radiation hazards that may be present. Instruments used for quantitative radiation measurements must be calibrated periodically (e.g., annually) for the radiation measured.

Discussion: Licensees must possess calibrated and operable radiation instruments to detect and measure radiation levels, radioactive contamination, and radioactivity, as applicable. Appropriate instruments must be available for use at all times when byproduct material is in use. The licensee should possess radiation monitoring instruments sufficiently sensitive to measure the type and energy of radiation used. Radiation detection and measurement instruments should be used for radiation protection activities, including:

- package preparation and receipt surveys
- personnel and facility contamination measurements
- sealed source leak tests

- air sampling measurements
- bioassay measurements
- effluent release measurements
- dose rate surveys

For the purposes of this NUREG, radiation monitoring instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some types of 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
- area monitors
- liquid scintillation counter (LSC)
- well-type scintillation counters
- stack monitors
- continuous air monitors
- 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). Radiopharmacies typically use a broad energy range of gamma and beta radiation emitters and need to use radiation detectors appropriate for those energies. Additionally, some radiopharmacies may handle or distribute alpha-emitting radiopharmaceuticals. Applicants should discuss the types of instruments to be used for each type of survey or measurement to be performed and the availability of a sufficient quantity of these instruments at their facility.

Instrument calibrations may be performed by the commercial radiopharmacy or by another person specifically authorized by the NRC or an Agreement State to perform that function. If the applicant wishes to calibrate its instruments, the applicant must develop, implement, and maintain written radiation survey meter calibration procedures to ensure that instruments are properly calibrated. If the applicant chooses to use the services of another person for instrument calibration, the applicant should ensure that person has been authorized by either the NRC or an Agreement State to perform that activity. Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts an authorized firm to perform calibrations, the licensee must retain records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made, in accordance with 10 CFR 20.2103(a). Appendix F of this NUREG, “General Radiation Monitoring Instrument Selection Guidelines and Radiation Instrument Calibration Guidelines,” provides general instrument selection guidelines and instrument calibration guidelines.

Response from Applicant: Provide the following:

- A statement that, “We will use calibrated and operable equipment that is capable of detecting the type(s) of radiation being monitored (e.g., gamma, beta, alpha) and the energy or energy range of the radiation being measured.”

OR

- A description of the calibrated and operable instrumentation that will be used to perform radiation monitoring (e.g., portable or stationary count rate meters, LSCs, well-type scintillation counters, air monitors).

AND

- A statement that, "We reserve the right to upgrade our monitoring instrumentation as necessary, as long as the instruments are adequate to measure the type of radiation and energy range of the radiation for which they are used."

AND

- If calibration is performed by a person or firm outside the applicant's organization, specify that the calibration will be performed by an NRC or Agreement State licensee specifically authorized to perform instrument calibration as a service to other licensees, and state the frequency of the calibrations.

OR

- If the calibration is to be performed in-house, submit the instrument calibration procedure that will be used, and state the frequency of the calibrations. In addition, identify the qualifications of the individuals who will perform the calibrations.

***Note**:* Instrument calibration guidelines are included in Appendix F of this NUREG, and they may be used to assist with development of the instrument calibration procedure.

8.10.3 Material Receipt and Accountability

Regulations: 10 CFR 20.1501(a), 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 20.2001, 10 CFR 20.2201, 10 CFR 20.2207, 10 CFR 30.35(g), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 37.49, 10 CFR 37.71, 10 CFR 37.75, 10 CFR 37.77, 10 CFR 40.36(f), 10 CFR 40.51, 10 CFR 40.61

Criteria: Licensees must ensure the security and accountability of licensed material and must open packages safely. Licensees must also do the following, as applicable:

- develop, maintain, and implement a procedure to account for licensed material
- maintain records of receipt, transfer, and disposal of licensed material
- update transactions in the National Source Tracking System (NSTS), including performing annual inventory reconciliation, if applicable
- before transferring aggregated Category 1 or Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37, use NRC's license verification system to verify that the recipient licensee is authorized to possess the radioactive material
- preplan, coordinate, and provide advance notification of shipment of Category 1 quantities of radioactive material and coordinate shipment of Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37

Discussion: Licensees must track licensed materials from receipt (from another licensee or from its own radionuclide production operations) to disposal in order to ensure accountability at all times; identify when licensed material could be lost, stolen, or misplaced; and ensure that possession limits listed on the license are not exceeded. Licensees exercise control over licensed material accountability by including the following items (as applicable) in their Radiation Protection Program:

- conducting physical inventories at intervals not to exceed 6 months (or some other interval justified by the applicant and approved by the NRC) to account for all sealed sources, in accordance with license condition
- ordering and receiving licensed material
- opening packages
- maintaining material inventory within license possession limits
- transferring material, including distribution
- disposing of material

Licensees are required to develop, implement, and maintain written procedures for safely opening packages in accordance with 10 CFR 20.1906, "Procedures for receiving and opening packages." Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

A model procedure for safely opening packages containing licensed materials is included in Appendix L of this NUREG, "Material Receipt and Accountability."

NRC regulations in 10 CFR 20.1906(b) and (c) state the requirements for monitoring packages containing licensed material. These requirements are described in Table 8-1.

Table 8-1. Package Monitoring Requirements

Package	Contents	Survey Type	Survey Time*
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater Than Type A	Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas or Special Form Greater Than Type A	Contamination and Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less Than Type A	None	None
Labeled (White I, Yellow II, Yellow III)	Not Gas or Special Form Less Than Type A	Contamination	As soon as practicable, but not later than 3 hours after receipt of package
Not Labeled	Licensed Material	None	None

Table 8-1. Package Monitoring Requirements			
Package	**Contents**	**Survey Type**	**Survey Time***
Damaged	Licensed Material	Contamination and Radiation Level	As soon as practicable, but not later than 3 hours after receipt of package
*Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has 3 hours after the beginning of the next work day to perform the required surveys.			

Under 10 CFR 20.1906(d), the licensee is required to immediately notify the final delivery carrier and NRC Operations Center when removable radioactive surface contamination exceeds the limit in 10 CFR 71.87(i); or external radiation levels exceed the limit in 10 CFR 71.47, "External radiation standards for all packages."

For aggregated Category 1 and Category 2 quantities of radioactive material, licensees must, according to 10 CFR 37.49(a)(1), continuously monitor and detect, without delay, all unauthorized entries into security zones. Additionally, for Category 1 quantities of radioactive material, 10 CFR 37.49(a)(3)(i) requires immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. For Category 2 quantities of radioactive material, 10 CFR 37.49(a)(3)(ii) requires weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

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

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

Note: Licensees are required under 10 CFR 20.2207(g) to reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the NSTS. This reconciliation must be conducted during the month of January in each year. Licensees must submit to the NSTS confirmation that the data in NSTS is correct by January 31 of each year.

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

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

Licenses will normally contain specific conditions requiring the licensee to perform inventories and leak tests of sealed sources every 6 months. Because the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program. Sources in storage that are used infrequently may not require leak testing every 6 months; however, the inventory must still be performed at the specified interval.

With regard to unsealed licensed material, licensees use various methods (e.g., computer programs, manual ledgers, log books) to account for receipt, use, transfer, disposal, and radioactive decay. These methods help 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.

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 3 years from the date of the inventory, in accordance with license conditions
Transfer	For 3 years after each transfer unless a specific requirement dictates otherwise
Disposal	Until 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.

Typically, these records contain the following types of information:

- radionuclide and the activity (in units of becquerels or curies) of byproduct material in each sealed source
- manufacturer's or distributor's name, model number, and serial number (if appropriate) of each device containing byproduct material

- location of each sealed source and device

- for inventories, the date of the inventory and name and signature of the individual conducting the inventory

- for materials transferred or disposed of, the date of the transfer or disposal, the name and license number of the recipient, and a description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's or distributor's name and model number, serial number)

Material accountability records typically contain the following information:

- radionuclide and activity (in units of Bq or Ci), and date of measurement of byproduct material

- for each sealed source, manufacturer, model number, location and serial number and as appropriate, manufacturer and model number of device containing the sealed source

- date of the transfer and name and license number of the recipient, and description of the radioactive material (e.g., radionuclide, activity, manufacturer's name and model number, serial number)

- for licensed materials disposed of as waste, the radionuclide, activity, date of disposal, and method of disposal (e.g., decay, sewer)

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

Information about locations where licensed material is used or stored is among the records important to decommissioning and required by 10 CFR 30.35(g) and 10 CFR 40.36(f). Also see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

Response from Applicant: Provide the following statements:

- "We will develop, implement, and maintain written procedures for safely opening packages that meet the requirements in 10 CFR 20.1906."

AND

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

AND

- "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:

  — license possession limits are not exceeded

  — licensed material in storage is secured from unauthorized access or removal

— licensed material not in storage is maintained under constant surveillance and control

— records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

AND

- If applicable, provide that following statement: "We will comply with the NSTS reporting requirement as described in 10 CFR 20.2207."

8.10.4 Occupational Dose

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

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

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

- adults who are likely to receive an annual dose from sources external to the body in excess of any of the following (each evaluated separately):

  — 5 mSv [0.5 rem] deep-dose equivalent (DDE)
  — 15 mSv [1.5 rems] lens (of the eye) dose equivalent
  — 50 mSv [5 rems] shallow-dose equivalent (SDE) to the skin
  — 50 mSv [5 rems] SDE 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] DDE
  — 1.5 mSv [0.15 rem] lens (of the eye) dose equivalent
  — 5 mSv [0.5 rem] SDE to the skin
  — 5 mSv [0.5 rem] SDE to any extremity

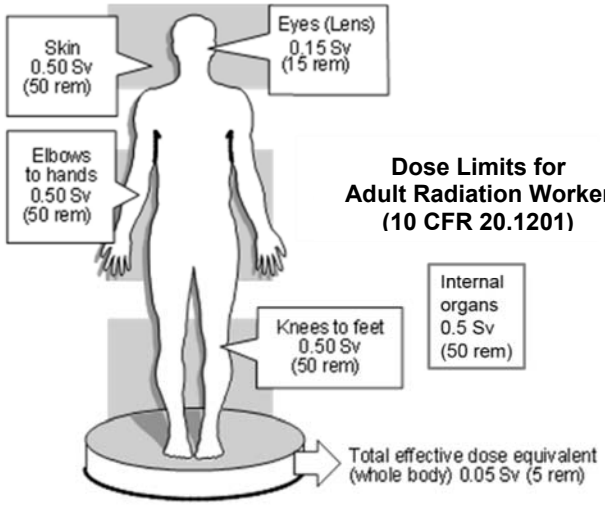
- declared pregnant women who are likely to receive a dose from radiation sources external to the body during the entire pregnancy in excess of 1.0 mSv [0.1 rem] DDE

- 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 a year, an intake in excess of 10 percent of the applicable annual limit on intake for ingestion and inhalation

- minors likely to receive, in a year, a CEDE in excess of 1.0 mSv [0.1 rem] and declared pregnant women likely to receive, during the entire pregnancy, a CEDE in excess of 1 mSv [0.1 rem]



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

Figure 8-4. Annual Dose Limits for Adult Radiation Workers

Discussion: If an adult radiation worker is likely to receive in a year a dose greater than 10 percent of any applicable limit (See Figure 8-4 for annual dose limits), monitoring for occupational exposure is required. Monitoring is required for minors and declared pregnant women as shown in the criteria section. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

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.

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

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

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

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

Table 8-3. Guidance on Personnel Monitoring and Bioassay

Regulatory Guide 8.7, Revision 4	Instructions for Recording and Reporting Occupational Radiation Exposure Data
Regulatory Guide 8.9, Revision 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program
Regulatory Guide 8.20, Revision 2	Applications of Bioassay for Radioiodine
Regulatory Guide 8.21, Revision 1	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
Regulatory Guide 8.25, Revision 1	Air Sampling in the Workplace
Regulatory Guide 8.32	Criteria for Establishing a Tritium Bioassay Program
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Radiation Doses
Regulatory Guide 8.35, Revision 1	Planned Special Exposures
Regulatory Guide 8.36	Radiation Dose to the Embryo/Fetus
ANSI N13.30-2011	Performance Criteria for Radiobioassay
Information Notice 2000-10	Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits

Response from Applicant: Provide one of the following statements:

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

OR

"We will monitor individuals in accordance with the guidance in the section titled, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Vol. 13, Rev. 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."

OR, IN LIEU OF THESE STATEMENTS,

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

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

8.10.5 Public Dose

Regulations: 10 CFR 20.1003, 10 CFR 20.1101(d), 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2107, 10 CFR 20.2203, 10 CFR 20.2205

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

- Ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv [100 mrem] TEDE in a year from licensed activities.
- Ensure that the radiation dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any 1 hour, from licensed activities.
- Ensure that air emissions of radioactive material to the environment, excluding radon-222 and its daughters, will not result in a TEDE in excess of 0.1 mSv [10 mrem] to individual members of the public in a year from those emissions.
- Prevent unauthorized access, removal, or use of licensed material.

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

There are many possible exposure pathways that can contribute to public dose. The three major exposure pathways that can contribute to dose are

(i) Airborne radioactive effluents (e.g., inhalation)
(ii) Liquid radioactive effluents (e.g., ingestion)
(iii) External (direct) radiation exposure (e.g., source)

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 (including direct radiation, liquid effluents, and airborne effluents) arising from licensed activities does not exceed 1.0 mSv [100 mrem] to the maximally exposed member of the public. In addition, the licensee must ensure that the fraction of the public dose limit allocated to airborne emissions is ALARA. This is accomplished by the licensee's control of its air emissions, such that the individual member of the public likely to receive the highest dose will not be expected to receive a TEDE in excess of 0.1 mSv [10 mrem] per year from those emissions. In accordance with 10 CFR 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits," if the dose limits for an individual member of the public are exceeded or if the licensee exceeds the constraint on airborne emissions, the licensee is required to make a report to the NRC and take prompt corrective actions to ensure against recurrence.

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1101(d) and 10 CFR 20.1302(b). The extent and frequency of monitoring will depend upon each licensee's scope and extent of licensed activities. For additional guidance regarding monitoring of effluents, refer to Section 8.10.7, "Surveys."

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 licensed operations does not exceed the annual limit and the dose constraint. See Appendix G of this NUREG for examples of methods to demonstrate compliance.

Response from Applicant: No response is required from the applicant, but records demonstrating compliance will be examined during the inspection.

References:

Regulatory Guide 4.20, Rev. 1, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," April 2012

Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," July 1993

8.10.6 Safe Use of Radionuclides 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 30.34(g), 10 CFR 30.50, 10 CFR 37 (Subpart B), 10 CFR 37.21(a), 10 CFR 37.45, 10 CFR 37.49, 10 CFR 40.60

Criteria: Licensees must do all of the following:

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

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

Discussion: Licensees are responsible for the security and safe use of all licensed material from the time it arrives or is produced at their facility until its use, transfer, or disposal. Licensees should develop written procedures to ensure safe use of licensed material. The procedures should also include operational and administrative guidelines, as well as procedures to ensure that reports of events are complete and made in a timely manner in accordance with reporting requirements. See Appendix P of this NUREG. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers, members of the public, and the environment.

All licensed materials stored in controlled or unrestricted areas must be secured from unauthorized access or removal so that individuals who may not be knowledgeable about radioactive materials cannot be exposed to or contaminated by the material, and so that unauthorized individuals cannot access the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material and prevent unauthorized persons from removing the material from the area.

Licensees should develop procedures that clearly state acceptable methods to secure licensed material at a facility. Particular attention may be required at facilities that have unusual needs because of the activities performed, such as hot cells and waste processing facilities.

General Safety Procedures

The written procedures should include the following elements:

- contamination controls
- waste disposal practices
- personnel and area monitoring (including limits)
- use of protective clothing and equipment
- safe handling of radioactive materials
- recording requirements
- reporting requirements
- responsibilities

These procedures should include policies for:

- frequency of personnel monitoring

- performing Mo-99 breakthrough measurements of each eluate of a Mo-99/Tc-99m generator

- reporting to the NRC and the distributor when there is more than 0.15 kilobecquerel of Mo-99 per megabecquerel of Tc-99m (0.15 microcurie of Mo-99 per millicurie of Tc-99m) in the eluate

- use of personal protective equipment, such as lab coats and frequent glove changes to minimize exposure to the individual and to avoid spread of contamination in the facility

- special procedures for higher risk activities, such as use of radioiodine and repair of chemistry synthesis equipment for PET radiopharmaceuticals

- use of appropriate shielding (see Figure 8-5)

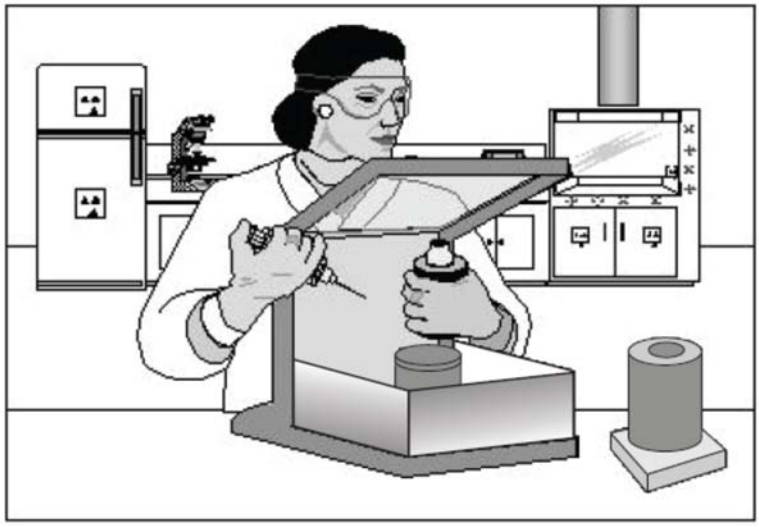


Figure 8-5. Use of Appropriate Shielding in a Fume Hood

Applicants should also develop radionuclide-specific procedures based on the respective hazards associated with the radionuclides. General safety guidelines are described in Appendix M of this NUREG. Applicants should use these guidelines to aid in the development of their own procedures for the safe use of radionuclides.

Furthermore, applicants that produce radioactive materials using an accelerator should also refer to the safety procedures found in NUREG–1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator."

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

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

- in accordance with 10 CFR 37.21(a), establish, implement, and maintain its access authorization program in accordance with the requirements of 10 CFR Part 37, Subpart B;

- in accordance with 10 CFR 37.45, coordinate with their local law enforcement agency (LLEA) for responding to threats to a licensee's facility; and

- in accordance with 10 CFR 37.49, be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones, including those surrounding mobile devices.

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

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

Emergency Procedures

Accidents and emergencies can happen during any operation with radionuclides, including their receipt, transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material and fires involving radioactive material, can adversely affect the safety of personnel and members of the public. Applicants should develop and implement procedures to minimize, to the extent practical, the potential impact of these incidents on personnel, members of the public, and the environment.

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of staff and the RSO. In addition, the licensee should develop procedures for routine contacts with its local fire department officials to inform them of its operations and identify locations of radioactive materials and elevated radiation levels in the event of their response to a fire. Except for minor spills or releases of radioactivity that can be easily controlled and cleaned up by the user, licensee staff should have a clear understanding of their limitations in an emergency with step-by-step instructions and clear direction of whom to contact. The licensee should establish clear delineations between minor contamination events, minor spills, and major spills and events. An example of a minor spill is when low millicurie quantities of material with a short half-life in a nonvolatile liquid spills onto a nonabsorbent surface.

Emergency spill response materials should be strategically placed in well-marked locations for use by all trained staff. All equipment should be periodically inspected for proper operation and replenished as necessary. Appendix M 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.

Certain incidents and emergencies must be reported to the NRC. Appendix P of this NUREG, "NRC Incident Notifications," provides a list of major NRC reporting and notification requirements relevant to commercial radiopharmacies.

Response from Applicant:

The applicant should provide the following statements:

"We have developed and will implement and maintain written procedures for the safe and secure use of radioactive materials that address:

- facility and personnel radioactive contamination minimization, detection, and control
- performing Mo-99 breakthrough measurements on each eluate from a Mo-99/Tc-99m generator
- reporting under the requirements in 10 CFR 30.34(g) if there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of Mo-99 per millicurie of Tc-99m) in the eluate
- performing breakthrough measurements on each eluate of other generators (e.g., Ge-68/Ga-68 generators)
- using protective clothing and equipment by personnel to support meeting the requirements in 10 CFR 20.1101
- securing licensed material during use and storage (10 CFR 20.1801, 10 CFR 20.1802)
- conducting Mo-99/Tc-99m generator Mo-99 breakthrough tests and conducting Sr-82/Rb-82 generator breakthrough tests for Sr-82 and Sr-85 contamination in accordance with 10 CFR 30.34(g) and 10 CFR 35.204
- posting the operating procedures applicable to commercial radiopharmacies (10 CFR 19.11(a)(3)

AND

"We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:

- lost, stolen, or missing licensed material
- exposures to personnel and the public in excess of NRC regulatory limits
- releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits

- excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas

- radioactive spills and contamination

- fires, explosions, and other disasters with the potential for the loss of containment of licensed material

- routine contacts with local fire departments and LLEA to meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203 and 10 CFR 30.50, 10 CFR 37.45, 10 CFR 40.60, and other requirements, as applicable."

8.10.7 Surveys

Regulations: 10 CFR 20.1501, 10 CFR 20.2103, 10 CFR 30.53, 10 CFR 40.63

Criteria: Licensees are required to make surveys of potential radiological hazards in their workplace. Records of survey results must be maintained.

Discussion: Survey is defined as an evaluation of radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation (see Figure 8-6). These evaluations may be measurements (e.g., radiation levels measured with a survey instrument, wipe test removable contamination results), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. Licensees should also use surveys to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public. In certain cases, environmental monitoring may be required to demonstrate compliance with 10 CFR Part 20. In order to meet regulatory requirements for surveying, measurements of radioactivity should be understood in terms of its properties (i.e., alpha, beta, and gamma) and compared to the appropriate limits.

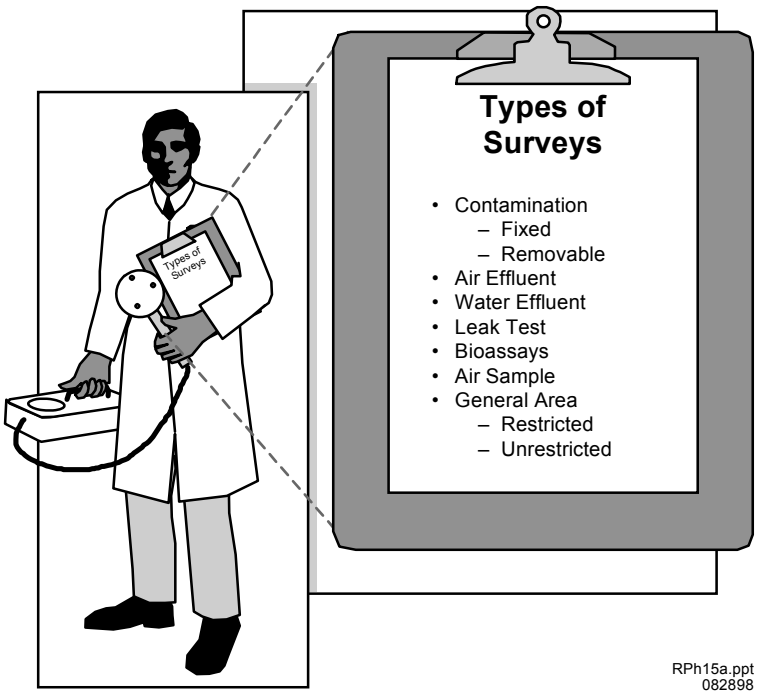


Figure 8-6. Types of Surveys
There are many different types of surveys performed by commercial radiopharmacy licensees.

Radiation surveys are used to detect and evaluate contamination of:

- facilities (restricted and unrestricted areas)
- equipment
- incoming and outgoing radioactive packages
- personnel (during and after use, transfer, or disposal of licensed material) (see Figure 8-7)

Surveying arms and hands using radiation survey meter and beta/gamma probe

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

Figure 8-7. Personnel Surveys
Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the restricted areas within the commercial radiopharmacy.

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 appropriate regulations. Many different types of surveys may need to be performed because of the particular use of licensed materials. Typical surveys may include the following:

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

- measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g., radioiodine) or where licensed material is or could be released to unrestricted areas

- surveys of external radiation exposure levels in both restricted and unrestricted areas [Note: external radiation exposure surveys should be done with the survey instrument probe close to the surface being measured and moved slowly enough to allow the instrument to detect radiation (e.g., probe is a half-inch from the surface and moved 2 inches per second)]

- surveys of radiopharmaceutical packages entering (e.g., from suppliers and returns from customers) and departing (e.g., prepared radiopharmaceuticals for shipment to customers)

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific facilities, equipment, and procedures that are designed to protect workers from external and internal exposure. Also, the frequency of the survey depends

on the type of survey, such as those listed above. Appendix N of this NUREG, "Radiation Survey Guidelines," contains additional radiation survey guidance.

Not all instruments can measure a given type of radiation (e.g., alpha, beta, and gamma) or energy range of a particular radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. The energy of the radiation may not be high enough to penetrate some detector windows and be counted. The correct selection, calibration, and use of radiation detection instruments are important aspects of any Radiation Safety Program.

Regulations in 10 CFR Part 20 specify dose limits for unrestricted areas (2 mrem in any 1 hour) and posting requirements (5 mrem in any 1 hour for "Radiation Areas"). Applicants should propose and justify their removable surface contamination and radiation level action levels that will require action to (i) reduce the contamination or radiation level, or (ii) institute additional restrictions on access to the area.

Undetected Contamination and Loss of Control of Licensed Material

Because of the large quantities of licensed material in unsealed form often handled by commercial radiopharmacy personnel, there can be a greater potential for radioactive material contamination. Radiation surveys, if properly conducted, will normally detect contamination before it leaves the licensee's restricted area (e.g., radiopharmaceutical preparation and packaging areas). If detected within the restricted area during or shortly following radiopharmaceutical preparation, the licensee can normally complete standard decontamination activities to mitigate the spread of the contamination outside the restricted area.

There have been several instances involving NRC licensees, including radiopharmacies, in which contamination has not been detected (usually due to no survey, or an inadequate survey, being performed) and has been inadvertently removed or released from the restricted area. Typically the contamination has been deposited on an outgoing package containing radioactive material, the skin or clothing of a licensee employee leaving the facility, or both. Once the contamination leaves the licensee's restricted area, control of the radioactive material is lost. At this point, the contamination has a high probability of reaching public locations outside the commercial radiopharmacy, including one or more of its customers (e.g., a hospital). Contamination incidents such as this can create public health, regulatory, and public relations problems for licensees. In virtually all cases, the events could have been avoided if licensee personnel had performed an adequate radiation survey to detect the contamination before it left the restricted area. NRC IN 98-18, "Recent Contamination Incidences Resulting From Failure to Perform Adequate Surveys," dated May 13, 1998, describes two examples of commercial radiopharmacies receiving contaminated packages from client facilities. The release of the contaminated packages to the commercial radiopharmacies was the result of the client licensee's failures to conduct adequate and timely surveys of spills of radioactive material at the client facilities.

Response from Applicant: Submit the following statement: "We have developed and will implement and maintain written procedures for a survey program that includes: (1) performance of radiation and contamination level surveys in restricted and unrestricted areas; (2) personnel contamination monitoring; (3) action levels; (4) survey frequencies; and (5) maintenance of survey records that meet the requirements in 10 CFR 20.1501, 10 CFR 20.2103, and 10 CFR 30.53, as applicable."

Reference: NRC IN 98-18, "Recent Contamination Incidences Resulting From Failure to Perform Adequate Surveys," dated May 13, 1998, can be found at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1998/in98018.html.

8.10.8 Dosage Measurement Systems

Regulation: 10 CFR 32.72(c)

Criteria: Commercial radiopharmacy licensees must possess and use instrumentation capable of accurately measuring the radioactivity in radioactive drugs.

Discussion: Because of the potential for commercial radiopharmacy errors to adversely affect their customers (medical facilities) and their customers' patients, each dosage of a radioactive drug must be measured before transfer to provide high confidence that the correct amount of the radioactive drug is transferred, in accordance with the customer's request.

The applicant must have procedures for the use of the instrumentation, including the measurement, by direct measurement or by a combination of measurement and calculation, of the amount of radioactivity in dosages of alpha-, beta-, gamma-, and photon-emitting radioactive drugs before their transfer for commercial distribution.

These procedures must ensure that the dose calibrator, or other dose measurement system, functions properly. This is accomplished by performing periodic checks and tests before first use, followed by checks at specified intervals, and following 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 most photon-emitters, activity measurement is a fairly straightforward determination; however, for low-energy photon emitters, beta-emitters, and alpha-emitters, a correction factor is often necessary to accurately determine the activity. There are inherent technical difficulties to overcome in the determination and application of low-energy photon-, beta-, and alpha-correction factors. These difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a NIST traceable standard for all radionuclides currently in use. If radiopharmacies intend to initially distribute (i.e., measure, prepare, and label) low-energy photon-, beta-, and alpha-emitting radionuclides, the applicant must provide the calculation to demonstrate its ability to accurately dispense such materials. If the applicant intends to use low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer, or other entity, it should include a means for ensuring the accuracy of the supplied factor. If commercial radiopharmacy applicants intend to only redistribute low-energy photon-, beta-, and alpha-emitting radionuclides that have been previously prepared and distributed by other persons licensed pursuant to 10 CFR 32.72, then the correction factor calculation is not required. The inherent technical difficulties in measuring alpha-emitting radionuclides are even greater than those of measuring beta emissions. In the absence of an additional photon, gamma, or beta particle emission that can be measured with traditional instrumentation used in nuclear medicine (e.g., ion chambers) and quantified in relation to the alpha particle emissions, most alpha measuring instruments (e.g., gas proportional counters and liquid scintillation counters) will require preparation and measurement of an aliquot of the unsealed byproduct material. Measurement of aliquots introduces additional uncertainties associated with removing precise and reproducible volumes from homogeneous samples. For example, NRC issued Information Notice (IN) 2016-03, "Revision to the National Institute of Standards and Technology Standard for Radium-223 and Impact on Dose Calibration for the

Medical Use of Radium-223 Dichloride," January 12, 2016, to notify licensees of a new calibration standard in measuring radium-223, which is primarily an alpha-emitter.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. The use of different vials or syringes may result in measurement errors, for example, because of the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

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. As required by 10 CFR 32.72(c)(1), tests for accuracy (for the activities across the range of energies measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and types of containers to be measured) must be done periodically; therefore, the applicant must include the frequency for conducting these tests in its written procedures for the performance of dose measurement system checks and tests.

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 and calibration.

Appendix K of this NUREG, "Dose Calibrator Testing Guidance," contains guidance for dose calibrator testing.

Response from Applicant: The applicant must describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs.

AND

For each dose measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, and photon-emitting 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 32.72(c)."

AND

If applicable, include a sample calculation for determining low-energy photon-, beta-, and alpha-correction factors for dose calibrators with ionization chambers.

AND

Provide the calculations to demonstrate the ability to accurately dispense low-energy photon-, beta-, and alpha-emitting radionuclides for radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) these materials.

***Note**:* Correction factor calculations are not required if radiopharmacy applicants intend to only redistribute low-energy photon-, beta-, or alpha-emitting radionuclides that were previously prepared and distributed by others who are licensed pursuant to 10 CFR 32.72.

OR

If applicable, include a means for ensuring the accuracy of low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer or other entity.

AND

If applicable, include a description of the methodology and equipment to be used for the assay of alpha-emitting radionuclides.

8.10.9 Transportation

Regulations: 10 CFR 20.1101, 10 CFR 30.41, 10 CFR 30.51, 10 CFR Part 37 (Subpart D), 10 CFR 40.51, 10 CFR 40.61, 10 CFR 71.5, 10 CFR 71.12, 10 CFR 71.13, 10 CFR 71.14, 10 CFR 71.17, 10 CFR 71.37, 10 CFR 71.47, 10 CFR 71.87, 10 CFR 71 Subpart H, 49 CFR 171-178

Criteria: Applicants who will prepare for shipment, ship, or transport radioactive materials, including radioactive waste, must develop, implement, and maintain safety programs for the transport of those materials to ensure compliance with NRC and DOT regulations.

In accordance with 10 CFR Part 37 (Subpart D), licensees must also preplan, coordinate and provide advance notification of the shipment of Category 1 quantities of radioactive material and coordinate the shipment of Category 2 quantities of radioactive material.

Discussion: In accordance with a memorandum of understanding between DOT and NRC, the NRC inspects and enforces DOT's regulations governing the transport of radioactive materials by NRC's licensees.

The types and quantities of radioactive materials shipped by a commercial radiopharmacy licensee will nearly always meet the criteria for shipment in a "Type A" package, as defined by DOT. The regulations for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling, and radiation levels and contamination limits. For radiopharmacies that transport their own packages, the packages must be blocked and braced, and shipping papers must be used and located properly in the driver's compartment.

Packaging used by a commercial radiopharmacy typically includes nylon "briefcases" and cardboard/fiberboard boxes. These packages will normally meet the criteria for "Type A" quantities, which must meet specified performance standards to demonstrate that they will maintain the integrity of containment and shielding under normal conditions of transport. Such packages will normally withstand minor accident situations and rough handling conditions.

The testing criteria for Type A packages are listed in 49 CFR 173.465, "Type A packaging tests," and 49 CFR 173.466, "Additional tests for Type A packagings designed for liquids and gases." Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped. In addition, the shipper must maintain records to furnish evidence of the quality of packaging for 3 years after the life of the packaging to which they apply.

The DOT regulations also 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 regulations, 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 (see Section 8.8.2, "Personnel Involved in Hazardous Materials Package Preparation and Transport").

An outline of DOT regulations generally relevant to a commercial radiopharmacy operation is included for applicant and licensee reference in Appendix I of this NUREG.

Import and Export of Commercial Radiopharmaceuticals

If radiopharmaceuticals will be procured from a company outside of the U.S. and imported into the U.S., the shipment must be made in accordance with appropriate DOT transportation regulations. In addition, the NRC licensee must also comply with the requirements applicable to importation of radioactive material containing byproduct material in 10 CFR Part 110, including the general license requirements in 10 CFR 110.27 and the advanced notification requirements for certain radioactive material imports in 10 CFR 110.50(c). Likewise, any exports of radiopharmaceuticals must be in compliance with the requirements pertaining to export of radioactive material containing byproduct material in 10 CFR Part 110, including general export license requirements in 10 CFR 110.23 and the advanced notification requirements for certain radioactive material exports in 10 CFR 110.50(c). Also be aware of the list of embargoed and restricted destinations, as stated in 10 CFR 110.28 and 110.29, and ensure that all exports are made under the appropriate general or specific license authority.

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

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

Response from Applicant: No response is required. The licensee's program for transportation of radioactive materials will be reviewed during inspection.

8.10.10 Minimization of Contamination

Regulation: 10 CFR 20.1406, 10 CFR Part 20 (Subpart K)

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 extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the

site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. Commercial radiopharmacy applicants usually do not need to address these issues as a separate item, because they are included in responses to other items of the application.

The majority of unsealed radioactive materials used by radiopharmacies have short physical half-lives (less than 120 days). Nearly all radioactive waste generated by radiopharmacies is stored for decay rather than transferred to a radioactive waste disposal facility.

The licensee may possess and redistribute sealed sources that contain radionuclides with long half-lives. These sealed sources have been approved by the NRC or an Agreement State and, if used according to the respective SSD registration certificate, usually pose little risk of contamination. Leak tests performed at the frequency specified in the SSD registration certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of in accordance with the disposal requirements in Subpart K of 10 CFR Part 20. In addition, leaking sources must be contained to prevent the spread of contamination and reduce radioactive waste associated with decontamination efforts. For example, a leaking source may be contained by placing it in a plastic bag and sealing the bag closed while implementing actions to prevent contamination spread. The leaking sources must also be transferred to an authorized recipient or disposed of according to NRC requirements.

Response from Applicant: The applicant does not need to provide a response to this item under the following condition: NRC will consider that the criteria have been met if the applicant's responses meet the criteria for the following sections of NUREG–1556, Volume 13: Section 8.9, "Facilities and Equipment;" Section 8.10.6, "Safe Use of Radionuclides and Emergency Procedures;" Section 8.10.7, "Surveys;" Section 8.10.13, "Leak Tests;" and Section 8.11, "Item 11: Waste Management."

8.10.11 Radioactive Drug Labeling for Distribution

Regulations: 10 CFR 20.1901, 10 CFR 20.1904, 10 CFR 20.1905, 10 CFR 32.72(a)(4)

Criteria: The labels affixed to radioactive drugs for distribution must have the required color, symbol, and wording.

Discussion: The licensee must label each "transport radiation shield" to show the radiation symbol as described in 10 CFR 20.1901. The label must also include the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. The phrase "transport radiation shield" refers to the primary shield for the radioactive drug, which may include the syringe, vial, or syringe or vial shield. The "transport radiation shield" should be constructed of material appropriate for the isotope to be transferred for commercial distribution. The "transport radiation shield" does not refer to the outer suitcase, packaging, or other carrying device, even though that barrier may provide some radiation shielding.

The licensee must label each syringe, vial, or other container (e.g., generator or ampoule) used to hold radioactive drugs to be transferred for commercial distribution to show the radiation symbol, as described in 10 CFR 20.1901. The label must include the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL," and an identifier that ensures the syringe, vial, or other container can be correlated with the information on the

"transport radiation shield" label. The identifier must provide a correlation between the syringe, vial, or other container and the information on the label of its "transport radiation shield." 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 Applicant: The applicant must:

- 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 on the container used to hold the radioactive drug)

AND

- agree to affix the required labels to all "transport radiation shields" and to each container used to hold the radioactive drugs

8.10.12 Radioactive Drug Shielding for Distribution

Regulations: 10 CFR 20.1201, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 32.72(a)(3)

Criteria: The shielding provided for each radioactive drug to be distributed must be adequate for safe handling and storage by the commercial pharmacy's customers to maintain occupational exposures ALARA.

Discussion: The applicant must provide appropriate "transport radiation shields" for the primary container of each 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 distribute. Typically, "transport radiation shields" used by radiopharmacies have included two-piece, shielded syringe, and vial containers (or "pigs"). Pharmacies have used lead and tungsten shields for gamma-emitting materials and Plexiglass inserts for beta-emitters.

"Transport radiation shields" for Tc-99m products generally ensure surface radiation levels of not more than 0.03 mSv/h [3 millirem per hour (mrem/h)], because of the ease of shielding the low-energy gamma emitted. For I-131, surface dose rates on "transport radiation shields" have been approved up to 0.5 mSv/h [50 mrem/h] for diagnostic dosages and up to 1.5 mSv/h [150 mrem/h] for therapeutic dosages. 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 Applicant: For each radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package), provide the following:

- Indicate the radionuclide and the maximum activity for each type of container (e.g., vial, 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: It is not acceptable to state that the applicant will comply with DOT regulations. The dose-rate limits that DOT imposes apply to the surface of the package, not the surface of the "transport radiation shield."

8.10.13 Leak Tests

Regulations: 10 CFR 20.1501, 10 CFR 20.2103, 10 CFR 30.53, 10 CFR 40.63

Criteria: The NRC requires testing to determine whether there is any radioactive leakage from the sealed sources. Licensees must maintain records of leak test results in accordance with license conditions or, if applicable, NRC regulations.

Discussion: When issued, a license will require performance of leak tests at intervals approved by NRC or an Agreement State and specified in 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] 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 instructions from the manufacturer (or distributor) and the leak test kit supplier. The licensee returns the sample to the leak test service provider for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. The NRC or an Agreement State may, in a license condition, specifically authorize commercial radiopharmacy licensees to conduct the entire leak test sequence themselves.

Response from Applicant: State either of the following:

- "Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the applicant, using a leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State, to provide leak testing services."

OR

- "Leak test sample collection and analysis will be done by the applicant." Provide the information noted in Appendix H of this NUREG supporting a request to perform leak test sample collection and sample analysis and either state that, "The applicant will follow the model procedures in Appendix H of NUREG–1556, Volume 13, Revision 2, "Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Commercial Radiopharmacy Licenses"' or submit alternative procedures.

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

8.10.14 Security Program for Category 1 and Category 2 Radioactive Material

Regulations: 10 CFR Part 37

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

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

Discussion:

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

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

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

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

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

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

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

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

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

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

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1904(b), 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2008, 10 CFR 20.2108, 10 CFR 30.51, 10 CFR 37.11(c), 10 CFR 40.61

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

Discussion: Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material, or unusable items contaminated with radioactive material (e.g., absorbent paper, gloves). Licensees may not receive radioactive waste from other licensees for processing, storage, or disposal, unless specifically authorized to do so by the NRC. Commercial radiopharmacies may request authorization to receive certain radioactive waste returned from their customers. For guidance on receiving radioactive waste from customers, refer to Section 8.11.1 titled, "Returned Wastes from Customers."

All radioactive waste must be stored in appropriate containers until its disposal, and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. In accordance with regulations in 10 CFR 20.2001-20.2003 and 20.2005-20.2008, the NRC requires commercial radiopharmacy licensees to dispose of radioactive waste generated at their facilities by one or more of the following methods:

- decay-in-storage (DIS)
- transfer to an authorized recipient
- release into sanitary sewerage

Licensees may choose any one or more of these methods to dispose of their radioactive waste. It has been the NRC's experience that most commercial radiopharmacies dispose of radioactive waste by DIS because the majority of licensed materials used by these facilities have short half-lives.

An applicant's programs for management and disposal of radioactive waste should include procedures for handling, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Regulations require that licensees maintain all appropriate records of disposal of radioactive waste.

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

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

Decay-in-Storage

The NRC has concluded that materials with half-lives of less than or equal to 120 days are appropriate for DIS. The holding time of the waste should be based on the radionuclide(s), half-life, and the activity present when the waste was placed into storage. Such waste may be disposed of as ordinary trash if radiation surveys 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. 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, low-level radioactive waste (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 5, 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW. This information was updated by NRC Regulatory Issue Summary (RIS) 2008-12, "Considerations For Extended Interim Storage of Low-Level Radioactive Waste By Fuel Cycle And Materials Licensees," dated May 9, 2008. In addition, the NRC issued Regulatory Issue Summary 2011-09, "Available Resources Associated With Extended Storage of Low-Level Radioactive Waste," dated August 16, 2011, which refers to other helpful guidance documents.

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. It has been NRC's experience that most commercial radiopharmacies only dispose of radioactive wastes with half-lives greater than 120 days to authorized recipients (e.g., low-level radioactive waste disposal facilities). Because commercial radiopharmacy licensees typically possess small quantities of these materials, the volume of materials disposed of in this manner would also be minimal, if any. Currently, radiopharmacies use this system for waste disposal infrequently; therefore, detailed guidance is not provided in this NUREG on the specific requirements related to the transfer of wastes to authorized recipients for disposal.

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

Release Into Sanitary Sewerage

Licensees may dispose of radioactive waste by release into sanitary sewerage if each of the following conditions are met:

- Material is readily soluble (or is readily dispersible biological material) in water.
- Quantity of licensed material or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer does not exceed the concentration specified in 10 CFR Part 20, Appendix B, Table 3.
- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3, cannot exceed unity.
- Total quantity of licensed material and other radioactive material released into the sanitary sewerage system in a year does not exceed the limits specified in 10 CFR 20.2003(a)(4).

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

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

Applicants should provide procedures that will ensure that all releases of radioactive waste into a public sanitary sewerage, if any, meet the criteria stated in 10 CFR 20.2003, "Disposal by release into sanitary sewerage." Licensees are required to maintain accurate records of all releases of licensed material into sanitary sewerage.

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

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

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

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

Extended Interim 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 is necessary. NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste for Fuel Cycle and Material Licensees," dated February 5, 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW. Regulatory Issue Summary 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated May 9, 2008, updates information provided in IN 90-09. In addition, the NRC issued Regulatory Issue Summary 2011-09, "Available Resources Associated with Extended Storage of Low-Level Radioactive Waste," dated August 16, 2011, which refers to other helpful guidance documents.

Response from Applicant: Submit the following statement: "We have developed, and will implement and maintain, written procedures for waste management that meet the requirements in 10 CFR 20.1904(b), 10 CFR 20.2001, 10 CFR 20.2003, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2008, 10 CFR 20.2108, 10 CFR 30.51, 10 CFR 40.61, as applicable."

AND

If needed, the applicant should request authorization for extended interim storage of waste. The applicant should use the references listed below for guidance and submit the required information with the application.

References:

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

RIS 2011-09, "Available Resources Associated With Extended Storage of Low-Level Radioactive Waste," dated August 16, 2011

RIS 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated May 9, 2008

RIS 2004-17, Revision 1, "Revised Decay-in-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material," dated September 27, 2005

IN 94-23, "Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of a Waste Minimization Program," dated March 25, 1994

IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," dated January 28, 1994

IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Material Licensees," dated February 5, 1990

IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted Under 10 CFR 20.303" (now 10 CFR 20.2003), dated December 21, 1984

8.11.1 Returned Wastes From Customers

Regulations: 10 CFR 20.2001(a), 10 CFR 30.33, 10 CFR 40.32, 10 CFR 71.5

Criteria: Commercial radiopharmacies may receive radioactive waste from customers. This radioactive waste is limited to items that originated at the commercial radiopharmacy and that contained (or contain) radioactive material delivered for customer use (e.g., commercial radiopharmacy-supplied syringes and vials and their contents).

Discussion: Commercial radiopharmacy licenses contain a license condition that permits radioactive waste, consisting of commercial radiopharmacy-supplied items, to be received from their customers. The customer may return, and the commercial radiopharmacy may accept for disposal, only items originating at the commercial radiopharmacy that contain radioactive material. This is limited to commercial radiopharmacy-supplied syringes and vials and their contents. It is *not* acceptable for customers to return items originating at their facilities that are contaminated with radioactive material supplied by the commercial radiopharmacy (e.g., gloves, absorbent material, and IV tubing) (see Figure 8-8). If an applicant wishes to obtain a broader authorization for radioactive waste retrieval, the applicant must apply for a separate license as a

radioactive waste broker under the general provisions of 10 CFR 20.2001(b) and 10 CFR 30.33, “General requirements for issuance of specific licenses.”

Radiopharmacy customers, who act as the shipper for returned materials, should be supplied with detailed written instructions on how to properly prepare and package radioactive waste for return to the radiopharmacy. These instructions should clearly indicate that only items that contained or contain radioactive materials supplied by the radiopharmacy may be returned. In addition, these instructions should be adequate to ensure that customers comply with DOT and NRC regulations for the packaging and transport of licensed materials and for the radiation safety of drivers and couriers. Since customers may return unused syringes and vials, which may contain significant quantities of licensed material, the radiopharmacy should also include in their instructions methods for determining that the activities of radionuclides returned to the pharmacy are "limited quantities." If the packages contain greater than “limited quantities” of radioactive material, the radiopharmacy should provide instructions to customers to prepare and offer packages for transport that meet the NRC and DOT regulations for these packages. The commercial radiopharmacy should also have written instructions for commercial radiopharmacy staff to address pick-up, receipt, and disposal of the returnable radioactive waste. Appendix O of this NUREG contains a model procedure for the return of commercial radiopharmacy radioactive wastes from customers.

If the pharmacy chooses to take the responsibility to act as the shipper for returned materials, the pharmacy must follow DOT and NRC regulations for the packaging and transport of these licensed materials and for the radiation safety of drivers and couriers in the return process.

Figure 8-8. Returned Waste
Only items that originated at the commercial radiopharmacy (commercial radiopharmacy-supplied syringes and vials and their contents) may be returned to the commercial radiopharmacy for disposal.

Response from Applicant: Submit the following statement: “We have developed, and will implement and maintain, written procedures for customer return of commercial radiopharmacy-supplied syringes and vials and their contents, to specify that:

- Only commercial radiopharmacy-supplied syringes and vials and their contents may be returned to the commercial radiopharmacy.

- Instructions will be provided to commercial radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the commercial radiopharmacy.

- Instructions will be provided to commercial radiopharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste to ensure compliance with 10 CFR 20.2001(a), 10 CFR 30.33, 10 CFR 40.32, and 10 CFR 71.5, as applicable."

8.12 Item 12: License Fees

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

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

8.13 Item 13: Certification

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

Notes:

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

- When the application references commitments, those items will be incorporated into the license and therefore, will become binding and conditions to the license.

9 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. However, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 32.72(b)(5), commercial radiopharmacy licensees may allow individuals not named on their licenses to work as authorized nuclear pharmacists (ANPs), provided that the individuals meet the minimum training and experience requirements of 10 CFR 32.72(b)(2) or (4), and the licensee notifies the U.S. Nuclear Regulatory Commission (NRC), in writing, with the documentation specified in 10 CFR 32.72(b)(5), as applicable, no later than 30 days after the licensee allows the individual to work as an ANP. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date [10 CFR 2.109, 10 CFR 30.36(a), 10 CFR 40.42(a)].

Applicants for license amendment or renewal should do the following:

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

9.1 Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b), 10 CFR 40.46

Criteria: Licensees must provide all supporting information and obtain the NRC's *prior, written consent*, before transferring control of the license, also referred to as a "change of ownership" or "transferring the license."

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not the NRC's intent to interfere with the business decisions of licensees, under 10 CFR 30.34(b), 10 CFR 40.46, and the Atomic Energy Act, licensees must obtain prior NRC written consent before transferring control of the license to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses or Agreement State licenses.
- Materials are properly handled and secured.
- Persons using these materials are capable, competent, and committed to implementing appropriate radiological controls.

- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material.

- Public health and safety are not compromised by the use of such materials.

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

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

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

10 APPLICATIONS FOR EXEMPTIONS

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

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

Discussion: Various sections of the NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, "Application for exemptions;" 10 CFR 20.2301, "Applications for exemptions;" 10 CFR 30.11, 10 CFR 40.14, "Specific exemptions"). These regulations state that the NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

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

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

11 TERMINATION OF ACTIVITIES

Regulations: Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1401, 10 CFR 20.1402, 10 CFR 20.1403, 10 CFR 20.1404, 10 CFR 20.1405, 10 CFR 20.1406, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36, 10 CFR 30.51, 10 CFR 40.36(f), 10 CFR 40.42, 10 CFR 40.46

Criteria: The licensee must do the following:

- Notify the U.S. Nuclear Regulatory Commission (NRC), in writing, within 60 days of the occurrence of any of the following:
  - — expiration of its license
  - — a decision to permanently cease principal activities[1] at the entire site
  - — for licensees subject to 10 CFR 30.36, a decision to permanently cease principal activities in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements
  - — for licensees subject to 10 CFR 40.42, a decision to permanently cease principal activities in any separate building or outdoor area
  - — no principal activities under the license have been conducted for a period of 24 months
  - — no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release according to NRC requirements
- Submit a decommissioning plan, if required by 10 CFR 30.36(g).
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j) and/or 10 CFR 40.42(h) and (j).
- Submit to the appropriate NRC regional office a completed NRC Form 314, “Certificate of Disposition of Materials” (or equivalent information), and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final surveys and results of leak tests of sealed sources).
- Before a license is terminated, send records important to decommissioning that are required by 10 CFR 30.35(g) and/or 10 CFR 40.36(f), to the appropriate NRC regional office in accordance with 10 CFR 30.51(f) and/or 10 CFR 40.61(f), respectively. If

[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.

licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b) and/or 10 CFR 40.46, transfer records important to decommissioning to the new licensee in accordance with 10 CFR 30.35(g) and/or 10 CFR 40.36(f), respectively.

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

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

The permanent cessation of principal activities[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.

This requirement also applies to buildings that were approved by the broad scope licensee as locations of use but not specifically named on the broad scope license.

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": https://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2015/.

For guidance on the disposition of licensed material, see Section 8.11 "Waste Management." For guidance on decommissioning records, see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

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

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

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

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

Reference:

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

APPENDIX A

UNITED STATES NUCLEAR REGULATORY COMMISSION FORM 313

U.S. Nuclear Regulatory Commission Form 313

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

NRC FORM 313 (10-2017) 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 Information Services Branch (T-2 F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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

IF YOU ARE LOCATED IN:

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

SEND APPLICATIONS TO:

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 MATERIALS WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   - BUSINESS TELEPHONE NUMBER
   - BUSINESS CELLULAR TELEPHONE NUMBER
   - BUSINESS E-MAIL ADDRESS

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

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.
6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
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)* — FEE CATEGORY _____ AMOUNT ENCLOSED $ _____
***Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.**

PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html.

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

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

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

FOR NRC USE ONLY

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

NRC FORM 313 (10-2017)

APPENDIX B

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

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

B.1 Item 1: Action Type

ACTION TYPE:	ADMINISTRATIVE REVIEW:
❒ New ❒ Amendment ❒ Renewal	❒ Current Guidance Used ❒ References in Application Based on Current Regulations ❒ All Attachments Referenced Included ❒ Signature on Application

B.2 Item 2: Legal Identity

NAME:	

B.3 Items 2 & 3: Address

STORAGE & LOCATION(s) OF USE ADDRESS:	MAILING ADDRESS:

B.4 Item 4: Person to Be Contacted About This Application

CONTACT PERSON:	
TELEPHONE NUMBER:	
EMAIL:	

B.5 Item 5: Materials to Be Possessed

Yes	No	Radionuclide	Form or Mfg/Model No.	Quantity	Purpose of Use	Specify Other Uses Not Listed on SSD Registration Certificate
		Byproduct Materials with Atomic No. 1-83	Any	____ mCi per nuclide, 1 Ci total possession, except as noted:	10 CFR 32.72 and 10 CFR 30.41	❒ Not applicable ❒ Uses are:
		Molybdenum-99	Any	____ Ci	10 CFR 32.72 and 10 CFR 30.41	❒ Not applicable ❒ Uses are:
		Technetium-99m	Any	____Ci	10 CFR 32.72 and 10 CFR 30.41	❒ Not applicable ❒ Uses are:
		Iodine-131	Any	____ mCi	10 CFR 32.72 and 10 CFR 30.41	❒ Not applicable ❒ Uses are:
		Fluorine-18	Any	____ mCi	10 CFR 32.72 and 10 CFR 30.41	❒ Not applicable ❒ Uses are:
		Iodine-123	Any	____ mCi	10 CFR 32.72 and 10 CFR 30.41	❒ Not applicable ❒ Uses are:
		Xenon-133	Any	____Ci	10 CFR 32.72 and 10 CFR 30.41	❒ Not applicable ❒ Uses are:
		Any Byproduct Material in a Brachytherapy Source, as listed in 10 CFR 35.400	Sealed Sources	____ mCi	10 CFR 32.74 and 10 CFR 30.41	❒ Not applicable ❒ Uses are:
		Any Byproduct Material in a sealed source for diagnosis, as listed in 10 CFR 35.500	Sealed Sources	____Ci per source and Ci total	10 CFR 32.74 and 10 CFR 30.41	❒ Not applicable ❒ Uses are:

Yes	No	Radionuclide	Form or Mfg/Model No.	Quantity	Purpose of Use	Specify Other Uses Not Listed on SSD Registration Certificate
		Any Byproduct Material or a radiation source approved for medical use that is not specifically addressed in subparts D through H of 10 CFR Part 35, as listed in 10 CFR 35.1000		____mCi		
		Any byproduct material listed in 10 CFR 31.11(a)	Prepackaged units for in vitro diagnostic tests	____mCi	10 CFR 31.11	❒ Not applicable ❒ Uses are:
		Any byproduct material authorized under 10 CFR 35.65	Sealed Sources	____mCi	Calibration and checking of the licensee's instruments and 10 CFR 32.74 and 10 CFR 30.41	❒ Not applicable ❒ Uses are:
		DU	Metal	____ kg	Shielding for molybdenum-99/technetium-99m generators	❒ Not applicable ❒ Uses are:
		Cesium-137	Sealed sources in compatible device as specified in SSD registration sheet	____Ci per source and ____ Ci total	Instrument calibration	❒ Not applicable ❒ Uses are:
		Other (specify)				

NOTE:

General Format for Response from Applicant for Materials to be Possessed
For unsealed materials:
Identify each radionuclide (element name and mass number) that will be used, the form, and the maximum requested possession limit, or provide the requested information using the checklist above. **AND** For potentially volatile materials (e.g., iodine-123, iodine-131), specify whether the materials will be manipulated at the commercial radiopharmacy and if so, specify where manipulation occurs (i.e., a hood or a hot cell).
For sealed sources and discrete sources of radium (Ra)-226:
(1) Identify each radionuclide (element name and mass number) that will be used in each source, the activity per source, and the maximum requested possession limit; (2) Provide the manufacturer's or distributor's name and model number for each sealed source and device and discrete source of Ra-226 requested; (3) Confirm that each sealed source, device, source/device combination, and discrete source of Ra-226 is registered as an approved sealed source, device, or discrete source by the NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available; • For each sealed source, device, and source and device combination that is not registered, provide the applicable information, as described in 10 CFR 30.32(g) and 32.210; (4) 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; **and** (5) If the above information cannot be provided for the discrete source of Ra-226, describe the discrete source.
For depleted uranium, specify the total amount (in kilograms)
Provide an emergency plan, if required by 10 CFR 30.32(i) and 10 CFR 30.72
5.2 Financial Assurance and Recordkeeping for Decommissioning No response is needed from most applicants. If a decommissioning funding plan or financial assurance is required, submit the documentation required under 10 CFR 30.35 and 10 CFR 40.36, as appropriate.

B.6 Item 6: Purpose of Use of Licensed Material

Item Number and Title	Suggested Response	Yes	Description Attached
6.1 Distribution and Redistribution of Sealed and Unsealed Materials	For all transferred, distributed, and redistributed sealed and unsealed materials:		
	Provide a statement that, "We have developed and will implement and maintain written procedures to meet the license verification requirements specified in accordance with 10 CFR 30.41(d).	❒	
	AND		
	Describe procedures to ensure that sealed and unsealed materials are securely and safely provided to mobile medical licensees if they are transferred, distributed, or redistributed to a mobile medical licensee's mobile van or coach, where there is no permanent structure for byproduct material storage. For example, procedures should ensure that delivery directly to the van or coach will only occur if the van or coach is occupied by mobile medical licensee personnel at the time of delivery.		❒
	AND		
	Provide the following, as applicable:		
	For radiopharmaceuticals:		
	Confirm that radiopharmaceuticals will be prepared under the supervision of an Authorized Nuclear Pharmacist (ANP) or will be obtained from a supplier authorized pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements.	❒	
	Describe all licensed material to be distributed or redistributed.		❒

Item Number and Title	Suggested Response	Yes	Description Attached
	For generators:		
	Confirm that the generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements.	❒	
	Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.	❒	
	For redistribution of used generators:		
	Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.		❒
	Confirm that the manufacturer's packaging and labeling will not be altered.	❒	
	Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.	❒	
	Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.	❒	
	Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.	❒	

Item Number and Title	Suggested Response	Yes	Description Attached
	For redistribution of sealed sources for brachytherapy or diagnosis:		
	Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements.	❒	
	Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.	❒	
	For redistribution of calibration and reference sealed sources:		
	Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 10 CFR 32.74, or under equivalent Agreement State requirements, to initially distribute such sources.	❒	
	Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.	❒	

Item Number and Title	Suggested Response	Yes	Description Attached
	For redistribution of prepackaged units for *in vitro* tests:		
	Confirm that the prepackaged units for *in vitro* tests to be redistributed will be obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to 10 CFR 32.71 or under an equivalent license of an Agreement State.	❒	
	For redistribution of prepackaged units for in vitro tests to general licensees:		
	Confirm that the manufacturer's packaging and labeling of the prepackaged units for *in vitro* tests will not be altered in any way.	❒	
	Confirm that each redistributed prepackaged unit for *in vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.	❒	
	For redistribution of prepackaged units for *in vitro* tests to specific licensees:		
	Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for *in vitro* tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11).	❒	
	Confirm that the labeling on redistributed prepackaged units for *in vitro* tests will conform to the requirements of 10 CFR 20.1901, "Caution signs" and 20.1904, "Labeling containers."	❒	

Item Number and Title	Suggested Response	Yes	Description Attached
	For redistribution of discrete sources of radium-226:		
	Confirm that the discrete sources of radium-226 will be obtained by a manufacturer authorized to distribute it.	❒	
	Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing sources.	❒	
6.2 Preparation of Radiopharmaceuticals	For radiopharmaceutical preparation, we will perform:		
	• compounding of iodine-131 capsules	❒	
	• radioiodination	❒	
	• chemical synthesis of Positron Emission Tomography (PET) radiopharmaceuticals	❒	
	• technetium (Tc)-99m kit preparation	❒	
	• other, specify	❒	❒
6.3 Sealed Sources for Calibration and Checks and Possession of Discrete Sources of Radium-226 and Depleted Uranium	Supply specific information concerning the use of discrete sources of radium-226, sealed sources for reference and calibration, and DU shielding.		❒
6.4 Service Activities	For all services provided and marked yes below, include the information described in NUREG–1556, Vol. 18, as applicable.		
	We will provide customers the following radiation protection services involving licensed material:		
	• sealed source leak testing	❒	
	• instrument calibration	❒	
	• other, specify	❒	❒

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

Item Number and Title	Suggested Response	Yes	Description Attached
7. Individual(s) Responsible for Radiation Safety Program and Their Training and Experience	An organizational chart describing the management structure, reporting paths, and the flow of authority between executive management and the RSO.	❒	❒
7.1 RSO Name of Proposed RSO: _____	A copy of the license (NRC or Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, ANP, or AU.	❒	❒
	OR		
	Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience applicable to commercial nuclear pharmacies.	❒	❒
7.2 Authorized Nuclear Pharmacist(s) Name(s) of Proposed ANP(s): _____ _____ _____ _____ _____	For each proposed ANP:		
	Pharmacist's license number and issuing entity;	❒	❒
	AND		
	For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial radiopharmacy that has been authorized to identify ANPs (10 CFR 32.72(b)(2)(i)		
	Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Materials License broad scope permittee on which the individual was named as an ANP or a copy of an authorization as an ANP from a commercial	❒	❒

Item Number and Title	Suggested Response	Yes	Description Attached
	radiopharmacy that has been authorized to identify ANPs.		
	OR		
	For an individual qualifying under 10 CFR 32.72(b)(4):		
	• Documentation that the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material.	❒	❒
	AND		
	• Documentation that the individual practiced at a pharmacy at a Government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.	❒	❒
	OR		
	For an individual qualifying under 10 CFR 35.55(a):		
	• Copy of the certification(s) of the specialty board whose certification process has been recognized under 10 CFR 35.55(a).	❒	❒
	AND		
	• If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	❒	❒
	OR		
	For an individual qualifying under 10 CFR 32.72(b)(2)(ii):		
	• Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience.	❒	❒

Item Number and Title	Suggested Response	Yes	Description Attached
	AND		
	• Written attestation, signed by a preceptor ANP, that the individual has satisfactorily completed the requirements in 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an ANP.	❒	❒
	AND		
	• If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	❒	❒
7.3 Authorized User(s) Name(s) of Proposed AU(s): _____ _____ _____ _____ _____	For each proposed AU:		
	Types, quantities, and proposed uses of licensed material.	❒	❒
	AND		
	A copy of the license (NRC or Agreement State) on which the individual was specifically named as an AU for the types, quantities, and proposed uses of licensed materials.	❒	❒
	OR		
	A copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed uses of licensed materials.	❒	❒
	OR		
	A description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed materials.	❒	❒

B.8 Item 8: Training for Individuals Working in or Frequenting Restricted Areas (Instructions to Occupationally Exposed Workers and Ancillary Personnel)

Item Number and Title	Suggested Response	Yes	Description Attached
8. Training for Individuals Working In or Frequenting Restricted Areas	See sections below.		
8.1 Occupationally Exposed Workers and Ancillary Personnel	Provide a statement that, "We have developed and will implement and maintain written procedures for a training program for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."	❒	
8.2 Training for Personnel Involved in Hazardous Materials Package Preparation and Transport	Submit the following statement, "We have developed and will implement and maintain written records and written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704, as applicable."	❒	
8.3 Training for Supervised Individuals Preparing Radiopharmaceuticals	No response from the applicant is necessary. Supervision will be reviewed during inspection.	N/A	

B.9 Item 9: Facilities and Equipment

Item Number and Title	Suggested Response	Yes	Description Attached
9. Facilities and Equipment	Provide a copy of the registration or license from a State Board of Pharmacy as a licensed pharmacy, or provide evidence that the facility is operating as a nuclear pharmacy within a Federal medical institution.	❒	❒
	AND		
	Provide a description of the facilities and equipment at each location where radioactive material will be used, which includes the method and shielding used to physically transfer licensed material (e.g., transfer lines) to the different processes (e.g., chemical synthesis, dispensing).	❒	❒
	AND		
	Diagram(s) should also include:		
	• Descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials, and the location(s) for radioactive waste storage.	❒	❒
	• Sufficient detail in the diagram to indicate locations of shielding, the shielding thickness, and the materials used for shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety	❒	❒
	• A general description of any ventilation system that is used when handling radionuclides, including representative equipment such as glove boxes or fume hoods	❒	❒

Item Number and Title	Suggested Response	Yes	Description Attached
	• Confirmation that such ventilation systems will be employed for the use or storage of radioactive materials that are likely to become airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions.	❒	❒
	• Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the constraint for air emissions established under 10 CFR 20.1101(d).	❒	
	For PET Radiopharmacies Provide a copy of the registration or license from a State Board of Pharmacy as a licensed pharmacy or evidence that the facility is operating as a nuclear pharmacy within a federal medical institution.	❒	❒
	AND		
	Describe the facilities and equipment at each location where radioactive material will be used, which includes the method and shielding used to physically transfer licensed material (e.g., transfer lines) to the different processes (e.g., chemical synthesis, dispensing).	❒	❒
	AND		
	Diagram(s) should also include:		
	• Descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials and the location(s) for radioactive waste storage.	❒	❒

Item Number and Title	Suggested Response	Yes	Description Attached
	• Locations of shielding, the shielding thickness, the materials used for shielding, and the locations of 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 any ventilation system that is used when handling radionuclides, including representative equipment, such as glove boxes or fume hoods.	❒	❒
	• Confirmation that such ventilation systems will be employed for the use or storage of radioactive material likely to become 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 established under 10 CFR 20.1101(d).	❒	❒

B.10 Item 10: Radiation Safety Program

Item Number and Title	Suggested Response	Yes	Description Attached
10. Radiation Safety Program			
10.1 Audit and Review of Program	No response is required. The licensee's program for auditing its Radiation Safety Program may be reviewed during inspection.	N/A	
10.2 Radiation Monitoring Instruments	• A statement that: "We will use calibrated and operable equipment that is capable of detecting the type(s) of radiation being monitored (e.g., gamma, beta, alpha) and energy or energy range of the radiation being measured."	❒	
	OR		
	• A description of the calibrated and operable instrumentation that will be used to perform radiation monitoring (e.g., portable or stationary count rate meters, LSCs, well-type scintillation counters, air monitors)		❒
	AND		
	• A statement that: "We reserve the right to upgrade our monitoring instrumentation as necessary, as long as the instruments are adequate to measure the type of radiation and energy range of the radiation for which they are used."	❒	

Item Number and Title	Suggested Response	Yes	Description Attached
	AND		
	• If calibration is performed by a person or firm outside the applicant's organization, specify that the calibration will be performed by an NRC or Agreement State licensee specifically authorized to perform instrument calibration as a service to other licensees and state the frequency of the calibrations.		❒
	OR		
	• If the calibration is to be performed in-house, submit the instrument calibration procedure that will be used and state the frequency of the calibrations. In addition, identify the qualifications of the individuals who will perform the calibrations.		❒
10.3 Material Receipt and Accountability	"We will develop, implement, and maintain written procedures for safely opening packages that meet the requirements in 10 CFR 20.1906."	❒	
	AND		
	"We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months."	❒	
	AND		
	"We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:	❒	
	• License possession limits are not exceeded.		
	• Licensed material in storage is secured from unauthorized access or removal.		

Item Number and Title	Suggested Response	Yes	Description Attached
	• Licensed material not in storage is maintained under constant surveillance and control.		
	• Records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material are maintained."		
	AND		
	• If applicable, provide the following statement, "We will comply with the NSTS reporting requirement as described in 10 CFR 20.2207."		
10.4 Occupational Dose	Provide one of the following statements:		
	"We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502."	❒	
	OR		
	"We will monitor individuals in accordance with the guidance in the section titled, "Radiation Safety Program–Occupational Dose" in NUREG–1556, Vol. 13, Rev. 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses.""	❒	
	OR, IN LIEU OF THESE STATEMENTS		❒
	Provide a description of an alternative method for demonstrating compliance with the referenced regulations.		

Item Number and Title	Suggested Response	Yes	Description Attached
10.5 Public Dose	No response is required from the applicant, but records demonstrating compliance will be examined during the inspection.	N/A	
10.6 Safe Use of Radionuclides and Emergency Procedures	"We have developed and will implement and maintain written procedures for the safe and secure use of radioactive materials that address:	❒	
	• Facility and personnel radioactive contamination minimization, detection, and control.		
	• Performing molybdenum-99 breakthrough measurements of each eluate from a molybdenum-99/technetium -99m generator.		
	• Reporting under the requirements in 10 CFR 30.34(g) if there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in the eluate		
	• Performing breakthrough measurements on each eluate of other generators (e.g., Ge-68/Ga-68 generators)		
	• Using protective clothing and equipment by personnel to support meeting the requirements in 10 CFR 20.1101		
	• Securing licensed material during use and storage (10 CFR 20.1801, 10 CFR 20.1802)		

Item Number and Title	Suggested Response	Yes	Description Attached
	• Conducting Mo-99/Tc-99m generator Mo-99 breakthrough tests and conducting Sr-82/Rb-82 generator breakthrough tests for Sr-82 and Sr-85 contamination in accordance with 10 CFR 30.34(g) and 10 CFR 35.204		
	• Posting the operating procedures applicable to commercial radiopharmacies (10 CFR19.11(a)(3)		
	AND		
	"We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:	❒	
	• Lost, stolen, or missing licensed material.		
	• Exposures to personnel and the public in excess of NRC regulatory limits.		
	• Releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits.		
	• Excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas.		
	• Radioactive spills and contamination.		
	• Fires, explosions, and other disasters with the potential for the loss of containment of licensed material.		
	• Routine contacts with local fire departments and LLEA to meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201- 20.2203, and		

Item Number and Title	Suggested Response	Yes	Description Attached
	10 CFR 30.50, 10 CFR 37.45, 10 CFR 40.60, and other requirements, as applicable.		
10.7 Surveys	"We have developed and will implement and maintain written procedures for a survey program that includes: (1) performance of radiation and contamination level surveys in restricted and unrestricted areas; (2) personnel contamination monitoring; (3) action levels; (4) survey frequencies; and (5) maintenance of survey records that meet the requirements in 10 CFR 20.1501, 10 CFR 20.2103, and 10 CFR 30.53, as applicable."	❒	
10.8 Dosage Measurement Systems	Describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs.	❒	❒
	AND		
	For each dosage measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, and photon-emitting radioactive drugs, state: "We have developed, and will implement and maintain, a written procedure for the performance of dosage measurement system checks and tests that meet the requirements in 10 CFR 32.72(c)."	❒	
	AND		
	If applicable, include a sample calculation for determining low-energy photon-, beta-, and alpha-correction factors for dose calibrators with ionization chambers.	❒	❒

Item Number and Title	Suggested Response	Yes	Description Attached
	AND		
	Provide the calculations to demonstrate the ability to accurately dispense low-energy photon-, beta-, and alpha-emitting radionuclides for radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) these materials.	❒	❒
	OR		
	If applicable, include a means for ensuring the accuracy of low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer or other entity.	❒	❒
	AND		
	If applicable, include a description of the methodology and equipment to be used for the assay of alpha-emitting radionuclides.		
10.9 Transportation	No response is required. The licensee's program for transportation of radioactive materials will be reviewed during inspection.	N/A	
10.10 Minimization of Contamination	The applicant does not need to provide a response to this item under the following condition: NRC will consider that the criteria have been met if the applicant's responses meet the criteria for the following sections of this NUREG:	❒	
	• Facilities and Equipment		
	• Radiation Safety Program-Safe Use of Radionuclides and Emergency Procedures		
	• Radiation Safety Program-Surveys		
	• Radiation Safety Program-Leak Tests		

Item Number and Title	Suggested Response	Yes	Description Attached
	• Waste Management		
10.11 Radioactive Drug Labeling for Distribution	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).	❒	❒
	AND		
	Agree to affix the required labels to all "transport radiation shields" and each container used to hold the radioactive drugs.	❒	❒
10.12 Radioactive Drug Shielding for Distribution	For each radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package), provide the following:		
	• The radionuclide and the maximum activity for each type of container (e.g., vial, 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.	❒	❒
10.13 Leak Tests	State either of the following:		
	"Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the applicant using a leak test kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by	❒	

Item Number and Title	Suggested Response	Yes	Description Attached
	the NRC or an Agreement State to provide leak testing services"		
	OR		
	"Leak test sample collection and analysis will be done by the applicant." Provide the information noted in Appendix H of this NUREG supporting a request to perform leak test sample collection and sample analysis and either state that, "The applicant will follow the model procedures in Appendix H of NUREG–1556, Volume 13, Revision 2, "Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Commercial Radiopharmacy Licenses"" or submit alternative procedures.	❒	❒
10.14 Security Program for Category 1 and Category 2 Materials	No response is required from an applicant or licensee. Compliance with access authorization and security program requirements may be reviewed during NRC inspections.	N/A	

B.11 Item 11: Waste Management (Commercial Radiopharmacy-Generated Radioactive Wastes)

Item Number and Title	Suggested Response	Yes	Description Attached
11. Waste Management (Commercial Radiopharmacy-Generated Radioactive Wastes)	"We have developed, and will implement and maintain, written procedures for waste management that meet the requirements in 10 CFR 20.1904(b), 10 CFR 20.2001, 10 CFR 20.2003, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2008, 10 CFR 20.2108, 10 CFR 30.51, and 10 CFR 40.61, as applicable."	❒	
	AND		
	If needed, the applicant should request authorization for extended interim storage of waste. The applicant should use the references listed at the end of Section 8.11 of this NUREG for guidance and submit the required information with the application.	❒	❒
11.1 Returned Wastes from Customers	"We have developed, and will implement and maintain, written procedures for customer return of commercial radiopharmacy-supplied syringes and vials and their contents, to specify that:	❒	
	• Only commercial radiopharmacy-supplied syringes and vials and their contents may be returned to the commercial radiopharmacy.		
	• Instructions will be provided to commercial radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the commercial radiopharmacy.		

Item Number and Title	Suggested Response	Yes	Description Attached
	• Instructions will be provided to commercial radiopharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste to ensure compliance with 10 CFR 20.2001(a), 10 CFR 30.33, 10 CFR 40.32, and 10 CFR 71.5, as applicable.”		

APPENDIX C

FORMATS FOR DOCUMENTING TRAINING AND EXPERIENCE FOR INDIVIDUALS RESPONSIBLE FOR RADIATION PROTECTION PROGRAM

Formats for Documenting Training and Experience for Individuals Responsible for Radiation Protection Program

Table C–1. Authorized User or Radiation Safety Officer Training and Experience in Handling Radionuclides

Name (Last, First, Initial)	

Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RPP	BH	IR	INST	REG
			TOTALS					

RPP - Radiation Protection Principles
BH - Biological Hazards
IR - Ionizing Radiation Units & Characteristics
INST - Radiation Detection Instrumentation
REG - NRC Regulations and Standards

Table C–2. Authorized User or Radiation Safety Officer Training and Experience In Handling Radionuclides (Actual Use of Radionuclides Under the Supervision of an AU or RSO)

Name (Last, First, Initial)	

Isotope(s) Used	Physical Form	Maximum Amount Used at Any One Time	Location of Use	Description of Experience*	Total Hours of Experience

*Description of experience

1. Shipping, receiving, and performing related radiation surveys.
2. Using and performing checks for proper operation of dose calibrators, radiation survey meters, and other instruments used to measure photon- and high-energy beta-emitting radionuclides.
3. Using and performing checks for proper operation of instruments used to measure alpha- and low-energy beta-emitting radionuclides.
4. Calculating, assaying, and safely preparing radioactive materials.
5. Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures.

Documentation of Training and Experience to Identify an Individual on a License as an Authorized Nuclear Pharmacist

(1) Experienced Authorized Nuclear Pharmacists (ANP)

An applicant or licensee that wants to add an experienced ANP to its commercial radiopharmacy application or license only needs to provide evidence that the individual is listed as an ANP on a license issued by the U.S. Nuclear Regulatory Commission (NRC) or Agreement State, a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master materials broad scope permittee, and that the individual meets the recentness of training criteria described in 10 CFR 35.59, "Recentness of training." The applicant may also provide evidence that the individual is identified as an ANP by a commercial radiopharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not listed on, the commercial radiopharmacy license, medical broad scope license, or Master Materials License medical broad scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

(2) Applications That Include Individuals for Authorized Nuclear Pharmacist Recognition by NRC

Applicants should submit NRC Form 313A (ANP) to show that the individual meets the correct training and experience criteria in 10 CFR Part 35, "Medical use of byproduct material," Subpart B. There are two primary training and experience routes to qualify an individual as an ANP. The first is by means of certification by a board recognized by the NRC and listed on the NRC Web site at https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html as provided in 10 CFR 35.55(a).

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestations in 10 CFR 35.55(b).

(3) Recentness of Training

The required training and experience, including board certification, described in 10 CFR Part 35, "Medical use of byproduct material," must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience include the following:

- successful completion of classroom and laboratory review courses that include radiation safety practices relative to the practice of radiopharmacy
- practical experience in radiopharmacy under the supervision of an ANP at the same or another licensed facility that is authorized as a commercial radiopharmacy

(4) General Instructions and Guidance for Filling Out NRC Form 313A Series

If the applicant wishes to identify a license and it is an Agreement State license, the applicant should provide a copy of the license. If the applicant wishes to identify a Master Materials License permit, the applicant should provide a copy of the permit. If the applicant wishes to identify a preceptor who is authorized under a broad scope license or broad scope permit of a

Master Materials License, the applicant should provide a copy of the permit issued by the broad scope licensee or permittee. Alternatively, the applicant may provide a statement signed by the RSO or chairperson of the Radiation Safety Committee similar to the following: "_____ (name of preceptor) is authorized under _____ (name of licensee/permittee) broad scope license number_____ to be an ANP during _____ (time frame)."

INTRODUCTORY INFORMATION

Name of Individual

Provide the individual's complete name so that the NRC can distinguish individuals with similar names.

***Note**:* Do not include personal or private information (e.g., date of birth, Social Security Number, home address, personal cellular phone number) as part of the qualification documentation.

State or Territory where Licensed

Note that the NRC requires pharmacists to be licensed by a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

Requested Authorization(s)

Check all authorizations that apply and fill in the blanks as provided.

Part I. Training and Experience

There are multiple pathways provided for each training and experience section. Select the applicable one.

Item 1. Board Certification

The applicant or licensee may use this pathway if the proposed nuclear pharmacist is certified by a board recognized by the NRC (to confirm that the NRC recognizes that board's certifications, see NRC's Web page at https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html). **Written attestation, signed by a preceptor ANP, is not required.**

Notes:

- An individual that is board-eligible will not be considered for this pathway until the individual is actually board-certified. Further, individuals holding other board certifications not recognized by the NRC will not be considered for this pathway.

- The applicant or licensee must provide a copy of the board certification as indicated on the attached NRC Form 313A (ANP).

- As indicated on the form, additional information is needed if the board certification was obtained more than 7 years ago.

Item 2. Structured Educational Program for a Proposed Authorized Nuclear Pharmacist

This pathway is used for those individuals who do not meet the requirements for the board certification pathway and are not listed on the license as an ANP.

The regulatory requirements refer to a structured educational program consisting of both (a) classroom and laboratory training, and (b) supervised practical experience in radiopharmacy. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and be allocated to one of the topics in 10 CFR 35.55(b)(1)(i).

The proposed ANP may receive the required classroom and laboratory training, and supervised practical experience at a single training facility or at multiple training facilities; therefore, space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year (mm/dd/yyyy) format. Under the "classroom and laboratory training," provide the number of clock hours spent on each of the topics listed in the regulatory requirements.

The proposed ANP may obtain the required "classroom and laboratory training" in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that particular need and taught on consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, the NRC will broadly interpret "classroom and laboratory training" to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

Under the "supervised practical experience in a radiopharmacy" section of the form, provide the number of clock hours for each topic. The supervised practical experience topics for the nuclear pharmacists include all the basic elements in the practice of radiopharmacy. Therefore, all the hours of supervised experience are allocated to these topics.

***Note**:* As indicated on the form, additional information is needed if the training and/or supervised practical experience was completed more than 7 years ago.

Part II. Preceptor Attestation (A preceptor attestation <u>is not required</u> for ANP training and experience provided through <u>board certification</u>)

The NRC defines the term "preceptor" in 10 CFR 35.2, "Definitions," to mean "an individual who provides, directs, or verifies training and experience required for an individual to become an AU, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer." While the supervising individual for the practical experience in radiopharmacy may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must provide an attestation in writing regarding the training and experience of a pharmacist applying through the structured educational program for a proposed authorized nuclear pharmacist. The preceptor must attest that the individual has satisfactorily completed the appropriate training and experience criteria and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist. This preceptor also has to meet specific requirements.

The NRC Form 313A (ANP) Part II-Preceptor Attestation has two sections. The preceptor must complete both sections; including the structured educational program attestation, the preceptor's authorization to use licensed material, and the preceptor's signature. If the preceptor is listed as an ANP on an Agreement State license or a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master materials broad scope permittee, the licensee should submit a copy of the Agreement State license or permit along with NRC Form 313A (ANP) to prove the individual is qualified to serve as a preceptor.

U.S. NUCLEAR REGULATORY COMMISSION FORM 313A (ANP)

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

NRC FORM 313A (ANP) (MM-YYYY) — U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED NUCLEAR PHARMACIST TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION
[10 CFR 35.55]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (MM/DD/YYYY)

Name of Proposed Authorized Nuclear Pharmacist	State or Territory Where Licensed

PART I -- TRAINING AND EXPERIENCE
(Select one of the two methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

☐ 1. **Board Certification**

a. Provide a copy of the board certification and stop here.

☐ 2. **Structured Educational Program for Proposed Authorized Nuclear Pharmacist**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
Total Hours of Training: ☐			

NRC FORM 313A (ANP) (MM-YYYY) PAGE 1

NRC FORM 313A (ANP) U. S. NUCLEAR REGULATORY COMMISSION
(MM-YYYY)

AUTHORIZED NUCLEAR PHARMACIST TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION [10 CFR 35.55] (continued)

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys			
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides			
Calculating, assaying, and safely preparing dosages for patients or human research subjects			
Using administrative controls to avoid medical events in administration of byproduct material			
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures			
Total Hours of Experience:			
Supervising Individual			

c. Go to and complete Part II Preceptor Attestation.

AUTHORIZED NUCLEAR PHARMACIST TRAINING, EXPERIENCE, AND PRECEPTOR ATTESTATION [10 CFR 35.55] (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section
Complete the following:

Structured Educational Program

☐ I attest that _____ has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both practical experience in nuclear pharmacy and 200 hours of classroom and laboratory training, as required by 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

Second Section
Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for _____,
Nuclear Pharmacy or Medical Facility

_____.
License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date

APPENDIX D

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, security, and compliance with U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Transportation (DOT) regulations and with the conditions of the license (see Figure D–1). Typically, these duties and responsibilities include ensuring the following:

- General surveillance is provided over all activities involving radioactive material, including routine monitoring, special surveys, and responding to events.

- Security of radioactive material will be maintained at all times. For licensees possessing an aggregated Category 1 or Category 2 quantity of radioactive material, he or she will participate in the development and implementation of a security program for radioactive material in accordance with 10 CFR Part 37. A "Category 1 quantity of radioactive material" and a "Category 2 quantity of radioactive material" are defined terms in 10 CFR 37.5, and the radionuclides referenced in these 10 CFR 37.5 definitions are listed in Appendix A to 10 CFR Part 37.

- All incidents and personnel exposures to radiation in excess of 10 CFR Part 20 limits are responded to and investigated, their cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.

- Proper authorities are notified of incidents such as damage, fire, or theft.

- Proper NRC and distributor notification is made when there is more than 0.15 kilobecquerel of molybdenum (Mo)-99 per megabecquerel of technetium (Tc)-99m (0.15 microcurie of Mo-99 per millicurie of Tc-99m) in an eluate.

- Corrective actions are developed, implemented, and documented when violations of regulations or license conditions or program weaknesses are identified.

- All activities are immediately terminated following any unsafe condition or activity that is found to be a threat to public health and safety.

- He or she is the primary source of radiation protection information for personnel at all levels of responsibility.

- All radiation workers are properly trained.

- Up-to-date operating, emergency, and security procedures for the safe use of radioactive materials are developed, implemented, maintained, and distributed, as appropriate.

- The licensee's procedures and controls, based upon sound radiation protection principles, are periodically reviewed to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA).

- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent (TEDE) to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit.

- Prospective evaluations are performed of occupational exposures, and those individuals likely to receive, in a year, a radiation dose in excess of 10 percent of the allowable limits are provided with personnel monitoring devices.

- When necessary, personnel radiation monitoring equipment is distributed and processed; the need for and evaluation of bioassays is determined; and personnel radiation exposure and bioassay records are monitored and maintained. Also, monitored individuals are notified when radiation exposures are approaching established limits and appropriate corrective actions are taken.

- The performance of fume hoods and gloveboxes used for volatile radioactive material work are monitored for proper operation.

- The receipt, opening, and delivery of all packages of radioactive material arriving at the commercial radiopharmacy are overseen and coordinated. Also, radiation surveys of all shipments arriving or leaving from the facility, as well as packaging and labeling of radioactive material leaving the facility are overseen.

- An inventory of all radioactive materials is maintained, and the types and quantities of radionuclides at the facility are limited to the forms and amounts authorized by the license.

- Sealed sources are leak-tested at required intervals.

- There is effective management of the radioactive waste program, including effluent monitoring and recording of waste storage and disposal records.

- Packaging and transport of radioactive material is in accordance with all applicable DOT regulations.

- Maintain understanding of and keep up-to-date copies of NRC regulations, the license, and revised licensee procedures.

- License amendment and renewal requests, and notifications of new authorized nuclear pharmacists (ANPs), authorized users (AUs), or other changes relative to the license are submitted in a timely manner.

- Radiation Safety Program audits are performed at least annually and documented. Audits results and corrective actions are communicated, as appropriate, through management, to all personnel who use licensed material.

- He or she acts as liaison to the NRC.

- All required records are properly maintained.

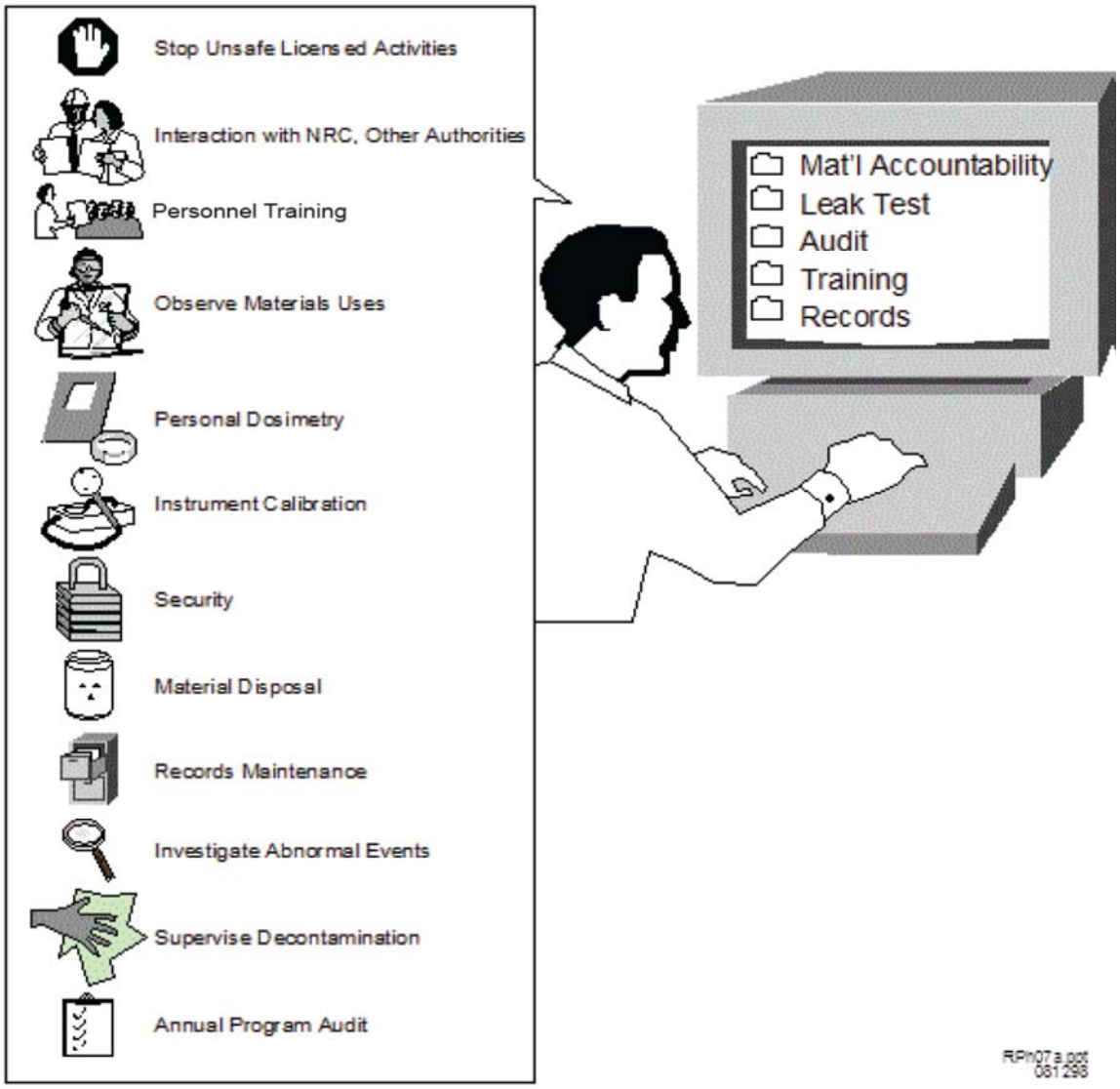


Figure D–1. Typical Duties and Responsibilities of the RSO

Model Delegation of Authority

Memo

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

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

_____ _____
Signature of Management Representative Date

I accept the above responsibilities,

_____ _____
Signature of Radiation Safety Officer Date

cc: Affected department heads

APPENDIX E

SUGGESTED COMMERCIAL RADIOPHARMACY AUDIT CHECKLIST

Suggested Commercial Radiopharmacy Audit Checklist

***Note**:* All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit. Effective audits include observations of licensed activities being conducted and staff demonstrations of how they would respond to normal and abnormal situations based on credible scenarios posed by the auditor.

Date of This Audit _____

Date of Last Audit _____

Next Audit Date _____

Auditor _____

Date _____

_____
(Signature)

Management
Review_____Date_____

_____
(Signature)

Audit History

A. Last audit of this location conducted on (date)

B. Were previous audits conducted annually? [10 CFR 20.1101]

C. Were records of previous audits maintained? [10 CFR 20.2102]

D. Were any deficiencies identified during the last two audits or 2 years, whichever is longer?

E. If deficiencies were identified during the last two audits or 2 years, were corrective actions completed?

F. Were the corrective actions sufficient to correct the deficiencies and prevent recurrence?

G. What corrective actions from previous audits, if any, are still in progress?

Organization and Scope of Program

A. If the mailing address or places of use changed, was the license amended? [10 CFR 30.34, 10 CFR 40.41]

B. If ownership changed or bankruptcy filed, was the U.S. Nuclear Regulatory Commission's (NRC's) prior consent obtained or was the NRC notified? [10 CFR 30.34, 10 CFR 40.41, or license conditions (L/C)]

C. Authorized Nuclear Pharmacists

1. New Authorized Nuclear Pharmacist (ANP) since last audit? If so, does new ANP meet NRC training requirements? [10 CFR 32.72, 10 CFR 35.2, 10 CFR 35.55(b)]

2. If an individual began work as an ANP, was NRC notified within 30 days or was license amended? [10 CFR 32.72, 10 CFR 35.13(b), 10 CFR 35.14(a)]

D. Radiation Safety Officer

1. New Radiation Safety Officer (RSO) since last audit? If so, does new RSO meet NRC training requirements?

2. If the RSO was changed, was license amended?

3. Is RSO fulfilling his/her duties?

4. To whom does RSO report?

E. Authorized Users

1. New authorized user (AU) since last audit? If so, does new AU meet NRC training requirements?

2. If an AU was added, was license amended?

F. If the designated contact person for NRC changed, was NRC notified?

G. Type and quantity of byproduct material

1. Does the license authorize all of NRC-regulated radionuclides possessed?

2. Is actual possession of those radionuclides (including radioactive waste) within the limits on the license?

Facilities

A. Are facilities as described in NRC license application?

B. If facilities have changed, has NRC license been amended?

Equipment and Instrumentation

A. Are there a sufficient number and type of instruments capable of detecting the type and energy of radiation(s)?

B. Are instruments and equipment used for quantitative radiation measurements calibrated periodically for the radiation measured? [10 CFR 20.1501]

C. Are calibration records maintained? [10 CFR 20.2103(a)]

D. If instrument calibration is performed in-house, have appropriate calibration procedures been developed, implemented, and maintained?

E. Is there sufficient shielding (L-block, etc.) for work with radionuclides?

F. Are generators housed in a separate room and/or properly shielded to keep doses as low as is reasonably achievable (ALARA)?

G. Are procedures established for identifying, evaluating, and reporting safety component defects? [10 CFR 21.21]

H. Dose Calibrators for Photon-Emitters [10 CFR 32.72(c)]

1. Constancy, at least once each day before assay of patient dosages (plus or minus 10 percent)?

2. Linearity, at installation and at required frequency (plus or minus 10 percent)?

3. Geometry dependence, at installation (plus or minus 10 percent)?

4. Accuracy, at installation and at required frequency (plus or minus 10 percent)?

5. After repair, adjustment, or relocation of the dose calibrator, were appropriate tests above repeated?

I. Dose Measurement Systems for Beta- and Alpha-Emitters [10 CFR 32.72(c)]

1. Calibrated for each isotope used, with that isotope?

2. Constancy, at least once each day before assay of patient dosages (plus or minus 10 percent)?

3. Geometry dependence, at installation (plus or minus 10 percent)?

4. Accuracy, at installation and at manufacturer's recommended frequency (plus or minus 10 percent)?

5. Linearity, at installation and at manufacturer's recommended frequency (plus or minus 10 percent)?

6. After repair, adjustment, or relocation of the dose calibrator, were appropriate tests above repeated?

Area Surveys and Contamination Control [10 CFR 20.1501]

A. Are area surveys being performed at applicable locations and required frequencies? Are records maintained? [10 CFR 20.2103]

B. Are removable contamination surveys being performed at applicable locations and required frequencies? Are records maintained? [10 CFR 20.2103]

C. Was prompt and appropriate corrective action taken and documented when excess radiation or contamination levels were detected?

Leak Tests

A. Was each sealed source leak tested every 6 months or at other prescribed intervals?

B. Was the leak test performed according to the license?

C. Are records of results retained with the appropriate information included?

D. Were any sources found leaking and if yes, was the NRC notified?

Sealed Source Inventory

A. Is a record kept showing the receipt of each sealed source? [10 CFR 30.51(a)(1), 10 CFR 40.61(a)(1)]

B. Are all sealed sources physically inventoried every 6 months?

C. Are records of inventory results with appropriate information maintained?

Training and Instructions to Workers

A. Were all workers who are likely to exceed 1 mSv [100 mrem] in a year instructed per 10 CFR 19.12? Was refresher training provided, as needed? Are records maintained? [10 CFR 30.34]

B. Were other workers trained as needed (e.g., radiopharmacy technicians, AUs, couriers/drivers, ancillary personnel)? Are records maintained? [10 CFR 30.34]

C. Are workers knowledgeable of applicable 10 CFR Part 20, radiation protection procedures, emergency response procedures, and license conditions?

D. Was HAZMAT training provided, if required? [49 CFR 172.700, 49 CFR 172.701, 49 CFR 172.702, 49 CFR 172.704]

Material Use Control and Transfer

A. Are restricted and unrestricted areas delineated?

B. Are radioactive materials that are stored in a controlled or unrestricted area secured from unauthorized access or removal? [10 CFR 20.1801]

C. Are radioactive materials that are in a controlled or unrestricted area and not in storage controlled and maintained under constant surveillance? [10 CFR 20.1802]

D. Are there procedures for receiving and opening packages? [10 CFR 20.1906]

E. Is byproduct material transferred only to authorized recipients? [10 CFR 30.41; 10 CFR 32.71; 10 CFR 32.72, 10 CFR 32.74]

F. Are records kept of receipt and transfer? [10 CFR 30.51, 10 CFR 40.61]

G. For licensees possessing aggregated Category 1 or Category 2 quantities of radioactive materials referenced in Appendix A to 10 CFR Part 37, is the access program content and implementation reviewed at least annually in accordance with the requirements in 10 CFR 37.33?

H. For licensees possessing aggregated Category 1 or Category 2 quantities of radioactive materials referenced in Appendix A to 10 CFR Part 37, is the security program content and implementation reviewed at least annually in accordance with the requirements in 10 CFR 37.55?

Personnel Radiation Protection

A. Are ALARA considerations incorporated into the Radiation Protection Program? [10 CFR 20.1101(b)]

B. Were prospective evaluations performed showing that unmonitored individuals receive less than or equal to 10 percent of the limit? [10 CFR 20.1502(a)] Did these evaluations consider doses to minors [10 CFR 20.1502(a)(2)] and declared pregnant women [10 CFR 20.1502(a)(3)]?

C. Did unmonitored individuals' activities change during the year, which could put them over 10 percent of limit?

D. If yes to C. above, was a new evaluation performed?

E. Is external dosimetry required (individuals likely to receive greater than 10 percent of limit)? And is dosimetry provided to these individuals?

1. Is the dosimetry in accordance with the requirements in 10 CFR 20.1501(d)?

2. Are the dosimeters exchanged at the appropriate frequency?

3. Are dosimetry reports reviewed by the RSO when they are received?

4. Are the records on NRC Forms or equivalent completed? [10 CFR 20.2104(d), 10 CFR 20.2106(c)]

   a. NRC-Form 4 "Cumulative Occupational Dose History" completed?

   b. NRC-Form 5 "Occupational Dose Record for a Monitoring Period" completed?

5. Declared pregnant worker/embryo/fetus

   a. If a worker declared her pregnancy, was compliance with 10 CFR 20.1208 achieved?

   b. Were records kept of the embryo/fetus dose? [10 CFR 20.2106(e)]

F. Are individuals monitored for internal dose if they are likely to receive greater than 10 percent of the annual limit on intake (ALI)?

G. Are workers notified annually of their exposures?

H. Are records of exposures, surveys, monitoring, and evaluations maintained? [10 CFR 20.2102, 10 CFR 20.2103, 10 CFR 20.2106]

I. If required by 10 CFR 20.2206, were individual monitoring results reported annually to the NRC?

Waste Management

A. Waste storage areas

1. Is storage area properly posted? [10 CFR 20.1902]

2. Are containers properly labeled? [10 CFR 20.1904]

B. Decay-in-Storage

1. Do radionuclides being stored all have physical half-lives less than 120 days?

2. Are radionuclides being segregated for storage according to half-life?

3. Before waste is disposed of

   a. Is a survey performed at the container surface with an appropriate survey instrument set on its most sensitive scale, with no interposed shielding, to determine that its radioactivity cannot be distinguished from low background?

   b. Are all radiation labels removed or obliterated, as appropriate?

4. Are records kept?

C. Disposal by release into sanitary sewerage.

1. Is licensed material readily soluble (or readily dispersible biological material) in water? [10 CFR 20.2003]

2. Does the quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer not exceed the concentration specified in 10 CFR Part 20 Appendix B, Table 3?

3. If more than one radionuclide is released, does the sum of the ratios of the average monthly discharge of each radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3, not exceed unity?

4. Does the total quantity of licensed material released into the sanitary sewerage system in a year not exceed the limits specified in 10 CFR 20.2003(a)(4)?

D. Transfer to Authorized Recipient

1. Is waste being transferred to a person specifically authorized to receive it? [10 CFR 20.2001]

2. Is waste properly manifested? [10 CFR 20.2006]

Receipt of Radioactive Waste from Customers

A. Does returned waste consist only of items that contained radioactive materials that the commercial radiopharmacy supplied (e.g., commercial radiopharmacy supplied syringes, vials)?

B. Are waste packages checked for removable contamination upon receipt?

Effluents

A. Are effluents from materials being maintained ALARA?

B. Are fume hoods checked to confirm an adequate airflow?

C. Is effluent monitored to determine activity being released?

D. Are filters being used and maintained according to the manufacturer's instructions and commercial radiopharmacy procedures?

Public Dose

A. Are licensed activities conducted such that doses to members of the public from exposure to radioactive materials, such as radioactive effluents, are below 1 mSv [100 mrem] TEDE in a year? [10 CFR 20.1301(a)(1)]

B. Was the constraint on air emissions met such that an individual member of the public will not receive a TEDE in excess of 0.1 mSv [10 mrem] in a year? [10 CFR 20.1101(d)]

C. Have surveys and/or evaluations been performed per 10 CFR 20.1501(a)?

1. Have there been any changes to the facility, storage of licensed materials, or the amount and/or types of licensed activities? If so, was a new survey or re-evaluation performed?

D. Does the dose in unrestricted areas exceed 0.02 mSv [2 mrem] in any 1 hour? [10 CFR 20.1301(a)(2)]

E. Are sufficient records maintained to demonstrate compliance? [10 CFR 20.2103, 10 CFR 20.2107]

F. Are licensed materials stored in a manner that would prevent unauthorized access or removal? [10 CFR 20.1801]

Use and Emergency Procedures

A. Are procedures for safe use of radioactive materials and emergency procedures developed and implemented?

B. Do the procedures contain the required elements?

C. Are radioactive materials being handled safely?

D. Does the staff use protective clothing, personnel monitors, and other equipment as appropriate?

E. Is assistance coordinated with outside agencies for emergency response (e.g., fire department)?

F. Did any emergencies occur?

1. If so, were they handled properly?

2. Were appropriate corrective actions taken?

3. Was NRC notification and reporting completed as required? [10 CFR 20.2201, 10 CFR 20.2202, 10 CFR 20.2203, 10 CFR 30.50]

Transportation

A. Are DOT Type A or other authorized packages used? [49 CFR 173.415]

B. Are package performance test records on file?

C. Does each package have two labels (e.g., Yellow-II) with transportation index (TI), Nuclide, Activity, and Hazard Class? [49 CFR 172 -Subpart E]

D. Are packages properly marked? [49 CFR 172- Subpart D]

E. Are packages closed and sealed during transport? [49 CFR 173.412(a) – for Type A packages, 49 CFR 173.475(f)]

F. Are shipping papers properly prepared and used? [49 CFR 172 Subpart C]

G. Do shipping papers contain proper entries? [Shipping name; Hazard Class; Identification Number (UN Number); Total Quantity; Package Type; Nuclide; Reportable Quantity (RQ); Physical and Chemical Form; Activity (SI units required); Category of Label; TI; Shipper's Name, Certification, and Signature; Emergency Response Phone Number; Emergency Response Information; and Cargo Aircraft Only (if applicable)] [49 CFR 172-Subpart C]

H. Are shipping papers within driver's reach and readily accessible during transport? [49 CFR 177.817(e)]

I. Are packages secured against movement? [49 CFR 177.834, 49 CFR 177.842]

J. Are incidents reported to DOT? [49 CFR 171.15, 49 CFR 171.16]

K. If Category 1 and 2 materials referenced in Appendix A to 10 CFR Part 37 are transported, are safety and security plans in accordance with 49 CFR Part 172, Subpart I (i.e., 49 CFR 172.800 and 172.802) and 10 CFR Part 37, Subpart D

Security of Radioactive Material (For Programs Possessing Category 1 or Category 2 Radioactive Material)

A. Have background investigations and an access control program been implemented and maintained? [10 CFR Part 37, Subpart B]

B. Have physical protection requirements been implemented and maintained? [10 CFR Part 37, Subpart C]

C. Have the requirements regarding transportation of Category 1 and Category 2 quantities of radioactive material been implemented and maintained? [10 CFR Part 37, Subpart D]

D. Are all records required by 10 CFR Part 37 maintained? [10 CFR Part 37, Subpart F]

Auditor's Independent Survey Measurements (If Made)

A. Provide the type, location, results of measurements, and survey date. Also note the survey instrument used, serial number, calibration date. Does any radiation level exceed regulatory limits? [10 CFR 20.1501(a), 10 CFR 20.1301(a)(2)]

Notification and Reports

A. Was any radioactive material lost or stolen? If so, were reports made? [10 CFR 20.2201]

B. Did any reportable incidents occur? Were reports made? [10 CFR 20.2202, 10 CFR 30.34(g), 10 CFR 30.50, 10 CFR 40.60]

C. Did any overexposures or high radiation levels occur? If so, were they reported? [10 CFR 20.2203, 10 CFR 30.50, 10 CFR 40.60]

D. Were any packages received with surface contamination and/or external radiation levels that exceeded regulatory limits? If so, were they reported to the NRC? [10 CFR 20.1906(d)]

E. If any events (as described in items A through D above) occurred, what was the root cause? Were appropriate notifications made and corrective actions taken?

F. Is the management/RSO aware of the telephone number (301-816-5100) for the NRC Emergency Operations Center?

Posting and Labeling

A. Is NRC-Form 3, "Notice to Workers" posted? [10 CFR 19.11]

B. Are NRC regulations and license documents posted or is a notice posted? [10 CFR 19.11, 10 CFR 21.6, Section 206 of Energy Reorganization Act of 1974]

C. Are other posting and labeling requirements met? [10 CFR 20.1902, 10 CFR 20.1904]

Recordkeeping for Decommissioning

A. Are records kept of information important to decommissioning? [10 CFR 30.35(g), 10 CFR 40.36(f), as appropriate]

B. Do records include all information outlined in 10 CFR 30.35(g), and 10 CFR 40.36(f), as appropriate?

Bulletins and Information Notices

A. NRC Correspondence (e.g., RISs, Bulletins, Information Notices, NMSS newsletters) issued since last audit have been reviewed?

B. Was appropriate training and action taken in response?

Special License Conditions

A. Was compliance with special license conditions achieved?

Deficiencies Identified During Audit; Corrective Actions

A. Summarize problems/deficiencies identified during the audit.

B. If problems/deficiencies were identified in this audit, describe corrective actions planned or taken to prevent recurrence. Include date(s) when corrective actions are implemented.

C. Provide any other recommendations for improvement.

Evaluation of Other Factors

A. Is senior management appropriately involved with the Radiation Protection Program and/or RSO oversight?

B. Does the RSO have sufficient time to perform his/her radiation safety duties?

C. Is there sufficient staff to support the Radiation Protection Program?

APPENDIX F

GENERAL RADIATION MONITORING INSTRUMENT SELECTION GUIDELINES AND RADIATION INSTRUMENT CALIBRATION GUIDELINES

General Radiation Monitoring Instrument Selection Guidelines and Radiation Instrument Calibration Guidelines

Radiation Instrument Selection Guidelines

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

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

Applicants may wish to consider the following instrument selection guidelines:

- Alpha emitters and low-energy beta emitters, such as carbon-14 and sulfur-35, are difficult to detect with GM probes. The detection efficiency generally is about 2 percent for low-energy beta emitters. Licensees should use the proper surveying method (e.g., speed and height above surface), in order to perform adequate surveys. Additionally, wipes should be taken and counted with a LSC to verify potential removable contamination.

- Medium- to high-energy beta emitters, such as phosphorus-32 and calcium-45, can be detected with a pancake Geiger-Mueller (GM) probe. The efficiency ranges from 15 percent to 40 percent, depending on the beta energy.

- Low-energy gamma emitters, such as I-125, can be detected with a NaI probe or a thin-window GM probe (pancake or thin end-window). If the NaI probe possesses a thin window and thin crystal, the detection efficiency is approximately 20 percent. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower and care should be taken to ensure that the GM probe is capable of detecting any established action levels.

- Medium- to high-energy gamma emitters, such as I-131 or high-energy photon emitters, such as F-18, can be detected with either GM or NaI probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for NaI probes.

Further guidance regarding instrumentation can be found in Chapter 9 of the Handbook of Health Physics and Radiological Health, Fourth Edition, Edited by Bernard Shleien, Lester A. Slaback, Jr., and Brian Kent Birky, 2012.

Model Radiation Survey Instrument Calibration Program

Radiation Instrument Calibration Guidelines

This appendix does not contain a step-by-step procedure for performing instrument calibrations. Instead, it provides general guidelines that licensees should consider when developing an instrument calibration program and when developing specific instrument calibration procedures. Licensees should refer to instrument manufacturer instructions and/or nationally recognized standards when developing instrument calibration procedures.

When developing calibration procedures, licensees should consider the conditions under which calibrations will be performed, such as the space available to perform calibrations, any necessary shielding, and any anticipated radiation exposures to personnel and members of the public. Other considerations include the procurement of any necessary equipment, including appropriate radiation sources to perform calibrations. The calibration program should be designed to provide the desired or necessary degree of accuracy.

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; and
  - — biological effects of radiation
- On-the-job training will consist of the following:
  - — observing authorized personnel performing radiation survey instrument calibration; and
  - — 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 Rate or Exposure Rate 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 used for calibrating dose and dose rate measuring instruments should be well-collimated, and the calibration area should be designed to minimize scatter of radiation, which could affect the calibration process.

The calibration area should be appropriately controlled so that persons entering the area will be aware if a radiation source is in use. Evaluate posting of the calibration area with appropriate radiation warning signs, as required by Subpart J of 10 CFR Part 20.

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

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

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 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 measurements instruments should be performed as recommended by the manufacturer.

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

Calibration Sources for Dose and Dose Rate Measuring Instruments

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

- The sources should approximate a point source.
- Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 µGy/h [0.1 mrad/h] and 10 percent for dose rates less than 1.0 µGy/h [0.1 mrad/h].
- The sources should contain a radionuclide that emits radiation of identical or similar type and energy as the environment in which the calibrated device will be used.

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

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

Calibration of Dose or Dose Rate Measuring Instruments

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

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

  — Background to 10 µGy/h [1.0 mrad/h]; ±× = ±30%
  — 10 µGy/h [1.0 mrad/h] to 1.0 mGy/h [100 mrad/h]; ±× = ±20%
  — 1.0 mGy/h [100 mrad/h] to 10 Gy/h [1,000 Rad/h]; ±× = ±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 1 Roentgen per hour need not be calibrated, unless the licensee expects to make measurements at higher dose rates; regardless, such scales should be checked for operation and response to radiation.

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 ±× 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]; ±× = ±20%
  — 2.0 Bq/cm^2 to 200 Bq/cm^2 [12,000 to 1,200,000 dpm/100 cm^2]; ±× = ±10%

- beta measurement

  — 0.05 Bq/cm^2 to 2.0 Bq/cm^2 [300 to 12,000 dpm/100 cm^2]; ±× = ±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 (millicuries) 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.

Model procedures for the calibration of LSCs, well-type scintillation counters, gas-flow proportional counters, and single or multi-channel analyzers are not provided in this document. For compliance with 10 CFR 20.1501(c), users should refer to manufacturers' instructions and/or nationally recognized standards for instrument calibration information. In general, manufacturers' instructions typically specify that for these types of instruments, calibration is expected to produce readings within plus or minus 20 percent of the actual values over the range of the instrument. The minimum detectable activity (MDA) for instruments used should be a fraction (10 to 50 percent) of the criteria that is to be met.

General Guidelines for Calibrating Installed Radiation Detection Instrumentation

Installed instruments are those that operate using line power and are not designed to be portable or hand-carried. Such equipment includes fixed-type area monitors. When developing calibration procedures for these types of instruments, licensees should refer to the manufacturer or vendor's instructions and/or nationally recognized standards, such as American National Standards Institute (ANSI) N323D-2002, "American National Standard for Installed Radiation Protection Instrumentation," January 27, 2003.

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

General Guidelines for Calibrating Air Monitoring Instruments

Air monitoring equipment consists of installed/fixed, portable, personal air monitoring instruments, and continuous air monitors. The quantity of airborne radioactive material can be determined by sampling or continuous monitoring. Sampling involves taking or collecting a sample of the air and then determining the amount of radioactivity in that sample. This type of sampling can be performed during special or infrequent operations that could involve airborne radioactivity or can be performed on a routine basis for a continuous or ongoing process. When performing sampling, it is important to accurately determine the volume of air sampled. Continuous monitoring is a real-time analysis of the amount of radioactivity present. Air sampling or monitoring can be used by licensees to evaluate potential exposures to workers and to evaluate effluents released from the facility that contribute to public dose.

Guidance for NRC licensees can be found in NRC Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," June 1992, as well as NUREG-1400, "Air Sampling in the Workplace," September 1993, which is available at Agencywide Documents and Management System (ADAMS) Accession No. ML13051A671.

When developing calibration procedures for these types of instruments, licensees should refer to the manufacturer or vendor's instructions and/or nationally recognized standards, such as ANSI N323C-2009, "American National Standard for Radiation Protection Instrumentation Test and Calibration-Air Monitoring Instruments," May 21, 2009.

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

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

Frequency of Calibration of Air Sampling Equipment

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

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

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

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

Error Limit for Measurement of Air Sample Volume

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

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

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

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

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

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

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

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

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

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

T_1 = temperature of V_1 in K
P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

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

References:

- Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," June 1992
- NUREG–1400, "Air Sampling in the Workplace," September 1993 (available at the ADAMS Accession No. ML13051A671)
- Health Physics and Radiological Health, 4th Edition. Edited by Thomas E. Johnson and Brian Kent Birky, 2012
- ANSI N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments," December 16, 2013
- "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 9th Edition, 2001
- ANSI N323D-2002, "American National Standard for Installed Radiation Protection Instrumentation," January 27, 2003
- ANSI N323C-2009, "American National Standard for Radiation Protection Instrumentation Test and Calibration-Air Monitoring Instruments," November 6, 2009

APPENDIX G

PUBLIC DOSE

Public Dose

This appendix describes methods for determining radiation doses to members of the public. Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in a calendar year resulting from the licensee's possession or use of licensed materials.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv [2 mrem] in any 1 hour.

- Air emissions of radioactive materials to the environment, excluding radon-222 and its daughters, do not result in doses greater than 0.1 mSv [10 mrem] per year total effective dose equivalent (TEDE). As required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1101(d), if the licensee exceeds the 0.1 mSv [10 mrem] per year air emission dose constraint, the licensee must report the exceedance as provided in 10 CFR 20.2203, and promptly take appropriate corrective action to ensure against recurrence.

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

Doses to Members of the Public	
INCLUDE doses from • radiation or radioactive material released by a licensee • sources of radiation under the control of a licensee • effluents from sources of licensed radioactive materials • licensed material in transportation or storage at the licensee's facility	DO NOT INCLUDE doses from • sanitary sewerage discharges from licensee action taken in accordance with 10 CFR 20.2003 • natural background radiation • medical administration of radioactive material including patients released under 10 CFR 35.75 • voluntary participation in medical research

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

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

- demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose, in an unrestricted area from the licensed operations, does not exceed 1 mSv [100 mrem] in a year, or

- demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in Table 2, "Effluent Concentrations," of Appendix B, to 10 CFR Part 20. {The licensee must also should show that if a member of the public was continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv [2 mrem] in any 1 hour and 0.5 mSv [50 mrem] in a year,} and

- demonstrating that air emissions of radioactive materials to the environment, excluding radon-222 and its daughters, do not result in doses greater than the constraint limit of 0.1 mSv [10 mrem] TEDE

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

Measurements

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

- dose rate surveys for radiation exposures from external radiation sources
- measurements of radionuclides in air and water 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 when volatile materials are used, such as during iodinations, but the discharge itself usually is not continuous because volatile materials often are used periodically rather than continuously. Liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

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

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

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

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

Records

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

Records demonstrating the dose to an individual member of the public should identify the instruments used in the survey, the name of the surveyor, the date of the survey, the location of the 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.

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

APPENDIX H

MODEL LEAK TEST PROGRAM

Model Leak Test Program

Training

Before allowing an individual to perform leak testing, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak testing and sample analysis independently.

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

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and instrument use
- mathematics and calculations used for measuring radioactivity
- biological effects of radiation

Appropriate on-the-job-training consists of

- observing authorized personnel collecting and analyzing leak test samples

- collecting and analyzing leak test samples under the supervision, and in the physical presence of, an individual authorized to perform leak testing and sample analysis

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, analyze leak tests in a low-background area.

- Use a calibrated and operable survey instrument to check leak-test samples for gross contamination before they are analyzed.

- Analyze the leak-test sample using an instrument that is appropriate for the type of radiation to be measured [e.g., NaI(Tl) well-counter system for gamma emitters, liquid scintillation counters for beta emitters, and gas-flow proportional counters for alpha emitters].

- If the sensitivity of the counting system is unknown, the MDA should be determined. The minimum detectable activity (MDA) may be determined using the following formula:

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

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

For example:

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

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

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

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

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

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

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

Frequency for Conducting Leak Tests of Sealed Sources

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

Leak Testing Kits

Leak-test kits will contain

- for example, swabs, wipes, absorbent-tipped sticks, that are to be used to make the wipes on the specified sources or devices
- for example, envelopes, vials, where the leak-test sample will be placed after the sample has been taken
- step-by-step instructions for safe use of the particular kit (these instructions will be specific to the types of devices/sealed sources that the kit is designed)
- procedures for shipping the sample for analysis

- a label that contains the following information:

  — customer's (or Company) name
  — license number
  — date leak test was taken
  — source or device (by manufacturer, model number, nuclide and activity)
  — the name of the individual who performed the leak test

Procedure for Performing Leak Testing and Analysis

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

- Use a radiation survey meter to monitor exposure.

- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.

- Number each wipe to correlate with identifying information for each source.

- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking, but do not wipe the surface of a plated or foil source (see manufacturer's instructions).

- Select an instrument that is sensitive enough to detect 185 Bq [0.005 microcuries] of the radionuclide contained in the sealed source.

- Using the selected instrument, count and record background count rate.

- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. The calibration source should be in the same configuration as the sample. Accuracy of standards should be within plus or minus 5 percent of the stated value and traceable to primary radiation standards such as those maintained by the National Institute of Standards and Technology.

- Calculate the counting efficiency of the detector.

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

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

- Count each wipe sample and determine the net count rate.

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

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

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

- If the wipe test activity is 185 Bq [0.005 microcurie] 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:

NUREG-1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses"

APPENDIX I

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS

U.S. Department of Transportation Regulations

***Note**:* The following list of U.S. Department of Transportation (DOT) regulations is provided to inform licensees about typical requirements that apply to the transportation of licensed material including the preparation of shipments of licensed material. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, transportation requirements change; therefore, licensees should consult the regulations for definitive information about current requirements. Additional information on transportation requirements may be found at the DOT Web site: https://www.dot.gov/.

Title 10 of the *Code of Federal Regulations* (10 CFR) 71.5 requires compliance with DOT regulations in 49 CFR 107, 171 through 180, and 390 through 397, appropriate to the mode of transport. The following are the major areas in DOT regulations most relevant for transporting radioactive materials as Type A or Type B quantities:

- Table of Hazardous Materials and Special Provisions—49 CFR 172, Subpart B
  - 49 CFR 172.101—Hazardous Materials Table [proper shipping name, hazard class, identification number]
  - 49 CFR 172.101—List of Hazardous Substances and Reportable Quantities, Table 2 to Appendix A—Radionuclides
- Shipping Papers—49 CFR 172, Subpart C
  - 49 CFR 172.201—Preparation and retention of shipping papers
  - 49 CFR 172.202—Description of hazardous material on shipping papers
  - 49 CFR 172.203—Additional description requirements
  - 49 CFR 172.204—Shipper's certification
- Marking—49 CFR 172, Subpart D
  - 49 CFR 172.300—Applicability
  - 49 CFR 172.301—General marking requirements for non-bulk packagings
  - 49 CFR 172.304—Marking requirements
  - 49 CFR 172.310—Class 7 (radioactive) materials
  - 49 CFR 172.324—Hazardous substances in non-bulk packagings [designation of "reportable quantities" with the letters "RQ"]
- Labeling—49 CFR 172, Subpart E
  - 49 CFR 172.400—General labeling requirements
  - 49 CFR 172.400a—Exceptions from labeling
  - 49 CFR 172.401—Prohibited labeling
  - 49 CFR 172.403—Class 7 (radioactive) material
  - 49 CFR 172.406—Placement of labels
  - 49 CFR 172.436—RADIOACTIVE WHITE-I label
  - 49 CFR 172.438—RADIOACTIVE YELLOW-II label
  - 49 CFR 172.440—RADIOACTIVE YELLOW-III label

- Placarding—49 CFR 172, Subpart F

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

- Emergency Response Information—49 CFR 172, Subpart G

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

- Training—49 CFR 172, Subpart H

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

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

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

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

  - 49 CFR 173.25—Authorized packagings and overpacks
  - 49 CFR 173.403—Definitions
  - 49 CFR 173.411—Industrial packages
  - 49 CFR 173.412—Additional design requirements for Type A packages
  - 49 CFR 173.413—Requirements for Type B packages
  - 49 CFR 173.415—Authorized Type A packages
  - 49 CFR 173.416—Authorized Type B packages
  - 49 CFR 173.433—Requirements for determining basic radionuclide values, and for the listing of radionuclides on shipping papers and labels
  - 49 CFR 173.435—Table of A1 and A2 values for radionuclides
  - 49 CFR 173.441—Radiation level limitations and exclusive use provisions
  - 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission approved packages
  - 49 CFR 173.475—Quality control requirements prior to each shipment of Class 7 (radioactive) materials
  - 49 CFR 173.476—Approval of special form Class 7 (radioactive) materials

- Carriage by Public Highway—49 CFR Part 177

  - 49 CFR 177.817—Shipping papers
  - 49 CFR 177.842—Class 7 (radioactive) material [includes requirement for blocking and bracing during transport]

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

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

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

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

Radioactive Material Quantity[3]		Limited Quantities and Articles	Type A[4] [9]	Type B
Activity Restrictions		≤ the limits specified in Table 4 of § 173.425	≤ A_1 for special form ≤ A_2 for normal form	> A_1 for special form > A_2 for normal form
Contents of Package	Non-fissile and Fissile Excepted	Excepted Package	Type A Package	Type B(U) or Type B(M) package
	Fissile	N/A	Type AF[10] package	Type B(U)F or Type B(M)F package

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

Type(s) of LSA and/or SCO	LSA-I	LSA-II	LSA-III	SCO-I	SCO-II
Category of Package for Domestic or International Transport[7,8]	Unpackaged[8] **IP-1:** solids or liquids/exclusive use **IP-2:** liquids/non-exclusive use **Specification tank cars or cargo tank motor vehicles:** liquids/exclusive use	- - **IP-2:** exclusive use[9] **IP-3:** liquids or gases/non-exclusive use[9]	- - **IP-2:** exclusive use **IP-3:** non-exclusive use	Unpackaged[8] IP-1 - -	- - IP-2 -
Alternative Provisions for Domestic only Transport[8]	**Packaging shall meet the requirements of §§ 173.24, 24a, and 173.410.** **Transportation shall be an exclusive use shipment.** **Activity per shipment must be less than an A_2 quantity (see § 173.427(b)(4)).**				

[1] Additional provisions may apply for radioactive materials that are pyrophoric, oxidizing, fissile excepted, or uranium hexafluoride.

[2] Each NRC licensee shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397 (see § 71.5).

[3] Materials that contain radionuclides, where both the activity concentration and the total activity in the consignment exceed either the values specified in the table in § 173.436 or the values derived according to the instructions in § 173.433, must be regulated in transport as Class 7 (radioactive) material.

[4] Except for LSA material and SCO, a Type A package may not contain a quantity of Class 7 (radioactive) material greater than A_1 or A_2 (see § 173.431(a)). See A_1 and A_2 definitions in § 173.403.

[5] The external dose rate from LSA material or SCO in a single package may not exceed 10 mSv/h (1 rem/h) at 3 meters from the unshielded material or objects (see §§ 173.427(a)(1) and (d)).

[6] LSA material and SCOs that are or contain fissile material in quantities that are not fissile excepted must be packaged in appropriate Type AF or Type BF packages, and not classified as LSA material or SCO. For alternate domestic transport provisions, see § 173.427(b)(4). For comprehensive guidance on packaging and transportation of LSA material and SCO, see NUREG-1608.

[7] For the quantity of LSA material and SCO transported in a single conveyance, see the limits specified in § 173.427(a)(2).

[8] LSA material or SCO shall be appropriately packaged in accordance with § 173.427(b) or (d). Certain LSA-I material and SCO-I may be transported unpackaged under the conditions in § 173.427(c).

[9] See §§ 173.411(c) and 173.415(a) for requirements related to package record retention (2 years) and associated documentation of physical tests.

[10] See §§ 71.22(a), 71.23(a) and 173.417(a) for regulations regarding the use of non-AF packages for fissile materials.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The non-fixed contamination shall be determined by:

(a) wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;
(b) ensuring each wipe area is 300 cm^2 in size;
(c) measuring the activity on each single wiping material and dividing that value by the surface area wiped and the efficiency of the wipe procedure, where an actual wipe efficiency may be used, or it may be assumed to be 0.10.

Alternatively, the contamination level may be determined using alternative methods of equal or greater efficiency.
A conveyance used for non-exclusive use shipments is not required to be surveyed unless there is reason to suspect that it exhibits contamination (see § 173.443(a)(2)).

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

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

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

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

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

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

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

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

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

- Before each shipment of any radioactive materials package, the offeror must ensure, by examination or appropriate tests, that:
  (a) the packaging is proper for the contents to be shipped;
  (b) the packaging is in unimpaired physical condition, except for superficial marks;
  (c) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;
  (d) for fissile material, each moderator and neutron absorber, if required, is present and in proper condition;
  (e) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed;
  (f) each closure, valve, or other opening of the containment system is properly closed and sealed;
  (g) each packaging containing liquid in excess of an A_2 quantity and intended for air shipment has been tested to show that it will not leak under an ambient atmospheric pressure of not more than 25 kPa, absolute (3.6 psia), where the test must be conducted on the entire containment system, or on any receptacle or vessel within the containment system, to determine compliance with this requirement;
  (h) the internal pressure of the containment system will not exceed the design pressure during transportation; and
  (i) the external radiation and contamination levels are within the allowable limits specified in §§ 173.441 and 173.443.

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

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information. [1]

Shipping Paper Entries

Always Required	Sometimes Required	Optional Entries
Basic description (in sequence): • **UN Identification number** • **Proper Shipping Name** • **Hazard Class (7)** • **Maximum activity contained in each package in SI units** (e.g., Bq, TBq), or in both SI and customary units (e.g., Ci, mCi) with customary units in parentheses following the SI units • **Number and type of packages** Additional description: • **Name of each radionuclide**[2] • **Description of physical and chemical form** (unless special form) • **"Special form" when not in the proper shipping name** • **Category of label** used • **Transport index (TI)** of each package bearing a Yellow-II or Yellow-III label Additional entry requirements: • 24 hour **emergency telephone number** • **Shipper's Certification** shall be provided by each person offering radioactive material for transportation[3] • Proper page numbering (e.g., Page 1 of 4)	Materials-based Requirements: • The criticality safety index (CSI) or "Fissile Excepted" for fissile material • "Highway route controlled quantity" or "HRCQ" for highway route controlled quantities • The letters "RQ" entered either before or after the basic description for each hazardous substance [see § 171.8] • Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required • A hazardous waste manifest and the word "Waste" preceding the proper shipping name is required for radioactive material that is hazardous waste Package-based Requirements: • The applicable DOE or NRC package approval identification marking for each Type B(U), Type B(M), or fissile material package • The International Atomic Energy Agency (IAEA) Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package Shipment- and Administrative-based Requirements: • Specify "exclusive use shipment" as required • Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use • Specify the notation "DOT–SP" followed by the special permit number for a special permit shipment	• The weight in grams or kilograms may be inserted instead of activity units for fissile radionuclides, except for Pu-239 and Pu-241 • The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units • Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information

Special Considerations/Exceptions for Shipping Papers

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

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

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

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

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

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

Markings on Packages

Markings Always Required Unless Excepted[1]

For Non-bulk Packages:

- Proper shipping name
- Identification number (preceded by "UN" or "NA," as appropriate)
- Name and address of consignor or consignee, unless the package is:
  - highway only and no motor carrier transfers; or
  - part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee

For Bulk Packages:

- Identification number on orange panel or white square-on-point display [see §§ 172.332 or 172.336]:
  - on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more[2], or
  - on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons)[2]

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 (e.g., "USA")
- Radiation (trefoil) symbol[3] on outside of outermost receptacle of each Type B(U) or Type B(M) packaging design

- Each NRC-approved package (e.g., Type AF, Type B(U), Type B(M), Type B(U)F, and Type B(M)F) must be marked with the identification marking indicated in the package approval
- For Specification 7A packaging, mark on the outside with "USA DOT 7A Type A", and the name and address or symbol of the manufacturer satisfying §§ 178.3 and 178.350

Materials-based requirements:

- For a non-bulk IP–1 package containing a liquid, use underlined double arrow symbol indicating upright orientation[4], where the symbol is placed on two opposite sides of the packaging [see § 172.312]

- For a non-bulk package containing a hazardous substance, mark the outside of each package with the letters "RQ" in association with the proper shipping name

Administrative-based requirements:

- For each Type B(U), Type B(M) or fissile material package destined for export shipment, mark "USA" in conjunction with specification marking, or certificate identification; and package identification indicated in the U.S. Competent Authority Certificate
- Mark "DOT–SP" followed by the special permit number assigned for each package authorized by special permit
- Competent authority identification marking and revalidation for foreign made Type B(U), Type B(M), Type H(U), Type H(M), or fissile material package for which a Competent Authority Certificate is required

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.

For marking exceptions for LSA material and SCO, [see § 173.427(a)(6)(vi)] (e.g., RADIOACTIVE-LSA, RADIOACTIVE-SCO, or RQ, as appropriate).

For an overpack, the marking "OVERPACK" in lettering 12 mm (0.5 inches) high. This marking is not required if the package type contained in the overpack is visible from the outside [see § 173.25].

Special Considerations for Marking Requirements

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

[1] Some marking exceptions exist for excepted packages, as specified in §§ 173.421, 173.422, 173.424, 173.426 and 173.428.

[2] If the identification number marking on a bulk package is not visible, the transport vehicle or freight container must be marked on each side and each end [see § 172.331].

[3] The radiation symbol shall be resistant to the effects of fire and water, plainly marked by embossing, stamping or other means resistant to the effects of fire and water and conform to the size requirements of Appendix B to Part 172.

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

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

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

Requirements for Labels[1]

- Label each package, except for (a) excepted packages of radioactive material; and (b) Low Specific Activity (LSA) material and Surface Contaminated Objects (SCO), packaged or unpackaged, when transported under exclusive use controls domestically and when the material or object contains less than an A_2 quantity.
- Labels are required to be (a) printed or affixed to a surface other than the bottom of the package, (b) placed near the proper shipping name marking, (c) printed or affixed to a background of contrasting color or have a dotted or solid line outer border, (d) clearly visible, (e) not obscured by markings or other attachments, (f) representative of the hazardous material content, and (g) in conformance with the label specifications of § 172.407.
- The appropriate radioactive label must be affixed to opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material.

Category of Radioactive Labels [3]

White-I

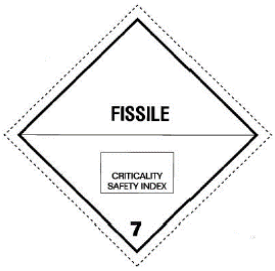
Yellow-II

Yellow-III

Maximum Radiation Surface Level (RSL)			
mSv/h	**RSL** ≤ 0.005	0.005 < **RSL** ≤ 0.5	0.5 < **RSL** ≤ 2[5]
mrem/h	**RSL** ≤ 0.5	0.5 < **RSL** ≤ 50	50 < **RSL** ≤ 200[5]

Transport Index (TI):[4]		
TI = 0	0 < **TI** ≤ 1	1 < **TI** ≤ 10[5]

Other Radioactive Labels[2]



Fissile

Fissile labels required for each package containing fissile material, other than fissile-excepted material; and labels must be affixed adjacent to radioactive category labels.

Empty

Empty labels required for empty Class 7 (radioactive) packages satisfying § 173.428; and any previously-used labels must not be visible.

Contents on Labels

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

[1] Additional labels may be required if the contents of a package contains material that also meets the definition of one or more other hazard class. See §§ 172.402 and 406(c) for details on additional labeling requirements. [See §§ 172.400a, 173.421 through 173.427 for details when labels are not required, and see § 172.407 for details on label durability, design, size, color, form identification, exceptions, and the trefoil symbol size].

[2] A "Cargo Aircraft Only" label is required for each package containing a hazardous material which is authorized for cargo aircraft only [see § 172.402(c)].

[3] The category of the label must be the higher of the two values specified for RSL and TI [see § 172.403(b)].

[4] The TI is determined from the radiation level 1 meter from the package surface [see TI definition in § 173.403]. If the measured TI is not greater than 0.05, the value may be considered to be zero. When an overpack is used, it must be labeled in accordance with § 72.403(h).

[5] Packages with a TI > 10 or an RSL > 2 mSv/h (200 mrem/h) must be transported under exclusive use provisions [see § 173.441(b)]. Any package containing a Highway Route Controlled Quantity (HRCQ) must be labelled as RADIOACTIVE YELLOW-III.

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

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

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

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

Visibility and Display of Radioactive Placards [§ 172.516]

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

Radioactive Placards

PLACARD (FOR OTHER THAN HRCQ)	PLACARD FOR HRCQ
	
White triangular background color in the lower portion with yellow triangle in the upper portion; trefoil symbol, text, class number and inner and outer borders in black. [see § 172.556 and Appendix B of Part 172]	Square background must consist of a white square surrounded by one-inch black border. The placard inside the square is identical to that for other than HRCQ. [see § 172.527]

General Specifications for Placards and Subsidiary Hazard Placarding

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

[1] See § 172.512 for exceptions and variations to the placarding requirements for freight containers and aircraft unit load devices.
[2] See § 173.403 for the definition of Highway Route Controlled Quantity (HRCQ). A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels [see §§ 172.403(c) and 172.507(a)].
[3] Required placarding of the front of a motor vehicle may be on the front of a truck-tractor instead of or in addition to the placarding on the front of the cargo body to which a truck-tractor is attached § 172.516(b).

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

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

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

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

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

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

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

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

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

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

Guidance on Responding to Emergencies (Emergency Response Guidebook)

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

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

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

Training (49 CFR 172, Subpart H)

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

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

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

APPENDIX J

MODEL PERSONNEL TRAINING PROGRAM

Model Personnel Training Program

Training Program

1. General instructions

    1.1 Training will be provided

    - before an employee assumes duties with or in the immediate vicinity of radioactive materials
    - at least annually, as refresher training for all employees
    - whenever a significant change occurs in duties, regulations, or the terms of a U.S. Nuclear Regulatory Commission (NRC) license

    1.2 Subjects covered for individuals working with, or in the vicinity of, radioactive materials or radiation

    - safe radiation practices associated with the job (examples of topics that may be covered are found in Section 3 of this appendix)
    - site-specific radiation safety practices
    - applicable NRC regulations

    1.3 Subjects covered for ancillary personnel

    - significance of the radiation symbol and its use on signs and labels
    - location of unrestricted areas
    - whether the individual is authorized access to the restricted areas of the facility

    1.4 Type of instruction

    - Instruct individuals in the licensee's site-specific Radiation Safety Program and NRC regulatory requirements in the form of lecture, demonstrations, videotape, or self-study, and include practical subjects important to the safe use of licensed material.
    - Provide individuals receiving instructions an opportunity to ask questions.

2. Instruction for individuals likely to receive an occupational dose in excess of 1 mSv [100 mrem]

    2.1 Instruction will be provided:

    - before an employee assumes duties with or in the immediate vicinity of radioactive materials

- at least annually, as refresher training

- whenever a significant change occurs in duties, regulations, or terms of NRC license

2.2 Licensees must provide instruction on subjects covered in 10 CFR 19.12, "Instruction to workers."

2.3 Records of initial and refresher training will be maintained and will include

- name of the individual who provided the instruction
- names of the individuals who received the instruction
- date of instruction
- list of the topics covered

3. Suggested radiation safety training topics for individuals working with, or in the vicinity of, byproduct material (this section is intended as a guide to topics covered in a typical radiation safety training program; topics selected will be commensurate with the individuals' duties).

3.1 Basic radiation safety information

- basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues)

- radiation safety

  — radiation vs. contamination
  — internal vs. external exposure
  — biological effects of radiation
  — as low as is reasonably achievable (ALARA) concept
  — use of time, distance, and shielding to minimize exposure

- risk estimates, including comparison with other health risks (10 CFR 19.12)

- regulatory requirements

  — RSO
  — material control and accountability
  — dose to individual members of the public
  — personnel dosimetry
  — occupational dose limits and their significance
  — dose limits to the embryo/fetus, including instruction on declaration of pregnancy
  — workers' right to be informed of occupational radiation exposure
  — Radiation Safety Program audits
  — ordering and receipt of packages
  — transfer
  — waste disposal
  — security

— recordkeeping
— surveys
— postings
— labeling of containers
— handling and reporting of incidents or events
— licensing and inspection by the NRC
— need for complete and accurate information
— employee protection
— deliberate misconduct
— packaging and shipment

3.2 General topics for safe use of radionuclides

- Wear a laboratory coat or other protective clothing at all times when working with radioactive materials.

- Use syringe shields and vial shields when preparing and handling radioactive drugs.

- Measure all radiopharmaceuticals before transfer.

- Measure the molybdenum (Mo)-99 content of each generator elution, and do not transfer those radiopharmaceuticals for human medical use that will contain more than 0.15 microcuries of Mo-99 per mCi of technetium (Tc)-99m at the time of administration. NRC notification is required when there is more than 0.15 kilobecquerel of Mo-99 per megabecquerel of Tc-99m (0.15 microcurie of Mo-99 per millicurie of Tc-99m) in an eluate per 10 CFR 30.34(g) and 10 CFR 35.3204.

- Wear disposable gloves at all times when handling radioactive materials, and change gloves frequently to minimize the spread of contamination.

- Before leaving the hot lab, monitor hands, shoes, and clothing for contamination in a low-background area, allowing sufficient time for instrument response (e.g., move probe 2 inches per second a half-inch from the surface).

- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.

- Do not store food, drink, or personal effects in areas where licensed material is stored or used (see Figure M-1 of this NUREG). Personal items brought into the restricted area (e.g., radios, portable music players, notepads, books) will be surveyed for contamination before removal from the area.

- Clearly label food and beverages used in the preparation of radiopharmaceuticals with “Not for personal consumption” if stored with radioactive materials.

- 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).

3.3 Instruction on radiopharmacy-specific program elements

- applicable regulations and license conditions
- areas where radioactive material is used or stored
- potential hazards associated with radioactive material in each area where the individuals will work
- special procedures for handling volatile materials
- proper use of radiation shielding
- proper use of survey and analytical instruments
- appropriate response to spills, emergencies, or other unsafe conditions
- emergency procedures
- previous incidents, events, and accidents
- survey program
- effluent monitoring and control
- customer-returned waste pickup, receipt, and handling
- waste management and minimization
- personnel monitoring
- procedures for receiving packages containing radioactive materials
- procedures for opening packages
- sealed sources and leak tests
- other topics, as applicable

APPENDIX K

DOSE CALIBRATOR TESTING GUIDANCE

Dose Calibrator Testing Guidance

Guidance for Testing Dose Calibrators Used to Measure Photon-Emitting Radionuclides

This guidance can be used by applicants and licensees for checking and testing dose calibrators that are used to measure photon-emitting radionuclides. The majority of radionuclides distributed by radiopharmacies have prominent photon emissions and can easily be measured in a dose calibrator using measurement standard techniques. Advances in medicine have resulted in the development of radiopharmaceuticals that have prominent alpha or beta emissions. For the measurement of alpha- and beta-emitting radionuclides, it is important that applicants and licensees closely follow any dose calibrator testing and measurement guidance provided by the manufacturer. Additional guidance is presented below.

Guidance

1. Test for the following at the indicated frequency (if the dose calibrator falls outside the suggested tolerances, the dose calibrator should be repaired or replaced):

    1.1 Constancy, at least once each day before assay of patient dosages (a safe margin is considered to be below plus or minus 5 percent)

    1.2 Linearity at installation and at least quarterly thereafter (a safe margin is considered to be below plus or minus 5 percent)

    1.3 Geometry dependence at installation (a safe margin is considered to be below plus or minus 10 percent)

    1.4 Accuracy, at installation and at least annually thereafter (a safe margin is considered to be below plus or minus 10 percent)

2. After repair, adjustment, or relocation of the dose calibrator, such that proper function of the ionization chamber or electronics would likely be in doubt, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as cesium (Cs)-137, cobalt-60, cobalt (Co)-57, or radium (Ra)-226, using a reproducible geometry each day before using the calibrator; consider using two or more sources with different photon energies and activities.

    3.1 Assay each reference source using the appropriate dose calibrator setting (e.g., use the Cs-137 setting to assay Cs-137).

    3.2 Measure background at the same setting, and subtract or confirm the proper operation of the automatic background circuit if it is used.

    3.3 For each source used, either plot or log (i.e., record in the dose calibrator log book) the background level for each setting checked and the net activity of each constancy source.

3.4 Using one of the sources, repeat the above actions for all commonly used radionuclide settings. Plot or log the results.

3.5 Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the Authorized Nuclear Pharmacist (ANP) or the RSO of a suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The dose calibrator will be repaired or replaced if the error exceeds 10 percent.

4. The linearity of a dose calibrator should be ascertained over the range of its use between the maximum activity in a vial and 30 microcuries. Note that with radionuclides with short half-lives, such as PET radionuclides, there may be difficulties measuring a low activity such as 30 microcuries. Therefore, the lowest activity that is measurable, which must be below the lowest dose distributed, is acceptable. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This example uses a vial of technetium (Tc)-99m that has the anticipated maximum activity to be assayed (e.g., the first elution from a new generator) and assumes the predetermined safety margin is plus or minus 5 percent.

4.1 Time Decay Method

4.1.1 Inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

4.1.2 Assay the Tc-99m vial in the dose calibrator and subtract background to obtain net activity in mCi.

4.1.3 Repeat step in Section 4.1.2 at time intervals of 6, 24, 30, and 48 hours after the initial assay.

***Note**:* Time intervals used for other radionuclides may vary depending on the radionuclide's half-life.

4.1.4 Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time[1] (hours)	Correction Factor
0	31.6
6	15.8
24	2.00
30	1.00
48	0.126

[1]Assay times should be measured in whole hours, and correction factors should be used to three significant figures as indicated. The half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

Example: If the net activity measured at 30 hours was 15.6 mCi, the calculated activities for 6 and 48 hours would be 15.6 mCi × 15.9 = 248 mCi and 15.6 mCi × 0.126 = 1.97 mCi, respectively.

4.1.5 Plot both the measured net activity and the calculated activity versus time.

4.1.6 On the graph, the measured net activity plotted should be within plus or minus 5 percent of the calculated activity if the instrument is linear and functioning properly. If variations greater than 5 percent are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.

4.1.7 If instrument linearity cannot be corrected, for routine assays, it will be necessary to use either an aliquot of the eluate that can be accurately measured or the graph constructed in Section 4.1.5 to relate measured activities to calculated activities.

4.2 Shield Method: If a set of "sleeves" of various thicknesses are used to test for linearity, it will first be necessary to calibrate them.

4.2.1 Begin the linearity test by assaying the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in mCi. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time. After making the first assay, the sleeves can be calibrated as follows. (Steps in Sections 4.2.2 through 4.2.4 must be completed within 6 minutes.)

4.2.2 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

4.2.3 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4.2.4 Continue for all sleeves.

4.2.5 Complete the following decay-method linearity test steps:

4.2.5.1 Repeat the assay at about noon, and again at about 4:00 p.m. Continue on subsequent days until the assayed activity is less than 30 microcuries. For dose calibrators on which the range is selected with a switch, select the range normally used for the measurement.

4.2.5.2 Convert the time and date information recorded to hours elapsed since the first assay.

4.2.5.3 On a sheet of semilog graph paper, label the logarithmic vertical axis in mCi and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.

4.2.5.4 Draw a “best fit” straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-line) = deviation

4.2.5.5 If the worst deviation is more than plus or minus 0.05, the dose calibrator should be repaired or replaced. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to “true activity.”

4.2.6 From the graph made in Section 4.2.5.3, find the decay time associated with the activity indicated with sleeve 1 in place. This is the “equivalent decay time” for sleeve 1. Record that time with the data recorded in Section 4.2.2.

4.2.7 Find the decay time associated with the activity indicated with sleeve 2 in place. This is the “equivalent decay time” for sleeve 2. Record that time with the data recorded in Section 4.2.3.

4.2.8 Continue for all sleeves.

4.2.9 The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

4.2.10 Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in mCi. Record the net activity.

4.2.11 Steps in Section 4.2.12 through 4.2.14 below must be completed within 6 minutes.

4.2.12 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

4.2.13 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4.2.14 Continue for all sleeves.

4.2.15 On a sheet of semilog graph paper, label the logarithmic vertical axis in mCi, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

4.2.16 Plot the data using the equivalent decay time associated with each sleeve.

4.2.17 Draw a “best fit” straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-line) = deviation.

4.2.18 If the worst deviation is more than plus or minus 0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to "true activity."

5. Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence should be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following example assumes that injections are done with 3-cc plastic syringes, that radiopharmaceutical kits are made in 30-cc glass vials, and that the predetermined safety margin is plus or minus 5 percent.

5.1 In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. Tap water may be used.

5.2 Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and mCi.

5.3 Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and mCi indicated.

5.4 Repeat the process until a volume of 2.0 cc has been assayed. The entire process must be completed within 10 minutes.

5.5 Select as a standard the volume closest to that normally used for injections. For all other volumes, divide the standard mCi by the mCi indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal error lines above and below the chosen "standard volume."

5.6 If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the error lines, it will be necessary to make a correction table or graph that will allow a conversion from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model and serial number of the calibrator.

5.7 To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and mCi indicated.

5.8 Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and mCi indicated.

5.9 Repeat the process until a volume of 19.0 cc has been assayed. The entire process must be completed within 10 minutes.

5.10 Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard mCi by the mCi indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed, with horizontal 5 percent error lines drawn above and below the chosen "standard volume."

5.11 If any correction factors are greater than 1.05, or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

6. Accuracy means that, for a given calibrated reference source, the indicated mCi value is equal to the mCi value determined by the NIST or by the supplier who has compared that source to a source that was calibrated by NIST. Certified sources are available from NIST and from many radionuclide suppliers. At least two sources with different principal photon energies (such as Co-57, cobalt-60, Cs-137) should be used. One source should have a principal photon energy between 100 keV and 500 keV. If a Ra-226 source is used, it should be at least 10 microcuries; other sources should be at least 50 microcuries. Consider using at least one reference source with an activity that is within the range of activities normally assayed.

6.1 Assay a calibrated reference source at the appropriate setting (e.g., use the Co-57 setting to assay Co-57) and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of 3 determinations.

6.2 Average the 3 determinations. The average value should be within the predetermined safety margin, which in this example is 5 percent of the certified activity of the reference source, mathematically corrected for decay.

6.3 Repeat the procedure for other calibrated reference sources.

6.4 If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The dose calibrator should be repaired or replaced if the error exceeds 10 percent.

6.5 At the same time the accuracy test is performed, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radionuclide settings. Record the settings and indicated mCi values with the accuracy data.

7. The individual performing the tests will sign or initial and date the records of all geometry, linearity, and accuracy tests.

8. Additional considerations for the measurement of alpha- and beta- emitting radionuclides

8.1 For beta- emitting radionuclides

8.1.1 If the radiopharmacy will only redistribute beta-emitting radionuclides that have been previously prepared and distributed by other persons licensed pursuant to 10 CFR 32.72, additional testing of the dose calibrator is not necessary.

8.1.2 If the radiopharmacy will initially distribute (i.e., measure, prepare, and label) beta-emitting radionuclides, a correction factor is often necessary to accurately determine activity.

The radiopharmacy should: (1) develop, implement, and maintain a procedure to be used to determine correction factors; or (2) use correction factors supplied by the instrument manufacturer or other entity, such as the distributor of the radionuclide. In either case, consideration should be given to the correction factor's dependence on geometry, the types of vials and syringes that may be measured, and the potential need for a NIST traceable standard.

8.2 For alpha-emitting radionuclides

8.2.1 If the radiopharmacy will only redistribute alpha-emitting radionuclides that have been previously prepared and distributed by other persons licensed pursuant to 10 CFR 32.72, additional testing of the dose calibrator is not necessary.

8.2.2 If the radiopharmacy will initially distribute (i.e., measure, prepare, and label) alpha-emitting radionuclides, consideration needs to be given to other emissions that may be more easily measured in a dose calibrator, such as photon or beta particles with sufficient detection efficiency.

The commercial radiopharmacy should: (1) develop, implement, and maintain a procedure to be used to measure alpha-emitting radionuclides; or (2) follow the guidance provided by the instrument manufacturer or other entity, such as the distributor of the radionuclide.

References:

ANSI N42.13-2004, "Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides"

NCRP Report 58, "A Handbook of Radioactivity Procedures" November 1, 1978

APPENDIX L

MATERIAL RECEIPT AND ACCOUNTABILITY

Material Receipt and Accountability

Prior to any transfer from the license, the licensee must verify that the recipient is authorized to receive the licensed material, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 30.41 and 40.51.

The regulations in 10 CFR 30.51 and 40.61 require the licensee to maintain records of receipt, transfer, and disposal of all licensed materials.

Sample Model Procedure for Ordering and Receiving Radioactive Material

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

- Instruct carriers to deliver radioactive packages directly to the designated receiving area.

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, within 3 hours of receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering a damaged package to the facility remain at the facility until they are monitored by the licensee.

Outside of normal working hours, deliveries usually will be handled by trained individuals, as described in the procedures in this appendix. Because certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as required by 10 CFR 20.1906. Packages should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.

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

Name _____

Phone _____

Sample Procedure for Safely Opening Packages Containing Licensed Materials

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

- Wear gloves to prevent hand contamination.

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

- Monitor the external surfaces of a labeled package, according to specifications in Table 8-1, "Package Monitoring Requirements," Section 8.10.3 of this NUREG and 10 CFR 20.1906.

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

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

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

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

- Notify the final delivery carrier and the U.S. Nuclear Regulatory Commission Operations Center, 301-816-5100, by telephone when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i), or external radiation levels exceed the limits of 10 CFR 71.47.

- If applicable, comply with the National Source Tracking System reporting requirement as described in 10 CFR 20.2207, "Reports of Transactions Involving Nationally Tracked Sources."

Sample Procedure for Accountability for Unsealed Materials

- The licensee should maintain an accountability log (inventory) of all radioactive materials possessed under the license that demonstrates that the license limits are not exceeded, that all materials received are accounted for, and that material is disposed of or transferred prior to being removed from the current inventory.

- For each radionuclide listed on the license, the licensee should enter the receipts directly into the inventory record for each shipment of material received under the license and indicate the total amount possessed from all shipments.

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

APPENDIX M

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 licensee using radioactive material will establish general rules for the safe use of the material so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times when working with radioactive materials.

  Note: The radiation safety and ALARA guidance (including contamination control) for unsealed radioactive material for compounding alpha-emitters does not significantly differ from gamma or beta emitters; however, particular attention is warranted to prevent intakes of alpha-emitters (e.g., personal protection equipment such as masks, gloves).

- Use syringe shields and vial shields when preparing and handling radioactive drugs.

- Measure all radiopharmaceuticals before transfer.

- Measure the molybdenum-99 content of each generator elution, and do not transfer those radiopharmaceuticals for human medical use that will contain more than 0.15 microcuries of molybdenum-99 per mCi of technetium-99m at the time of administration.

- Follow manufacturer instructions for generator elution of other types of generators (i.e., Germanium-68/Gallium-68).

- Wear disposable gloves at all times when handling radioactive materials, and change gloves frequently to minimize the spread of contamination.

- Before leaving the hot lab, monitor hands, shoes, and clothing for contamination in a low-background area, allowing sufficient time for instrument response.

- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.

- Do not store food, drink, or personal effects in areas where licensed material is stored or used (see Figure M-1).

- Survey for contamination personal items brought into the restricted area (e.g., radios, music players, cell phones, notepads, books) before they are removed from the area.

- Clearly label “Not for personal consumption” on food and beverages used in preparation of radiopharmaceuticals if it is stored with radioactive materials.

- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.

- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

- Never pipette by mouth.

- Store radioactive solutions in clearly labeled containers.

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

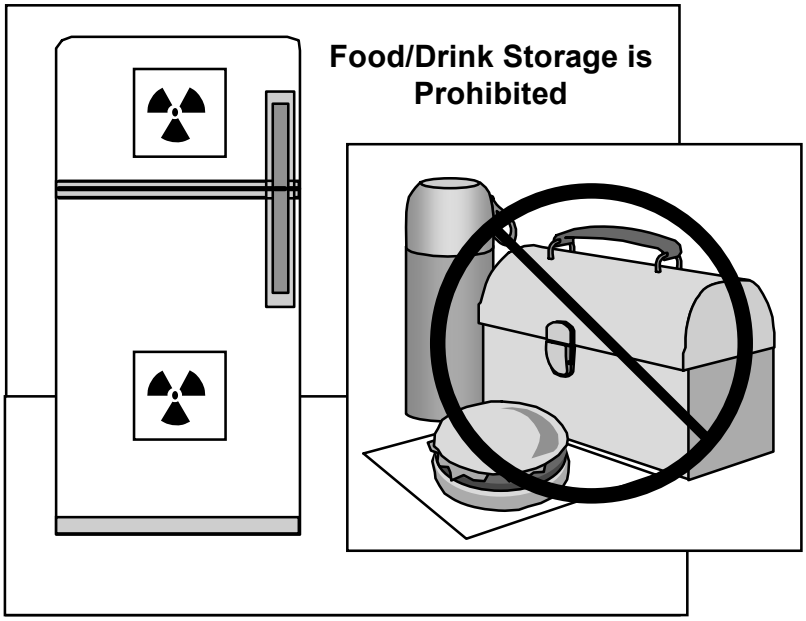


Figure M–1. Storage of Food and Drink
Food or drink for personal consumption should not be stored in refrigerators with radionuclides.

Model Procedures for Handling Millicurie Quantities of Radioiodine

Because of the potential for significant intakes due to volatility and accidental inhalation and ingestion and the potential for skin exposures from contamination, licensees will establish specific procedures for the containment and handling of mCi quantities of radioiodine (most commonly iodine-131) as a means for compliance with Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201 and 20.1101. The following guidance is the minimum that should be considered if the applicant intends to manipulate radioiodine:

- Manipulation of radioiodine (e.g., handling or compounding capsules, performing radioiodination, dispensing from bulk solution) will be conducted in an isolated area within the main hot lab of the commercial radiopharmacy. This will aid in maintaining exposures as low as is reasonably achievable (ALARA) and provide a means to isolate the area in the event of a spill.

- Radioiodine handling will only be performed inside a glovebox or fume hood that has a minimum face velocity of 100 to 150 linear feet per minute. The ventilation for

gloveboxes and fume hoods will be checked at least once every 6 months to ensure adequate airflow and confirm negative pressure with respect to the area around the glovebox or fume hood. Exhaust stacks for gloveboxes and fume hoods used for handling radioiodine will not be located near ventilation intakes to minimize the likelihood of recirculation to the pharmacy or to other tenants in a shared building.

- Gloveboxes and fume hoods must include appropriate filters (activated charcoal) to minimize effluents from radioiodine handling.

- Filters must be installed and used in accordance with the manufacturer's specifications (e.g., adequate air flow to ensure adequate residence time).

- Check filters at installation and periodically, based on use, but not less than once per calendar quarter, to ensure continued efficiency.

- Air flow through fume hoods and gloveboxes will be confirmed before each use.

- Magna-helic sensors, if used, will be checked before each use of the glovebox or fume hood, to ensure minimum flow across the filter.

- Locate absorbent materials and dry chemical buffers, for use in the event of a spill, near the area where mCi quantities of radioiodine are handled.

- Additional protective clothing will be used when handling mCi quantities of radioiodine. Personnel will be double-gloved and use shoulder-length sleeve guards. The gloves and glove seals on gloveboxes will be checked periodically and replaced when needed.

- Bioassay is necessary when the cumulative amount of radioactivity of volatile iodine that is used in unsealed forms, during any 3-month period, exceeds the specified quantities in NRC Regulatory Guide 8.20, Revision 2, "Applications of Bioassay for Radioiodine."

Bioassay Monitoring

Frequency of Required Bioassay Measurements

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

- potential exposure of the individual
- retention and excretion characteristics of the 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 who are likely to exceed 10 percent of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements, and nonroutine (emergency) measurements further determine the frequency and scope of measurements.

Routine Bioassay Measurements

Routine bioassay measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose.

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 greater than 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, since external exposure generally is the predominate exposure pathway.

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

Nonroutine (Emergency) Bioassay Monitoring

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

- 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
- elevated air monitoring results

Model Procedures for Responding to Events

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

This model provides acceptable procedures for responding to emergencies involving spills of radioactive materials. Applicants using unsealed licensed material may either adopt this model or develop alternative procedures to meet the requirements of 10 CFR 20.1101. No emergency procedure can anticipate every likely event; therefore, flexibility and judgment must be incorporated into procedures for responding to spills/contamination events.

General Safety Procedures to Handle Spills

The name and telephone number of the radiation safety officer (RSO) should be posted conspicuously in areas of use, so that it is readily available in case of emergencies. Licensees should have emergency equipment readily available for handling spills. Spill/contamination kits should include the following items:

- disposable 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
- wipes for removable contamination
- instructions for “Emergency Procedures”
- clipboard with copy of Radioactive Spill Report Form
- pencil or pen
- appropriate survey instruments, including batteries

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

For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest annual limit on intake (ALI), an alternative spill/contamination procedure, if practical based on facility operations, may be to restrict access to the area pending decay. In most cases, determination of a major versus minor spill should be based on the lowest ALI for the radionuclide(s) involved in the spill or contamination.

The licensee should estimate the amount of radioactivity spilled and initiate a major or minor spill/contamination procedure. Use Table M–1 as general guidance to determine whether a major spill/contamination procedure or a minor spill/contamination procedure will be implemented. Spills/contamination events above these millicurie (mCi) amounts should be considered major, and spills/contamination events below these levels are considered minor.

Table M–1. Major/Minor Spill/Contamination Values for Common Radionuclides

Radionuclide	mCi	MBq	Radionuclide	mCi	MBq
nitrogen-13	100	3700	technetium-99m	100	3700
carbon-14	10	370	indium-111	10	370
oxygen-15	100	3700	iodine-123	10	370
fluorine-18	100	3700	iodine-125	1	37
phosphorus-32	1	37	iodine-131	1	37
gallium-67	10	370	samarium-153	10	370
gallium-68	100	3700	ytterbium-169	10	370
rubidium-82	10	370	mercury-197	10	370
strontium-82	1	37	gold-198	10	370
strontium-85	10	370	thallium-201	100	3700
strontium-89	1	37	alpha emitters	*	*
yttrium-90	1	37			

*For radiopharmaceuticals where the primary emission is alpha, consider implementing major spill precautions.

Note: A report to U.S. NRC may be required pursuant to 10 CFR 30.50 for certain unplanned contamination events.

Minor Spills/Contamination Events Involving Liquids and Solids

Instructions to Workers

- Notify persons in the area that a spill or contamination event has occurred.
- Prevent the spread of contamination by covering the spill with absorbent paper. Paper should be dampened, if solids are spilled.
- Wear gloves and protective clothing such as a lab coat and booties, and clean up the spill using absorbent paper. Clean up the spill by wiping from the perimeter of the spill to the center of the spill, wearing disposable gloves and using absorbent paper.
- Carefully fold the absorbent paper with the clean side out and place in a bag labeled “caution radioactive material” for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
- Survey the area with an appropriate low-range radiation detection instrument sufficiently sensitive to detect the radionuclide. Survey for removable contamination to ensure contamination levels are below licensee-established action levels. Survey the area around the spill.
- Continue to clean up the spill and re-survey until radiation levels and removable contamination are below licensee-established action levels.

- Survey hands, clothing, and shoes for contamination prior to leaving the area.
- Report the incident to the RSO promptly.
- Cooperate and follow the instructions of the RSO and the RSO staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples or analysis, decontamination techniques, surveys, documentation).

Reminders to RSO

- Follow up on the decontamination activities and document the results.
- As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
- If required pursuant to 10 CFR 30.50, 10 CFR 20.2202, or other reporting requirement, notify the NRC.

Major Spills/Contamination Events Involving Liquids and Solids

Instructions to Workers

- Clear the area. Notify all persons not involved in the spill to vacate the room.
- Prevent the spread of contamination by covering the spill with absorbent paper labeled "caution radioactive material," but do not attempt to clean it up. Paper should be dampened, if solids are spilled. To prevent further spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
- Shield the spilled material only if it can be done without further contamination or a significant increase in radiation exposure.
- Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
- Notify the RSO immediately.
- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. Document personnel decontamination efforts.
- Cooperate and follow the instructions of the RSO and the RSO's staff (e.g., criteria for returning to the work area following decontamination or decay, potential need for additional qualified personnel to support for decontamination efforts, investigation of root cause, provision of requested bioassay samples or analysis, determination of personnel dose from skin contamination or intakes, decontamination techniques, surveys, documentation).

Reminders to RSO

- Supervise and 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 the perspiration.
- Evaluate and determine personnel radiation doses. Beta-emitting radionuclides have a high potential for resulting in shallow-dose exposures in excess of regulatory limits from small (microcurie) quantities of contamination.
- Document decontamination results, including all surveys, location of surveys, and decontamination results.
- Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
- If required pursuant to 10 CFR 30.50, 10 CFR 20.2202, or other reporting requirement, notify the NRC.

Minor Fires

- Instructions to workers
  - — If possible, immediately attempt to put out the fire by approved methods (e.g., fire extinguisher) if other fire hazards or radiation hazards are not present.
  - — Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department or 911 (as instructed by the RSO).
  - — Once the fire is out, isolate the area to prevent the spread of possible contamination.
  - — Ensure injured personnel receive medical attention.
  - — Survey all persons involved in fighting the fire for possible contamination.
  - — Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap.
  - — In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area.
  - — Allow no one to return to work in the area unless approved by the RSO.
  - — Follow the instructions of the RSO (e.g., with regard to decontamination techniques, surveys, submission of bioassay samples, requested documentation).

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

- Reminders to RSO

  — Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested.

  — Supervise decontamination activities at the facility.

  — 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 the perspiration.

  — Consult with fire safety officials to ensure that there is no likelihood of fire restarting and that it is safe to re-enter the building.

  — Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin. Document the incident.

  — If required pursuant to 10 CFR 30.50, 10 CFR 20.2202, or other reporting requirement, notify the NRC.

Fires, Explosions, or Major Emergencies

- Instructions to workers

  — Notify all persons in the area to leave immediately.

  — Notify the fire department or 911.

  — Notify the RSO and other facility safety personnel.

  — Ensure injured personnel receive medical attention.

  — 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, such as by use of high-pressure water.

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

  — Follow the instructions of the RSO (e.g., with regard to decontamination techniques, surveys, submission of bioassay samples, requested documentation).

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

- Reminders to RSO

  — Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested.

  — Coordinate activities with local fire department or other emergency personnel.

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

  — Once the fire is extinguished, provide assistance to firefighters or other emergency personnel who may need to re-enter restricted areas to determine the extent of the damage to the licensed material use and storage areas. To the extent practical, assist firefighters and emergency personnel in maintaining their exposures ALARA if the fire resulted in a significant release of radioactive material or loss of shielding capability, such that excessive radiation levels (greater than 100 mrem/h) are created.

  — Perform thorough contamination surveys of firefighters and emergency personnel and their equipment before they leave the controlled area, and decontaminate if necessary.

  — Supervise decontamination activities.

  — Consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin. Document the incident.

  — If required pursuant to 10 CFR 30.50, 10 CFR 20.2202, or other reporting requirement, notify the NRC.

Copies of emergency procedures should be provided to all users. A current copy of the emergency procedures should be posted in each area where radioactive material is used.

APPENDIX N

RADIATION SURVEY GUIDELINES

Radiation Survey Guidelines

Radiological surveys in a radiopharmacy include measurements of ambient radiation levels, surface contamination levels, and concentrations of radiation in effluents. Surveys are necessary in order to demonstrate compliance with regulatory requirements, characterize and evaluate changes in workplace radiological conditions, ensure proper posting of radiological conditions, plan work activities, evaluate the effectiveness of administrative and engineering controls (i.e., shielding), evaluate trends, reduce personnel exposure, and evaluate effluent releases and their impact on the public or environment. Licensees should develop, implement, and maintain written procedures for the performance of surveys and monitoring that meet the regulatory requirements. Surveys should be performed to assess radiation and contamination levels in restricted and unrestricted areas. The licensee's written procedures for a survey program should include action levels, frequencies, and records maintenance of those surveys.

Individuals performing radiation surveys should be appropriately trained and qualified to conduct and document surveys and identify unexpected or abnormal conditions requiring action to reduce radiation levels or contamination levels. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured. Licensees must possess calibrated and operable radiation instruments to detect and measure radiation levels, radioactive contamination, and radioactivity, as applicable. The licensee should possess radiation monitoring instruments sufficiently sensitive to measure the type and energy of radiation used.

Ambient Radiation Level Surveys

Radiation level surveys are used to monitor the workplace and reduce radiation exposure and are important for maintaining radiation doses as low as is reasonably achievable (ALARA).

- At a minimum, dose-rate surveys 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.

- At a minimum, dose-rate surveys should be performed in locations where members of the public could receive TEDE of 1 mSv [100 mrem] in a year, or the dose in any unrestricted area from external sources could exceed 0.02 mSv [2 mrem] in any 1 hour.

- Dose-rate surveys should be performed in a manner and frequency that is representative of the use of radioactive materials. As appropriate, radiation surveys should be performed before, during, and after activities involving radioactive materials. At a minimum, radiation surveys should be conducted daily in areas of radioactive material use, where exposures to workers could reasonably occur (e.g., generator storage/elution and dose preparation stations). Other areas, where radiological conditions are not expected to change appreciably from day to day, should be surveyed weekly (e.g., radioactive waste storage areas).

- Dose-rate surveys should be performed whenever changes in the facility layout/design occur, or whenever licensed activities change and could result in changes to the radiological conditions.

- Dose-rate surveys should be performed to demonstrate compliance with regulatory requirements, characterize and evaluate changes in workplace radiological conditions, ensure proper posting of radiological conditions, plan work activities, evaluate the effectiveness of administrative and engineering controls (e.g. shielding), evaluate trends, reduce personnel exposure, and evaluate doses to the general public.

Surface Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in unacceptable levels of exposure to workers or to the public. Contamination surveys can provide insight into whether work practices and engineering controls are effective in handling radioactive materials. Radioactive contamination, if undetected, can be spread throughout a facility, can be spread to personnel, and can be spread into unrestricted or public areas, including the environment. Exposure of individuals to contamination can result in external as well as potential internal radiation dose through inhalation or ingestion of the material.

Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through wipe surveys, which should be analyzed using an appropriate counting instrument. A standardized method for wipe testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A wipe taken from an area of approximately 100 cm^2 is acceptable to indicate levels of removable contamination. Fixed contamination may be measured directly at the surface of the contamination with the appropriate instrument detector held at close proximity to the surface without direct contact. Instruments used for contamination surveys should be operable and calibrated and be appropriate to detect or measure the type of radiation.

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

- to evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, or equipment
- after any spill or contamination event
- to evaluate the immediate work area at the end of each day when licensed material is used
- to evaluate potential personnel contamination each time an individual exits the restricted area and to evaluate the contamination of any items being removed from the restricted area
- in unrestricted areas at frequencies consistent with the types and quantities of materials in use
- in areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment

All areas where radioactive materials are eluted, prepared, assayed, dispensed, or packaged for transport should be surveyed daily, as appropriate for the radionuclide(s) being used. All other

areas where radioactive materials are used or stored should be surveyed weekly or as necessary to evaluate any potential spills or contamination events.

Licensees should establish action levels for the detection of contamination. Typically, licensees establish action levels that are twice the known background radiation level. Licensees can use other appropriate criteria to establish action levels for the detection of contamination. Contamination found in unrestricted areas that exceeds the action levels should be immediately decontaminated to background levels. When decontamination efforts fail to achieve background levels, the licensee should take other actions to maintain radiation doses ALARA. These measures can include the use of shielding or other materials to cover the contaminated area, or restricting access to the contaminated area to allow for radioactive decay.

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). Table N–1 contains acceptable contamination survey frequencies based on ALIs. The acceptable frequencies of surveys are 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 N–1. Suggested Contamination Survey Frequency

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

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee should ensure that the amounts do not exceed the contamination levels listed in Table N–2, taken from the "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) (Agencywide Documents and Management System (ADAMS) Accession No. ML030590504).

Note that, for the purposes of release of facilities for unrestricted use or termination of the license, these values have been superseded by 10 CFR 20, Subpart E, "Radiological Criteria for License Termination," and cannot be used for that purpose. In particular, the acceptable contamination levels listed in Table N–2 for most alpha emitters exceed the levels that will meet the 10 CFR 20, Subpart E criteria. Table N–2 levels can continue to be used for release of equipment and material from licensed material facilities during operational activities prior to license termination (see 63 FR 64132; November 18, 1998).

Table N–2. Acceptable Surface Contamination Levels

Nuclide[1]	Average[2,3,6]	Maximum[2,4,6]	Removable[2,5,6]
U-nat, U-235, U-238, and associated decay products	83.3 Bq/100 cm^2 [5,000 dpm/100 cm^2]	250 Bq/100 cm^2 [15,000 dpm/100 cm^2]	16.7 Bq/100 cm^2 [1,000 dpm/100 cm^2]
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-125, I-129	1.7 Bq/100 cm^2 [100 dpm/100 cm^2]	5.0 Bq/100 cm^2 [300 dpm/100 cm^2]	0.3 Bq/100 cm^2 [20 dpm/100 cm^2]
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133	16.7 Bq/100 cm^2 [1,000 dpm/100 cm^2]	50.0 Bq/100 cm^2 [3,000 dpm/100 cm^2]	3.3 Bq/100 cm^2 [200 dpm/100 cm^2]
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]

[1]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.

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

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

[4]The maximum contamination level applies to an area of not more than 100 centimeters squared (cm^2).

[5]The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

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

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

Survey Record Requirements

Each survey report should include the following:

- diagram of the area identifying specific locations surveyed (see Figure 8-2 of this NUREG)
- equipment surveyed
- ambient radiation levels with appropriate units
- contamination levels with appropriate units
- make, model, and serial number of instruments used
- background levels
- name of the person making the evaluation and recording the results and date
- corrective actions taken for elevated levels identified and results of resurveys

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 recurrence of contamination, times and dates, and surveyor's signature. In addition, 10 CFR 30.35(g) and 10 CFR 40.36(f) require, in part, that records of information important to the decommissioning of a facility, including records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site, must be maintained.

Airborne Radioactivity Monitoring

Airborne radioactivity monitoring should be performed in areas where individuals may be exposed to airborne radiation that could result in doses in excess of 10 percent of the annual limits on intake. Monthly or quarterly grab samples or some other measurements may be appropriate to confirm that airborne radioactivity levels are indeed low. Licensees that perform air monitoring should carefully consider their equipment selection based on the specific activities that are to be monitored. Equipment for airborne activity monitoring includes air sampling equipment (portable and fixed) as well as continuous air monitors.

Airborne radioactivity monitoring can be used to do the following:

- determine the effectiveness of engineering controls
- 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

Air Effluent Release Monitoring

Airborne radioactive effluents should be monitored at the release points (e.g., stack) to provide accurate measurements to estimate public exposure and to demonstrate compliance with effluent release criteria. Licensees should verify the performance of effluent monitoring systems by regular calibration of equipment and checks of filtration to ensure effluent monitoring systems reliability and effectiveness.

Regulatory Guide 4.20, Rev. 1., "Constraints on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," April 2012, provides guidance on methods acceptable (calculation or COMPLY code) to the U.S. Nuclear Regulatory Commission (NRC) for compliance with the constraint on air emissions to the environment.

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

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."

Radioiodine Monitoring

The handling of radioiodine requires additional surveys and monitoring. Such surveys and monitoring should include

- routine surveys of air filters incorporated in fume hoods and gloveboxes to identify when filters should be exchanged before saturation
- routine surveys in the area where radioiodine is handled immediately following each use to identify elevated radiation and contamination levels
- continuous monitoring of the air effluent during radioiodine use

***Note**:* In-line filters should be monitored periodically to determine actual effluents.

Sanitary Sewerage Release Monitoring

The licensee must evaluate the concentrations of radioactive material in water and liquid effluent that is released to the environment and to the sanitary sewer. These releases must meet the limits in 10 CFR 20.1302, "Compliance with dose limits for individual members of the public," and 10 CFR 20.2003, "Disposal by release into sanitary sewerage," respectively.

References:

Regulatory Guide 4.20, Revision 1., "Constraints on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated April 2012.

Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," dated July 1993.

Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992.

Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Doses," dated July 1992

Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993.

NUREG-1400, “Air Sampling in the Workplace,” dated September 1993.

NUREG/CR-4884, “Interpretation of Bioassay Measurements,” dated July 1987.

ANSI N13.1-2011, “Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities,” dated January 2011.

ANSI N42.18-2004, “Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactivity in Effluents,” dated 2004.

ANSI/HPS N13.49-2001, “Performance and Documentation of Radiological Surveys,” dated June 2001 (Reaffirmed in 2011).

APPENDIX O

MODEL PROCEDURE FOR RETURN OF RADIOACTIVE WASTES FROM CUSTOMERS

Model Procedure for Return of Radioactive Wastes from Customers

Procedures for Customers to Return Radioactive Waste to the Radiopharmacy

Return only items that contained or contain radioactive materials supplied by the radiopharmacy (e.g., pharmacy-supplied syringes and vials and their contents). Most return shipments to radiopharmacies will qualify as excepted packages of limited quantity, in accordance with Title 49 of the *Code of Federal Regulations* (49 CFR) 173.421. For those packages containing radioactive material in excess of the limited quantity, customers will ensure that all applicable U.S. Department of Transportation (DOT) regulations are met for the packages. These include, but are not limited to, certification packaging (Type A), package marking and labeling, and shipping papers. For specific guidance on preparing these types of packages, follow the in-house procedures for shipping radioactive material packages or contact the pharmacy for guidance.

Preparation of radioactive materials for return as an excepted package of limited quantity

- Ensure that the activities of material being returned are limited quantities as defined by DOT in Table 4 of 49 CFR 173.425. Special attention will be given for the return of unused doses that may still contain significant activities of radionuclides. The amount of radioactivity in unused doses may necessitate that a syringe or vial be held for decay to reduce the activity to that permitted for shipment of limited quantities.

- Place the syringe or vial in the original, labeled shield in which it was delivered.

- Place shielded waste into the shipping package in which it was delivered.

Note: Packages used to ship radioactive material to customers must meet the DOT package regulations for transport of limited quantities.

Preparation of Limited Quantity package

- Using a calibrated radiation survey meter, measure the radiation levels at all points on the surface of the package to ensure that levels are less than or equal to 0.5 mrem/h (5.0 μSv/h).

- Use contamination wipes on the surface of the package to ensure that the removable contamination does not exceed the limit specified in 49 CFR 173.443(a). Label the package as an “Excepted Package-Limited Quantity of Material.”

- Seal the package so that it will be evident upon receipt if the package was opened during shipment.

Procedure for Receipt and Opening of Packages from Customers Containing Radioactive Waste

- Place all returned packages in an identifiable location within the radiopharmacy.

- Put on disposable gloves.

- Monitor the package for removable contamination. If wipe tests indicate contamination levels greater than the limits of 10 CFR 20.1906(d)(1), notify the customer and the U.S. Nuclear Regulatory Commission (NRC), survey the driver or courier who retrieved the waste and the vehicle used to transport the waste to the radiopharmacy, and decontaminate the package or remove it from service for decay.

- Open the package and identify each nuclide in the shielded containers.

- Dispose of radioactive waste into the appropriate container for the half-life of the nuclide being disposed of, in accordance with the radiopharmacy's procedures for disposal of waste by decay-in-storage.

Survey the transport radiation shields for contamination with a low-level radiation survey meter. Decontaminate or remove from service any transport radiation shield that indicates activity exceeding low-background readings.

APPENDIX P

NRC INCIDENT NOTIFICATIONS

NRC Incident Notifications

Table of Required Incident Notifications and Reporting

***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 P–1. Typical Notifications Required for Commercial Radiopharmacy Licensees

Event	Telephone Notification	Written Report	Regulatory Requirement
Package received with removable radioactive surface contamination exceeding the limits of Title 10 of the *Code of Federal Regulations* (10 CFR) 71.87(i) or external radiation levels exceeding the limits of 10 CFR 71.47	Immediate [NRC and final delivery carrier must be notified]	None	10 CFR 20.1906(d)
Theft or loss of material	Immediate	30 days	10 CFR 20.2201(a)(1)(i) & 20.2201(b),
Whole body dose greater than 0.25 Sv [25 rem]	Immediate	30 days	10 CFR 20.2202(a)(1)(i) & 20.2203(a)(1)
Extremity dose greater than 2.5 Gy [250 rads]	Immediate	30 days	10 CFR 20.2202(a)(1)(iii) & 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rem] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i) & 20.2203(a)(1)
Extremity dose greater than 0.5 Sv [50 rem] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii) & 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems]	None	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv [100 mrem]	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)
Molybdenum-99 content of a generator eluate that is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m)	Within 7 days	30 days	10 CFR 30.34(g) & 10 CFR 35.3204

Table P–1. Typical Notifications Required for Commercial Radiopharmacy Licensees

Event	Telephone Notification	Written Report	Regulatory Requirement
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); and 40.60(a) & (c)(2
Unplanned contamination event that requires restricted access for more than 24 hours and involves a quantity of material greater than 5 times the lowest annual limits 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); and 40.60(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); and 40.60(b)(2) & (c)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4) & (c)(2); and 40.60(b)(4) & (c)(2)
Intake of 5 times the annual limit on intake (ALI)	Immediate	30 days	10 CFR 20.2202(a)(2) & 20.2203(a)(1)
Intake of one ALI	24 hours	30 days	10 CFR 20.2202(b)(2) & 20.2203(a)(1)
Filing petition for bankruptcy under U.S. Code Title 11	None	Immediately after filing petition	10 CFR 30.34(h)
Expiration of license	None	60 days	10 CFR 30.36(d)(1)
Decision to permanently cease licensed activities at *entire site*	None	60 days	10 CFR 30.36(d)(2)
Decision to permanently cease licensed activities in any *separate building or outdoor area* that is unsuitable for release for unrestricted use	None	60 days	10 CFR 30.36(d)(2)
No principal activities conducted for 24 months *at the entire site*	None	60 days	10 CFR 30.36(d)(3)
No principal activities conducted for 24 months *in any separate building or outdoor area* that is unsuitable for release for unrestricted use	None	60 days	10 CFR 30.36(d)(4)

Table P–1. Typical Notifications Required for Commercial Radiopharmacy Licensees

Event	Telephone Notification	Written Report	Regulatory Requirement
Determination that any licensee that has not previously implemented the Security Orders (i.e., orders issued by the NRC to require licensees to implement interim security measures) or been subject to the provisions of 10 CFR Part 37, Subpart C will aggregate radioactive material to a quantity that equals or exceeds the Category 2 threshold	None	90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold	10 CFR 37.41(a)(3)
Coordination with local law enforcement agency (LLEA) has failed, either because the LLEA has not responded or because the LLEA does not plan to participate	3 business days	Submittal of a written report concerning failures of coordination with LLEA as described in 10 CFR 37.45(b) is not required; however, licensees must document their efforts to coordinate with the LLEA and keep this documentation for 3 years	10 CFR 37.45(b)&(c)
Determination that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material	As soon as possible (but not at the expense of causing delay or interfering with the LLEA response), but no later than 4 hours after discovery	30 days	10 CFR 37.57(a)&(c)
Assessment of any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material	As soon as possible, but no later than 4 hours after notifying the LLEA	None	10 CFR 37.57(b)

Table P–1. Typical Notifications Required for Commercial Radiopharmacy Licensees

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

Table P–1. Typical Notifications Required for Commercial Radiopharmacy Licensees			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Upon recovery of any lost or missing Category 1 quantity of material	As soon as possible. Also notify the LLEA as soon as possible	To be included in the 30-day report of an event described in 10 CFR 37.81(g), if recovered during that time or in a subsequent update	10 CFR 37.81(e)&(h)
Upon recovery of any lost or missing Category 2 quantity of material	As soon as possible	To be included in the 30-day report of an event described in 10 CFR 37.81(g), if recovered during that time or in a subsequent update	10 CFR 37.81(f)&(h)

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

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APPENDIX Q

CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)

Checklist for Requests to Withhold Proprietary Information from Public Disclosure (Under 10 CFR 2.390)

In order to request that the U.S. Nuclear Regulatory Commission (NRC) withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:

☐	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
☐	A nonproprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the 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 R

SAFETY CULTURE POLICY STATEMENT

Safety Culture

The Safety Culture Policy Statement was published in the Federal Register (76 FR 34773) on June 14, 2011, and can be found at: https://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf. It is also posted in the U.S. Nuclear Regulatory Commission (NRC) Agencywide Documents Access and Management System Accession Number ML11146A047.

Safety Culture Policy Statement

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

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

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

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

The following are traits of a positive safety culture:

(1) *Leadership Safety Values and Actions*—Leaders demonstrate a commitment to safety in their decisions and behaviors,

(2) *Problem Identification and Resolution*—Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance,

(3) *Personal Accountability*—All individuals take personal responsibility for safety,

(4) *Work Processes*—The process of planning and controlling work activities is implemented so that safety is maintained,

(5) *Continuous Learning*—Opportunities to learn about ways to ensure safety are sought out and implemented,

(6) *Environment for Raising Concerns*—A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination,

(7) *Effective Safety Communication*—Communications maintain a focus on safety,

(8) *Respectful Work Environment*—Trust and respect permeate the organization, and

(9) *Questioning Attitude*—Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

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

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

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 13, Revision 2: Final Report

2. TITLE AND SUBTITLE
Consolidated Guidance About Materials Licenses-Program-Specific Guidance About Commercial Radiopharmacy Licenses (NUREG-1556, Volume 13, Revision 2) - Final Report

3. DATE REPORT PUBLISHED

MONTH	YEAR
March	2019

4. FIN OR GRANT NUMBER

5. AUTHOR(S)
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6. TYPE OF REPORT
Technical

7. PERIOD COVERED (Inclusive Dates)
November 2007 - March 2019

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 Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

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 materials licenses for commercial radiopharmacies. 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.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)
NUREG-1556
Volume 13
Commercial Radiopharmacy
Nuclear Pharmacy
Radiopharmaceutical
License

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. 13
Revision 2, Final

Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses

March 2019