United States Nuclear Regulatory Commission

Protecting People and the Environment

NUREG-1556
Volume 11, Rev. 1

Consolidated Guidance about Materials Licenses

Program-Specific Guidance about Licenses of Broad Scope

Draft Report for Comment

Office of Federal and State Materials and
Environmental Management Programs

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Program-Specific Guidance about Licenses of Broad Scope

Draft Report for Comment

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ABSTRACT

This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses of broad scope. 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.

NUREG-1556, Volume 11, Revision 1, is not intended to be used alone. Because broad scope licensees may be involved in many different program areas (e.g., medicine, research and development, manufacturing and distribution), this document frequently refers the user to other more program-specific guidance documents in the NUREG-1556 series.

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This NUREG contains and references information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collection requirements were approved by the Office of Management and Budget (OMB), approval numbers 3150-0044, 3150-0014, 3150-0017, 3150-0001, 3150-0015, 3150-0010, 3150-0158, 3150-0214, 3150-0130, 3150-0020, 3150-0009, 3150-0008, and 3150-0120.

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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
8	Program-Specific Guidance about Exempt Distribution Licenses
9	Program-Specific Guidance about Medical Use Licenses
10	Program-Specific Guidance about Master Materials Licenses
11	Program-Specific Guidance about Licenses of Broad Scope
12	Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution
13	Program-Specific Guidance about Commercial Radiopharmacy Licenses
14	Program-Specific Guidance about Well Logging, Tracer, and Field Flood Study Licenses
15	Guidance about Changes of Control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
16	Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees

Volume No.	*Volume Title*
17	Program-Specific Guidance about Special Nuclear Material of Less Than Critical Mass Licenses
18	Program-Specific Guidance about Service Provider Licenses
19	Guidance for Agreement State Licensees about NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)
20	Program-Specific Guidance about Administrative Licensing Procedures
21	Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator
22	Reserved

The current document, NUREG-1556, Volume 11, Revision 1, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses of Broad Scope," 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 11, dated April 1999.

This report takes a risk-informed, performance-based approach to licensing. 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 users of byproduct material under a broad scope license.

NUREG-1556, Volume 11, Revision 1, is not a substitute for NRC regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable if they include a basis for the staff to make the determinations needed to issue or continue a license.

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
ALI	annual limit of intake
ANSI	American National Standards Institute
Bq	becquerel
CFR	*Code of Federal Regulations*
Ci	curie
cm^2	square centimeters
cpm	counts per minute
DAC	derived air concentration
DFP	decommissioning funding plan
DIS	decay-in-storage
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
dpm	disintegrations per minute
EPA	U.S. Environmental Protection Agency
FA	financial assurance
FSME	Office of Federal and State Material and Environmental Management Programs
GBq	gigabecquerel
G-M	Geiger-Mueller
GPO	Government Printing Office
IAEA	International Atomic Energy Agency
IN	information notice
kBq	kilobecquerel
LLW	low-level radioactive waste
MBq	megabecquerel
µCi	microcurie
mCi	millicurie
mR	milliroentgen
mrem	millirem
mSv	millisievert
ND	not detectable
NMSS	Office of Nuclear Material Safety and Safeguards
NR	not required
NRC	U.S. Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OMB	Office of Management and Budget
rem	roentgen equivalent man
RG	regulatory guide
RSC	radiation safety committee
RSO	radiation safety officer
SSD	sealed source and device
Sv	Sievert
TEDE	total effective dose equivalent

1. PURPOSE OF REPORT

This report provides guidance to an applicant in preparing a broad scope license application and provides the NRC staff with criteria for evaluating such applications. This document uses the terms "byproduct material," "licensed material," and "radioactive material," interchangeably. Whereas, the applicant for a limited scope license generally must submit to the NRC for review and approval the specific training and experience of each proposed user and the facilities and equipment available to support each proposed use, the applicant for a broad scope license normally must submit to the NRC for review and approval a description of the internal review process and criteria that will be used to approve users and uses. As opposed to limited scope licenses, which typically identify specific isotopes that may be possessed, the broad scope license typically authorizes the possession and use of a wide range of byproduct radioactive materials.

Because the NRC grants significant decision making authority to broad scope licensees through the license, a broad scope license is not normally issued to a new licensee. An applicant for a broad scope license typically has several years of experience operating under a limited scope license and a good regulatory performance history. This document is intended to provide the additional guidance required by the experienced limited scope licensee to prepare an application for a broad scope license. Guidance related to specific program areas, which may not apply to all broad scope licensees, is not included in this document but can be found in other volumes of NUREG-1556, often referred to in this document as "the base NUREGs" or "the base documents," or in guidance documents that have not yet undergone the consolidation process.

Applicants should first have established limited scope licensed programs in accordance with the guidance described in the appropriate base NUREG(s) and then use this document to complete the application for a broad scope license. For example, applicants for a broad scope license that use byproduct material for research and development should review NUREG-1556, Volume 7, "Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope," for guidance. Similarly, applicants for broad scope licenses that use byproduct material for medical purposes should review NUREG-1556, Volume 9, "Program-Specific Guidance about Medical Use Licenses." A list of the currently available base NUREGs is included in the "Foreword" to this document.

This report identifies the information needed to complete NRC Form 313 (Appendix B), "Application for Material License," for the use of byproduct material for licenses of broad scope. The Office of Management and Budget (OMB) has approved the information collection requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and NRC Form 313 under OMB Clearance Nos. 3150-0017 and 3150-0120, respectively.

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

- Regulations—references the regulations applicable to the item
- Criteria—outlines the criteria used to judge the adequacy of the applicant's response

- Discussion—provides additional information about the topic
- Response from Applicant — provides suggested response or responses, offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process

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

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11, as indicated on the form. Applicants should address those items on separate sheets of paper and submit them along with the completed NRC Form 313. For the convenience and streamlined handling of applications in the materials licensing process, Appendix C, "Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313," may be used by to provide supporting information. Appendices H through V contain additional information on various radiation safety topics.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE), as defined in 10 CFR Part 20. Rem and its International System of Units (SI) equivalent, sievert (Sv) (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. This is done because 10 CFR Part 20 sets dose limits in terms of rem (sievert), rather than rad or roentgen. When the radioactive material emits beta and gamma rays, 1 roentgen is assumed to equal 1 rad, which is assumed to equal 1 rem. For alpha and neutron-emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from alpha particles and neutrons requires the use of an appropriate quality factor (Q) value. These Q values are used to convert absorbed dose (rad) to dose equivalent (rem). Tables 1004(b)(1) and (2) in 10 CFR 20.1004, "Units of radiation dose," address the Q values for alpha particles and neutrons.

Overview of Broad Scope Programs

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," provides for three distinct categories of broad scope license (i.e., Type A, Type B, and Type C), which are defined in 10 CFR 33.11, "Types of Specific Licenses of Broad Scope."

Type A licenses of broad scope are typically the largest licensed programs and encompass a broad range of uses. Type A broad scope licensees use a Radiation Safety Committee (RSC), radiation safety officer (RSO), and criteria developed and submitted by the licensee and approved by the NRC during the licensing process to review and approve all uses and users under the license. The requirements for issuance of a Type A broad scope license are described in 10 CFR 33.13, "Requirements for the Issuance of a Type A Specific License of Broad Scope."

An applicant for a Type A broad scope license must establish administrative controls and provisions related to organization and management, procedures, recordkeeping, material control, and accounting and management review necessary to ensure safe operations, including:

- establishment of an RSC
- appointment of a qualified RSO
- establishment of appropriate administrative procedures to ensure the following:
  - control of procurement and use of byproduct material
  - completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures
  - review, approval, and recording by the RSC of safety evaluations of proposed uses
- byproduct material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's RSC.

Type B broad scope licensed programs are normally smaller and less diverse than Type A broad scope programs. Type B broad scope licensees use an RSO and criteria developed and submitted by the licensee and approved by the NRC during the licensing process to review and approve all uses and users under the license. Because the RSO reviews and approves all uses and users under the license, rather than a full RSC, as established for Type A broad scope programs, the types and quantities of byproduct material authorized by the Type B broad scope license are limited to those described in 10 CFR 33.11(b) and 10 CFR 33.100, "Schedule A," Column I. While the quantities of individual radionuclides described in Schedule A may be large, the "unity rule" further restricts total license possession limits (see Section 8.5.1, "Unsealed or Sealed Byproduct Material," of this NUREG volume for additional information on license possession limits and the unity rule). Generally, the scope of authorization for Type B licenses is limited to the experience and knowledge of the RSO. The requirements for issuance of a Type B broad scope license are described in 10 CFR 33.14, "Requirements for the Issuance of a Type B Specific License of Broad Scope."

An applicant for a Type B broad scope license must also establish administrative controls and provisions related to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to ensure safe operations, including:

- appointment of a qualified RSO
- establishment of appropriate administrative procedures to ensure the following:
  - control of procurement and use of byproduct material

– completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures

– review, approval, and recording by the RSO of safety evaluations of proposed uses

- byproduct material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's RSO.

Type C broad scope licensed programs typically are issued to institutions that do not require significant quantities of radioactive material but need the flexibility to possess a variety of different radioactive materials. Users of licensed material under these programs are approved by the licensee based on training and experience criteria described in 10 CFR 33.15(b). The types and quantities of byproduct material authorized by the Type C broad scope license are limited to those described in 10 CFR 33.11(c) and 10 CFR 33.100, Schedule A, Column II, again, considering the unity rule. The requirements for issuance of a Type C broad scope license are described in 10 CFR 33.15, "Requirements for the Issuance of a Type C Specific License of Broad Scope."

While 10 CFR 33.15 does not require Type C broad scope licensees to appoint an RSO, the licensee must establish administrative controls and provisions related to procurement of byproduct material, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations. This should include the appointment of someone responsible for the day-to-day operation of the radiation safety program, such as an RSO.

Except for activities specifically excluded from broad scope licenses by 10 CFR 33.17(a), a Type A broad scope license can include any licensed material the applicant needs and for which it qualifies. An application for a Type A broad scope license can include uses of source material and special nuclear material under the same program (e.g., laboratory-scale research and development or the use of uranium as shielding) as the byproduct material to be possessed under the provisions of 10 CFR 30.32(d). However, applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of byproduct material under the Type A broad scope license (e.g., use of source material in subcritical assemblies and special nuclear material in cardiac pacemakers).

In practice, 10 CFR Part 33 reduces the administrative burden for both licensees and the Commission without reducing the safety standards or lessening the licensing requirements for training, experience, facilities, and equipment. Both the NRC and the licensee benefit from the reduction in license amendments that might otherwise be needed to change authorized radionuclides, quantities, or names of individuals who may use, or supervise the use of, byproduct material.

Part 33 does not specifically permit a broad scope licensee to make other types of changes to the radiation program as described in the application, such as changing the dosimetry provider, without amendment of the license. However, the NRC has permitted broad scope licensees, on a case-by-case basis, to build in limited program flexibility during the licensing process.

For example, rather than requiring that the applicant identify the company that would provide personnel dosimetry, the broad scope licensee could specify that dosimetry would be provided by an organization holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology. The NRC will continue to allow licensees to build in this type of program flexibility.

2. AGREEMENT STATES

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

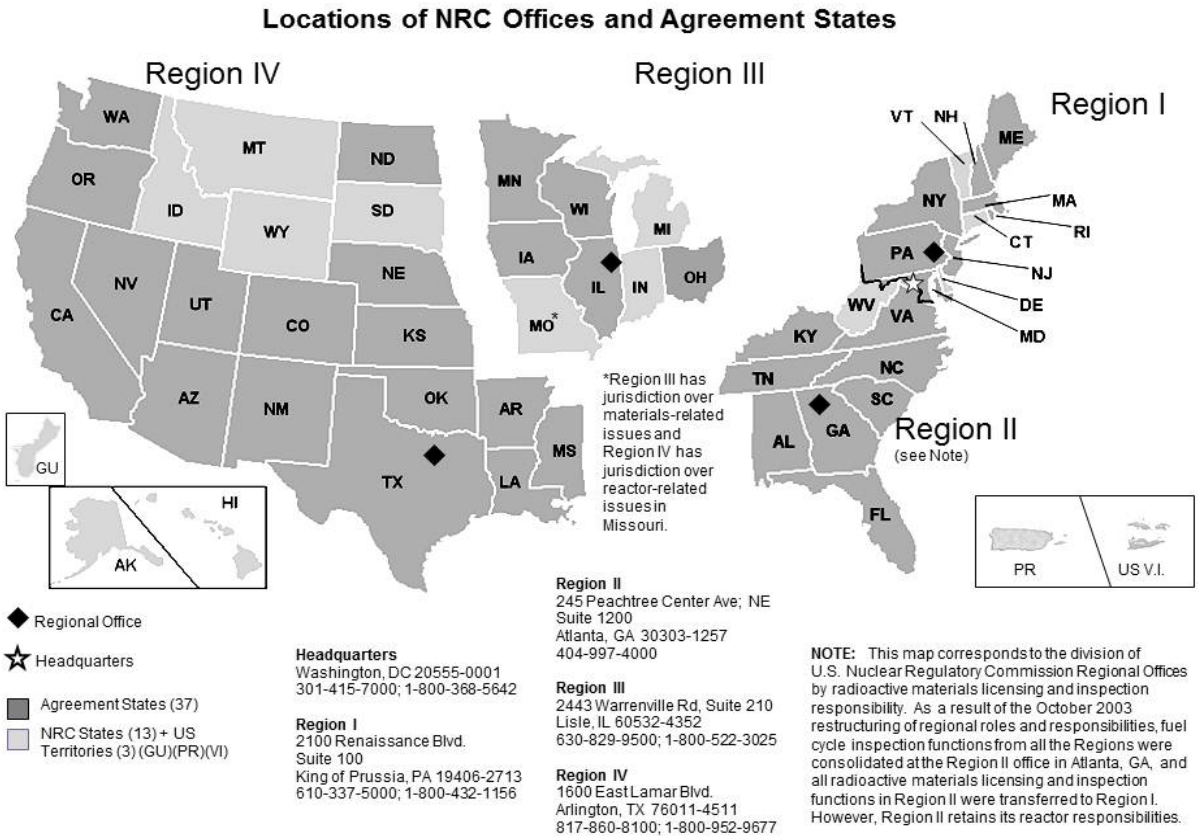

Figure 2.1 U.S. map: locations of NRC offices and Agreement States

In the special situation of work at Federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the land to determine whether the NRC or the Agreement State has regulatory authority. These areas can also include tribal lands of federally recognized Indian tribes.[1]

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

The NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State has jurisdiction over nonexclusive Federal jurisdiction land. Applicants are responsible for determining in advance the jurisdictional status of the specific areas where they plan to conduct licensed operations. The NRC recommends that applicants contact their local office of the Federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) for assistance in determining the jurisdictional status of the land and to provide the information in writing to ensure compliance with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in the Office of Federal and State Materials and Environmental Management Program's (FSME) procedures in the State Agreement (SA) series, SA-500, "Jurisdiction Determination," which is available at http://nrc-stp.ornl.gov/. Once on the Web site, use the link for "FSME Procedures" in the left hand column under "Resources & Tools." The link will take you to another Web page where you can search for FSME Procedures.

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

Table 2.1 Who Regulates the Activity?

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

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

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

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

[3] Section 274m. of the AEA gives the NRC regulatory authority over radioactive materials covered under the Section 274b. Agreement when the activity can affect the Commission's authority to protect the common defense and security, to protect restricted data, or guard against the loss or diversion of special nuclear material at a site. (This is an uncommon situation which NRC usually evaluates on a case-by-case basis.) Companies that wish to possess or use licensed material at these sites should contact the licensee to determine the jurisdictional status for specific AEA radioactive materials they intend to possess or use at the site.

3. MANAGEMENT RESPONSIBILITY

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

- Radiation safety, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of radiation safety records and all information provided to the NRC (10 CFR 30.9, "Completeness and accuracy of information");
- Knowledge about the contents of the license and application;
- Compliance with current NRC and Department of Transportation (DOT) regulations and the licensee's operating, emergency, and security procedures
- Commitment to provide adequate resources (including space, equipment, personnel, time and, if needed, contractors) to the radiation protection program to ensure that public and workers are protected from radiation hazards and compliance with regulations is maintained;
- Commitment to report defects, noncompliances, or reportable events in accordance with regulations;
- Selection and assignment of qualified individuals to serve on the RSC, if required, and to serve as RSO for their licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities;
- Commitment to ensure that radiation workers have adequate training;

- Prevention of discrimination of employees engaged in protected activities (10 CFR 30.7, "Employee protection");

- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 30.7 and 10 CFR 30.10, "Deliberate misconduct," respectively;

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

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

For further discussion of management responsibilities, see Section 8.7, "Item 7: Individual(s) Responsible for Radiation Safety Program."

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

3.2 Safety Culture

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

"Nuclear safety culture" is defined in the NRC's safety culture policy statement (76 FR 34773; June 14, 2011) as *the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment*. Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). Refer to Table 3.1 for the traits of a positive safety culture from NRC's safety culture policy statement.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that

consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, NRC's safety culture policy statement and traits are not incorporated into the regulations. Safety culture traits may or may not be inherent to an organization's existing radiation safety practices and programs. For instance, laboratory facilities that perform iodinations require that air monitoring be performed of the effluents released through the stack. The need to monitor effluent releases may correspond with the safety culture trait specified in Table 3.1 as "Work Processes" (the process of planning and controlling work activities is implemented so that safety is maintained). However, licensees should be aware that this is just an example, and should still consider reviewing their radiation safety programs and develop and implement a safety culture commensurate with the nature and complexity of their organization and functions.

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

Table 3.1 Traits of a Positive Safety Culture

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

4. APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of Title 10 of the *Code of Federal Regulations* (10 CFR) contain regulations applicable to the use of licensed material by broad scope licensees. These parts will apply to many, if not all, licensees.

The current versions of these parts can be found under the "Basic References" link at the NRC's online library at http://www.nrc.gov/reading-rm.html; 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 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"
- 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"
- 10 CFR Part 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC"

The following Parts of 10 CFR Chapter 1 contain regulations that, depending on the type or types of activities authorized by the license, may be applicable to the use of licensed material by broad scope licensees:

- 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 34, "Licenses for Radiography and Radiation Safety for Radiographic Operations"
- 10 CFR Part 35, "Medical Use of Byproduct Material"
- 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"
- 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging"
- 10 CFR Part 40, "Domestic Licensing of Source Material"
- 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste"
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"
- 10 CFR Part 170, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters under Section 274"

Copies of the above documents may be obtained by calling the Government Printing Office order desk toll free at (866) 512-8600, or in Washington, DC, at (202) 512-1800, or online at http://bookstore.gpo.gov.

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

NRC regulations and amendments can also be accessed from the "NRC Library" link on the NRC's public Web site at http://www.nrc.gov. The NRC and all other Federal agencies publish amendments to their regulations in the *Federal Register*.

5. HOW TO FILE

5.1 Paper Application

Applicants for a materials license should do the following:

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

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

5.2 Where to File

Applicants wishing to possess or use licensed material in any State, U.S. territory, or U.S. possession subject to NRC jurisdiction must file an application with the NRC regional office for the locale in which the material will be possessed or used. Figure 2.1 identifies the NRC's four regional offices and their respective areas for licensing purposes and the Agreement States. Note that all materials applications are submitted to Regions I, III, or IV. All applicants for materials licenses located in the Region II geographical area should send their applications to Region I.

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

5.3 Transfer to Electronic Format

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

- Submit printed or typewritten—not handwritten—text on smooth, crisp paper that will feed easily into the scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Future, or Univers (the text of this document is in Arial font).
- Use 12-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

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

6. IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

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

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

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

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

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

7. APPLICATION AND LICENSE FEES

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

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16, "Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC." Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities."

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

8. CONTENTS OF AN APPLICATION

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

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

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

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

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

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

After an application for broad scope authority has been reviewed by the NRC staff and found to be generally complete and responsive to NRC Form 313 (Appendix B) and this guidance, a pre-licensing visit may be scheduled by the NRC at the licensee's facility. A visit or conference may also be scheduled as part of the license renewal process. A pre-licensing visit provides the NRC staff with an opportunity to better evaluate the proposed program and the necessity for a broad scope license. The pre-licensing visit also provides the NRC staff an opportunity to meet with licensee management and others responsible for the radiation protection program and stress the importance of their responsibilities under a broad license, as well as to discuss and agree on additional information and commitments that may be needed. If a broad license is not warranted, NRC staff may discuss the continuation of the program with an appropriate specific license.

Refer to Appendix R for guidance regarding the definition of construction and the consideration of activities that maybe performed by materials license applicants and potential applicants and

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

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

8.1 Item 1: License Action Type

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

Type of Action	License No.
[ ] 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 pre-licensing visit may be required prior to issuance of the license. Also note that an initial security inspection may be conducted in accordance with NRC Inspection Manual Chapter 2800, "Materials Inspection Program," before issuance of the license.

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

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

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

8.2 Item 2: Applicant's Name and Mailing Address

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

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

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

8.2.1 Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h)

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

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

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

Reference: See NUREG-1556, Volume 15, "Consolidated Guidance about Materials Licenses: Guidance about Changes of Control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses."

8.3 Item 3: Address(es) where Licensed Material will be Used or Possessed

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

If byproduct material is to be used at more than one location, applicants should give the specific address of each location. Applicants for a broad scope license need not identify each facility at a particular address where byproduct material will be used. For example, applicants can specify that byproduct material will be used on the Main Campus of ABC University located in Anytown, State.

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

If byproduct material (e.g., portable gauging devices) will be used at temporary job sites, so indicate, and describe the scope of these activities.

If byproduct material is to be used in field studies, the activities must be specifically identified and authorized on the license. Appendix D contains information required of applicants prior to granting authorization for field use of licensed material.

An NRC-approved license amendment is required before receiving, using, and storing licensed material at an address or location not included with the application or already listed on the license.

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

If an applicant submits documents that give the exact location of use and storage for materials greater than or equal to Category 2 quantities, as defined in 10 CFR 37.5, "Definitions," the applicant should mark these documents as "Security-Related Information—Withhold under 10 CFR 2.390." See Chapter 6, "Identifying and Protecting Sensitive Information," for more details.

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

8.4 Item 4: Person to be Contacted about this Application

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

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

8.5 Item 5: Radioactive Material

8.5.1 Unsealed or Sealed Byproduct Material

Regulations: 10 CFR 30.32(d), 10 CFR 30.32(g), 10 CFR 30.32(i), 10 CFR 30.33(a), 10 CFR 32.210, 10 CFR 33.11, 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15, 10 CFR 33.17

Criteria: An application for a license will be approved if the requirements of 10 CFR 30.32; 10 CFR 30.33(a); 10 CFR 33.11; 10 CFR 33.12; 10 CFR 33.13; 10 CFR 33.14; 10 CFR 33.15, as appropriate; and 10 CFR 33.17 are met.

Discussion: Applicants for a Type A broad scope license typically request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. When establishing individual radionuclide and total cumulative quantities, all materials possessed under the license should be included (i.e., materials received awaiting use, materials in use/process, and those categorized as waste awaiting disposal). The maximum quantity for each individual radionuclide and total cumulative possession should be commensurate with the applicant's needs, facilities, procedures, and demonstrated experience/capability. If certain individual radionuclides will be needed in much larger quantities than described in the atomic number 1-83 request, they should be listed separately rather than increasing the possession limit for all radionuclides. Similarly, if applicants know that certain relatively more hazardous radionuclides (e.g., strontium-90) are needed only in smaller quantities, they should be listed separately.

If needed, an applicant for a Type A broad scope license may request authorization to possess byproduct materials with atomic numbers greater than 83 (e.g., atomic numbers 84 to 96). For this request, the applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides.

Note that authorization to possess byproduct materials with atomic numbers 84 through 96 does not authorize the possession of naturally occurring isotopes of uranium or thorium, or of plutonium because, even though these elements have atomic numbers within the range of 84 through 96, these materials are either source material or special nuclear material and not byproduct material. Licensees may request source material and special nuclear material when use of these materials is directly related to the use of byproduct material under the broad scope license (e.g., laboratory-scale research and development or the use of depleted uranium as shielding). Applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of byproduct material under the broad scope license (e.g., subcritical assemblies and nuclear pacemakers).

A separate listing should also be submitted for sealed sources needed in quantities larger than that described in the atomic number 1-83 request (e.g., self-contained irradiators, instrument calibrators, sealed sources used for medical therapy, portable and non-portable gauging devices). 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 a Sealed Source and Device (SSD) registration certificate. or provide the information requested by 10 CFR 30.32(g) to allow the NRC to conduct a case-by-case review. Sealed sources or devices containing sealed sources built to unique specifications of a given user (custom source) and that are intended for use solely under broad scope licenses, and are not transferred to another licensee, need not be evaluated by the NRC or Agreement State for registration if: 1) they contain less than 7.4 gigabecquerels (GBq) (200 mCi)of radioactive material or less than 740 GBq (20 Ci) of tritium, and 2) the licensee performs its own safety evaluation in accordance with the administrative procedures required by 10 CFR 33.13(c)(3)(ii), and 33.14(b)(2)(ii), as appropriate. Custom sources and devices which contain an activity greater that these values must be submitted to the NRC or Agreement State for evaluation and registration in accordance with the guidance provided in NUREG-1556, Volume 3. ,

Applicants should determine if the type, form, and amounts of any of the materials requested exceed those for Category 1 and Category 2 sources, which must be tracked in the National Source Tracking System (NSTS) in accordance with 10 CFR 20.2207, "Reports of Transactions Involving Nationally Tracked Sources." Such sources will also require the implementation of the requirements in 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Refer to Section 8.10.9, "Security Program for Category I and Category 2 Materials," for more information on the security of radioactive material.

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

In most cases, the NRC or an Agreement State will perform a safety evaluation of sealed sources and devices before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in an SSD registration certificate. Paragraph (g) of 10 CFR 32.210 provides some exceptions to this requirement. For additional guidance related to sealed sources and devices, see also NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

Possession requests should be categorized into: (1) general areas of use (e.g., research and development activities, teaching, training, animal studies, and environmental studies); and (2) special areas of use, (e.g., gauging activities, irradiators, instrument calibrators, and medical applications).

Applicants for Type A broad scope license should review the requirements for financial assurance (FA) and decommissioning before specifying possession limits for radionuclides with a half-life greater than 120 days. These requirements are discussed in Section 8.5.2 of this document.

Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in 10 CFR 33.100, Schedule A. The possession limit for a Type B broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows. For each radionuclide, determine the ratio of the quantity to be possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity. The possession limit for a Type C broad scope license, if only one radionuclide is to be possessed, is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the sum of the ratios, determined in the same manner as discussed above, for all radionuclides possessed under the license shall not exceed unity. This is sometimes referred to as the "unity rule" or the "rule of ratios."

Type B and Type C broad scope applicants/licensees that require materials not specified in Schedule A should either: (1) develop Type A broad scope programs, or (2) carry these additional materials under a separate specific license of limited scope. For the latter option, the applicant should review the base NUREG related to the planned specific use of this material and submit the information needed by the license reviewer as described in that document. For example, applicants that require materials not specified in Schedule A for purposes of research and development should review NUREG-1556, Volume 7, "Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope," and submit the information described therein.

Type B licensees that require quantities of material in excess of that permitted by 10 CFR 33.11(b) should: (1) develop a Type A broad scope program and apply for a Type A license, or (2) apply for a separate specific license of limited scope for these additional quantities, as described in the previous paragraph. Type C licensees that require quantities of material in excess of that permitted by 10 CFR 33.11(c) should: (1) develop, as appropriate, a Type A or Type B broad scope program, and apply for such a license or (2) apply for a separate specific license of limited scope for these additional materials.

Applicants for Type B or Type C broad scope license may consider limiting their possession of isotopes described in Schedule A with half lives greater than 120 days below that amount permitted by 10 CFR 33.11(b) or 33.11(c), respectively, to avoid being required to submit certification of FA or a decommissioning funding plan. See Section 8.5.2 of this document for a discussion of Financial Assurance and Recordkeeping for Decommissioning.

Response from Applicant: Applicants for a Type A broad scope license should request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. The applicant should separately list individual radionuclides needed in much larger quantities or in much smaller quantities than that described in the atomic number 1 through 83 request. The maximum quantities of nuclides with atomic numbers above 83 also should be listed separately. A separate listing should also be submitted for sealed sources needed in larger quantities than that described in the atomic number 1 through 83 request. 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 a SSD registration certificate or specifically approved on a license. Applicants must also provide the maximum activity per source and the total possession limit. For sources and devices not registered, as allowed by 10 CFR 32.210(g)(2), the applicant must have adequate training and experience and facilities and equipment to handle comparable quantities of material in any form under 10 CFR 30.33(a)(2) and (3) and must provide information about the unregistered sealed sources and devices in accordance with 10 CFR 30.32(g)(4).

Possession requests should be categorized into general areas of use (e.g., research and development activities, routine gauging activities, self-shielded irradiators, instrument calibrators, and medical applications).

In accordance with 10 CFR 30.32(i), applications to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities listed in 10 CFR 30.72 must include either of the following:

- an evaluation showing that the maximum offsite dose caused by a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid

- an emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3)

Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in 10 CFR 33.100, Schedule A. Type B applicants should request the quantity of material specified in 10 CFR 33.11(b). Type C applicants should request the quantity of material specified in 10 CFR 33.11(c).

8.5.2 Financial Assurance and Recordkeeping for Decommissioning

Regulations: 10 CFR 30.32(h), 10 CFR 30.35, 10 CFR 30.36(e), 10 CFR 30.36(g)(4)(v), 10 CFR 30.51(d), 10 CFR 30.51(e), 10 CFR 30.51(f), 10 CFR 40.31(i), 10 CFR 40.36, 10 CFR 40.42(e), 10 CFR 40.42(g)(4)(v), 10 CFR 40.61(d), 10 CFR 40.61(e), 10 CFR 40.61(f), 10 CFR 70.22(a)(9), 10 CFR 70.25, 10 CFR 70.38(e), 10 CFR 70.38(g)(4)(v), 10 CFR 70.51(b)

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25—all entitled "Financial Assurance and Recordkeeping for Decommissioning"—must meet the requirements for decommissioning FA. 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. Licensees must transfer these records either to the new licensee, when licensed activities are transferred or assigned or to the appropriate NRC regional office when the license is terminated.

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

NRC decommissioning FA regulations are designed to provide reasonable assurance that the decommissioning of licensed facilities will be accomplished in a safe and timely manner and that licensees will provide adequate funds to cover all costs associated with decommissioning. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee that funds will be available. Applicants are required to provide FA when the possession of radioactive material of half life ($T_{1/2}$) greater than 120 days exceeds certain limits. Criteria for determining if an applicant is required to submit a decommissioning funding plan (DFP) or has an option of submitting either a DFP or a certification of FA are stated in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25. A DFP contains a site-specific cost estimate and a certification of FA. A Certification of Financial Assurance includes a certification that the licensee has provided the required FA and an acceptable FA instrument.

Acceptable FA includes prepayment option of a trust fund; surety, insurance, or other guarantee methods (letters of credit, surety bonds, parent company guarantees, insurance policies), and statements of intent for Government entities. Criteria for parent company guarantees and self guarantees can be found in 10 CFR Part 30, Appendix A, Appendix C, Appendix D, and Appendix E.

NUREG-1757, “Consolidated Decommissioning Guidance,” Volume 3, Revision 1, “Financial Assurance, Recordkeeping, and Timeliness” (NUREG-1757, Vol. 3, Revision 1), 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.

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

In accordance with10 CFR 30.35(g), licensees must transfer records important to decommissioning to the new licensee before licensed activities are transferred or assigned according to 10 CFR 30.34(b).

Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, each licensee shall forward the records required by 10 CFR 30.35(g) to the appropriate regional office.

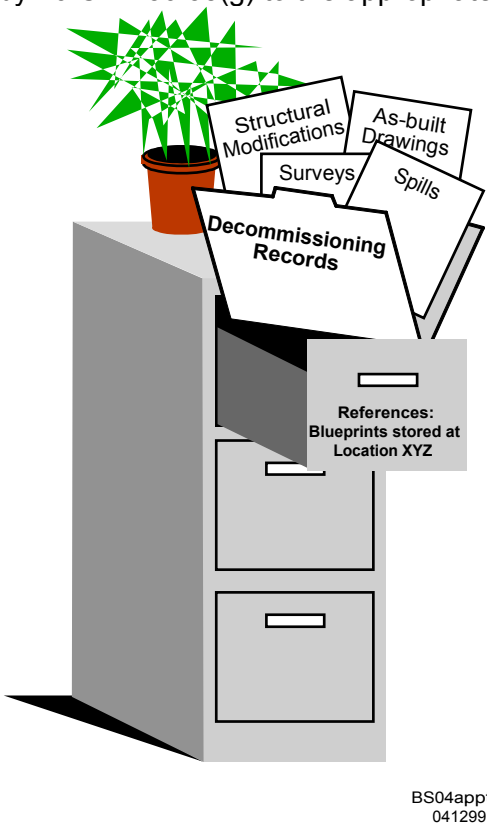

Figure 8.1 Types of Records that Must be Maintained for Decommissioning

10 CFR 30.35(g) and 30.51(f), Requirements for Disposition of Records Important to Decommissioning

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

OR

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

Response from Applicant:

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

AND

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

8.5.3 EMERGENCY PLAN

Regulations: 10 CFR 30.32(i); 10 CFR 30.72

Criteria: Applicants who will be authorized to possess radioactive material in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities listed in 10 CFR 30.72 must be prepared for the potential release of radioactive material.

Discussion: When requesting authorization for possession limits in excess of the quantities listed in Schedule C of 10 CFR 30.72, you must provide in conjunction with the license application either:

(1) an evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or

(2) an emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3).

For NRC to grant authorization to possess quantities equal to the activities specified in Schedule C of 10 CFR 30.72, it is necessary to provide the information outlined in 10 CFR 30.32(i) sufficient to evaluate the need for an emergency plan.

Response from Applicant: If an emergency plan is required, provide either:

(1) an evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or

(2) an emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3).

References:

- Regulatory Guide 3.67, Rev. 1, “Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities.”

8.6 Item 6: Purpose(s) for which Licensed Material will be Used

Regulations, 10 CFR 30.32(d), 10 CFR 30.33(a)(1), 10 CFR 33.13, 10 CFR 33.14, or 10 CFR 33.15, as appropriate, 10 CFR 33.17(a)

Criteria: Requested radionuclides must be used for purposes authorized by the Atomic Energy Act of 1954, as amended. Sealed sources and devices containing licensed material must be used only for the purpose for which they are designed and according to the manufacturer's (distributor's) instructions and recommendations for use as specified in the SSD registration certificate. Certain types of sealed sources and devices containing licensed material that are intended for use solely under broad scope licenses, and that will not be transferred to another licensee, need not be evaluated by the NRC prior to use if the licensee is authorized to possess the requested quantity of radioactive material in unsealed form and has administrative controls and provisions established for ensuring safety in accordance with 10 CFR 33.13, 10 CFR 33.14, or 10 CFR 33.15, as appropriate. Additional licensing guidance for the possession and use of certain types of sealed sources and devices that are not required to have an SSD registration certificate is provided in Chapter 5 of NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

Note: Applicants desiring certain radionuclide activities and type of uses disallowed by 10 CFR 33.17(a) should apply for specific authorization. Refer to the "Discussion" section for further explanation.

Discussion: The applicant should describe in general terms the purposes for which the licensed material will be used. New applicants should describe why a broad scope license is needed rather than amendments to an existing limited scope license. The uses should be consistent with prior licensed activities. Sufficient information should be provided to enable the reviewer to have a clear understanding of each use and to determine the potential for exposure of workers and members of the public to radiation and radioactive materials. The information provided regarding "Purpose of Use" is understood by the NRC staff as a self-imposed limitation contained within the application. If a broad scope licensee desires to initiate a use other than those described in its application and committed to in its license, the licensee must submit an amendment to the license to modify or expand the "purpose."

If the material will be used in tracer/field studies in which licensed material is deliberately released into the environment, or in animal studies that may result in the release of licensed material into the environment, an environmental assessment (EA) may be needed in accordance with 10 CFR 51.21. NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," addresses procedures that staff should use in conducting environmental reviews. Memorandum dated March 19, 2004 (ML040790751), and October 20, 2009 (ML092321078), provides further guidance. Both these memorandums are publicly available and can be accessed through the NRC's ADAMS. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

The exclusions stated in 10 CFR 33.17(a) provide that, unless specifically authorized by other parts of the regulations, persons licensed under broad scope licenses will not do any of the following:

- Conduct tracer studies in the environment involving the direct release of radioactive material (applies to field users)
- Receive, acquire, own, possess, use, transfer, or import devices containing 3.7×10^{15} becquerels (Bq) (100,000 curies) or more of byproduct material in sealed sources for irradiation of materials
- Conduct activities for which a specific license issued by the NRC under 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; 10 CFR Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations"; or 10 CFR Part 35, "Medical Use of Byproduct Materials," is required
- Add or cause the addition of byproduct material to any food or other product designated for ingestion or inhalation by, or application to, a human being.

Applicants desiring these activities should review the appropriate base NUREG (i.e., that volume of NUREG-1556 that most closely applies) and request specific authorization in accordance with the guidance contained therein. For example, broad scope licensees that wish to perform industrial radiography should review NUREG-1556, Volume 2, "Program-Specific Guidance about Radiography Licenses," and provide necessary information, as specified.

Response from Applicant: Describe in general terms the purposes for which the licensed material will be used.

8.7 Item 7: Individual(s) Responsible for Radiation Safety Program

Executive management, the radiation safety committee (RSC), if required, and the radiation safety officer (RSO) and his or her staff, as necessary, work as a team to oversee the broad scope program. Each plays a critical role within a given area of responsibility. The roles and responsibilities of executive management, the RSC, the RSO, and the radiation safety office staff are discussed in the sections that follow.

Note: NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," published May 1997, describes the role of executive management, the RSC, and the RSO at medical facilities but contains information pertinent to all broad scope programs.

8.7.1 Executive Management

Regulations: 10 CFR 20.1101(c), 10 CFR 33.13(c), 10 CFR 33.14(b), 10 CFR 33.15(c)

Criteria: The applicant must have administrative controls and provisions relating to organization and management and management review necessary to ensure safe operations.

Discussion: Executive management is the individual at the senior management level who is responsible for oversight of the facility's radiation safety program and has the ultimate responsibility for the license and the activities associated with the license. Executive management has an important role in implementing and managing the radiation safety program.

Because of the various structures of different organizations, the NRC recognizes that executive management may need to delegate certain responsibilities to other managers for the day-to-day oversight of the program. For example, a large company may have several licenses issued to it for different facilities or for different activities. In this case, a company may choose to establish a senior level manager with responsibility for all of the licenses issued to that company, with the day-to-day responsibility for each license designated to the facility senior manager or program area senior manager. There are numerous ways in which an applicant may wish to structure its management oversight to meet the needs of the organization. However, there must still be one level of management, as the licensee's representative, with ultimate responsibility for the radiation safety program.

In a Type A broad scope program, executive management or her or his delegate is a vital member of the RSC and should attend committee meetings. In all licensed programs, executive management should be knowledgeable of the results of periodic audits and the annual review of the licensed program to ensure all activities comply with regulatory requirements and the conditions of the license and that activities are being conducted in a safe manner. Annual reviews and audits are discussed in more detail in Section 8.10.1 of this guidance document.

The licensee should consider several factors when selecting executive management for the radiation safety program. This individual represents the highest level of facility management and has the authority to delegate resources for the program and appropriate funds in a timely manner. This individual must be available to facilitate effective and immediate action on behalf of management, the RSC (for Type A broad scope programs), and the RSO, particularly in the event of an emergency. Executive management must have the authority to make prompt decisions without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all radiation safety practices are in accordance with the regulations and conditions of the license.

Executive management is involved in selecting the chairperson and members of the RSC (for Type A broad scope) and the RSO (for Type A and Type B broad scope), and defines the role, duties, and responsibilities of each. Executive management should support the RSC and the RSO, creating an atmosphere of cooperation and professionalism such that individuals feel comfortable raising radiation safety concerns. Authority will be enhanced if authorized users clearly understand that there is strong management support for, and participation in, the licensed program. Many problems can be avoided if management takes proactive steps before radiation safety problems escalate. Individuals should understand management's expectations regarding internal enforcement of program requirements and the consequences for noncompliance.

NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," Chapter 1, describes the role of executive management at medical facilities, but it also contains information pertinent to all broad scope programs.

Response from Applicant: The applicant must describe administrative controls and provisions relating to organization and management and management review necessary to ensure safe operations. It is recommended that the applicant submit an organizational chart that describes the management structure, reporting paths, and the flow of authority between executive management, the RSC (for Type A broad scope), and the RSO (For Type A and Type B broad scope).

8.7.2 Radiation Safety Committee

Regulations: 10 CFR 33.13(c)(1), 33.13(c)(3)(iii)

Criteria: Type A broad scope licensees must establish an RSC that works with executive management and the RSO in implementing the radiation safety program. Type B and Type C broad scope licensees are not required to establish an RSC.

Discussion: An applicant for a Type A broad scope license must establish an RSC pursuant to 10 CFR 33.13(c)(1). The RSC works with executive management and the RSO to implement the radiation safety program, and will be involved in establishing policies and procedures for managing the radiation safety program. The RSC, through the executive management, must have the authority and flexibility necessary to effectively fulfill its role in managing the radiation safety program.

The RSC for a Type A broad scope program is composed of such persons as the RSO, executive management, and persons trained and experienced in the safe use of byproduct materials. Each area of use under the license should be represented on the RSC.

The licensee should select a chairperson for the committee. There are several factors to consider when making this selection. An individual with a knowledge of radiation safety issues, good leadership abilities, the authority and credibility by virtue of their position within the facility, and a desire to serve as chairperson will facilitate the effectiveness of the RSC. Additionally, the individual chosen as the chairperson must have the time to devote to the position in addition to other responsibilities he or she might have within the facility. Executive management should delegate a level of authority to the position so that the chairperson is effective. In general, the RSO should not be appointed as the chairperson of the committee, since the RSO is responsible for the day-to-day operation of the radiation safety program and may be too closely involved with the licensed activities to be objective.

The RSC should establish a quorum for RSC meetings. The NRC considers as acceptable the following: a quorum consisting of the chairperson of the committee (or his or her designee), the RSO, the executive management (or his or her alternate), a representative from each area of use from which specific issues will be discussed, and any other member whose field of expertise is necessary for the discussion.

Regulations in 10 CFR Part 33 do not specify the meeting frequency for RSC meetings for broad scope programs. The RSC should meet as often as needed to ensure the radiation safety program is operating in compliance with the license, established procedures, and the regulations. For most programs, quarterly RSC meetings are needed to adequately oversee the program.

The RSC should maintain minutes of its meetings. The minutes should include the date of the meeting, the members present and absent to demonstrate a quorum was present, a summary of the discussions, recommendations, and the results of votes. The RSC should also document its review of new users, uses, and program changes. The minutes should also include information related to the ALARA program reviews and the annual radiation safety program review.

Duties and Responsibilities

The radiation safety committee is required, pursuant to 10 CFR 33.13(c)(3)(iii), to review, approve, and record safety evaluations of proposed uses of byproduct materials. Pursuant to 10 CFR 33.17(b), the material possessed under the broad scope program may only be used by, or under the supervision of, individuals approved by the RSC. Therefore, one of the primary responsibilities of the RSC for a broad scope program is to evaluate new users and new uses of byproduct material. The RSC should consider all available information in making decisions. This includes evaluating the training and experience of applicants that request authorization to use radioactive material at the facility, using criteria developed by the RSC. The RSC members should be aware of the regulatory training and experience criteria that apply to each type of use at their institution. The criteria developed by the committee should include such things as the requester's training and experience, the proposed facilities, the protocol for using radioactive material to ensure that all procedures are in accordance with good radiation safety practices, and waste disposal.

Broad scope programs that also include activities that are under other NRC regulations must meet all applicable requirements of those regulations. Most common are medical licensees of broad scope, which must meet the requirements of 10 CFR Part 35, as well as those of Part 33. Broad scope licensees should review other base NUREGs that may apply to their licensed program, such as NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licensees: Program Specific Guidance about Medical Use Licenses," which provides guidance for licensees that possess radioactive material for medical use. Similarly, guidance can be found for other uses of radioactive materials commonly found at broad scope programs, such as self-shielded irradiators (NUREG-1556, Vol. 5), use in animals including veterinary treatment (NUREG-1556, Vol. 7), and uses of small sealed sources in devices such as x-ray fluorescence devices or gas chromatographs (NUREG-1556, Vol. 7) or portable gauges (NUREG-1556, Vol. 1) and fixed gauges (NUREG-1556, Vol. 4).

In addition, the committee is responsible for reviewing personnel dosimetry results, and discussing the results of required radiation surveys and any significant incidents, including spills, contamination, and medical events. Since the licensee is required under 10 CFR 20.1101 to maintain a radiation program based upon sound radiation protection principles to achieve doses that are ALARA, the RSC should review the program for maintaining doses ALARA and providing any necessary recommendations to ensure this. The overall compliance status for authorized users should be thoroughly reviewed. The RSC, working with the executive management, shares responsibility with the RSO for conducting periodic audits of the radiation safety program. Additionally, the RSC reviews any consultant's audit findings and documents the acceptance or rejection of the consultant's findings in the RSC Committee minutes. The RSC also reviews the results of the annual review of the radiation safety program. Licensees should analyze possible trends and suggest timely and corrective actions.

Problems should be clearly defined and reviewed in the future as open items. An assessment of the effectiveness of corrective actions is also helpful in deterring or eliminating future problems and violations.

For Type A broad scope licensees or applicants for a Type A broad scope license that desire the flexibility to make certain program changes and changes to certain procedures as discussed in Section 1 of this document, the RSC, along with executive management and the RSO, will review and approve program and procedural changes in accordance with criteria developed and approved by the RSC. The criteria for reviewing and approving such changes should include provisions for training staff before implementing new procedures and ensure that the proposed changes will not degrade the effectiveness of the currently approved program. Additionally, the audit program should include an evaluation process that will ensure that changes have been properly implemented by the staff and will determine the effectiveness of changes made in achieving program goals.

Response from Applicant: Applicants for a Type A broad scope license should submit the following:

- Description of the duties and responsibilities of the RSC.
- Criteria used for selecting members of the RSC, including what members and the number of members constituting a quorum. Members should be indicated by position title, rather than by name.
- Criteria and procedure describing the approval process used by the RSC and RSO for authorizing new users and new uses.

In addition, applicants for a Type A broad scope license that request the flexibility to make some program changes and revise some procedures previously approved by the NRC without amendment of the license should submit the following:

- A description of the duties and responsibilities of the RSC, including:
  - — review and approval of permitted program and procedural changes prior to implementation
  - — implementation of program and procedural changes
  - — audit of licensed operations to determine compliance
  - — appropriate actions taken when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence
- A description of the process for procedure and program review and approval, including documentation of the specific change. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.

8.7.3 Radiation Safety Officer

Regulations: 10 CFR 30.33(a)(3), 10 CFR 33.13(c)(2), 10 CFR 33.14(b)(1)

Criteria: 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," requires that Type A and Type B broad scope licensees must have a radiological safety officer, more commonly known as a Radiation Safety Officer (RSO), who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiological safety matters. The RSO's training and experience must include the types and quantities of licensed material to be authorized on the license. While regulation does not require Type C broad scope licensees to have an RSO, 10 CFR 33.15, "Requirements for the issuance of a Type C specific license of broad scope," requires that the licensee establish administrative controls and provisions related to procurement of byproduct material, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations. Type C broad scope licensee management should appoint someone responsible for the day-to-day operation of the radiation safety program, such as an RSO.

Discussion: Each Type A and Type B program that uses byproduct materials must appoint an RSO who is responsible for radiation safety and compliance with the regulations for the use of byproduct material. Each Type C broad scope program should appoint an individual who is responsible for the day-to-day operation of the radiation safety program and who will be listed on the license as the RSO. In a Type A broad scope license, the RSO is a member of the RSC and works closely with the RSC and executive management to implement the radiation safety program. In a Type B broad scope license, the RSO is the individual responsible for implementing the radiation safety program. In a Type C broad scope license, the RSO is the technical contact person for matters related to the license.

Duties and Responsibilities

For all broad scope licenses, the RSO must ensure that the licensee is performing all radiation safety activities safely according to approved policies and procedures, and that all regulatory requirements are met. The RSO should have full access to all activities that involve the use of byproduct material and the authority to terminate any activity in which health and safety appear to be compromised without consulting with executive management or the RSC, if required. The applicant should submit a "Radiation Safety Officer Delegation of Authority" signed by executive management. Appendix E contains a model "delegation of authority" that the NRC considers acceptable.

- In a Type A broad scope licensed program, the RSO typically performs a preliminary review of proposed new uses and users, prior to formally discussing the proposal with the RSC. The RSC grants the formal approval of new users and uses in a Type A broad scope license.

- In a Type B broad scope licensed program, the task of reviewing and approving proposed uses and users is the responsibility of the RSO. The Type B broad scope RSO should be qualified by training and experience to provide advice and assistance to others working with materials under the Type B broad scope license. The Type B broad scope RSO also is required to perform the review, approval, and recording of safety

evaluations of proposed uses prepared in accordance with 10 CFR 33.14(b)(2)(ii) before use of the byproduct material

- In a Type C broad scope program, individuals are qualified as users if they meet the training and experience criteria described in 10 CFR 33.15(b). While no licensee, committee, or individual is required by regulation to make the determination that an individual is qualified to use the material possessed under the Type C broad scope license, or that a particular use of byproduct material is safe, licensee management ultimately is responsible for assuring safe operations. The licensee should designate one individual to be named as the RSO on the license. This individual will be the NRC's primary technical contact for matters related to the Type C broad scope license.

The RSO performs audits of all areas of use and individuals who are authorized to use byproduct material to ensure work is done in accordance with the license, regulations, and user permit conditions. Specific duties and responsibilities of the RSO include:

- monitoring and surveys of all areas in which radioactive material is used
- overseeing ordering, receipt, surveys, and delivery of byproduct material
- packaging, labeling, surveys, etc., of all shipments of byproduct material leaving the institution
- monitoring programs, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits
- training all personnel
- overseeing the waste disposal program
- monitoring inventory and leak tests of sealed sources
- overseeing decontamination
- investigating incidents and responding to emergencies
- maintaining all required records

The applicant or licensee may not transfer the responsibilities of the RSO to other individuals. Many tasks and duties associated with managing the program may be assigned or delegated to other qualified individuals. The responsibility for these tasks and duties, however, lies with the RSO. The NRC does recognize that a qualified individual will have to fill in for the RSO when the RSO will be away for short periods of time for professional conferences, vacation, or illness. However, this should not occur for extended or indefinite periods of time. The applicant or licensee should have a plan in place for contacting the RSO in the event of an emergency.

When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position and select an individual who is qualified to serve. The RSO will need a basic technical

knowledge sufficient to understand, in general, the majority of the work being done with byproduct materials under his or her responsibility. The NRC recognizes that an RSO may not be an expert in all areas that might be involved in a broad scope program. The RSO should be qualified by training and experience to perform the duties required for the position. Executive management should ensure that enough time is allocated to the individual selected as the RSO to carry out the responsibilities of the position.

RSO Qualifications and Training

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

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

The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested. For instance, in addition to a college degree, RSOs at a broad scope license where workers handle curie quantities of radioactive material should be specialists in the field of radiation protection and may need 40 hours of radiation safety training specific to their job duties, as well as a year of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be an RSO. On the other hand, RSOs at Type C broad scope licenses may only require a few hours of radiation safety training to be qualified as an RSO.

The RSO designee should have obtained the above training in a formal course designed for RSOs, presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts. In addition, the proposed RSO's experience must be sufficient to identify and control the anticipated radiation hazards. For example, the RSO should have experience planning and conducting evaluations, surveys, and measurements similar to those required by the licensee's radiation safety program.

The applicant should also be aware of specific regulatory requirements for the RSO that may apply to their licensed program. For example, 10 CFR Part 35 contains specific requirements for an RSO in a medical program. However, an individual who qualifies as a medical RSO is not necessarily qualified to be an RSO in a broad scope program.

Chapters 3 and 4 of NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," describes the role of the RSO and selection of the RSO at medical facilities, but it also contains information pertinent to all broad scope programs.

Response from Applicant:

For Type A, Type B, and Type C applicants:

- Submit the name of the proposed RSO.
- Describe the training for the proposed RSO that demonstrates the individual is qualified to perform the duties required under the license.
- Address the RSO's experience in performing each of the duties listed in the "Duties and Responsibilities" section, when and where the experience was gained, and the type, form, and quantity of radionuclides involved.
- Submit a statement delineating the RSO's duties and responsibilities.
- Submit a radiation safety officer delegation of authority signed by the licensee's executive management.

In addition, for Type B applicants, submit the criteria used by the RSO to approve new users and uses of byproduct material. Also, submit the criteria that the RSO will use to evaluate the radiation safety aspect of proposed used, prior to approval.

For Type C applicants, submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program (e.g., the RSO, who will be contacted if there are additional questions about this application) and who is duly authorized to act for the applicant or licensee, as required by 10 CFR 30.32(c).

Applicants should provide specific information about the proposed RSO's training and experience that is relevant to the requested licensed material types, forms, and quantities requested in the application.

Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. This only serves to slow down the review process.

Applicants should not submit personal information, such as birth dates, social security numbers, home addresses, personal telephone or cell phone numbers, for the proposed RSO. Such information is not required to be submitted and under the Privacy Act, documents containing such information must be handled separately, which may delay completion of the review process.

Note: It is important to notify the NRC as soon as possible, typically within 30 days, of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to the NRC as part of an amendment request. Applicants should review the regulations for specific program areas, such as medical uses, that have specific requirements regarding changes in the RSO.

8.7.4 Radiation Safety Office Staff

Criteria: Licensees should provide sufficient staff to assist the RSO in implementing the radiation safety program.

Discussion: The licensee should provide the RSO with a sufficient staff of professional and administrative support personnel. The number of staff and their qualifications will vary depending on the scope of the program. For small programs, the RSO may not require any assistance. Licensees should evaluate the licensed program and ensure that the RSO has adequate resources to effectively manage the program.

Chapters 6 and 7 of NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," discuss the subjects of radiation safety program resources and the use of consultants and service companies at medical facilities. However, these chapters also, contain information pertinent to all broad scope programs.

Response from Applicant: No response is required.

8.8 Item 8: Training for Individuals Working in or Frequenting Restricted Areas (Instructions to Occupational Workers and Ancillary Personnel)

Regulations: 10 CFR 19.11, 10 CFR 19.12, 10 CFR 19.13, 10 CFR 30.33(a)(3), 10 CFR 30.34(e)

Criteria: Before beginning work with or in the vicinity of licensed material, all individuals who are likely to receive an occupational dose in excess of 1 millisievert (mSv) (100 millirem (mrem)) in a year must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training.

Discussion: Requirements in 10 CFR 19.12(a) =establish the training that licensees must are required to provide to individuals who, in the course of their employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Section 19.12(b) of 10 CFR requires that the licensee, in determining which individuals are subject to the training requirements of 19.12(a), consider assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during the life of a licensed facility. While many licensees can demonstrate that it is not likely during a normal situation for a laboratory worker, manufacturing technician, hospital technologist, or environmental services worker at the facility to receive in a year an occupational dose in excess of 1 mSv (100 mrem), these individuals and others could reasonably be expected to receive this level of exposure during abnormal situations (e.g., radioactive material left unsecured, a contamination event, or improper disposal of radioactive material in the regular trash) or, by their actions, cause others to receive this level of exposure. Untrained workers represent a potential hazard to themselves, other individuals, and property.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Practical, site-specific training should be provided for all individuals prior to beginning work with or in the vicinity of licensed material. Periodic refresher training should also be provided. Topics covered should, at a minimum, include those described in 10 CFR 19.12(a). The training may take any form. Many licensees use videotapes or interactive online or offline computer programs to provide training. The licensee should determine if 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 who is familiar with the licensee's program.

Retraining should be performed whenever there is a change in duties or the work environment and at a frequency sufficient to ensure that all staff members are adequately trained.

Applicants should review the model training program described in the appropriate base NUREG corresponding to the particular type of licensed program. For example, NUREG-1556, Volume 7, "Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope," describes a training program that is acceptable to the NRC for licensees that are involved in research and development, and Volume 9 describes a training program that is acceptable to the NRC for licensees that possess radioactive material for medical use.

The applicant should also be aware of additional specific training requirements that may apply to their licensed program. For example, 10 CFR Part 35 contains specific requirements for the training of individuals who will work under the supervision of medical authorized users.

Response from Applicant:

Applicants should do one of the following:

- Submit a description of the radiation safety training program developed for each group of workers, including: topics covered, qualifications of the instructors, method of training, method for assessing the success of the training, and the frequency of training and refresher training.

- Identify the model training program described in the appropriate base NUREG corresponding to your particular type of licensed program and submit a statement that this training program will be implemented.

In addition, Type A broad scope licensees or applicants that want the flexibility to revise their radiation safety training program without amendment of the license (as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document) should describe the process that will be used to revise and implement their submitted training programs.

8.9 Item 9: Facilities and Equipment

Regulations: 10 CFR 20.1101(b), 10 CFR 20.1101(d), 10 CFR 20.1406, 10 CFR 30.33(a)(2), 10 CFR 30.34(e), 10 CFR 30.35(g), 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. They must minimize the possibility of contamination and keep exposures to workers and the public ALARA.

Discussion: Applicants for all broad scope licenses need to demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the types and quantities of radioactive materials to be used. Facilities and equipment designed to control exposure can range from a vial that contains licensed material to buildings, fences, or exclusion areas that are between the source and the maximally exposed member of the public. These facilities not only reduce the exposure from the source but may also limit access to the source. The licensee should list and describe these facilities for the following purposes:

- to show compliance with a regulation
- to demonstrate the use of the material will be within the ALARA concept
- to meet emergency response requirements

Licensees should consider controlling exposures through available engineering options, as well as through limiting the releases of effluents to the environment. The licensee should describe

all facilities and equipment essential to achieving these goals. The licensee will also need to describe the criteria that will be used by the RSC and/or RSO, as appropriate, to review and approve proposed facilities. Facilities and equipment used for special applications in which the effect on workers or the public could be significant if radioactive material were to be released accidentally, should be specifically described. These would include, for example, self-shielded irradiators, specialized radio-labeling (iodination or titration) facilities, alpha laboratories, radioactive waste processing facilities (including incinerators, compactors, liquid reclamation processors, etc.), radioactive waste storage facilities (including decay-in-storage locations), individual laboratories processing 3.7 gigabecquerels (GBq) (100 millicuries) or more of radioactive materials per experiment or process, nuclear pharmacies, specially designed therapy rooms, and sealed source storage areas. Significant modifications that affect facilities and equipment should have prior RSO review and RSC approval before being adopted.

Also note that if radioactive materials will be used in or on animals, licensees should discuss a description of the animal handling and housing facilities. Appendix E of NUREG-1556, Volume 7, "Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope," provides guidance on the information that should be addressed concerning the use of radioactive materials in animals.

In discussing the criteria used to evaluate their facilities and equipment, applicants should include information on how a laboratory or facility classification scheme relates to toxicity and quantity of radioactive material and your facility and equipment requirements. For example, the IAEA, as well as other health physics and industrial hygiene professional organizations, has developed classification schemes used in assessing minimum needs (e.g., equipment and facilities, user training, personnel monitoring, and surveys) that consider the hazard and quantity of byproduct materials to be used (IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides, 1973 Edition.") Applicants may consider the development of such a classification scheme since it can be correlated with all aspects of the radiation safety program. Each applicant's scheme should be based upon the types and quantities of radioactive material anticipated to be used. The criteria used to develop the classification scheme should be provided to each RSC member for use when evaluating requests to use licensed materials.

Appendix F provides the radionuclide toxicity and laboratory classification information excerpted from IAEA and that is acceptable to the NRC staff. This table is not all-inclusive and is meant to serve only as an example only. Based on chemical and physical form, need and quantities, an applicant's classification scheme may differ from that of the IAEA excerpt. Applications will need to describe the minimum facilities and equipment requirements for each laboratory classification.

Appendix G provides additional guidance regarding facilities and equipment used to handle radioactive materials in a laboratory setting.

Response from Applicant: Describe the criteria your RSC or RSO, as appropriate, will use to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.). The description will need to include the method of classifying laboratories based on type, toxicity, and quantity of byproduct material being requested. Sample diagrams should be provided for each classification scheme that take into consideration shielding, the proximity of radiation sources to unrestricted areas, and other

items related to radiation safety. When reviewing facilities where radioactive materials may become airborne, sample diagrams should take into consideration descriptions of the ventilation systems—including pertinent airflow rates, pressures, filtration equipment, and monitoring systems. For special application facilities, such as those facilities described above, you will need to specify their locations (i.e., buildings and room numbers) and special considerations that the RSC or RSO (or both) will use in authorizing byproduct material use. Also describe procedures for control, review, and approval of significant facilities or equipment modifications.

8.10 Item 10: Radiation Safety Program

8.10.1 Audit Program

Regulations: 10 CFR 33.13(c), 10 CFR 33.14(b), 10 CFR 33.15(c), 10 CFR 20.1101, 10 CFR 20.2102

Criteria: Applicants for Type A, Type B, and Type C broad scope licenses are required by 10 CFR 33.13(c), 33.14(b), and 33.15(c), respectively, to establish administrative controls and provisions related to management review necessary to ensure safe operations.
10 CFR 20.1101(c) requires the licensee to review the radiation program content and implementation, periodically (at least annually). 10 CFR 20.2102, "Records of radiation protection programs," requires licensees to keep records of radiation protection programs including: (1) the provisions of the program; and (2) audits and other reviews of the program contents and implementation.

Discussion:

Management and Radiation Safety Committee Audits

The application for a Type A, B, or C broad scope license should discuss executive management oversight of the licensed program and the mechanisms they will use to ensure awareness of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program. This oversight may include independent audits of the program, frequent meetings with the RSC or RSO (or both), as appropriate, and periodic tours of selected facility areas.

In a Type A broad scope program, the RSC assists executive management in performing this oversight function. Detailed written procedures should be developed and implemented for the operation of the RSC to ensure that appropriate oversight is provided. The RSC should be fully aware of the operations and activities of the RSO. The RSC should conduct periodic interactive management audits and evaluations of the radiation safety program's performance, including: nonconformance reports, corrective action, status reports and audits, incident investigation reports, ALARA program development and implementation, effluent releases, qualification and radiological safety training, and performance of the RSO. Licensees should report results of the RSC's audit and program reviews to executive management to allow for timely remedial actions sufficient in scope to ensure compliance with NRC regulations and license conditions.

Appendix H contains a model audit program that the NRC finds acceptable for use in the review of most nonmedical broad scope programs.

10 CFR 20.1101(c) requires the licensee to review the radiation program content and implementation periodically (at least annually). Reviews should be conducted at least once every 12 months.

Internal Audits

The application should describe the audit mechanism implemented by the RSO and her or his staff, or other individual who is responsible for the day-to-day operation of the licensed program, to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC- or RSO-approved permits (as appropriate), good health physics practices, and ALARA principles. The audit program should include performance based routine unannounced inspections of each user's facility and practices to supplement and audit the routine monitoring performed by the user. Facility inspections should include the following:

- Review of user inventory and survey records.
- Evaluation of user and technician training through discussion and observation of work practices.
- Performance of independent surveys of user work areas.
- Evaluation of compliance with NRC regulations, the conditions of the license, and the RSC and RSO permit and safety manual requirements.
- Evaluation of performance based instruction for users and technical-level staff.

The types and frequencies of monitoring performed by the RSO should be indicated. The intervals of surveys and audits should be frequent enough to ensure close communications and proper surveillance of individual radioactive material users. Applicants should consider developing survey and audit schedules based on activity and use (e.g., high use facilities and users of volatile radioactive materials may be audited weekly or biweekly; intermediate use facilities may be audited monthly; and low-level facilities may be audited quarterly).

If an audit identifies violations of NRC requirements, the licensee should evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. Certain identified problems or potential violations may require notification or a report to the NRC. Appendix I of this document describes the more common NRC reporting requirements. The NRC encourages licensees to contact the agency for guidance if there is any uncertainty regarding a reporting requirement. The NRC routinely reviews licensee's records to verify if appropriate corrective actions were implemented in a timely manner to address recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. The NRC can opt to exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented.

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

The NRC's emphasis on performance-based inspections encourages applicants to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of byproduct material users to determine if, for example, safe use of radionuclide procedures and emergency procedures are available and are being followed.

Recordkeeping

Regulations in 10 CFR 20.2102 require licensees to maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. Records of audits should include: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. Licensees must maintain these records for inspection by the NRC.

Response from Applicant:

- Describe the mechanisms executive management used to ensure adequate oversight of the program. In addition, if a licensee is upgrading its limited scope license to a Type A broad scope license or is renewing its Type A broad scope license, describe the RSC's involvement in these oversight mechanisms.

- The applicant is not required to, and should not, submit its program for conducting the annual audit required by 10 CFR 20.1101, "Radiation protection programs," to the NRC for review during the licensing phase. The NRC will review the adequacy of this audit program during inspection.

- Describe the audit mechanism implemented by the RSO or other responsible individual to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC- or RSO-approved permits (as appropriate), and good health physics practices.

In addition, Type A broad scope licensees or applicants that want the flexibility to revise the audit mechanism implemented by the RSO without amendment of the license, as discussed in Chapter 1,"Purpose of Report" and Section 8.7.2, "Radiation Safety Committee," of this document, should describe the process they will use to revise and implement their audit program.

References: The NRC's Enforcement Policy, which is located on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement.html, and IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," which is available in the "Reference Library" on the NRC's Web site, http://www.nrc.gov.

8.10.2 Radiation Monitoring Instruments

Regulations: 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2), 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15

Criteria: Pursuant to 10 CFR 20.1501, "General," licensees must possess and periodically calibrate radiation monitoring instruments that are necessary to protect health and minimize danger to life or property.

Discussion: Licensees must possess an adequate number of radiation detection and measurement instruments, as necessary, to comply with regulations and to maintain radiation safety. Licensees must ensure instruments are calibrated periodically for the radiation being measured. For purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. The choice of instrument needs to be appropriate for the type of radiation to be measured and for the type of measurement to be taken (count rate, dose rate, etc.).

The applicant should submit the criteria used in determining what radiation detection and monitoring equipment will be required for each type of use by authorized users and the availability of a sufficient quantity of these instruments to both the radiation safety office and authorized users (e.g., ion-chambers, Geiger-Muellers (G-Ms), air samplers, liquid scintillation counters).

The NRC requires that survey instruments used to determine compliance with regulatory requirements be calibrated periodically by the instrument manufacturer or persons specifically authorized by the NRC or an Agreement State. Survey instruments should be calibrated at least annually (every 12 months), unless another frequency is specified by regulation or license condition. Licensees seeking authorization to perform their own survey instrument calibrations will need to submit calibration procedures for review. The licensee may wish to review available industry standards for calibration of instruments, such as American National Standards Institute (ANSI) N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Appendix J of this document provides useful information about instrument specifications and model calibration procedures that the NRC considers to be acceptable.

Some instruments may only need to be checked periodically for operability and response to radiation rather than receive full calibration. For example, G-M detection instruments used to identify contamination in laboratories may only need to be checked for ability to detect low-level contamination.

Applicants will need to submit their method for assuring that instruments are checked and calibrated at proper frequencies.

Response from Applicant:

- Provide the criteria used by the RSC or RSO (or both), as appropriate, to review and approve radiation monitoring instrumentation to ensure that appropriate radiation monitoring equipment will be used during licensed activities.

- Discuss how the RSC or RSO, as appropriate, will ensure that instruments are properly calibrated at prescribed frequencies.

- Submit procedures for instrument calibration or state that instruments will be calibrated by a vendor licensed by the NRC or an Agreement State to perform instrument calibrations. Licensees that want authorization to calibrate their own survey instruments may commit to implementing the model procedures published in Appendix J of this document.

In addition, Type A broad scope licensees or applicants that want the flexibility to revise their instrument specifications and procedure for calibration of instruments without amendment of the license, as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document, should describe the process that they will use to revise and implement these submitted procedures.

Note: If you wish to perform instrument calibration as a commercial service, you will need to either amend your existing broad scope license or apply for a new NRC license authorizing commercial calibration service.

8.10.3 Material Receipt and Accountability

Regulations: 10 CFR 20.1501(a), 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 20.2001, 10 CFR 20.2108(b), 10 CFR 20.2201, 10 CFR 20.2207, 10 CFR 30.34(e), 10 CFR 30.35(g), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15

Criteria: Licensees must—pursuant to 10 CFR Parts 20, 30, and 33—develop, implement, and maintain written procedures for all of the following:

- purchasing and receipt of radioactive material
- safely receiving and opening packages
- ensuring control and accountability of licensed material

Licensees must also do the following:

- Maintain records of receipt, transfer, and disposal of licensed material.

- Update transactions in the National Source Tracking System (NSTS), including performing an annual inventory reconciliation, if applicable.

Discussion: Licensed materials must be tracked from receipt to transfer to ensure accountability at all times; identify when licensed material may be lost, stolen, or misplaced; and ensure that the possession limit stated on the license is not exceeded. The NRC requires applicants for a broad scope license to establish appropriate administrative controls and provisions that are necessary to ensure safe operations, including procedures to regulate the control of procurement and use of byproduct material. Administrative procedures must ensure that only authorized individuals receive radioactive materials and then only the types and quantities of radioactive material that they are authorized to receive.

Applicants for a broad scope license are strongly encouraged to develop an administrative procedure to control procurement and use of radioactive material that emphasizes centralized purchasing and receipt. The NRC has found centralized purchasing and receipt, involving the radiation safety officer as an active part of the process, to be effective in controlling licensed materials entering the licensed institution through normal commercial channels, particularly for larger institutions. Procedures must also be established to control licensed materials obtained outside of the normal channels (e.g., through the loan or transfer of materials without purchase or through surplus). Appendix K of this document describes a model procedure for controlling procurement and use of specifically licensed and generally licensed radioactive material that is acceptable to the NRC.

Licensees are required to develop, implement, and maintain written procedures for safely receiving and opening packages in accordance with 10 CFR 20.1906, "Procedures for receiving and opening packages." Appendix P of this document describes a model procedure for safely receiving and opening packages containing licensed materials that the NRC finds to be acceptable.

Table 8.1 Package Monitoring Requirements

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

* Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has 3 hours after the beginning of the next work day to perform the required surveys.

Applicants for a broad scope license are required to establish appropriate administrative controls and provisions related to material control and accounting that are necessary to ensure safe operations. Licensees use various methods to account for receipt, use, transfer, disposal, and radioactive decay of unsealed licensed material (e.g., computer programs, manual ledgers,

log books). These methods help to ensure that licensee and individual authorized user possession limits are not exceeded. Licensees that possess sealed sources are required to perform periodic inventories. The frequency of these inventories is normally established by license condition as every 6 months; however, regulation may specify a different inventory frequency (e.g., sealed sources used for medical therapy are required to be inventoried every 3 months).

The NRC considers licensed material to become part of the licensee's inventory at the time that it is received by the licensee, be it during normal working hours or after hours when delivered by the carrier in accordance with procedures established by the licensee. If through some error, the licensee receives material it is unauthorized to possess or receives quantities of material that would result in the total inventory being in excess of license possession limits, the licensee should place the package in secure storage and arrange for the return of these materials in a timely manner. If return of the materials is not possible, the licensee should contact the NRC regional office and request issuance of an expedited license amendment. The materials must not be used until the amendment is granted.

Licensees are required under 10 CFR 20.1801 and 20.1802 to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage. Applicants for broad scope licenses must establish policies and procedures to ensure compliance with security requirements.

Regulations in 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources," 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 for each type of transaction specified, in order to track high-risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay enough to no longer be of concern. Section 8.10.9, "Security Program for Category 1 and Category 2 Materials," provides additional information on this subject.

Licensees must maintain records of receipt, use, transfer, and disposal of all licensed material. Table 8.2 below lists each type of record and how long the record must be maintained.

Table 8.2 Record Maintenance

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until the NRC terminates the license
Important to decommissioning	Until the site is released for unrestricted use
Information about locations where licensed material is used or stored are among the records important to decommissioning and required by 10 CFR 30.35(g). See also the section on "Financial Assurance and Recordkeeping for Decommissioning."	

Response from Applicant:

- Describe the administrative procedures used to ensure control of procurement and use of byproduct material.

- While the applicant is required to develop and implement safe opening procedures for packages containing radioactive material, the applicant need not submit the procedures during the licensing process. The NRC will review these procedures during inspection.

- Provide the following statement: "We will develop, implement and maintain procedures for ensuring accountability of licensed materials at all times."

- Describe the administrative controls and provisions related to materials control, accounting and security. Describe the method for maintaining accountability of licensed material at all times.

- If applicable, provide the following statement: "We will comply with the NSTS reporting requirement as described in 10 CFR 22.2207."

In addition, Type A broad scope licensees or applicants that want the flexibility to revise their administrative procedures to ensure control of procurement and use of byproduct material without amendment of their licenses (as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document) should describe the process their RSC will use to revise these administrative procedures, controls, and provisions. Licensees and applicants should also do this when making revisions to their administrative controls and provisions related to material control, accounting, and security.

8.10.4 Occupational Dose

Regulations: 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 20.2106, 10 CFR 20 Appendix B

Criteria: Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure. If dosimeters are required, licensees must provide employees with film, thermoluminescent dosimeters (TLDs), optically stimulated luminescent dosimeters (OSLs), or other personal dosimetry processing that have been accredited under the National Voluntary Laboratory Accreditation Program (NVLAP) operated by the National Institute of Standards and Technology (NIST).

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 in excess of any of the following (each evaluated separately):
  – 0.005 Sv (0.5 rem) deep-dose equivalent
  – 0.015 Sv (1.5 rem) eye-dose equivalent
  – 0.05 Sv (5 rem) shallow-dose equivalent to the skin
  – 0.05 Sv (5 rem) shallow-dose equivalent to any extremity

- Minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  – 1.0 mSv (0.1 rem) deep-dose equivalent
  – 1.5 mSv (0.15 rem) eye-dose equivalent
  – 0.005 Sv (0.5 rem) shallow-dose equivalent to the skin
  – 0.005 Sv (0.5 rem) shallow-dose equivalent to any extremity

- Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period.

- Individuals entering a high or very high radiation area.

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

- Adults likely to receive in 1 year an intake in excess of 10 percent of the applicable Annual Limit of Intake (ALI) for ingestion and inhalation.

- Minors and declared pregnant women likely to receive in 1 year a committed effective dose equivalent in excess of 1.0 mSv (0.1 rem).

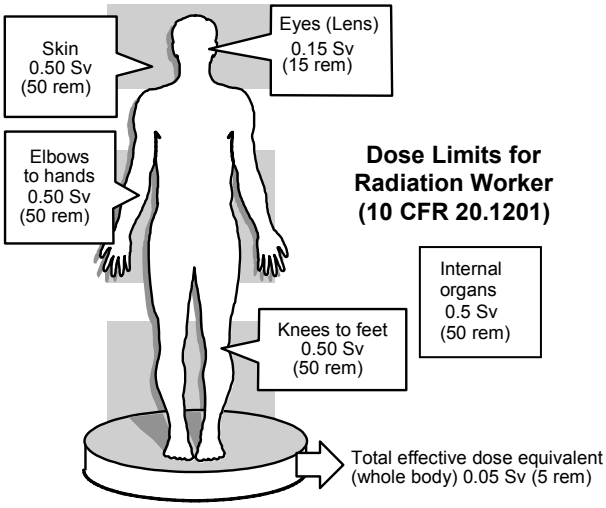

Figure 8.2 Annual dose limits for occupationally exposed individuals

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

Discussion:

If an adult is likely to receive in 1 year a dose greater than 10 percent of any applicable limit, monitoring is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

If this prospective evaluation shows that the 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 received exposure at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring, and therefore, recordkeeping and reporting requirements. If it is determined that monitoring is not required and a subsequent evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received.

If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter "NR" for "not required" in the blocks on

NRC Forms 4 and 5 to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter "ND" for "not detectable."

If the prospective evaluation shows that the individual is likely to exceed 10 percent of an applicable limit, then monitoring and reporting of the results of monitoring performed—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.

Table 8.3 Documents that Contain Guidance Relating to Personnel Monitoring and Bioassay that May be Applicable

Regulatory Guide 8.7, Revision 2	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 1	Applications of Bioassay for I-125 and I-131
Regulatory Guide 8.21, Revision 1	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
Regulatory Guide 8.23, Revision 1	Radiation Safety Surveys at Medical Institutions
Regulatory Guide 8.25, Revision 1	Air Sampling in the Workplace
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Doses
Regulatory Guide 8.35, Revision 1	Planned Special Exposures
Regulatory Guide 8.36	Radiation Dose to the Embryo or Fetus
Regulatory Guide 8.37	ALARA Levels for Effluents from Materials Facilities
ANSI N13.30-2011	Performance Criteria for Radiobioassay
Information Notice 2000-10	Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits

Additional References for Further Reading:

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

Response from Applicant: Submit a description of the method used to demonstrate compliance with the referenced regulations or submit a statement that an evaluation disclosed that individuals do not require monitoring.

In addition, Type A broad scope licensees or applicants that want the flexibility to revise their personnel dosimetry program without amendment of the license, as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document, should describe the process they will use to revise and implement their submitted personnel dosimetry program.

8.10.5 Public Dose

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

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

Discussion: Public dose is defined in 10 CFR Part 20 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 doses or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with 10 CFR 20.2003, "Disposal by release into sanitary sewage." 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 if the individual is in a restricted area, a controlled area, or an unrestricted area when the dose is received.

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

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1302(b). The extent and frequency of monitoring will depend on the nature of the licensee's operations, potential release pathways, and potential exposures that can contribute to public dose or environmental releases. For additional guidance on monitoring of effluents, refer to the section entitled "Radiation Safety Program – Surveys."

Regulations in 10 CFR 20.2107, "Records of dose to individual members of the public," require that licensees maintain survey and monitoring records that demonstrate compliance with the dose limits for members of the public until the Commission terminates the license.

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

For guidance about accepted methodologies for determining doses to members of the public, see Appendix L of this document.

8.10.6 Safe Use of Radionuclides and Emergency Procedures

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.1406; 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 30.32(i), 10 CFR 30.34(e), 10 CFR 30.50, 10 CFR 30.72, 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15

Criteria: Licensees are required, pursuant to the regulations stated above, to keep radiation doses to workers and members of the public ALARA; ensure security of licensed material; and make required notifications to the NRC of events.

Discussion: Licensees are responsible for developing and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facilities until it is used, transferred, and/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

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 individuals cannot take the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material and prevent unauthorized persons from removing the material from the area.

Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include:

- storing and using licensed materials only in restricted areas
- limiting access to an entire facility or building or portion of the building to radiation workers
- providing storage areas that can be locked to prevent access to the material
- implementing procedures that require a radiation worker to be within “line of sight” of the materials whenever licensed materials are in use

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, animal care facilities, and waste processing facilities. Security procedures may be in a separate document or included in the "General Safety Procedures."

Applicants should develop radionuclide-specific procedures based on the respective hazards associated with the radionuclides. Appendix M of this document describes general safety guidelines. Licensees are encouraged to use these guidelines in developing procedures for the safe use of radionuclides.

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

Applicants need to establish written procedures to handle emergencies ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, individual users should have a clear understanding of their limitations in an emergency, with step-by-step instructions and clear direction for whom to contact. Appendix M of this document describes model emergency procedures that the NRC considers acceptable.

Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished, as necessary. The licensee should also consider establishing an emergency response team composed of individuals experienced in various emergency response functions (e.g., radiological, medical, emergency management, security, and fire protection).

Regulations in 10 CFR 20.2201–20.2203, 10 CFR 21.21, "Notification of failure to comply or existence of a defect and its evaluation," and 10 CFR 30.50, "Reporting requirements," require certain incidents and emergencies be reported to the NRC. Appendix I of this document provides examples of some events that require notification and/or reports. Note that Appendix I is not all inclusive, as there are other notification and/or reporting requirements that may apply to specific programs (e.g., 10 CFR Parts 32, 34, 35, 36, and 39).

If licensees plan to possess quantities of material in excess of the applicable amounts listed in 10 CFR 30.72, "Schedule C," then they may also be required to submit an "emergency response plan for responding to a release." See Section 8.5.1, "Unsealed or Sealed Byproduct Material," of this document for specific information related to this requirement.

Response from Applicant: Submit procedures for safe use of radionuclides and emergencies. Submissions should include procedures for maintaining security of licensed radioactive

materials. As an alternative, state, “We will adopt the procedures for the safe use of radionuclides and emergencies as published in Appendix M of NUREG-1556, Volume 11, Revision 1, “Program-Specific Guidance about Licenses of Broad Scope.”

In addition, Type A broad scope licensees or those applying for a Type A broad scope license that want the flexibility to revise their safe use and emergency procedures without amendment of the license, as described in Chapter 1, “Purpose of Report,” and Section 8.7.2, “Radiation Safety Committee,” of this document, should discuss the process that will be used to revise and implement their submitted safe use and emergency procedures.

8.10.7 Surveys

Regulations: 10 CFR 20.1501, 10 CFR 20.1906; 10 CFR 20.2103, 10 CFR 30.53, 10 CFR 33.13, 10 CFR 33.1410 CFR 33.15, 10 CFR 35.67(d), 10 CFR 35.2067(a), 10 CFR 36.81(h), 10 CFR 39.35(a)

Criteria: Licensees are required, pursuant to the regulations listed above, to make surveys of potential radiological hazards in their workplace. The NRC requires testing to determine if there is any radioactive leakage from sealed sources. Licensees must retain records of surveys and leak test results.

Discussion: Survey is defined as an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. These evaluations may be measurements (e.g., radiation levels measured with a survey instrument or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The licensees must interpret and evaluate such measurements and calculations to take appropriate action. 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.

Surveys are required when it is necessary for the licensee to comply with the regulations or to evaluate a radiological hazard. Many different types of surveys may need to be performed because of the particular use of licensed materials. The most important are as follows:

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

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

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

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

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

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

Appendix N of this document describes survey procedures that are acceptable to the NRC.

The regulations in 10 CFR Part 20 do not specify limits for surface contamination. Each applicant should propose and justify which removable surface contamination limits will be allowable before decontamination will be performed in each work area. However, Subpart E of 10 CFR, Part 20 specifies dose limits for residual contamination at the time of license termination. This criteria should also be used at the time of decommissioning of facilities that are to be released for unrestricted use, even as the license continues in effect at other locations. Guidance for survey criteria to meet the license termination criteria may be found in NUREG-1757, "Consolidated Decommissioning Guidance," dated September 2006.

Also, NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," dated August 2000, contains additional guidance concerning surveys during the decommissioning of facilities. Licensees that have facilities to decommission should review this document.

Leak Test

When issued, a license will require performance of leak tests of sealed or plated foil sources at intervals as approved by the NRC or an Agreement State and specified by the SSD registration certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 becquerels (Bq) (0.005 microcuries) of radioactivity.

Leak tests are not required if:

- Sources contain only hydrogen-3 (tritium).

- Sources contain only byproduct material with a half-life of less than 30 days.

- Sources contain only a radioactive gas.

- Sources contain 3.7 megabecquerels (MBq) (100 microcuries) or less of beta-emitting or gamma-emitting material or 370 kilobecquerels (kBq) (10 microcuries) or less of alpha-emitting material.

- Sources are stored and are not being used (must be leak tested before use or transfer).

For more information regarding leak tests, see Appendix O of this document.

Response from Applicant:

- Surveys
  Submit procedures to evaluate radiological hazards, both external and internal. As an alternative, you may state, "we will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix N of NUREG-1556, Volume 11, Revision 1, 'Program-Specific Guidance About Licenses of Broad Scope.'"

- Leak Testing
  Submit leak test procedures. As an alternative, you may state, "We will implement the model leak test program published in Appendix O of NUREG-1556, Volume 11, Revision 1, 'Program-Specific Guidance about Licenses of Broad Scope.'"

In addition, Type A broad scope licensee or those applying for a Type A broad scope license that want the flexibility to revise their survey or leak test program without amendment of the license, as described in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document, should discuss the process that will be used to revise and implement their submitted survey and leak test program.

8.10.8 Transportation

Regulations: 10 CFR 20.1101, 10 CFR 30.41, 10 CFR 30.51, 10 CFR 33.13, 10 CFR 33.14, 10 CFR 33.15, 10 CFR 34.35, 10 CFR 71.5, 10 CFR 71.12, 10 CFR 71.13, 10 CFR 71.14, 10 CFR 71.47, 10 CFR 71.87, 49 CFR Parts 171-185

Criteria: Broad scope licensees that will transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material to ensure compliance with NRC and U.S. Department of Transportation (DOT) regulations.

Discussion: DOT regulations (Title 49 of the *Code of Federal Regulations* (49 CFR), "Transportation") were written to help ensure that hazardous materials in *commerce* were transported uniformly and safely. NRC licensees that transport byproduct material (hazardous material) in commerce are, therefore, required to comply with all applicable DOT regulations. However, many NRC licensees routinely transport byproduct material that is not in commerce. In 1979, 10 CFR 71.5, "Transportation of Licensed Material," was codified to ensure that all NRC licensees that transport byproduct material, in commerce or not, transport it in a uniformly safe manner. Some broad scope licensees have applied for certain exemptions to 10 CFR 71.5; however, the NRC did not grant these exemption requests. The NRC's position regarding the transportation regulations in 49 CFR is that these regulations already allow for flexibility and are thus considered to be performance-based requirements rather than prescriptive requirements. For example, packages shipped by broad scope licensees frequently meet the "limited quantity" criteria as described in 49 CFR 173.421, "Excepted Packages for

Limited Quantities of Class 7 (Radioactive) Materials," and are therefore excepted from certain DOT requirements, provided that certain other less-restrictive requirements are met. Appendix P of this document provides an overview of the transportation requirements that commonly affect NRC licensees. Broad scope licensees' radiation safety staff should be thoroughly familiar with 10 CFR 71.5 and 49 CFR and how they interrelate in order to be able to comply with and to take full advantage of the flexibility inherent in DOT requirements.

Licensed material, including radioactive waste, must be packaged and transported in accordance with NRC and DOT requirements if the transportation involves the use of public highways. In addition, broad scope licensees should develop and maintain their own radiation safety procedures for transporting licensed material within their facilities if such transportation does not involve the use of public highways.

Licensees also should consider the safety of all individuals who may handle or may come in contact with the packages containing licensed material. Therefore, the licensee's primary concern in transporting licensed material should be to ensure that package is properly prepared prior to transport, that package integrity is not compromised during transport and that the radiation levels (including removable contamination levels) not only meet the regulatory requirements of 10 CFR 71.47, "External radiation standards for all packages," but also are ALARA.

Licensees shipping radioactive waste for disposal must prepare appropriate documentation as specified in 10 CFR Part 20, Appendix G, "Requirements for transfers of low-level radioactive waste intended for disposal at licensed land disposal facilities and manifests."

Response from Applicant: No response is needed from applicants during the licensing phase. Compliance with transportation requirements will be reviewed during NRC inspections.

Reference: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 Revision)" can be obtained by calling DOT's Office of Hazardous Materials Safety Administration Training Office, at (202) 366-4900. The Memorandum of Understanding with DOT on the Transportation of Radioactive Material (signed June 6, 1979) is available from the NRC on its public website under "Enforcement Guidance" at http://www.nrc.gov/about-nrc/regulatory/enforcement/moudot.pdf.

8.10.9 Security Program for Category 1 and Category 2 Materials

Regulations: 10 CFR 20.2207, 10 CFR Part 37

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

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

Discussion: The regulations in 10 CFR 20.2207 require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and

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

In accordance with 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," licensees authorized to possess Category 1 or Category 2 quantities of radioactive material must establish, implement, and maintain a security program to ensure physical protection of the radioactive material. For additional guidance implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

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

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

Per 10 CFR Part 37, Subpart B, licensees must establish an access authorization program to ensure that individuals who have unescorted access to Category 1 and 2 quantities of radioactive material and reviewing officials are trustworthy and reliable. Per 10 CFR Part 37, Subpart C, licensees must establish a physical protection program to monitor and, without delay, detect, assess, and respond to any actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material in use or storage.

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

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

Response from Applicant:

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

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1501, 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2108, 10 CFR 30.51

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

Discussion: The applicant should discuss the methods for management and disposal of radioactive waste. The program should include procedures for the handling of waste, safe and secure storage, waste characterization, waste minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Licensees may not receive radioactive waste from other licensees for processing, storage, or disposal unless specifically authorized by the NRC.

The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce hazardous waste. The NRC transmitted this guidance to licensees in IN-94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program," dated March 1994. NRC Regulatory Issue Summary 2011-09, "Available Resources Associated with Extended Storage of Low-Level Radioactive Waste," also contains useful information. Applications should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (radioactive from nonradioactive, short from long half-life, liquid from solid waste, etc.).

Waste Volume Reduction

Licensees may implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity or increased radiation levels) to workers, members of the public, and the environment. Safety procedures to address these concerns should be implemented. Applicants must describe in detail waste volume reduction operations that could create a radiological hazard to licensee employees or the general public. Appendix Q of this guidance document describes a model procedure for waste compaction.

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

Transfer to an Authorized Recipient

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

Decay-in-Storage

The NRC has concluded that materials with half-lives of less than or equal to 120 days are appropriate for decay-in-storage (DIS) and interim 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. All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed. Applicants must maintain accurate records of such disposals.

Appendix Q of this guidance document provides a model procedure for DIS.

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 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 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees." In addition, the NRC issued Regulatory Issue Summary 2011-09, "Available Resources Associated with Extended Storage of Low-Level Radioactive Waste," which refers to other helpful guidance documents.

Release into Air and Water

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

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of 10 CFR 20.2003. The regulations in 10 CFR 20.2003 authorizes disposal of licensed material by release into a public sanitary sewerage system if certain conditions are met. Licensees are responsible for demonstrating that licensed materials discharged into the public sewerage system are readily soluble in water or are biological materials that are readily dispersible in water. NRC IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR 20," dated January 1994, provides the criteria for evaluating solubility of waste. Licensees should carefully consider the possibility of reconcentration of radionuclides that are released into the sewer. The NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary

sewerage systems in IN 84-94, “Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted under 10 CFR 20.303 [now 10 CFR 20.2003],” dated December 1984.

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

If your facility maintains a private sewerage treatment system, a septic system, or leach fields, the regulations of 10 CFR 20.2003 are not applicable for releases to these systems (see 10 CFR 20.1003, “Definitions,” for the definition of “sanitary sewerage”). Applicants may make releases of liquids to private sewerage systems, septic systems, or leach fields as effluents released to unrestricted areas pursuant to 10 CFR 20.1302(b)(2)(i).

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

Incineration

Applicants that wish to treat or dispose of licensed material by incineration must comply with the requirements of 10 CFR 20.2004, “Treatment or disposal by incineration.” Applicants proposing incineration should be aware that a notice in the *Federal Register* may be required before disposal of ash as ordinary waste can be approved. However, approval of incineration pursuant to 10 CFR 20.2004 does not require notice in the *Federal Register* if the ash is disposed as radioactive waste or transferred to a specific licensee. Policy and Guidance Directive PG 8-10, “Disposal of Incinerator Ash as Ordinary Waste,” dated January 1997, provides guidance on the disposal of ash. Appendix Q of this guidance document offers a model procedure for incineration of waste.

Applicants that are considering disposal of radioactive material by incineration should review Regulatory Guide 8.37, “ALARA Levels for Effluents from Materials Facilities,” dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring.

Disposal of Specific Waste as if it Were Not Radioactive

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

- liquid scintillation medium containing no more than 1.85 kBq (0.05 microcuries) of H-3 or C-14 per gram of the medium

- animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 microcuries) of H-3 or C-14 per gram averaged over the weight of the entire animal

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

Burial

- Licensees previously authorized to bury radioactive materials pursuant to 10 CFR 20.304 before January 28, 1981, should describe the locations, condition, and current status of these former sites (i.e., controlled or uncontrolled, active monitoring of the site, and current condition of the burial site). If the licensee plans to decommission a burial site prior to termination of the license, the licensee may be required to notify the NRC and develop a decommissioning plan in accordance with 10 CFR 30.36. Additional guidance is provided in NUREG-1757, "Consolidated Decommissioning Guidance."

Other Methods Specifically Approved by the NRC Pursuant to 10 CFR 20.2002

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

The application should describe the ALARA considerations taken before disposal of radioactive materials. The request should discuss the potential for unmonitored or unanticipated release of radioactive materials to work areas and from release points (i.e., hoods and incinerator stacks). To be in compliance with the ALARA philosophy stated in 10 CFR 20.1101, "Radiation protection programs," radioactive material waste stream concentrations should be a fraction (generally 10 to 20 percent) of the limits specified in Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," Table II, 10 CFR Part 20.

Furthermore, because of the variability of inventory control programs for monitoring disposal and releases of byproduct material in use, a program for physically measuring releases should be in place whenever releases exceed the specified ALARA action point.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Response from Applicant:

Provide procedures for waste collection, storage, and the disposal by any of the authorized methods described in this section. Applicants should contact the appropriate regional office of the NRC for guidance to obtain approval of any method(s) of waste disposal other than those discussed in this section.

Note: Applicants do not need to provide information to the NRC if they plan to dispose of LLW through transfer to an authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14, as authorized by 10 CFR 20.2005.

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

8.13 Item 13: Certification

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

Notes:

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

9. AMENDMENTS AND RENEWALS TO A LICENSE

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

Applicants for license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request.
- Submit either an NRC Form 313 or a letter requesting amendment or renewal.
- Provide the license number and docket number.
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, the NRC's guidance, the licensee's organization, or the licensee's radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

9.1 Timely Notification of Change of Control

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

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

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

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

- The transferee has the financial resources to decommission the license, if necessary.
- Public health and safety are not compromised by the use of such materials.

Response from Applicant: No response is required from an applicant for a new license. However, current licensees should refer to NUREG-1556, Volume 15, for more information about transfer of ownership.

10. APPLICATIONS FOR EXEMPTIONS

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

Criteria: Licensees may request exemptions to regulations. The licensee must demonstrate that the exemption is authorized by law, will not endanger life, property, or the common defense and security, and is otherwise in the public interest.

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

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

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

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

11. TERMINATION OF ACTIVITIES

Regulations: 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36(d), 10 CFR 30.36(g), 10 CFR 30.36(h), 10 CFR 30.36(j), 10 CFR 30.51(f), 10 CFR 20.1401, 10 CFR 20.1402, 10 CFR 20.1403, 10 CFR 20.1404, 10 CFR 20.1405, 10 CFR 20.1406

Criteria: The licensee must do the following:

- Notify the NRC, in writing, within 60 days of the occurrence of any of the following:

  – Expiration of its license

  – A decision to permanently cease licensed activities at the entire site.

  – A decision to permanently cease licensed activities in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements.

  – No principal activities under the license have been conducted for a period of 24 months.

  – No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements.

- Submit decommissioning plan, if required by 10 CFR 30.36(g).

- Conduct decommissioning, as required by 10 CFR 30.36(h) and 10 CFR 30.36(j).

- Submit to the appropriate NRC regional office a completed NRC Form 314, "Certificate of Disposition of Materials" (or equivalent information), and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final leak tests).

- Before a license is terminated, send the records important to decommissioning to the appropriate NRC regional office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee in accordance with 10 CFR 30.35(g).

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

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

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 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. Appendix B of the handbook contains a comprehensive list of the NRC’s decommissioning regulations and guidance. Licensees that have large facilities to decommission should review NUREG-1575, “Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM),” Revision 1, dated August 2000. The computer code “DandD” offers an acceptable method for calculating screening values to demonstrate compliance with the unrestricted dose limits. Supplemental information on the implementation of the final rule on radiological criteria for license termination was published in the *Federal Register* (63 FR 64132) on November 18, 1998. .

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

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

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

APPENDIX A

LIST OF DOCUMENTS CONSIDERED IN DEVELOPMENT OF THIS NUREG

This report incorporates and updates the guidance previously found in the NUREG reports, regulatory guides (RGs), and information notices (INs) listed below. The authors also consulted other NRC documents, such as manual chapters (MCs), inspection procedures (IPs), regulatory issue summaries (RISs), policy and guidance directives (PGs), and memoranda of understanding (MOUs) during the preparation of this report.

List of Documents Considered in Development of this NUREG

Table A.1 List of Documents Considered in Development of this NUREG

Document Identification	Title	Date
RG 4.22	Regulatory Guide 4.22, "Decommissioning Planning During Operations," ADAMS No. ML12158A361	December 2012
RG 8.10	Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," ADAMS No. ML003739563	May 1977
NUREG-1516	NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities"	May 1997
NUREG-1757, Volume 1	NUREG-1757, Volume 1, "Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees," Revision 2 ADAMS No. ML070390074	September 2006
NUREG-1757, Volume 2	NUREG-1757, Volume 2, "Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria," Revision 1 ADAMS No. ML070390081	September 2006
NUREG-1757, Volume 3	NUREG-1757, Volume 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," Revision 1 ADAMS No. ML12048A683	February 2012
RG 3.67	Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," Revision 2, ADAMS No. ML103360487	April 2011
NUREG-1140	NUREG 1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees, Final Report," ADAMS Accession No. ML062020791.	January 1988
NUREG-1748	NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs" ADAMS No. ML032450279	August 2003

Document Identification	Title	Date
PG 8-10	PG 8-10 technical basis, “Generic Dose Assessment for Disposal of Incinerator Ash in a Landfill,” ADAMS Accession No. ML003752866	September 1994
PG 8-10	Technical Justification Addendum for PG 8-10: “Generic Dose Assessment for Disposal in a Landfill of Incinerator Ash Containing: S-35, Ca-45, Fe-59, P-32, and Tc-99m, Using RESRAD and NUREG\1500 Methodology,” ADAMS Accession No. ML003744988	March 1996
IP 87126	NRC Inspection Manual, Inspection Procedure 87126, “Industrial/Academic/Research Program,” ADAMS No. ML052730315	September 2005
NUREG-1516	NUREG-1516, “Management of Radioactive Material Safety Programs at Medical Facilities”	May 1997
NUREG-1575	NUREG-1575, “Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM),” Revision 1	August 2000
NUREG-2155	Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"	February 2013
ANSI N323A-1997	ANSI N323A-1997, “Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments”	1997
ANSI N13.30-2011	ANSI N13.30-2011, “Performance Criteria for Radiobioassay”	2011
IN 84-94	Information Notice 84-94, “Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 [now 10 CFR 20.2003],” ADAMS No. ML082321340	December 1984
IN 90-09	Information Notice 90-09, “Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licenses”	February 1990
IN 97-30	Information Notice 97-30, “Control of Licensed Material During Reorganizations, Employee-Management Disagreements and Financial Crises”	June 1997
IN 89-25 (Revision 1)	Information Notice 89-25 (Revision 1), “Unauthorized Transfer of Ownership or Control of Licensed Activities”	December 1994

Document Identification	Title	Date
IN 96-28	Information Notice 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” ADAMS No. ML090080059	May 1996
IN 94-07	Information Notice 94-07, “Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20”	January 1994
IN 94-23	Information Notice 94-23, “Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Programs”	March 1994
RIS 2005-31	Regulatory Issue Summary 2005-31, “Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material” ADAMS No. ML053480073	December 2005
RIS 2007-04	Regulatory Issue Summary 2007-04, “Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission” ADAMS No. ML063470597	March 2007
RIS 2011-09	Regulatory Issue Summary 2011-09, “Available Resources Associated With Extended Storage Of Low-Level Radioactive Waste” ADAMS No. ML111520042	August 2011
RIS 2008-12	Regulatory Issue Summary 2008-12, May 2008, “Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees,” ADAMS No. ML073330725	May 2008
Administrative Letter 96-05	Administrative Letter 96-05, Compliance with the Rule “Timeliness in Decommissioning of Material Facilities,” ADAMS Accession No. ML031200667	November 1996
Memo	Staff Memorandum dated March 19, 2004, “Updated Guidance on Review of Environmental Assessments,” ADAMS Accession No. ML040790751	March 2004
Memo	Staff Memorandum dated October 20, 2009, “Updated Guidance for Distinguishing Between ‘Simple’ and ‘Complex’ Environmental Assessment,” ADAMS Accession No. ML092321078	October 2009

Document Identification	Title	Date
SP-96-022	“All Agreement States Letter,” SP-96-022, dated February 16, 1996	February 1996
Administrative Letter 96-05 (Revision 1)	Administrative Letter 96-05 (Revision 1), Compliance with the Rule “Timeliness in Decommissioning of Material Facilities,” ADAMS Accession No. ML081570203)	July 1998

APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION FORM 313

United States Nuclear Regulatory Commission Form 313
Please use the most current version of this form, which may be found at:
http://www.nrc.gov/reading-rm/doc-collections/forms/

NRC FORM 313 (03-2013) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 05/31/2015**

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

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

SEND APPLICATIONS TO:

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

IF YOU ARE LOCATED IN:

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

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

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

SEND APPLICATIONS TO:

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

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

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

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

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

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

BUSINESS TELEPHONE NUMBER | BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

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

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maiximum 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 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 $ _____

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, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A C RIMINAL 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 (03-2013)

APPENDIX C

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

Instructions:

If you check a box in the column marked “Description Attached,” then you must provide that information on separate sheets.

Item No.	Suggested Response	Description Attached
5.	**RADIOACTIVE MATERIAL** **Unsealed and Sealed Sources** Applicants for a Type A broad scope license should request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. The applicant should list separately individual radionuclides needed in much larger quantities or in much smaller quantities than that described in the atomic number 1–83 request. The maximum quantities of nuclides with atomic numbers above 83 also should be listed separately.	[ ]
	A separate listing should be submitted for sealed sources needed in larger quantities than described in the atomic number 1–83 request. Applicants must provide the manufacturer’s name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated and registered in a SSD registration certificate or specifically approved on a license. This information need not be submitted if the applicant is to be authorized to possess the requested quantity of radioactive material in unsealed form and has established administrative controls to ensure safety in the use of the source and device.	[ ]

Item No.	Suggested Response	Description Attached
5.	**RADIOACTIVE MATERIAL *(Cont'd)*** **Unsealed and Sealed Sources *(Cont'd)*** Possession requests should be categorized into general areas of use (e.g., research and development activities, routine gauging activities, self-shielded irradiators, instrument calibrators, and medical applications). Applicants for licenses to possess radioactive materials in excess of the quantities listed in 10 CFR 30.72 must provide with the application either of the following: (1) an evaluation showing that the maximum off-site dose caused by a release of radioactive materials would not exceed 0.01Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid, or (2) an emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3).	
	Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in 10 CFR 33.100, "Schedule A." Type B licensees should request the quantity of material specified in 10 CFR 33.11(b). Type C licensees should request the quantity of material specified in 10 CFR 33.11(c).	

Item No.	Suggested Response	Description Attached
	Financial Assurance and Recordkeeping for Decommissioning Applicants requesting authorization to possess licensed material in excess of the limits specified in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25 must submit a decommissioning funding plan (DFP) or certification of financial assurance for decommissioning as described in NUREG-1757, "Consolidated NMSS [Office of Nuclear Material Safety and Safeguards] Decommissioning Guidance," Volume 3, "Financial Assurance, Recordkeeping, and Timeliness." **Emergency Plan** If an emergency plan is required, provide either: An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or An emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3).	[ ] [ ]
6.	**PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED** Describe in general terms the use or purpose of each requested radionuclide.	[ ]
7.	**INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM** **Executive Management** The applicant must describe administrative controls and provisions related to organization and management and management review necessary to ensure safe operations. The NRC recommends that the applicant submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management, the RSC (for Type A broad scope), and the RSO (For Type A and Type B broad scope).	[ ]

Item No.	Suggested Response	Description Attached
7.	**INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM *(Cont'd)***	
	Radiation Safety Committee	
	Applicants for a Type A broad scope license should submit the following: • Description of the duties and responsibilities of the RSC. • Criteria used for selecting members to the RSC, including which members and number of members constitute a quorum. Members should be indicated by position title rather than by name. • Criteria and procedure describing the approval process used by the RSC and RSO for authorizing new users and new uses.	[ ]
	In addition, applicants for a Type A broad scope license that are requesting the flexibility to make some program changes and revise some procedures previously approved by the NRC without amendment of the license, as described in Section 1 of this document, should submit the following: • A description of the duties and responsibilities of the RSC, including: – review and approval of permitted program and procedural changes prior to implementation – implementation of program and procedural changes – audit of licensed operations to determine compliance – the appropriate actions to take when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence • A description of the process for procedure and program review and approval, including documentation of the specific change. At a minimum, documentation should state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.	[ ]

Item No.	Suggested Response	Description Attached
7.	**INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM *(Cont'd)*** **Radiation Safety Officer** For Type A, Type B, and Type C applicants: • Submit the name of the proposed RSO. • Describe the training for the proposed RSO that demonstrates the individual is qualified to perform the duties required under the license. • Address the RSO's experience in performing each of the duties listed in the section 8.7.3, "Radiation Safety Officer," when and where the experience was gained, and the type, form, and quantity of radionuclides involved. • Submit a statement delineating the RSO's duties and responsibilities. • Submit a "Radiation Safety Officer Delegation of Authority" form signed by the licensee's executive management. In addition, for Type B applicants: • Submit the criteria used by the RSO to approve new users and uses of byproduct material. • Submit the criteria that the RSO will use to evaluate the radiation safety aspect of proposed used, prior to approval. In addition, for Type C applicants: Submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program (e.g., RSO) who will be contacted if there are further questions about this application, and who is duly authorized to act for the applicant or licensee as required by 10 CFR 30.32(c).	[ ] [ ]

Item No.	Suggested Response	Description Attached
8.	**TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (INSTRUCTIONS TO WORKERS)** Submit a description of the radiation safety training program developed for each group of workers, including: topics covered, qualifications of the instructors, method of training, method for assessing the success of the training, and the frequency of training and refresher training. Alternately, identify the model training program described in the appropriate base NUREG corresponding to your particular type of licensed program and submit a statement that this training program will be implemented. In addition, if you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety training program without amendment of the license, as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document, describe the process you will be used to revise and implement your submitted training program.	[ ]
9.	**FACILITIES AND EQUIPMENT** Describe the criteria your RSC and RSO, as appropriate, will use to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.). Your description will need to include your method of classifying laboratories based on type, toxicity, and quantity of byproduct material being requested. Sample diagrams should be provided for each classification scheme. These should take into consideration shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When reviewing facilities where radioactive materials may become airborne, sample diagrams should take into consideration description of the ventilation systems, including pertinent airflow rates, pressures, filtration equipment, and monitoring systems. For special application facilities, you will need to specify their locations, (i.e., buildings and room numbers) and special considerations that your RSC and RSO, as appropriate, will use in authorizing byproduct material use. Also, describe your procedures for control, review, and approval of significant facilities or equipment modifications.	[ ]

Item No.	Suggested Response	Description Attached
10.	**RADIATION SAFETY PROGRAM** **Audit Program** Describe the mechanisms used by executive management to ensure that adequate oversight of the program is exercised. In addition, if you are upgrading your limited scope license to a Type A broad scope license or you are renewing your Type A broad scope license, describe the RSC's involvement in these oversight mechanisms. The applicant is not required to, and should not, submit its program for conducting the annual audit required by 10 CFR 20.1101 to the NRC for review during the licensing phase. The adequacy of this audit program will be reviewed during NRC inspection. Describe the audit mechanism implemented by the RSO or other responsible individual to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC or RSO-approved permits (as appropriate), and good health physics practices. In addition, if you are a Type A broad scope licensee or applicant and you want the flexibility to revise the audit mechanism implemented by the RSO without amendment of the license, as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document, describe the process you will use to revise and implement your audit program.	[ ]

Item No.	Suggested Response	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Instruments** Provide the criteria used by your RSC and RSO, as appropriate, to review and approve radiation monitoring instrumentation to ensure that appropriate radiation monitoring equipment will be used during licensed activities. Discuss how the RSC and RSO, as appropriate, will ensure that instruments are properly calibrated at prescribed frequencies. Submit procedures for instrument calibration or state that instruments will be calibrated by a vendor that is licensed by the NRC or an Agreement State to perform instrument calibrations. Licensees that want authorization to calibrate their own survey instruments may commit to implementing the model procedures published in Appendix J of this document. In addition, if you are a Type A broad scope licensee or applicant and you want the flexibility to revise your instrument specifications and procedure for calibration of instruments without amendment of the license, as discussed in Sections 1 and 8.7.2 of this document, describe the process that will be used to revise and implement these submitted procedures.	[ ]

Item No.	Suggested Response	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Material Receipt and Accountability** Describe your administrative procedures to ensure control of procurement and use of byproduct material. Describe your method for maintaining accountability of licensed material at all times. While the applicant is required to develop and implement safe opening procedures for packages containing radioactive material, the applicant need not submit the procedures during the licensing process. These procedures will be reviewed during inspection. Describe your administrative controls and provisions relating to materials control, accounting, and security. If applicable, provide the following statement: "We will comply with the National Source Tracking System (NSTS) reporting requirement as described in 10 CFR 20.2207" In addition, if you are a Type A broad scope licensee or applicant and you want the flexibility to revise your administrative procedures to ensure control of procurement and use of byproduct material and your administrative controls and provisions relating to material control, accounting, and security without amendment of your license, describe the process that your radiation safety committee will use to revise these administrative procedures, controls, and provisions. Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document discusses this process.	[ ]

Item No.	Suggested Response	Description Attached
	Occupational Dose Submit a description of the method for demonstrating compliance with the referenced regulations or a statement that an evaluation has disclosed that individuals do not require monitoring. In addition, if you are a Type A broad scope licensee or applicant and you want the flexibility to revise your personnel dosimetry program without amendment of the license, as discussed in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document, describe the process you will use to revise and implement your submitted personnel dosimetry program.	[ ]
10.	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Public Dose** No response is required from the applicant, but the NRC will examine records and written materials documenting compliance during inspection. Licensees must be able to provide documentation demonstrating, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. For guidance about accepted methodologies for determining doses to members of the public, see Appendix L of this document.	
	Safe Use of Radionuclides and Emergency Procedures Submit your procedures for safe use of radionuclides, including security of materials and emergencies. As an alternative, you may state, "We will adopt the procedures for the safe use of radionuclides and emergencies as published in Appendix M of NUREG-1556, Volume 11, Revision 1, 'Program-Specific Guidance about Licenses of Broad Scope.'" In addition, if you are a Type A broad scope licensee or you are applying for a Type A broad scope license and you want the flexibility to revise your safe use and emergency procedures without amendment of the license, as described in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document, discuss the process you will use to revise and implement your submitted safe use and emergency procedures.	[ ]

Item No.	Suggested Response	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)***	
	Surveys	
	Submit procedures to evaluate radiological hazards, both external and internal. If you wish, you may state, "We will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix N of NUREG-1556, Volume 11, Revision 1, 'Program-Specific Guidance about Licenses of Broad Scope.'"	[ ]
	Leak Testing	
	Submit your leak test procedures or, as an alternative, you may state, "We will implement the model leak test program published in Appendix O of NUREG-1556, Volume 11, Revision 1, 'Program-Specific Guidance about Licenses of Broad Scope.'"	[ ]
	In addition, if you are a Type A broad scope licensee or you are applying for a Type A broad scope license and you want the flexibility to revise your survey or leak test program without amendment of the license, as described in Chapter 1, "Purpose of Report," and Section 8.7.2, "Radiation Safety Committee," of this document, discuss the process that will be used to revise and implement your submitted survey and leak test program.	
	Transportation	
	No response is needed from applicants during the licensing phase. The NRC will review compliance with transportation requirements during inspections.	
	Security Program for Category I and Category 2 Materials	
	In accordance with 10 CFR Part 37, licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material must establish, implement, and maintain an access authorization program and a security program to ensure physical protection of the radioactive material.	Need Not be Submitted with Application

Item No.	Suggested Response	Description Attached
11.	**WASTE MANAGEMENT** Provide procedures for waste collection, storage, and disposal by any of the authorized methods described in this section. Applicants should contact the appropriate regional office of the NRC for guidance to obtain approval of any method(s) of waste disposal other than those discussed in this section.	

APPENDIX D

INFORMATION NEEDED FOR FIELD USE OF BYPRODUCT MATERIAL

Information Needed for Field Use of Byproduct Material

Title 10 of CFR 51.22(c)(14)(v) identifies as a categorical exclusion (from the requirement to prepare an environmental assessment or impact statement) the use of radioactive material for research and development and for educational purposes. However, this categorical exclusion does not encompass, among other things, performance of field studies in which licensed material is deliberately released directly into the environment for purposes of the study (e.g., tagging of animals or insects that remain in the wild, and use of tagged pesticides on crops grown outdoors in fields).

These types of requests may require an environmental report filed by the applicant and an environmental assessment by NRC, pursuant to 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." Field studies that do not deliberately release radioactive material into the environment, such as tagging of animals and penning them to prevent escape or plant studies in greenhouse conditions, may be eligible for a categorical exclusion, pursuant to 10 CFR 51.22(c)(14)(xvi).

Applicants and licensees that desire to perform field studies in which licensed material is deliberately released to the environment for the purposes of studies should provide the following information:

1. A complete application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material.

2. A complete experimental protocol.

3. A description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment, if appropriate, and procedures for minimizing releases.

4. A description of the expected radiation dose to humans.

5. Written permission from the property owner to use radioactive materials at the proposed site.

6. A letter from the appropriate state health authorities indicating that they have reviewed your application and concur with your request.

APPENDIX E

MODEL DELEGATION OF AUTHORITY FOR RADIATION SAFETY OFFICER

MODEL DELEGATION OF AUTHORITY
RADIATION SAFETY OFFICER

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

_____ _____
Signature of Management Representative Date
I accept the above responsibilities,

_____ _____
Signature of Radiation Safety Officer Date

cc: Affected department heads

APPENDIX F

RADIONUCLIDES CLASSIFIED ACCORDING TO RELATIVE TOXICITY (EXCERPTED FROM IAEA SAFETY STANDARD, SAFETY SERIES NO. 1, “SAFE HANDLING OF RADIONUCLIDES, 1973 EDITION”)

This table is ***not*** all inclusive and is meant to be used as an example only. Based on chemical and physical form, need, and quantities, your classification scheme may differ from that of the IAEA excerpt.

Note: IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides, 1973 Edition," was superseded by "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards – Interim Edition General Safety Requirements Part 3," published 2011. However, Tables F.1 and F.2 continue to provide helpful information.

Table F.1 Radionuclides Classified According to Relative Radiotoxicity (Excerpted from IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides, 1973 Edition")

Group 1: Very High Radiotoxicity									
^{210}Pb	^{226}Ra	^{227}Th	^{231}Pa	^{233}U	^{238}Pu	^{243}Am	^{244}Cm	^{249}Cf	
^{210}Po	^{228}Ra	....	....	....					
Group 2: High Radiotoxicity									
^{22}Na	^{56}Co	^{95}Zr	^{125}Sb	^{131}I	^{144}Ce	^{181}Hf	^{207}Bi	^{228}Ac	
^{36}Cl	^{60}Co	^{125}I	^{192}Ir	....					
Group 3: Moderate Radiotoxicity									
^{7}Be	^{48}Sc	^{65}Zn	^{91}Sr	^{103}Ru	^{125m}Te	^{140}La	^{153}Gd	^{187}W	^{198}Au
^{14}C	^{48}V	^{69m}Zn	^{90}Y	^{32}P	^{35}S	^{51}Cr	^{24}Na	....	....
Group 4: Low Radiotoxicity									
^{3}H	^{58m}Co	^{71}Ge	^{87}Rb	^{97}Nb	^{103m}Rh	^{131m}Xe	^{125}Cs	^{191m}Os	^{232}Th
^{15}O	^{85}Kr	^{99m}Tc							

Table F.2: Limitations on Activities in Various Types of Working Place or Laboratory

Radiotoxicity of Radionuclides	Minimum Quantity	Type of Working Place or Laboratory Required		
	µCi	Type C	Type B	Type A
1. Very High	0.1 (3.7 kBq)	<10 µCi (<370 kBq)	10 µCi (370 kBq)	10 µCi or more (>370 kBq)
2. High	1.0 (37 kBq)	<100 µCi (<3.7 MBq)	100 µCi (3.7 MBq)	100 µCi or more (>3.7 MBq)
3. Moderate	10 (370 kBq)	<1 mCi (<37 MBq)	1 mCi - 1 Ci (37 MBq - 37 GBq)	1 Ci or more (>37 GBq)
4. Low	100 (3.7 MBq)	<10 mCi (<370 MBq)	10 mCi - 10 Ci (370 MBq - 370 GBq)	10 Ci or more (>370 GBq)

Laboratory Types correspond to the laboratory classification criteria of IAEA Safety Standard, Safety Series No. 1.

- Type C is a good quality chemical laboratory.
- Type B is a specially designed radionuclide laboratory.
- Type A is a specially designed laboratory for handling large activities of highly radioactive materials.

In the case of a conventional modern chemical laboratory with adequate ventilation and nonporous work surfaces, it may be possible to increase the upper limits of activity for Type C laboratories toward the limits for Type B for toxicity groups 3 and 4.

APPENDIX G

FACILITIES AND EQUIPMENT CONSIDERATIONS

Facilities and Equipment Considerations

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

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Applicants should submit scaled drawings and sketches showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.

- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Applicants should use trays or absorbent surface covers to catch and retain spilled liquids on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and nonporous to facilitate decontamination.

- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems, such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems.

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

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

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

- Plumbing and ductwork should be designed to avoid radioactive contamination buildup. This buildup of contamination can create external radiation exposure hazards and problems for decommissioning.

- To reduce radiation exposure from gamma-emitting radioactive materials, shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods, or in glove boxes

- To reduce the exposure from high-energy beta-emitting materials, shielding of low atomic number material, such as high-density plastic, may be used.

- Shielded shipping containers are frequently used for continued storage after receipt of materials.

- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.

- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from deposited radioactive materials.

- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.

- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down and isolated to contain radioactivity.

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

- Areas with the lowest possible background radiation levels should be designated for personnel dosimetry storage when not in use.

- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination buildup.

- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.

- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.

- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, applicants should follow the provisions of 10 CFR Part 20, Subpart H, “Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas.”

APPENDIX H

SAMPLE AUDIT PROGRAM - NON-MEDICAL

Sample Audit Program – Nonmedical

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

1. MANAGEMENT OVERSIGHT:

(Management support to radiation safety, RSC, RSO,, program audits (including annual reviews of program and ALARA reviews), control by authorized users, appropriate follow-up on events, and previous audit/inspection findings)

2. AMENDMENTS AND PROGRAM CHANGES:

(Amendments to the license properly implemented; if applicable, program and procedural changes were approved and implemented in accordance with license condition)

3. FACILITIES:

(Facilities as described in license, uses, control of access, engineering controls, calibration facilities, shielding, and air flow)

4. EQUIPMENT AND INSTRUMENTATION:

(Operable and calibrated survey equipment, procedures 10 CFR Part 21)

5. **MATERIAL USE, CONTROL, AND TRANSFER:**
(Materials and uses authorized, security and control of licensed materials, and procedures for receipt and transfer of licensed material)

6. **AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:**
(Radiological surveys, air sampling, leak tests, inventories, handling of radioactive materials, contamination controls, records, and public doses)

7. **TRAINING AND INSTRUCTIONS TO WORKERS:**
(Training and retraining requirements and documentation, interviews and observations of routine work, staff knowledge of all routine activities, requirements in 10 CFR Part 19 and 10 CFR Part 20 emergency situations, and supervision by authorized users)

8. **RADIATION PROTECTION:**
(Radiation protection program with ALARA provisions, external and internal dosimetry, exposure evaluations, dose and survey records and reports, annual notifications to workers, and bulletins and other generic communications)

9. **RADIOACTIVE WASTE MANAGEMENT:**
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents, and compactors; and license conditions for special disposal method)

10. DECOMMISSIONING:

(Records relevant to decommissioning; decommissioning plan and schedule, notification requirements, cost estimates, funding methods, financial assurance; "timeliness rule" requirements, and changes in radiological conditions since decommissioning plan was submitted – NUREG-1757, Volume 3, Revision 1, provides guidance on decommissioning)

11. TRANSPORTATION:

(Quantities and types of licensed material shipped, special form and packaging design requirements and documentation, shipping papers, hazardous materials (HAZMAT) communication procedures, return of sources, procedures for monitoring radiation and contamination levels of packages, HAZMAT training, and records and reports)

12. NOTIFICATIONS AND REPORTS:

(Reporting and follow-up of theft, loss, incidents, and overexposures. Notification of change in RSO or authorized user. Radiation exposure reports provided to individuals.)

13. POSTING AND LABELING:

(Notices; license documents; regulations; bulletins, and generic information; posting of radiation areas; and labeling of containers of licensed material)

14. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

(Areas surveyed, both restricted and unrestricted; measurements made; comparison of data with staff's results and regulations)

15. AUDIT FINDINGS:

REFERENCES

A. MANAGEMENT OVERSIGHT

1. Radiation Safety Committee
   Applicable license conditions

2. Radiation Safety Officer
   Applicable license conditions

3. Audits, Reviews, or Inspections
   10 CFR 20.1101, “Radiation protection programs.
   10 CFR 20.2102, “Records of radiation protection programs.
   Applicable license conditions

4. ALARA
   10 CFR 20.1101, “Radiation protection programs.”

5. Authorized Users
   Applicable license conditions

B. AMENDMENTS AND PROGRAM CHANGES
   Applicable license conditions

C. FACILITIES

1. Access Control
   10 CFR 20.1601, “Control of access to high radiation areas”
   10 CFR 20.1602, “Control of access to very high radiation areas”
   10 CFR 20.1801, “Security of stored material”
   10 CFR 20.1802, “Control of material not in storage”
   Applicable license conditions

2. Engineering Controls
   10 CFR 20.1101, “Radiation protection programs”
   10 CFR 20.1701, “Use of process or other engineering controls”
   Applicable license conditions

D. EQUIPMENT AND INSTRUMENTATION

1. Survey Instruments
   10 CFR 20.1501, “General”
   10 CFR 20.1701, “Use of process or other engineering controls””
   10 CFR 20.2103, “Records of surveys”
   Applicable license conditions

2. Safety Component Defects

10 CFR 21.21, “Notification of failure to comply or existence of a defect and its evaluation”

E. MATERIAL USE, CONTROL, AND TRANSFER

1. License and Applicable License Conditions

2. Security and Control

10 CFR 20.1003, “Definitions” (restricted area and unrestricted area)

10 CFR 20.1801, “Security of stored material”

10 CFR 20.1802, “Control of material not in storage”

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

10 CFR 20.2207, “Reports of transactions involving nationally tracked sources”

3. Receipt and Transfer of Licensed Material

10 CFR 20.1302, “Compliance with dose limits for individual members of the public”

10 CFR 20.1906, “Procedures for receiving and opening packages”

10 CFR 20.1501, “General”

10 CFR 20.2103, “Records of surveys”

10 CFR 30.41, “Transfer of byproduct material”

10 CFR 30.51, “Records”

F. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

1. Area Surveys

10 CFR 20.1302, “Compliance with dose limits for individual members of the public”

10 CFR 20.1501, “General”

10 CFR 20.2103, “Records of surveys”

10 CFR 20.2107, “Records of dose to individual members of the public”

Applicable license conditions

2. Leak Tests and Inventories

Applicable license conditions

G. TRAINING AND INSTRUCTIONS TO WORKERS

1. General

10 CFR 19.12, “Instruction to workers”

Knowledge of 10 CFR Part 20, “Standards for Protection Against Radiation”

Applicable license conditions

H. RADIATION PROTECTION

1. Radiation Protection Program

a. Exposure evaluation

10 CFR 20.1501, “General”

b. Programs

10 CFR 20.1101, “Radiation protection programs”

2. Dosimetry

a. Dose Limits

10 CFR 20.1201, “Occupational dose limits for adults”.

10 CFR 20.1202, “Compliance with requirements for summation of external and internal doses”

10 CFR 20.1207, “Occupational dose limits for minors”

10 CFR 20.1208, “Doses to an embryo or fetus”

b. External

10 CFR 20.1203, “Determination of external dose from airborne radioactive material”

10 CFR 20.1501, “General”

10 CFR 20.1502, “Conditions requiring individual monitoring of external and internal occupational dose”

Applicable license conditions

c. Internal

10 CFR 20.1204, “Determination of internal exposure”

10 CFR 20.1502, “Conditions requiring individual monitoring of external and internal occupational dose”

10 CFR Part 20, Subpart H, “Respiratory protection and controls to restrict internal exposure in restricted areas”

3. Records

10 CFR 20.2102, “Records of radiation protection programs”

10 CFR 20.2103, “Records of surveys”

10 CFR 20.2104, “Determination of prior occupational dose”

10 CFR 20.2106, “Records of individual monitoring results”

I. RADIOACTIVE WASTE MANAGEMENT

1. Disposal

10 CFR 20.1904, “Labeling containers.
10 CFR 20.2001, “General requirements.
10 CFR 20.2103, “Records of Surveys”

10 CFR 20.2108, “Records of Waste Disposal”
10 CFR 20.2003, “Disposal by Release into Sanitary Sewerage”

2. Effluents
   a. General
      Applicable license conditions

   b. Release to septic tanks
      10 CFR 20.1003, “Definitions” (sanitary sewerage)
      10 CFR Part 20, Appendix B, Table 2, “Effluent Concentrations”

   c. Incineration of waste
      10 CFR 20.2004, “Treatment or disposal by incineration”

   d. Control of air effluents and ashes
      10 CFR 20.1201, “Occupational dose limits for adults”
      10 CFR 20.1301, “Dose limits for individual members of the public”
      10 CFR 20.1501, “General”
      10 CFR 20.1701, “Use of process or other engineering controls”
      Applicable license conditions

3. Waste Management
   a. General
      10 CFR 20.2001, “General Requirements”
      Information Notice (IN) 90-09, “Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees”

   b. Waste compacted
      Applicable license conditions

   c. Waste storage areas
      10 CFR 20.1801, “Security of stored material”
      10 CFR 20.1902, “Posting requirements”
      10 CFR 20.1904, “Labeling containers”
      Applicable license conditions

   d. Packaging, control, and tracking
      10 CFR Part 20, Appendix F, “Requirements for low-level waste transfer for disposal at land disposal facilities and manifests”
      10 CFR 20.2006, “Transfer for disposal and manifests”

10 CFR 61.55, “Waste classification”

10 CFR 61.56, “Waste characteristics”

e. Transfer

10 CFR Part 20, Appendix F, “Requirements for low-level waste transfer for disposal at land disposal facilities and manifests”

10 CFR 20.2001, “General requirements”

10 CFR 20.2006, “Transfer for disposal and manifests”

f. Records

10 CFR 20.2103, “Records of surveys”

10 CFR 20.2108, “Records of waste disposal”

J. DECOMMISSIONING

10 CFR Part 20, Subpart E, “Radiological Criteria for License Termination”

10 CFR 30.35, “Financial assurance and recordkeeping for decommissioning”

10 CFR 30.36, “Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas”

K. TRANSPORTATION

1. General

10 CFR 71.5, “Transportation of licensed material”

2. Shippers—Requirements for Shipments and Packaging

a. General requirements

49 CFR Part 173, “Shippers—general requirements for shipments and packagings,” Subpart I, “Class 7 (Radioactive) Materials”

49 CFR 173.24, “General requirements for packaging and packages.”

49 CFR 173.448, “General transportation requirements.”

49 CFR 173.435, “Table of A_1 and A_2 values for radionuclides.”

b. Transport quantities

10 CFR 71.4, “Definitions”

i. All quantities

10 CFR 71.4, “Definitions”

49 CFR 173.410, “General design requirements.”

49 CFR 173.431, “Activity limits Type A and Type B packages”

49 CFR 173.441, “Radiation level limitations and exclusive use provisions”

49 CFR 173.443, “Contamination control.

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.”

ii. Limited quantities

49 CFR 173.421, “Excepted packages for limited quantities of Class 7 (radioactive) materials.”

49 CFR 173.422, “Additional requirements for excepted packages containing Class 7 (radioactive) materials.”

iii. Type A quantities

49 CFR 173.412, “Additional design requirements for Type A packages.”
49 CFR 173.415, “Authorized Type A packages.”

49 CFR 178.350, “Specification 7A; general packaging, Type A.”

iv. Type B quantities

49 CFR 173.416, “Authorized Type B packages”

49 CFR 173.467, “Package testing”

v. Low specific activity (LSA) material and surface contaminated objects (SCOs)

49 CFR 173.403, “Definitions”

49 CFR 173.427, “Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO).

c. HAZMAT Communication Requirements

49 CFR Part 172, “Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response, Information, Training Requirements, and Security Plans, Subpart C, “Shipping Papers”

49 CFR Part 172, Subpart D, “Marking”

49 CFR Part 172, Subpart E, “Labeling”

49 CFR Part 172, Subpart F, “Placarding”

49 CFR Part 172, Subpart G, “Emergency Response Information”

3. HAZMAT Training

49 CFR 172.702, “Applicability and responsibility for training and testing.”
49 CFR 172.704, “Training requirements.”

4. Transportation by Public Highway

49 CFR 171.15, “Immediate notice of certain hazardous materials incidents”
49 CFR 171.16, “Detailed hazardous materials incident reports”
49 CFR 177.800, “Purpose and scope of this part and responsibility for compliance and training”
49 CFR 177.816, “Driver training”
49 CFR 177.842, “Class 7 (radioactive) material”

L. NOTIFICATIONS AND REPORTS

10 CFR 19.13, “Notifications and reports to individuals”

10 CFR 20.2201, “Reports of theft or loss of licensed material”

10 CFR 20.2202, “Notification of incidents”

10 CFR 20.2203, “Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits”

10 CFR 30.50, “Reporting requirements”

M. POSTING AND LABELING

10 CFR 19.11, “Posting of notices to workers”

10 CFR 21.6, “Posting requirements”

10 CFR 20.1902, “Posting requirements”

10 CFR 20.1903, “Exemptions to posting requirements”

10 CFR 20.1904, “Labeling containers”

10 CFR 20.1905, “Exemptions to labeling requirements”

APPENDIX I

REPORTING REQUIREMENTS

Reporting Requirements

Typical U.S. Nuclear Regulatory Commission (NRC) Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii)
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 mrems)	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)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a); 40.60(a); and 70.50(a)
Unplanned contamination event that requires restricted access for more than 24 hours and involves a quantity of material greater than five times the lowest annual limits of the 10 CFR Part 20, Appendix B for the material 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); 40.60(b)(1); and 70.50(b)(1)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits when certain conditions are met	24 hours	30 days	10 CFR 30.50(b)(2); 40.60(b)(2); and 70.50(b)(2)

Event	Telephone Notification	Written Report	Regulatory Requirement
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material when certain conditions are met	24 hours	30 days	10 CFR 30.50(b)(4); 40.60(b)(4); and 70.50(b)(4)

Note: Telephone notifications shall be made to the NRC Operations Center at 301-816-5100, except as noted.

APPENDIX J

INSTRUMENT SPECIFICATIONS AND MODEL SURVEY INSTRUMENT AND AIR SAMPLER CALIBRATION PROGRAM

Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program

Radiation Monitoring Instrument Specifications

The specifications in Table J.1 will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility(ies).

Table J.1 Typical Survey Instruments[1]
(Instruments Used to Measure Radiological Conditions at Licensed Facilities)

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

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

Model Instrument Calibration Program

Training

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

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

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

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

- Observing authorized personnel performing survey instrument calibration.

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

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

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

- Individuals conducting calibrations will wear assigned dosimetry.

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

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

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

Model Procedure for Calibrating Survey Instruments

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

- approximate a point source

- approximate the same energy and type of radiation as the environment in which the calibrated device will be employed

- provide a source strong enough to give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hr (30 mR/hr) at 100 centimeters (cm) (e.g., 3.1 gigabecquerels (85 mCi of cesium-137 or 7.8×10^{2} megabecquerels (21 mCi) of cobalt 60. (Applies to dose rate and exposure rate instruments.)

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

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20 percent and 80 percent of full scale. The instrument's readings shall be within ±15 percent of the conventionally true values for the lower point and ±10 percent for the upper point.

- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10 percent of the full decade value.

- Meters with a digital display device shall be calibrated the same as meters with a linear scale.

- Readings above 2.58×10^{-4} coulomb/kilogram/hour (1 roentgen (R)/hr) need not be calibrated, but such scales should be checked for operation and response to radiation.

- The inverse square and radioactive decay law should be used to correct changes in exposure rate caused by changes in distance or source decay.

Surface Contamination Measurement Instruments[1]

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

- If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80 percent of full scale, and the reading at approximately 20 percent of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within ±20 percent of the conventionally true value.

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

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

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

- Approximate the geometry of the samples to be analyzed.
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

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

Calibration Records

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

- the owner or user of the instrument
- a description of the instrument, including the manufacturer's name, model number, serial number, and type of detector
- a description of the calibration source, including the exposure rate at a specified distance or activity on a specified date
- (for each calibration point) the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument
- (for instruments with external detectors) the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
- (for instruments with internal detectors) the angle between radiation flux field and a specified surface of the instrument
- (for detectors with removable shielding) an indication 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 of the person who performed the calibration and the date it was performed

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

- (for exposure rate meters) the source isotope used to calibrate the instrument (with correction factors) for each scale
- the efficiency of the instrument, for each isotope the instrument used to measure (if efficiency is not calculated before each use)
- (for each scale or decade not calibrated) an indication that the scale or decade was checked only for function but not calibrated
- the date of calibration and the next calibration due date
- the apparent exposure rate or count rate from the check source, if used

Air Sampler Calibration

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

Licensees can find guidance on total air sample volume calibration methods acceptable to NRC staff in the publication entitled "Air Sampling Instruments," which can be found in the 7th Edition, American Conference of Governmental Industrial Hygienists, 1989. This information is supplemented below.

Frequency of Calibration

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

Error Limit for Measurement of Air Sample Volume

Most methods of calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly

with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has been calibrated against a primary standard.

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

E_C: The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)[2]

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

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

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

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

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

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

$E_V = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\%$ 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:

Vs = V1 * (P1/760) * (273/T1)

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

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

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

1. Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," June 1992.

2. NUREG-1400, "Air Sampling in the Workplace," September 1993 (available at the ADAMS Accession No. ML102371083)

Additional References:

3. The Health Physics and Radiological Health Handbook, 3rd Edition. Edited by Bernard Shleien, Lester A. Slaback, Jr., and Brian Kent Birky, 1998.

4. ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered online at http://www.ansi.org.

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

APPENDIX K

MATERIAL RECEIPT AND ACCOUNTABILITY

Material Receipt and Accountability

Sample Model Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and do not exceed the possession limits.
- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the RSO (or designated receiving area).
- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

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

Any packages containing radioactive material that arrive between (state times, e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays) shall be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area. Security personnel (or other designated trained individual) should unlock the door, place the package in the designated secured storage area, and re-lock the door.

Radiation Safety Officer (RSO): _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

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

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

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

Name _____

Phone _____

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

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

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

If you possess generally licensed materials, and you wish to transfer them to a specific license, you must review the regulations in 10 CFR Part 30 and 10 CFR Part 31 to determine how this may be done.

Sample Model Procedure for Safely Opening Packages Containing Licensed Materials

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

- Wear gloves to prevent hand contamination.
- Approach the package with a survey meter to ensure that no unusual or unexpected radiation levels are present.
- Visually inspect the package for any sign of damage (e.g., crushed, punctured). If damage is noted, stop and notify the RSO.
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents so shipment does not exceed license possession limits.
- Monitor the external surfaces of a labeled package in accordance with 10 CFR 20.1906.
- Open the outer package (following supplier's directions, if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on the bottle or other container). Check integrity of the final source container (e.g., inspect for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Check again that the shipment does not exceed license possession limits. If you find anything other than expected, stop and notify the RSO.
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash.
- Maintain records of receipt, package survey, and wipe test results.
- Notify the final carrier by telephone, telegram, mailgram, or facsimile, and the Administrator of the appropriate NRC regional office listed in 10 CFR Part 20, Appendix D, "United States Nuclear Regulatory Commission Regional Offices," 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.

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or laboratory or authorized user's control to another should have prior approval from the RSO. A written transfer procedure should be developed by the RSO to ensure that transfers are done in accordance with the conditions of the license. All transfers shall be done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers.

External Transfers

Licensed material shall not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance with DOT, NRC, or U.S. Postal Service Regulations, whichever is applicable.

Gifts

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

APPENDIX L

METHODOLOGY FOR DETERMINING PUBLIC DOSE

Methodology for Determining Public Dose

This appendix describes methods for determining radiation doses to members of the public. Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) (100 millirem (mrem)) in 1 calendar year resulting from the licensee's possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any 1 hour.
- Air emissions of radioactive materials do not result in doses greater than 0.1 mSv (10 mrem) per year TEDE). As required by in 10 CFR 20.1101(d), if the licensee exceeds the 10 mrem per year air emission dose constraint, the licensee shall report the exceedance as provided in 10 CFR 20.2203, and promptly take appropriate corrective action to ensure against recurrence.

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

Doses to Members of the Public	
INCLUDE doses from: • Radiation and/or radioactive material released by a licensee • Sources of radiation under the control of a licensee • Air effluents from sources of licensed radioactive materials • Licensed material in transportation or storage at the licensee's facility	DO NOT INCLUDE doses from: • Sanitary sewerage discharges from licensee action taken in accordance with 10 CFR 20.2003 • Natural background radiation • Medical administration of radioactive material • Voluntary participation in medical research

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

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

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem) in a year.

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

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

Measurements

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

- Dose rate surveys for radiation exposures from external radiation sources.
- Measurements of radionuclides in air and water effluent.

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 since 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 at the boundary of the unrestricted area. The licensee must take into account the individual’s exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

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

If, 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 L.1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table L.1 Standard Occupancy Factors

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

Records

In accordance with 10 CFR 20.2107, 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.

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

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

Radionuclide-specific Procedures

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

Example 1:

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

- a mandatory radiation survey and wipe test for radioactive contamination after each use
- bioassay procedures for individuals working with millicurie quantities of unbound radioiodine or volatile compounds labeled with radioiodine
- the use of vented hoods for iodination procedures and for the storage of millicurie quantities of potentially volatile forms radioiodine
- a dry run prior to the performance of unfamiliar procedures to preclude unexpected complications. In addition, the NRC recommends that the RSO be present during new procedures.
- procedures for measuring the concentration of radioiodine effluents from the hoods

Example 2:

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

- the use of low-density plastic shielding to keep bremsstrahlung radiation to a minimum
- a mandatory radiation survey and wipe test for radioactive contamination after each use
- the use of extremity monitors for procedures that involve 1 mCi or more
- a dry run prior to the performance of unfamiliar procedures to preclude unexpected complications. In addition, the NRC recommends that the RSO be present during new procedures.
- the use of eye protection for procedures that involve 10 mCi or more

Model Procedures for Handling Emergencies

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

General Safety Procedures to Handle Spills

- Name and telephone number of RSO or an alternate person(s) should be posted conspicuously in areas of use so that they are readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:
  — disposable gloves
  — housekeeping gloves
  — disposable lab coats
  — disposable head coverings
  — disposable shoe covers
  — roll of absorbent paper with plastic backing
  — masking tape
  — plastic trash bags with twist ties
  — "radioactive material" labeling tape
  — marking pen
  — pre-strung "radioactive material" labeling tags
  — box of wipes
  — instructions for "emergency procedures"
  — clipboard with copy of the radioactive spill report form for the facility
  — pencil
  — appropriate survey instruments, including batteries (for survey meters)

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

Minor Spills of Liquids and Solids

- Instructions to Workers

  — Notify persons in the area that a spill has occurred.

  — Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)

  — Clean up the spill, wearing disposable gloves and using absorbent paper.

  — Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.

  — Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.

— Promptly report the incident to the RSO.

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

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

— Follow the instructions of the RSO and the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO

  — Follow up on the decontamination activities and document the results.

  — As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.

  — If necessary, notify the NRC.

Major Spills of Liquids and Solids

- Instructions to Workers

  — Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room.

  — Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened, if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

  — Shield the source only if it can be done without further contamination or significant increase in radiation exposure.

  — Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.

  — Notify the RSO immediately.

  — Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap.

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

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

— Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO

  — Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by perspiration.

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

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

  — If necessary, notify the NRC.

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

- Instructions to Workers

  — Notify all personnel to vacate the room immediately.

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

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

  — Notify the RSO immediately.

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

  — Survey all persons who could possibly have been contaminated. Decontaminate as directed by the RSO.

  — Promptly report suspected inhalations and ingestions of licensed material to the RSO.

  — Decontaminate the area only when advised and/or supervised by the RSO.

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

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

  — Follow the instructions of the RSO and the RSO's staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

- Reminders to RSO

  — Supervise decontamination activities.

  — Perform air sample surveys in the area before permitting resumption of work with licensed materials.

  — Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc.

  — Consider need for medical exam and/or whole body count before permitting involved individuals to return to work with licensed material.

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

  — If necessary, notify the NRC.

Minor Fires

- Instructions to Workers

  — 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 (as instructed by RSO).

  — Once the fire is out, isolate the area to prevent the spread of possible contamination.

  — Survey all persons involved in combating the fire for possible contamination.

  — Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap.

  — In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment necessary to decontaminate the area.

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

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

  — Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO

  — Supervise decontamination activities.

  — If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash affected area again to remove any contamination that was released by the perspiration.

  — Consult with fire safety officials to ensure that there are no other possibilities of another fire starting.

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

  — If necessary, notify the NRC.

Fires, Explosions, or Major Emergencies

- Instructions to Workers

  — Notify all persons in the area to leave immediately.

  — Notify the fire department.

  — Notify the RSO and other facility safety personnel.

  — Upon arrival of firefighters, inform them where radioactive materials are stored or where radionuclides were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc.

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

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

  — Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO

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

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

— Once the fire is extinguished, advise firefighters not to enter potentially contaminated areas where radioactive sources may be present or radiation areas until a thorough evaluation and survey are performed to determine the extent of the damage to the licensed material use and storage areas.

— Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary.

— Supervise decontamination activities.

— Consider bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.

— If necessary, notify the NRC.

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

Procedures for Collecting Bioassay Samples

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

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

APPENDIX N

RADIATION SAFETY SURVEY TOPICS

Radiation Safety Survey Topics

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

Training

Before allowing an individual to perform surveys, the RSO (or for Type C broad scope licensees, the individual designated as responsible for the day-to-day operation of the radiation safety program) will ensure that he or she has sufficient training and experience to perform surveys independently.

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

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

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

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples

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

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.

- A gamma counter system with a single or multichannel analyzer can be used to count samples containing gamma-emitters (e.g., iodine-125, cesium-137, cobalt-60).

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

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

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits or where an individual is working in a dose rate of 0.025 mSv (2.5mrem/hr) or more (50 mSv/year divided by 2,000 hr/year).

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

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

Contamination Surveys

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

Contamination surveys should be performed:

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

- after any spill or contamination event

- when procedures or processes have changed

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

- in unrestricted areas at frequencies consistent with the types and quantities of materials in use but generally not less frequently than quarterly

- in areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment

Contamination Survey Frequency

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

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

Table 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**		

Alternate Survey Frequency

Classification of Laboratories

Table N.2 Survey Frequency Category

Group	Low	Medium	High
1	< 370 kBq (10 µCi)	370 kBq (10 µCi) to 37 MBq (1 mCi)	> 37 MBq (1 mCi)
2	< 37 MBq (1 mCi)	37 MBq (1 mCi) to 3.7 GBq (100 mCi)	> 3.7 GBq (100 mCi)
3	< 3.7 GBq (100 mCi)	3.7 GBq (100 mCi) to 370 GBq (10 Ci)	> 370 GBq (10 Ci)
4	< 370 GBq (10 Ci)	370 GBq (10 Ci) to 37 TBq (1000 Ci)	> 37 TBq (1000 Ci)

The tables use proportional fractions for more than one isotope.

Table N.3 Survey Frequency Category Modifiers

Modifying Factors	Factors
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1

Modifying Factors	Factors
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of nonoccupational persons	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

The object is to determine how often to survey the laboratory. To do this, multiply the activity range under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of µCi ranges for LOW, MEDIUM, and HIGH survey frequency.

Survey Frequency:

- Low—Not less than once a month
- Medium—Not less than once per week
- High—Not less than once per normal working day.

Table N.4 Isotope Groups

Group 1	Pb-210 Po-210 Ra-223 Ra-226 Ra-228 Ac-227 Th-227 Th-228 Th-230 Pa-231 U-230 U-232 U-233 U-234 Np-237 Pu-238Pu-239 Pu-240 Pu-241 Pu-242 Am-241 Am-243 Cm-242 Cm-243 Cm-244 Cm-245 Cm-246 Cf-249 Cf-250 Cf-252
Group 2	Na-22 Cl-36 Ca-45 Sc-46 Mn-54 Co-56 Co-60 Sr-89 Sr-90 Y-91 Zr-95 Ru-106 Ag-110m Cd-115m In-114m Sb-124 Sb-125 Te-127m Te-129m I-124 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Ba-140 Ce-144 Eu-152 Eu-154 Tb-160 Tm-170 Hf-181 Ta-182 Ir-192 Tl-204 Bi-207 Bi-210 At-211 Pb-212 Ra-224 Ac-228 Pa-230 Th-234 U-236 Bk-249
Group 3	Be-7 C-14 F-18 Na-24 C1-38 Si-31 P-32 P-33 S-35 Ar-41 K-42 K-43 Ca-47 Sc-47 Sc-48 V-48 Cr-51 Mn-52 Mn-56 Fe-52 Fe-55 Fe-59 Co-57 Co-58 Ni-63 Ni-65 Cu-64 Zn-65 Zn-69m Ga-72 As-73 As-74 As-76 As-77 Se-75 Br-82 Kr-85m Kr-87 Rb-86 Sr-85 Sr-91 Y-90 Y-92 Y-93 Zr-97 Nb-93m Nb-95 Mo-99 Tc-96 Tc-97m Tc-97 Tc-99 Ru-97 Ru-103 Ru-105 Rh-105 Pd-103 Pd-109 Ag-105 Ag-111 Cd-109 Cd-115 In-115m Sn-113 Sn-125 Sb-122 Te-125m Te-127 Te-129 Te-131m Te-132 I-130 I-132 I-134 I-135 Xe-135 Cs-131 Cs-136 Ba-131 La-140 Ce-141 Ce-143 Pr-142 Pr-143 Nd-147 Nd-149 Pm-147 Pm-149 Sm-151 Sm-153 Eu-152 Eu-155 Gd-153 Gd-159 Dy-165 Dy-166 Ho-166 Er-169 Er-171 (9.2 hr) Tm-171, Yb-175 Lu-177 W-181 W-185 W-187 Re-183 Re-186 Re-188 Os-185 Os-191 Os-193 Ir-190 Ir-194 Pt-l91 Pt-193 Pt-197 Au-196 Au-198 Au-l99 Hg-197 Hg-197m Hg-203 Tl-200 Tl-201 Tl-202 Pb-203 Bi-206 Bi-212 Rn-220 Rn-222 Th-231 Pa-233 Np-239

Group 4	H-3 O-15 Ar-37 Co-58m Ni-59 Zn-69 Ge-71 Kr-85 Sr-85m Rb-87 Y-9lm Zr-93 Nb-97 Tc-96m Tc-99m Rh-103m In-113m I-129 Xe-131m Xe-133 Cs-134m Cs-135 Sm-147 Re-187 Os-191m Pt-193m Pt-197m Th-232 Th-Nat U-235 U-238 U-Nat

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in Table N.5.

Table N.5 Acceptable Surface Contamination Levels

Nuclide[1]	Average[2, 3]	Maximum[2, 4]	Removable[2, 5]
I-125, I-129	1.7 Bq/100 cm^2 (100 dpm/100 cm^2)	5.0 Bq/100 cm^2 (300 dpm/100 cm^2)	0.3 Bq/100 cm^2 (20 dpm/100 cm^2)
I-126, I-131, I-133, Sr-90	16.7 Bq/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, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

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 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.

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, the above table provides the maximum acceptable residual levels. To the extent practicable, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use to ensure that they meet these limits.

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 centimeters squared (cm^2) is acceptable to indicate levels of removable contamination.

Survey Record Requirements

Each survey record should include the following:

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

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

Air Monitoring in the Workplace

Air monitoring can be used to do the following:

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

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

Refer to Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992, and NUREG-1400, "Air Sampling in the Workplace," dated September 1993, which is available in the NRC ADAMS at Accession No. ML102371083, for further guidance on the air sampling.

Airborne Effluent Release Monitoring

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

Regulatory Guide 4.20, Revision 1,"Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated April 2012, provides guidance on methods acceptable (calculation or COMPLY code) to NRC for compliance with the constraint on air emissions to the environment.

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

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

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities," and IEEE N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents."

Liquid Effluent Release Monitoring

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

The topic of sanitary sewerage releases is more fully discussed in 10 CFR Part 20, Appendix B.

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. Consider the following elements:

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

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

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

Routine Measurements

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

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

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

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

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

Special Monitoring

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

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

References:

1. Regulatory Guide 4.20, “Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors,” dated December 1996.
2. Regulatory Guide 8.9, Revision 1, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,” dated July 1993.
3. Regulatory Guide 8.23, Revision 1, “Radiation Safety Surveys at Medical Institutions,” dated January 1981.
4. Regulatory Guide 8.25, Revision 1, “Air Sampling in the Workplace,” dated June 1992.
5. Regulatory Guide 8.32, “Criteria for Establishing a Tritium Bioassay Program,” dated July 1988.
6. Regulatory Guide 8.37, “ALARA Levels for Effluents from Materials Facilities,” dated July 1993.
7. NUREG-1400, “Air Sampling in the Workplace,” dated September 1993.
8. NUREG/CR-4884, “Interpretation of Bioassay Measurements,” dated July 1987.
9. ANSI N13.1 (1969), “Document to Sampling Airborne Radioactive Materials in Nuclear Facilities,” dated 1991.
10. ANSI N13.30-1996, “Performance Criteria for Radiobioassay,” dated 1996.

11. ANSI N42.18, “Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents,” dated 1991.

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

13. U.S. Department of Energy, DOE G 441.1-8, “Air Monitoring Guide,” March 17, 1999.

14. U.S. Department of Energy, DOE G 441.1-3, “Internal Dosimetry Program Guide,” March 17, 1999.

15. U.S. Department of Energy, DOE G 441.1-4, “External Dosimetry Program Guide,” March 17, 1999.

16. U.S. Department of Energy, DOE G 441.1-2, “Occupational ALARA Program Guide,” March 17, 1999.

APPENDIX O

MODEL LEAK TEST PROCEDURES

Model Leak Test Procedures

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

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective SSD registration certificate.

Procedure for Performing Leak Testing and Analysis

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

- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 μCi) of the radionuclide and ensure that its calibration is current.
- Using the selected instrument, count and record background count rate.
- Calculate efficiency of the detector. A sample calculation is shown in the next box.
- Count the sample.

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

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

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).

For example: $\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$

- Sign and date the list of sources, data and calculations. Retain records for 3 years (10 CFR 20.2103(a)).

- If the wipe test activity is 185 Bq (0.005 mCi) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly.

- Also notify the NRC.

APPENDIX P

TRANSPORTATION REQUIREMENTS

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

The following are the major areas in U.S. Department of Transportation (DOT) regulations that are most relevant for transportation of licensed material:

A. Table of Hazardous Materials and Special Provisions—49 CFR 172.101

1. 49 CFR 172.101, "Purpose and use of hazardous materials table"—proper shipping name, hazard class, identification number [includes proper shipping name, hazard class, identification number]

B. Shipping Papers—

1. 49 CFR 172.200— "Applicability"
2. 49 CFR 172.201—"Preparation and retention of shipping papers"
3. 49 CFR 172.202—"Description of hazardous material on shipping papers"
4. 49 CFR 172.203—"Additional description requirements"
5. 49 CFR 172.204—"Shipper's certification" [if applicable]

C. Package Markings—

1. 49 CFR 172.300—"Applicability"
2. 49 CFR 172.301—"General marking requirements for non-bulk packagings"
3. 49 CFR 172.304—"Marking requirements"
4. 49 CFR 172.310—"Class 7 (radioactive) materials"
5. 49 CFR 172.324—"Hazardous substances in non-bulk packagings" - nonbulk packaging [designation of "reportable quantities" with the letters "RQ"]

D. Package Labeling—

1. 49 CFR 172.400 —"General labeling requirements"
2. 49 CFR 172.400a — "Exceptions from labeling"
3. 49 CFR 172.403—"Class 7 (radioactive) materials," [Radioactive Materials, types and contents of labels]
4. 49 CFR 172.406—"Placement of labels"

E. Placarding of Vehicles—

1. 49 CFR 172.500—“Applicability of placarding requirements”

2. 49 CFR 172.504—“General placarding requirements”

3. 49 CFR 172.516—“Visibility and display of placards”

4. 49 CFR 172.556—“RADIOACTIVE placard”

F. Emergency Response Information—Subpart G

1. 49 CFR 172.600—“Applicability and general requirements”

2. 49 CFR 172.602—“Emergency response information”

3. 49 CFR 172.604—“Emergency response telephone number”

G. Training—Subpart H

1. 49 CFR 172.702—“Applicability and responsibility for training and testing,” [for HAZMAT employees]

2. 49 CFR 172.704— “Training requirements” [includes types of training, when it must be conducted, need for refresher training every 3 years, recordkeeping.].

H. Shippers—“General Requirements for Shipments and Packaging”—49 CFR Part 173

1. 49 CFR 173.25—“Authorized packagings and overpacks”

2. 49 CFR 173.403—“Definitions”

3. 49 CFR 173.411—“Industrial packagings,” [General design requirements]

4. 49 CFR 173.413—“Requirements for Type B packages”

5. 49 CFR 173.416—“Authorized Type B packages,” [includes packaging certification requirements]

6. 49 CFR 173.441—“Radiation levels limitations and excusive use provisions”

7. 49 CFR 173.471—“Requirements for U.S. Nuclear Regulatory Commission approved packages”

8. 49 CFR 173.476—“Approval of form Special Class 7 (radioactive) materials” [includes requirement for documentation of special form status]”

I. Carriage by Public Highway—49 CFR Part 177

1. 49 CFR 177.817—“Shipping papers,” [location of shipping papers during transport]”

2. 49 CFR 177.842—“Class 7 (radioactive) material,”[Radioactive) Material,” includes requirement for blocking and bracing during transport]

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

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

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

Radioactive Material Quantity[3]		Excepted Quantities and Articles	Type A[4]	Type B
Activity Restrictions		≤ the limits specified in Table 4 of §173.425	≤ A_1 for special form ≤ A_2 for normal form	> A_1 for special form > A_2 for normal form
Contents of Package	Non-fissile and Fissile Excepted	Excepted Package	Type A Package	Type B(U) or Type B(M) package
	Fissile	N/A	Type AF package	Type B(U)F or Type B(M)F package

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

Type(s) of LSA and/or SCO	LSA-I	LSA-II	LSA-III	SCO-I	SCO-II
Category of Package for Domestic or International Transport[7,8]	Unpackaged[9] IP-1: solids, or liquids/exclusive use IP-2 : liquids/non-exclusive use Specification tank cars or cargo tank motor vehicles: liquids/exclusive use	- - IP-2: exclusive use IP-3: liquids or gases/non-exclusive use	- - IP-2: exclusive use IP-3: non-exclusive use	Unpackaged[9] IP-1 - -	- - IP-2 -
Alternative Provisions for Domestic only Transport[9]	Packaging shall meet the requirements of §§173.24, 24a, and 410 Transportation shall be an exclusive use shipment Activity per shipment must be less than an A_2 quantity				

[1] Additional provisions may apply for radioactive materials that are pyrophoric, oxidizing, fissile excepted, or uranium hexafluoride.
[2] Each NRC licensee shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397 (see §71.5).
[3] Materials that contain radionuclides, where both the activity concentration and the total activity in the consignment exceed either the values specified in the table in §173.436 or the values derived according to the instructions in §173.433, must be regulated in transport as Class 7 (radioactive) material.
[4] Except for LSA material and SCO, a Type A package may not contain a quantity of Class 7 (radioactive) materials greater than A_1 or A_2.
[5] The external dose rate from LSA material or SCO in a single package may not exceed 10 mSv/h (1 rem/h) at 3 m from the unshielded material or objects (see §173.427(a)(1)).
[6] LSA material and SCOs that are or contain fissile material in quantities that are not fissile excepted must be packaged in appropriate Type AF or Type BF packages. For alternate domestic transport provisions, see §173.427(b)(4). For comprehensive guidance on packaging and transportation of LSA material and SCO, see NUREG-1608.
[7] For LSA material and SCO, transport of combustible solids, all liquids and all gases classified as LSA-II and LSA-III material, and transport of all SCO-I and SCO-II is limited to a maximum activity of 100 A_2 in a conveyance (see §173.427(a)(2)).
[8] Unless excepted by §§173.427(c) or (d), the material or object(s) shall be appropriately packaged in a Type IP, DOT-7A Type A or Type B package.
[9] Certain LSA-I and SCO-I may be transported unpackaged under the conditions specified in §173.427(c).

2. Radiation Level, TI and CSI Limits for Transportation by Road, Rail and Air[1] (49 CFR 172 - 177, and 10 CFR 71)

Type of Transport	Non-exclusive use	Exclusive use		
Mode of Transport	Road, Rail, Vessel and Air	Road and Rail	Vessel	Air (cargo only)
Radiation Level Limits[2]				
Package Surface[1]	2 mSv/h (200 mrem/h)	2 mSv/h (200 mrem/h): other than closed vehicles 10 mSv/h (1000 mrem/h): closed vehicles	None specified	2 mSv/h (200 mrem/h)[3]
Conveyance[4]	N/A	2 mSv/h (200 mrem/h): outer surfaces (sides, top and underside) of vehicle[5]	N/A	N/A
		0.1 mSv/h (10 mrem/h): at any point two (2) m (6.6 ft) from sides of the vehicle[5]	N/A	N/A
Occupied position	N/A	0.02 mSv/h (2 mrem/h): at any normally occupied area[6]	Requirement of §176.708 applies	N/A
Transport Index (TI) Limits[2]				
Package[1,7]	3: passenger aircraft 10: road, rail, vessels and cargo aircraft	No limit		10
Conveyance[4]	50: road, rail and passenger aircraft 50 to No limit: vessels[8] 200: cargo aircraft	No limit		200
Overpack	N/A: for road, rail 50 to 200: vessels[8] 3: passenger aircraft; 10: cargo aircraft	N/A	No limit[8]	N/A
Criticality Safety Index (CSI) Limit for fissile material[2]				
Package[1,7]	50	100	100	100
Conveyance[4]	50: road, rail and air 50: for holds, compartments or defined deck areas of vessels[8] 200 to No limit: for a total vessel[8]	100	200 to No limit: for a total vessel[8]	100
Overpack	50: road, rail, vessels[8] and air	N/A		

[1] The limits in this table do not apply to excepted packages.
[2] In addition to any applicable radiation level, TI and CSI limits, separation distance requirements apply to packages, conveyances, freight containers and overpacks; to occupied positions; and to materials stored in transit. Separation distances are based on the sum of the TIs and, for fissile materials, also the sum of the CSIs.
[3] Higher package surface radiation levels may be allowed through an approved special arrangement.
[4] Conveyance is, for transport by public highway or rail, any transport vehicle or large freight container; and for transport by air, any aircraft.
[5] The outer surfaces (sides, top and underside) of vehicles are defined for road and rail vehicles in §173.441.
[6] For rail, normally occupied areas include the transport vehicle and adjacent rail cars. The 0.02 mSv/h (2 mrem/h) limit does not apply to carriers operating under a State or federally regulated radiation protection program where personnel wear radiation dosimetry devices.
[7] Additional TI and CSI limits apply for individual packages when non-fissile radioactive material packages are mixed with fissile material packages. Also, see CSI limits established by §71.59.
[8] For details on TI and CSI limits for transport by vessel, see §176.708.

Based on U.S. DOT and NRC regulations in effect as of December 1, 2011.

Contacts: DOT – Rick.Boyle@dot.gov; NRC – John.Cook@nrc.gov

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

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

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

The level of non-fixed (removable) radioactive contamination on external surfaces of packages offered for transport must be kept as low as reasonable achievable, and shall not exceed the values shown in the following table:

Contaminant	Maximum permissible limits (§173.443(a), Table 9)		
	Bq/cm^2	µCi/cm^2	dpm/cm^2
Beta, gamma and low toxicity alpha emitters	4	10^{-4}	220
All other alpha emitting radionuclides	0.4	10^{-5}	22

The non-fixed contamination shall be determined by:

(a) wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;
(b) ensuring each wipe area is 300 cm^2 in size;
(c) measuring the activity on each single wiping material and dividing that value by the surface area wiped and the efficiency of the wipe procedure, where an actual wipe efficiency may be used, or it may be assumed to be 0.10.

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

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

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

- must be kept as low as reasonable achievable; and
- may not exceed the limits set forth in §173.443(a), Table 9 (as shown above).

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

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

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

- The levels of non-fixed radioactive contamination on the packages (a) at the beginning of transport, may not exceed the levels prescribed in the above table, and (b) at any time during transport, may not exceed ten times the levels prescribed in §173.443(a), Table 9 (as shown above).
- Each transport vehicle used for transporting the radioactive material packages must be surveyed with appropriate radiation detection instruments after each use. If contamination values exceed acceptable levels, the transport vehicle may not be returned to service until the radiation dose rate at each accessible surface is demonstrated to be 0.005 mSv/h (0.5 mrem/h) or less, and that there is no significant non-fixed radioactive surface contamination specified in §173.443(a), Table 9 (as shown above).

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

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

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

- Before each shipment of any radioactive materials package, the offeror must ensure, by examination or appropriate tests, that:
  (a) the packaging is proper for the contents to be shipped;
  (b) the packaging is in unimpaired physical condition, except for superficial marks;
  (c) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;
  (d) for fissile material, each moderator and neutron absorber, if required, is present and in proper condition;
  (e) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed;
  (f) each closure, valve, or other opening of the containment system is properly closed and sealed;
  (g) each packaging containing liquid in excess of an A_2 quantity and intended for air shipment has been tested to show that it will not leak under an ambient atmospheric pressure of not more than 25 kPa, absolute (3.6 psia), where the test must be conducted on the entire containment system, or on any receptacle or vessel within the containment system, to determine compliance with this requirement;
  (h) the internal pressure of the containment system will not exceed the design pressure during transportation; and
  (i) the external radiation and contamination levels are within the allowable limits specified in §173.441 and 443.

Based on U.S. DOT and NRC regulations in effect as of December 1, 2011.

Contacts: DOT – Rick.Boyle@dot.gov; NRC – John.Cook@nrc.gov

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

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

Shipping Paper Entries

Always Required	Sometimes Required	Optional Entries
Basic description (in sequence): • **UN Identification number** • **Proper Shipping Name** • **Hazard Class (7)** • **Total activity contained in each package in SI units** (e.g. Bq, TBq, etc.), or in both SI and customary units (e.g. Ci, mCi, etc.) with customary units in parentheses following the SI units • **Number and type of packages** Additional description: • **Name of each radionuclide**[1] • **Description of physical and chemical form** (unless special form) • **Category of label** used • **Transport index (TI)** of each package bearing a Yellow-II or Yellow-III label Additional entry requirements: • 24 hour **emergency telephone number** • **Shipper's Certification** shall be provided by each person offering radioactive material for transportation[2] • Proper page numbering (e.g. Page 1 of 4)	Materials-based Requirements: • The criticality safety index (CSI) or "Fissile Excepted" for fissile material • The words "Highway route controlled quantity" or the term "HRCQ" entered in the basic description for highway route controlled quantities • The letters "RQ" entered on the shipping paper either before or after the basic description for each hazardous substance (see §171.8) • Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required • A hazardous waste manifest and the word "Waste" preceding the proper shipping name is required for radioactive material that is hazardous waste Package-based Requirements: • The applicable DOE or NRC package approval identification marking for certified Type AF and Type B packages • The International Atomic Energy Agency (IAEA) Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package Shipment- and Administrative-based Requirements: • Specify "exclusive use shipment" as required • Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use • Specify the notation "DOT–SP" followed by the special permit number[3] for a special permit shipment	• The weight in grams or kilograms of radionuclides may be inserted instead of activity units for fissile radionuclides, except for Pu-239 and Pu-241 • The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units • The words "RESIDUE: Last Contained * * *" may be included in association with the basic description of the hazardous material last contained in the packaging • Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information

Special Considerations/Exceptions for Shipping Papers

- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, or be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, or be designated by an "X" (or "RQ" if appropriate).
- Emergency response information consistent with §§172.600-606 shall be readily available on the transport vehicle.
- Shipments of limited quantities of radioactive material in excepted packages, under UN2908, 2909, 2910 and 2911, are excepted from shipping paper requirements if (a) the package does not contain fissile material unless excepted by §173.453, and (b) the limited quantity of radioactive material is not a hazardous substance or hazardous waste.
- For road transport, the shipping papers shall be (a) readily available to authorities in the event of accident or inspection, (b) stored within the driver's immediate reach while he is restrained by the lap belt, (c) readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle, and (d) either in a holder mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat.

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

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

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

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

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

Markings on Packages

Markings Always Required Unless Excepted[1]	Additional Markings Sometimes Required	Optional Markings
Markings for Non-bulk Packagings: • Proper shipping name • Identification number (preceded by "UN" or "NA," as appropriate) • Name and address of consignor or consignee, unless the package is: ▪ highway only and no motor carrier transfers; or ▪ part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee **Markings for Bulk Packages:** • Identification number on orange rectangular panel: ▪ on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more, or ▪ on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons), or ▪ on each side and end of motor vehicle carrying cylinders permanently installed on a tube trailer	**Package-based marking requirements:** • Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 lb) • Package type as appropriate, i.e., "TYPE IP–1," "TYPE IP–2," "TYPE IP–3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"[1] • Marked with international vehicle registration code of country of origin for IP–1, IP–2, IP–3 or Type A package design [2] • Radiation (trefoil) symbol[3] on outside of outermost receptacle of each Type B(U) or Type B(M) packaging design • For NRC or DOE packaging, model number, serial number, gross weight, and package identification number for each certified package (Type AF, Type B(U), Type B(M), Type B(U)F, and Type B(M)F) • For Specification 7A packaging, mark on the outside with "USA DOT 7A Type A", and the name and address or symbol of the manufacturer satisfying §178.3 and §178.350. **Materials-based requirements:** • For non-bulk IP-1 package containing a liquid, use underlined double arrow symbol indicating upright orientation[4], where the symbol is placed on two opposite sides of the packaging • If a hazardous substance in non-bulk package, mark outside of each package with the letters "RQ" in association with the proper shipping name **Administrative-based requirements:** • For each Type B(U), Type B(M) or fissile material package destined for export shipment, mark "USA" in conjunction with specification marking, or certificate identification; and package identification indicated in U.S. Competent Authority Certificate • Mark "DOT–SP" followed by the special permit number assigned for each package authorized by special permit • Competent authority identification marking and revalidation for foreign made Type B(U), Type B(M), Type C, Type CF, Type H(U), Type H(M), or fissile material package for which a Competent Authority Certificate is required	• Both the name and address of consignor and consignee is recommended. • Other markings on packages such as advertising are permitted, but must be located away from required markings and labeling.

Special Considerations for Marking Requirements

- All markings are to be (a) on the outside of each packaging, (b) durable and legible, (c) in English, (d) printed on or affixed to the surface of a package or on a label, tag, or sign, (e) displayed on a background of sharply contrasting color, and (f) unobscured by labels or attachments.

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

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

[3] The radiation symbol shall be resistant to the effects of fire and water, plainly marked by embossing, stamping or other means resistant to the effects of fire and water that conform to the requirements of Appendix B to Part 172.

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

Based on U.S. DOT and NRC regulations in effect as of December 1, 2011.

Contacts: DOT – Rick.Boyle@dot.gov; NRC – John.Cook@nrc.gov

6. Hazard Communications for Class 7 (Radioactive) Materials:

Labeling of Packages (49 CFR 172.400-450)

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

Requirements for Labels [1]

- Label each package except for (a) excepted packages containing a limited quantity of radioactive material; and (b) Low Specific Activity (LSA) material and Surface Contaminated Objects (SCO), packaged or unpackaged, when transported domestically and when material or object contains less than an A_2 quantity.
- Labeling is required to be (a) printed or affixed to a surface other than the bottom of the package, (b) placed near the proper shipping name marking, (c) printed or affixed to a background of contrasting color or have a dotted or solid line outer border, (d) clearly visible, (e) un-obscured by markings or other attachments, and (f) representative of hazardous material content.
- Display duplicate labels on at least two opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material except as noted above for excepted packages, and packaged or unpackaged LSA material and SCO.

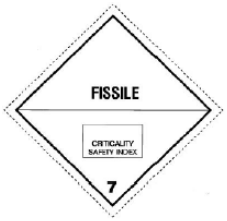
Radioactive Category Labels [3]

White-I

Yellow-II

Yellow-III

Other Labels[2]



Fissile

Empty

Radiation Surface Level (RSL):

	White-I	Yellow-II	Yellow-III
mSv/h:	**RSL** ≤ 0.005	0.005 < **RSL** ≤ 0.5	0.5 < **RSL** ≤ 2[4]
mrem/h:	**RSL** ≤ 0.5	0.5 < **RSL** ≤ 50	50 < **RSL** ≤ 200[4]

Transport Index (TI):[4]

White-I	Yellow-II	Yellow-III
TI = 0[4]	0[4] < **TI** ≤ 1	1 < **TI** ≤ 10[4, 5]

Fissile labels required for each package containing fissile material, other than fissile-excepted material; and labels must be affixed adjacent to radioactive category labels.

Empty labels required for shipments of empty Class 7 (radioactive) packages satisfying §173.428; and any previously-used labels cannot be visible

Contents on Labels

- Each radioactive category label must contain: (a) Except for LSA-I material, the names of the radionuclides in the package where, for mixtures of radionuclides, the names listed must be in accordance with the 95% rule specified in §172.433(g); and, for LSA-I material, the term "LSA-I"; (b) activity in appropriate SI units (*e.g.* Bq, TBq), or appropriate customary units (e.g. Ci, mCi) in parentheses following SI units; and (c) for Yellow-II or Yellow-III labels the Transport Index (TI). Abbreviations and symbols may be used. Except for Pu-239 and Pu-241, the weight in g or kg of fissile radionuclides may be inserted instead of activity units; for Pu-239 and Pu-241, the weight in g of fissile radionuclides may be inserted in addition to the activity units.
- Each fissile label must contain the relevant Criticality Safety Index (CSI).

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

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

[3] The category of the label must be the higher of the two values specified for RSL and TI; see §172.403(b).

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

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

Based on U.S. DOT and NRC regulations in effect as of December 1, 2011.

Contacts: DOT – Rick.Boyle@dot.gov; NRC – John.Cook@nrc.gov

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

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

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

- On bulk packages, road transport vehicles, rail cars, and freight containers, and on aircraft unit load devices having a capacity of 640 cubic feet or more[1], on each side and each end when they contain either a package with a Radioactive Yellow-III label, or low specific activity (LSA) material or surface contaminated objects (SCO) being transported under exclusive use.
- On a square background on any motor vehicle used to transport a package containing Highway Route Controlled Quantity (HRCQ) Class 7 (radioactive) materials[2].

Visibility and Display of Radioactive Placards [§172.516]

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

Radioactive Placards

PLACARD (FOR OTHER THAN HRCQ)	PLACARD FOR HRCQ
White triangular background color in the lower portion with yellow triangle in the upper portion; trefoil symbol, text, class number and inner and outer borders in black. [see §172.556 for detailed requirements]	Square background must consist of a white square surrounded by black border. The placard inside the square is identical to that for other than HRCQ. [see.§172.527 for detailed requirements]

Special Considerations/Exceptions for Placarding

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

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

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

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

Based on U.S. DOT and NRC regulations in effect as of December 1, 2011.

Contacts: DOT – Rick.Boyle@dot.gov; NRC – John.Cook@nrc.gov

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

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

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

- Any person, other than those excepted by §107.606, who offers for transportation, or transports, in foreign, interstate or intrastate commerce any of the following Class 7 (radioactive) materials must satisfy registration and fee requirements of Part 107, Subpart G:
  - a highway route-controlled quantity of radioactive material;
  - a shipment in a bulk packaging with a capacity ≥ 13,248 L (3,500 gallons) for liquids or gases, or > 13.24 cubic meters (468 cubic feet) for solids; or
  - any quantity of radioactive material that requires placarding, under provisions of Part 172, Subpart F.
- Any person required to register must submit a complete and accurate registration statement on DOT Form F 5800.2 by June 30th for each registration year, or in time to have on file a current Certificate of Registration in accordance with §107.620.
- Each registrant or designee must maintain for a period of 3 years from the date of issuance a copy of the registration statement and Certificate of Registration issued by PHMSA and must furnish its Certificate of Registration (or a copy thereof) and related records to an authorized representative or special agent of DOT upon request.
- Each motor carrier subject to registration requirements of this subpart must carry a copy of its current Certificate of Registration or another document bearing the registration number on board each truck and truck tractor, and the Certificate of Registration or document must be made available, upon request, to enforcement personnel.
- The amount of fees to be paid and procedures to be followed are found at §§107.612 and 616.

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

- When shipping papers for the transportation of radioactive materials are required (see Part 172, Subpart C), emergency response information shall
  - be provided and maintained during transportation and at facilities where materials are loaded for transportation, stored incidental to transportation, or otherwise handled during any phase of transportation;
  - be provided by persons who offer for transportation, accept for transportation, transfer or otherwise handle hazardous materials during transportation;
  - be immediately available for use at all times the hazardous material is present; and
  - include and make available the emergency response telephone number (see §172.604) to any person, representing a Federal, State or local government agency, who responds to an incident involving the material or is conducting an investigation which involves the material
- Emergency response information is information that can be used in mitigating an incident involving radioactive materials. It must contain at least the information specified in §§172.602 and 604; and includes an emergency response telephone number that is monitored at all times the material is in transportation by (a) knowledgeable person, or (b) a person who has immediate access to a knowledgeable person, or (c) an organization capable of accepting responsibility for providing the necessary detailed information concerning the material.
- Each carrier who transports or accepts for transportation radioactive material for which a shipping paper is required shall instruct, according to the requirements of §172.606, the operator of a conveyance to contact the carrier in the event of an incident involving the material.

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

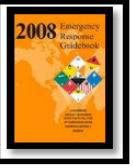
- Except for a road vehicle used solely for transporting Class 7 (radioactive) material, if radioactive material has been released in a road, rail, or air transport conveyance, the conveyance must be taken out of and remain out of service until the radiation dose rate at every accessible surface is less than 0.005 mSv/h (0.5 mrem/h) and the non-fixed radioactive surface contamination levels are below the values the limits in §173.443(a), Table 9 [see Chart 3].
- Each aircraft used routinely, and each motor vehicle used, for transporting radioactive materials under exclusive use, must be (a) periodically checked for radioactive contamination, (b) taken out of service if contamination levels are above acceptable limits, and (c) remain out of service until the radiation dose rates at accessible surfaces are less than 0.005 mSv/h (0.5 mrem/h) and non-fixed radioactive surface contamination levels are below the limits in §173.443(a), Table 9 [see Chart 3].
- Following any breakage, spillage, release or suspected radioactive contamination incident, any rail or air carrier shall notify, as soon as possible, the offeror (i.e. the consignor); special provisions apply for buildings, areas, and equipment that might become contaminated during rail transport. Alternative provisions may apply for motor vehicles transporting radioactive materials under exclusive use. [see §§174.750(a) and 750(e), and §177.843(b)]

Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (§§171.15 and 16)

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

Guidance on Responding to Emergencies (Emergency Response Guidebook)

- The DOT issues guidance to aid first responders in quickly identifying the specific or generic hazards of the dangerous goods involved in an accident or incident, and for protecting themselves and the general public during the initial response to the accident or incident. For each name or UN ID Number, the user is led to a specific guide that provides insight into potential hazards and steps to be taken for public safety and emergency response.
- The Emergency Response Guidebook 2008 (ERG2008) is available at the following URL: http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/erg2008_eng.pdf



Based on U.S. DOT and NRC regulations in effect as of December 1, 2011.

Contacts: DOT – Rick.Boyle@dot.gov; NRC – John.Cook@nrc.gov

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

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

Provisions for Training (49 CFR 172, Subpart H)

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

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

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

Applicants should visit the U.S. DOT Web site for additional information on transportation requirements: http://www.dot.gov/.

APPENDIX Q

MODEL WASTE MANAGEMENT PROCEDURES

Model Waste Management Procedures

General Guidelines

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary “non-radioactive” waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind workers that nonradioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire effect of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.

5. Waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.

6. Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

7. A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest in accordance with 10 CFR Part 20, Appendix G, “Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests.”

Model Procedure for Disposal by Decay-in-Storage

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

1. Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.

2. Short-lived waste should be segregated from long-lived waste.

3. Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.

4. Liquid and solid wastes must be stored separately.

5. When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.

6. The identification label should include the date when the container was sealed, the longest-lived radionuclide in the container, total activity, and the initials of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after many half-lives that persons performing surveys should be aware of the potential for measurable radiation.

7. The contents of the container should be allowed to decay for a sufficient time to ensure that all radionuclides in the container are essentially gone.

8. Prior to disposal as ordinary trash, each container should be monitored with an appropriate radiation detection instrument, on the lowest setting, as follows:

    a. Check the radiation detection survey meter for proper operation.

    b. Survey the contents of each container in a low background area.

    c. Remove any shielding from around the container.

    d. Monitor all surfaces of the container.

    e. Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e. surface readings are indistinguishable from background.

    f. If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.

    g. If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed, provided that the following is done: waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility; labels are removed from the waste barrels/containers; and that the waste is incinerated, not placed in a landfill; and the waste disposal firm is cautioned not to open the container prior to incineration.

Model Procedure for Disposal of Liquids into Sanitary Sewerage

1. Confirm that the sewer system is a public system, not a private sanitary sewer, septic system or leach field.

2. Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.

3. Calculate the amount of each radionuclide that can be discharged by using the information from prior, similar discharges and the information in 10 CFR Part 20, Appendix B.

4. Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR Part 20, Appendix B, Table 3 (records for individual users/laboratories).

5. If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 must not exceed unity.

6. Confirm that the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 Gbq (1 Ci) of all other radionuclides combined.

7. Record the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the initials of the individual discharging the waste.

8. Liquid waste should be discharged only via designated sinks or toilets.

9. Discharge liquid waste slowly to minimize splashing with water running, to be sure that the material moves out of the sink and into the sewer system.

10. Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces. Decontaminate as appropriate.

11. Decontaminate all areas or surfaces if found to be contaminated.

12. For all releases to the sanitary sewer from the licensed facility, maintain records of each radionuclide and its quantity and concentration that is released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Model Procedure for Incineration

These guidelines apply to noncommercial waste disposal, i.e., incineration of a licensee's own waste. You do not need specific NRC approval to incinerate certain categories of radioactive waste. For example, 10 CFR 20.2005 provides that tritium and carbon-14 in low level concentrations in liquid scintillation media and animal tissue may be disposed of without regard to radioactivity. After you review your program and confirm that you have waste that requires specific NRC approval for incineration, please provide the following information.

1. Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.

2. Describe the waste that is proposed to be incinerated, to include: the chemical and/or physical form of the waste containing licensed material and a description of how the waste is segregated, packaged, and labeled for transfer from the generation site to the incinerator; the name of the radionuclide; concentration of radioactivity averaged over

the weight of the material to be incinerated (microcuries per gram of waste medium) for each isotope to be incinerated; and the total radioactivity of each isotope per burn and the total number of burns per year. Describe procedures for ensuring that these frequencies and activities will not be exceeded.

3. Describe the procedures for packaging, handling, securing, and monitoring of waste to prevent contamination and/or unnecessary exposure to personnel or property during the waste life cycle.

4. Describe your method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe your procedures for collection, handling, and disposal of the ash residue.

5. Describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incinerations, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records must be maintained in the same units as applicable regulations.

6. Describe the characteristics of the incinerator and site location, including: height of the stack, rated air flow (cubic feet per hour or similar units), proximity of the stack or other discharge to occupied areas (e.g., residences, school, hospital), and distance to the nearest air intake ducts of adjacent buildings. Describe any scrubbers, filters, or air cleaning equipment that is present.

7. State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined. Describe any stack monitoring that is planned.

8. Provide a copy of the written safety analysis that demonstrates the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in 10 CFR Part 20.

9. Provide a written commitment that the applicant has coordinated with appropriate State and local authorities and that you have obtained such permits and other authorizations as may be necessary.

10. Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations and for monitoring all effluent generated by the incineration process. The procedures must ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant must describe how any ash generated exceeding regulatory limits will be disposed of.

Model Procedure for Compaction

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

1. Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations (e.g., manufacturer's specifications, annotated sketches, photographs, etc.).

2. Describe the type, quantities, and concentrations of waste to be compacted.

3. Provide an analysis of the potential for airborne release of radioactive material during compaction activities.

4. State the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange.

5. Discuss the methods used to monitor worker breathing zones and/or exhaust systems.

6. Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.

7. Discuss the instruction provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

APPENDIX R

INTERIM STAFF GUIDANCE ON CONSTRUCTION

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

PURPOSE AND SCOPE

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

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

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

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

BACKGROUND

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

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

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

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

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

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

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

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

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

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

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

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

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

DISCUSSION OF EXAMPLES

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

BYPRODUCT MATERIAL (10 CFR PART 30)

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

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

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

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

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

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

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

IRRADIATORS (10 CFR PART 36)

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

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

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

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

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

URANIUM CONVERSION FACILITIES, ENRICHMENT FACILITIES, FUEL FABRICATION FACILITIES, AND URANIUM HEXAFLUORIDE (UF_6) DECONVERSION FACILITIES (10 CFR PART 40 and 10 CFR PART 70)

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

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

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

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

Construction includes driving piles for buildings or structures that will contain licensed materials. Hence the driving of piles for such buildings or structures should not be performed before the NRC staff concludes its environmental review. Driving piles that do not ensure the structural stability or integrity of buildings or structures within the scope of the definition of “construction” (e.g., piles driven to support the erection of a bridge for a temporary or permanent access road) is not “construction”; therefore, those piles may be driven prior to the conclusion of the NRC staff’s environmental review.

In addition to 10 CFR 40.4, 51.4, and 70.4 criteria that are used to determine the scope of activities that fall within the definition of construction, construction includes the necessary excavation for safety related items. A necessary excavation is the portion of an excavation that provides sufficient construction access to the structures that are within the definition of construction. Applicants should ensure, and NRC staff will confirm, that these construction activities are separate from, and do not result in, adverse interactions with construction-related safety related item including influence on the stability (static and dynamic) analyses.

Construction includes any change made to the parent material in which the excavation occurs (e.g., soil compaction, rock grouting); the driving of piles; the installation of foundations; the installation of permanent drainage systems and geofabric; the placement of backfill, concrete (e.g., mudmats) or other materials that will not be removed before placement of the foundation of a structure; the placement and compaction of a subbase; and the installation of reinforcing bars to be incorporated into the foundation of any safety related items that fall within the definition of construction. The foregoing items fall within the definition of construction because they have a rational, direct link to ensuring that a licensed materials facility is operating, or will operate, in accordance with the NRC's regulations and in a manner that protects the public health and safety from radiological hazards.

ACTIVITIES WHICH HAVE NO REASONABLE NEXUS TO RADIOLOGICAL SAFETY OR SECURITY

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

(1) Changes for temporary use of the land for public recreational purposes;
(2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
(3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
(4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to 10 CFR Parts 30, 36, 40, or 70;
(5) Excavation;
(6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
(7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
(8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

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

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

FINAL RESOLUTION

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

APPLICABILITY

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

REFERENCES

1) NUREG-1556, Volume 6, "Consolidated Guidance About Material Facilities: Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses," January 1999.
2) NUREG-1556, Volume 12, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Possession Licenses for Manufacturing and Distribution," December 2000.
3) NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, May 2010.
4) Regulatory Issue Summary 2009-12, Uranium Recovery Policy Regarding Site Preparation Activities at Proposed, Unlicensed Uranium Recovery Facilities, September 23, 2009, ML092090353.
5) NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with Materials Facilities," August 2003.
6) DC/COL-ISG-4, "Interim Staff Guidance on the Definition of Construction and on Limited Work Authorizations," February 9, 2009, ML082970729.
7) Inspection Manual Chapter 2815, "Construction and Preoperational Inspection of Panoramic Wet-Source-Storage Gamma Irradiators," March 27, 2001, ML010990225.
8) Docket No. 030-36974, Final Environmental Assessment Related to the Proposed Pa'ina Hawaii, LLC, Underwater Irradiator in Honolulu, Hawaii; August 10, 2007; ML071150121.
9) Docket No. 70-7015, Environmental Assessment for an Exemption to 10 CFR Parts 30, 40, and 70, Commencement of Construction Requirements, Areva Enrichment Services, Eagle Rock Enrichment Facility, Bonneville County, Idaho, February 28, 2010, ML093220528.
10) NUREG-1811, "Environmental Impact Statement for an Early Site Permit at the North Anna ESP Site," December 2006.
11) NUREG-1947, "Final Supplemental Environmental Impact Statement for Combined License (COLs) for Vogtle Electric Generating Plant Unit 3 and 4," March 2011.

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APPENDIX S

SAFETY CULTURE STATEMENT OF POLICY

Safety Culture

The safety culture policy statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011 and can be found at: http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf. It is also posted in NRC's Agencywide Documents Access and Management System (ADAMS) 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.

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