United States Nuclear Regulatory Commission

Protecting People and the Environment

NUREG-1556
Volume 6, Rev. 1

Consolidated Guidance about Materials Licenses

Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses

Draft Report for Comment

Office of Federal and State Materials and
Environmental Management Programs

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Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses

Draft Report for Comment

Manuscript Completed: June 2013
Date Published: August 2013

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ABSTRACT

This technical report contains information intended to provide program-specific guidance and to assist applicants and licensees in preparing applications for irradiator licenses under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 36, "Licenses and Radiation Safety Requirements for Irradiators." In particular, the report describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

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FOREWORD

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

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 6, Revision 1, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiators," 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 6, issued January 1999. See Appendix A for a list of the documents considered in the development of this NUREG report.

This report takes a risk-informed, performance-based approach to licensing 10 CFR Part 36 irradiators. 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 irradiators.

NUREG-1556, Volume 6, 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 will 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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ACKNOWLEDGMENTS

The working group thanks the individuals listed below for assisting in the review and update of the report. All participants provided valuable insights, observations, and recommendations.

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

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

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ABBREVIATIONS

ACI	American Concrete Institute
ALARA	as low as is reasonably achievable
ANSI	American National Standards Institute
bkg	background
BPR	business process redesign
Bq	becquerel
BSR	bulk shielding reactor
C	Celsius
CaF_2	calcium fluoride
CFR	*Code of Federal Regulations*
C/kg	coulomb per kilogram
Ci	curie
cm	centimeter
Co-60	Cobalt-60
cpm	counts per minute
Cs-137	Cesium-137
d	day
DOE	U.S. Department of Energy
DOT	U.S. of Transportation
F	Fahrenheit
FSME	Office of Federal and State Materials and Environmental Management Programs
ft	foot
GBq	gigabecquerel
G-M	Geiger-Mueller
GPO	Government Printing Office
hr	hour
IAEA	International Atomic Energy Agency
IN	information notice
IP	inspection procedure
kg	kilogram
m	meter
MC	manual chapter
min	minute
mR	milliroentgen
mrem	millirem
mSv	millisievert
MOU	memorandum of understanding
NaI(Tl)	sodium iodide (thallium-activated)
NCRP	National Council on Radiation Protection and Measurements
NFPA	National Fire Protection Association
NIST	National Institute of Standards and Technology
NLTNIF	National Low-Temperature Neutron Irradiation Facility
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NSTS	National Source Tracking System

NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
ORNL	Oak Ridge National Laboratory
OSHA	Occupational Safety and Health Administration
OSLD	optically stimulated luminescence dosimeters
OSP	Office of State Programs
P&GD	policy and guidance directive
QA	quality assurance
rem	roentgen equivalent man
RG	regulatory guide
RQ	reportable quantities
RSO	radiation safety officer
SI	International System of Units (abbreviated from the French Le Systeme Internationale d'Unites)
SS&D	sealed source and device
std	standard
Sv	sievert
TAR	technical assistance request
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
wk	week
yr	year

1. PURPOSE OF REPORT

This report provides guidance to an applicant applying for an irradiator license under Title 10 *Code of Federal Regulations* (10 CFR) Part 36, "Licenses and Radiation Safety Requirements for Irradiators,"[1] and it provides the U.S. Nuclear Regulatory Commission (NRC) with criteria for evaluating such applications. This report is not intended to address the research and development or the commercial aspects of manufacturing, distributing, and servicing of 10 CFR Part 36 irradiators and their associated sources. Within this document, the phrases or terms, "10 CFR Part 36 irradiators," "irradiators," or "irradiators subject to the requirements of 10 CFR Part 36" are used interchangeably.

This report addresses the variety of radiation safety issues associated with irradiators of various designs whose dose rates exceed 5 Gray (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable to the irradiator's design. Table 1.1 describes the characteristics of commonly authorized irradiators. Figures 1.1, 1.2, 1.3, and 1.4 illustrate several irradiators. Because of differences in design, manufacturers provide appropriate written instructions and recommendations for proper operation and maintenance.

Table 1.1 Categories and Types of 10 CFR Part 36 Irradiators

Irradiator Type	Panoramic (ANSI N43.10 Category II or IV irradiators)	Panoramic dry-source-storage (ANSI N43.10 Category II irradiators)	Panoramic wet-source-storage (ANSI N43.10 Category IV irradiators)	Pool (ANSI N43.15 Category III or N43.10 Category IV irradiators	Underwater (ANSI N43.15 Category III irradiators)
Sources stored in pool and removed to irradiate package or product	✔		✔	✔	
Sources stored in pool and package or product lowered into pool to be irradiated				✔	✔
Dry source storage and in-air irradiation of package or product	✔	✔			
Teletherapy unit converted to nonhuman use	✔	✔			

[1] Self-shielded irradiators (American National Standards Institute (ANSI) Category I irradiators) are not subject to the requirements of 10 CFR Part 36 and are discussed in NUREG-1556, Vol. 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiators."

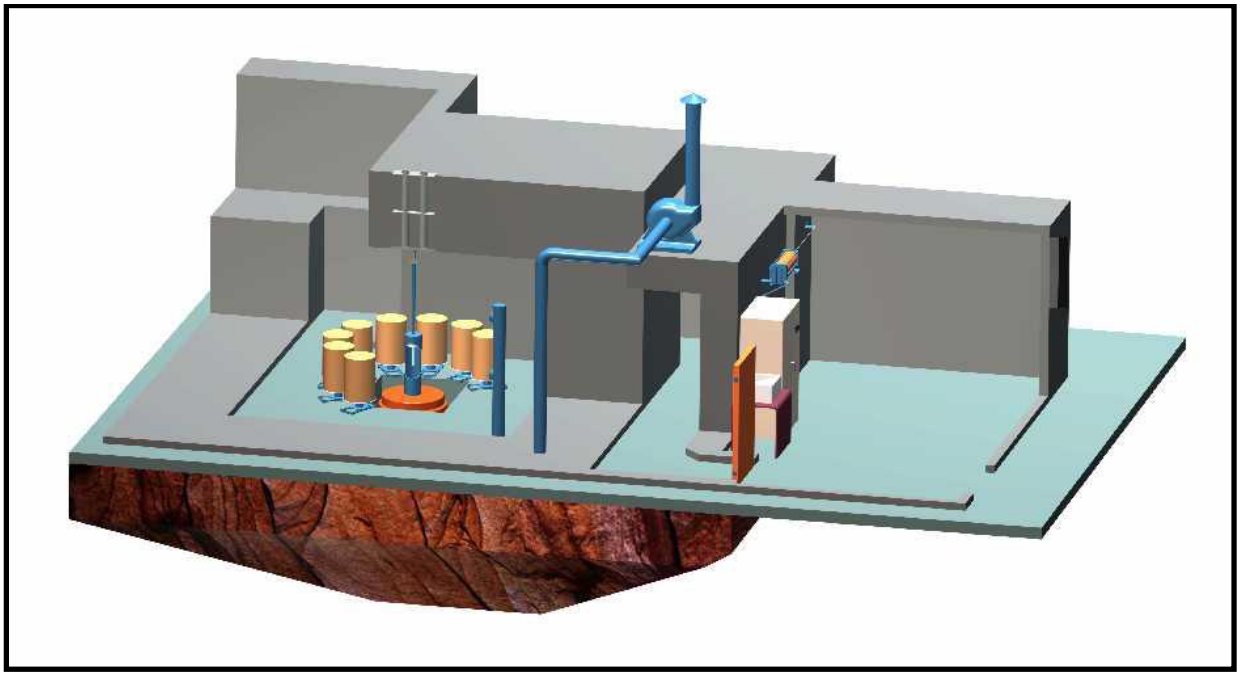

Figure 1.1 Dry source-storage irradiator (ANSI Category II irradiator)

The sealed sources are stored in a dry storage container constructed of solid materials. The sources are fully shielded when not in use. The sources are raised into the air to irradiate a product that may be moved into the irradiation room on a conveyor system.

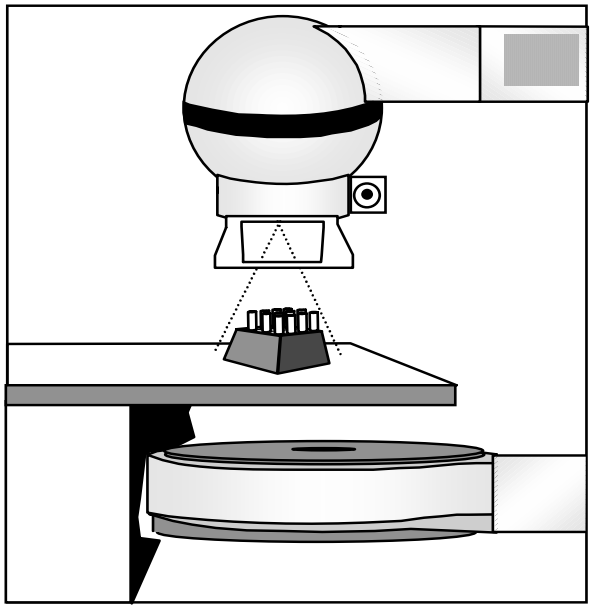

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Figure 1.2 Teletherapy unit converted to nonhuman use (ANSI Category II irradiator)

A teletherapy unit used for research is an example of a panoramic dry source-storage irradiator.

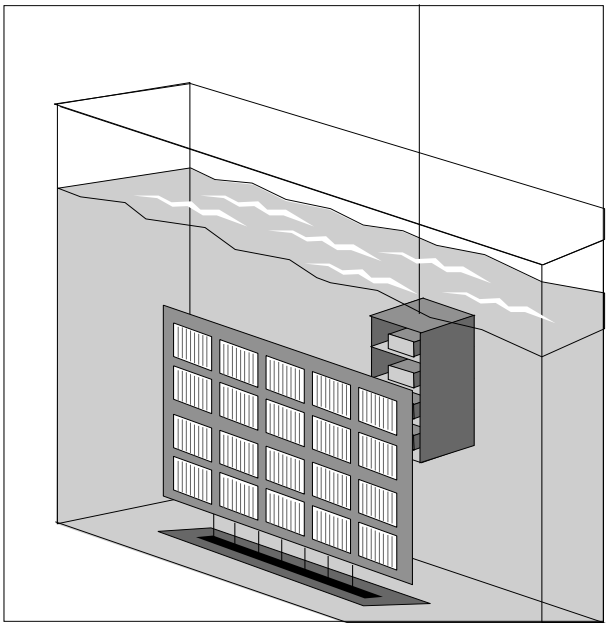

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Figure 1.3 Underwater irradiator (ANSI Category III irradiator)

The sealed sources remain in the water at all times. The product to be irradiated is placed in a water-tight container and lowered into the water.

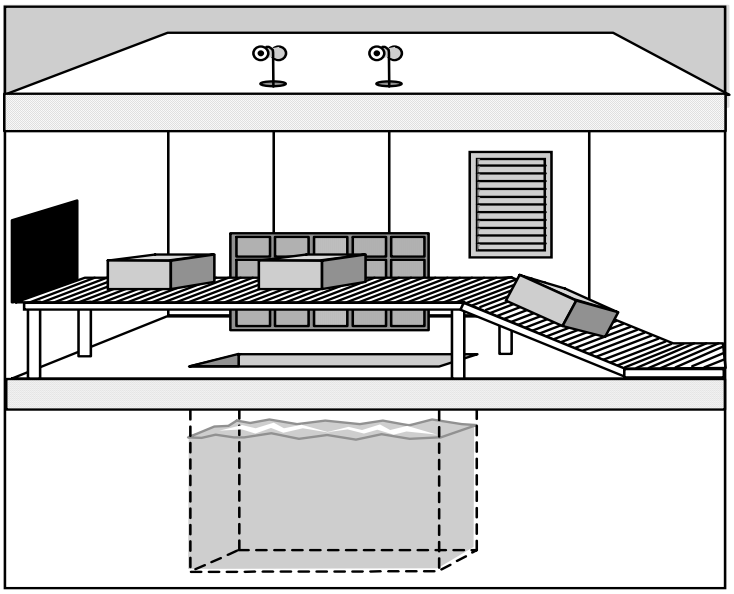

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Figure 1.4 Commercial wet-source-storage irradiator (ANSI Category IV irradiator)

The sealed sources are stored in water and raised into the air to irradiate a product that may be moved into the irradiation room on a conveyor system. This is an example of a panoramic wet-source-storage irradiator.

Chapter 8, "Contents of an Application," of this report identifies the information needed to complete NRC Form 313, "Application for Material License" (see Appendix B), for the use of sealed sources in 10 CFR Part 36 irradiators. The Office of Management and Budget (OMB) has approved the information collection requirements in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 10 CFR Part 36, and NRC Form 313 under OMB Clearance Nos. 3150-0017, 3150-0158, and 3150-0120, respectively

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

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

Notes and references are self-explanatory and may not be necessary 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 these sheets, along with the completed NRC Form 313. For the convenience and streamlined handling of Part 36 irradiator applications, Appendix C, "Suggested Format for Providing Information Requested in Items 5 through 11 of the U.S. Nuclear Regulatory Commission Form 313," may be used to provide supporting information.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE), as defined in 10 CFR Part 20, "Standards for Protection against Radiation." Roentgen equivalent man (rem) and its international system of units (SI) equivalent, sievert (Sv) (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. This is done because 10 CFR Part 20 sets dose limits in terms of rem, rather than rad or roentgen. When the radioactive material emits beta and gamma rays, for practical reasons, 1 roentgen is assumed to equal 1 rad, which is assumed to equal 1 rem. For alpha-emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from alpha particles 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.

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.

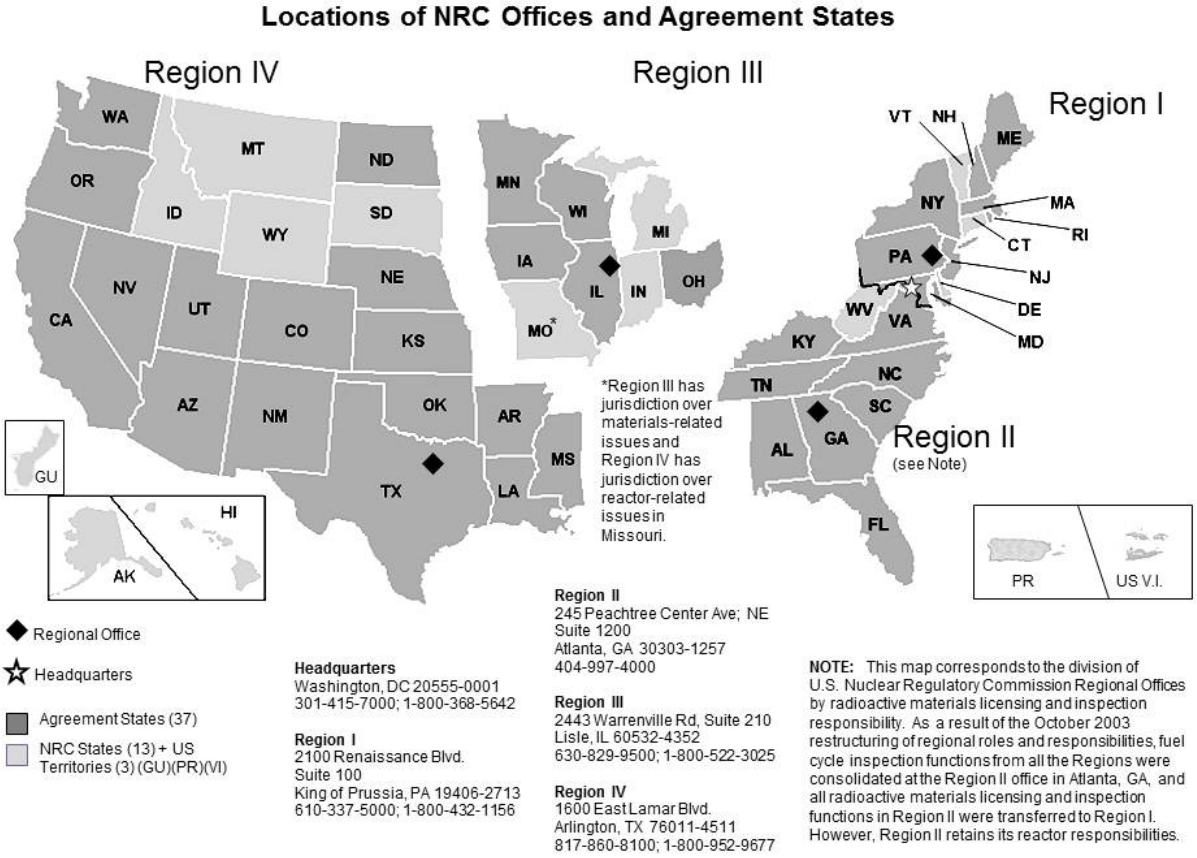

Figure 2.1 U.S. map: locations of NRC offices and Agreement States

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.[2]

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

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

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

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with 10 CFR 30.12, "Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts")	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or tribal member on Indian Tribal land	NRC
Non-federal entity on Federally recognized Indian Tribal land	NRC[3]
Federally recognized Indian Tribe or tribal member outside of Indian Tribal land in Agreement State.	Agreement State

[3] The NRC can exercise jurisdiction as the regulatory authority on tribal land of a Federally recognized Indian Tribe. Section 274b. Agreements do not give States the authority to regulate nuclear material in these areas. However, there 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[4]
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.

[4] 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 who signed the application is duly authorized to act for and on the behalf of the applicant or licensee. The signature on an application acknowledges the licensee's commitments and responsibilities for the following:

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

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

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

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

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

3.2 Safety Culture

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

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

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

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, NRC's safety culture policy statement and traits are not incorporated into the regulations. Many of the safety culture traits may be inherent to an organization's existing radiation safety practices and programs. One of the critical safety components for large irradiator installations are safety interlocks. Safety interlock failures, and the intentional bypass of safety interlocks, have often stemmed from a culture in which there is complacency, inattention to detail, lack of management oversight and deficient training. This has led to injury and in some cases proven fatal to irradiator workers. The need to be personally accountable for an individual's safety may correspond with the safety culture trait specified in Table 3.1 as "Personal Accountability" (all individuals take personal responsibility for safety).

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

4. APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of Title 10 of the *Code of Federal Regulations* (10 CFR) contain regulations applicable to Part 36 irradiators. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

The current versions of these parts can be found under the "Basic References" link at the NRC's online library at http://www.nrc.gov/reading-rm.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 32, "Specific Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"
- 10 CFR Part 37, "Physical Protection of Category 1 and 2 Quantities of Radioactive Material"
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"
- 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"
- 10 CFR Part 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC"

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

A single copy of the above documents may be requested from the NRC's regional offices (see Figure 2.1 for addresses and telephone numbers). 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 also can 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 8½ 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 according to 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, or Future (the text of this document is in the Arial font).
- Use 12-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

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

6. IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

All licensing applications, except for portions containing sensitive information, will be made available for review in the NRC's Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit 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 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 concept and philosophy. The application should document ALARA considerations, including establishing administrative action levels and monitoring programs.

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

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

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

Refer to Appendix P for guidance regarding the definition of construction and the consideration of activities that can be performed by materials license applicants and potential applicants, and licensees before the NRC has concluded its environmental review of the proposed licensing action. The majority of materials licensing actions will meet the criteria in 10 CFR 51.22(c)(14)(vii) 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 P 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 and initial security inspection will be conducted prior to issuance of the license. Also note that an initial security inspection may be conducted in accordance with NRC Inspection Manual Chapter 2800, "Materials Inspection Program," before issuance of the license.

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

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

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

8.2 Item 2: Applicant's Name and Mailing Address

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. Provide the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address.

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

Note: The NRC must be notified 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 filing of 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 its interests in the bankruptcy proceeding.

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

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

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

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

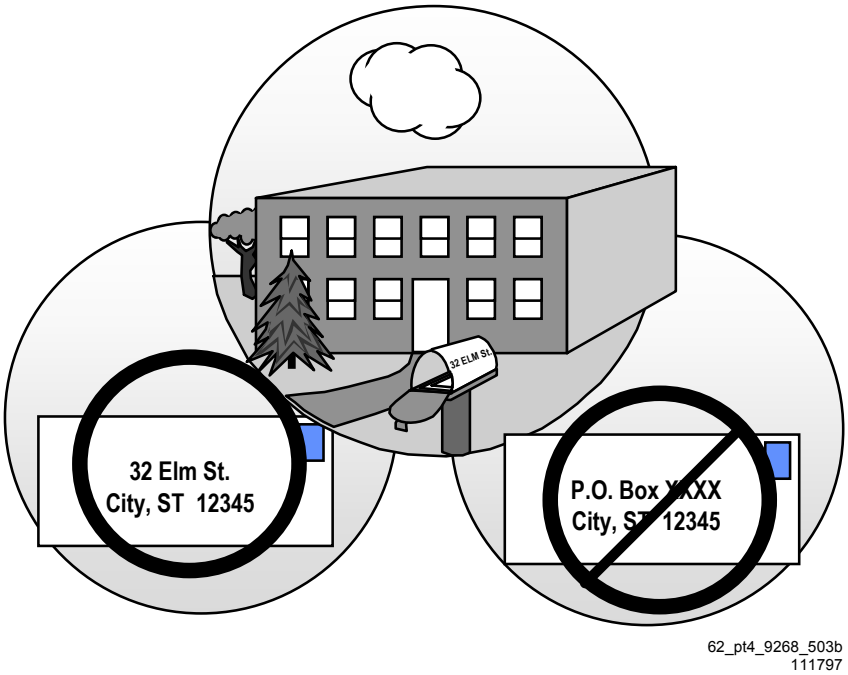

Figure 8.1 Location of use

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

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

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

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

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

Regulation: 10 CFR 30.32(g), 10 CFR 30.33(a)(2), 10 CFR 32.210, 10 CFR 36.21

Criteria: Applicants must provide the manufacturer's (or distributor's) name and model number for each irradiator. Applicants must provide the manufacturer's (or distributor's) name and

model number for each sealed source being requested. Licensees will only be authorized for irradiators or sealed sources containing byproduct material meeting NRC performance requirements and specifically approved or registered by the NRC or an Agreement State. In addition, applicants should identify any depleted uranium that is used as shielding material in teletherapy units converted to nonhuman use and any other irradiators that may contain depleted uranium.

Discussion: Guidance in 10 CFR 36.21, "Performance Criteria for Sealed Sources," and 10 CFR 32.210, "Registration of Product Information," lists criteria for sealed sources used in irradiators. Normally, tests used to demonstrate that the criteria can be met are conducted by the source manufacturer (or distributor), not the applicant. The manufacturer (or distributor) then applies to the NRC or an Agreement State agency for approval for use in irradiators. The safety evaluation is documented in a sealed source and device (SS&D) registration certificate. Therefore, if the NRC or an Agreement State approves sealed sources for use in the requested irradiator, the applicant need only note the manufacturer's (or distributor's) name and model number of the sources in its license application to demonstrate that the requirements are met.

If an applicant wishes to install sealed sources that are not currently listed on the license, the new sources must meet the requirements of 10 CFR 36.21 and be approved for use in the type of irradiator possessed by the licensee. In addition, the NRC needs to review and approve a license amendment request prior to source installation.

Licensees may not make any changes to the sealed sources that would alter the description or specifications from those indicated in the respective registration certificates without obtaining the NRC's prior permission in a license amendment. A custom registration review also may be required. This would increase the time needed to process a licensing action. Sealed sources used in irradiators are usually at or above Category 2 quantities. 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"). Category 1 and Category 2 sources regulated by the NRC and Agreement States must be tracked in the National Source Tracking System (NSTS) in accordance with 10 CFR 20.2207, "Reports of Transactions Involving Nationally Tracked Sources." Refer to Item 8.10.13, "Security Program," for more information.

Response from Applicant:

- Identify the manufacturer (or distributor) and model number of each sealed source to be used in each irradiator. For each source model, identify the radionuclide and the maximum activity per source.

- Identify the manufacturer (or distributor) and model number of each irradiator to be used. For each irradiator, identify the radionuclide, the source model number, maximum activity per source, and total possession limit. If applicable, identify any depleted uranium that is used as shielding material (e.g., teletherapy units converted to nonhuman use) and specify the total amount in kilograms.

- Confirm that the proposed sealed source and irradiator combination are registered with the NRC or an Agreement State and will be possessed and used in accordance with the

conditions specified in the registration certificate. Obtain a copy of the SS&D certificate from the manufacturer or distributor and provide the SS&D registry number with the application.

Mark the section related to possession of sealed sources and devices with manufacturers, model numbers, and possession limits as follows: "Security-Related Information—Withhold under 10 CFR 2.390."

8.5.2 Financial Assurance and Record Keeping for Decommissioning

Regulations: 10 CFR 30.34(b), 10 CFR 30.35, 10 CFR 36.81

Criteria: Irradiator licensees authorized to possess sealed sources containing byproduct material with a half life ($T_{1/2}$) greater than 120 days and in excess of the limits specified in 10 CFR 30.35, "Financial Assurance and Recordkeeping for Decommissioning," must provide evidence of financial assurance for decommissioning. See Table 8-1, "Minimum Inventory Quantity Requiring Financial Assurance."

Licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where devices are used or stored, as well as records related to leaking sources. Pursuant to 10 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 NRC Regional Office.

Discussion: The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most irradiator applicants and licensees need to comply with the financial assurance requirements because the thresholds for sealed sources containing byproduct material are 3.7×10^5 gigabecquerels (GBq) (10,000 curies (Ci)) of cobalt-60 and 3.7×10^6 GBq (100,000 Ci) of cesium-137. Applicants and licensees desiring to possess sources exceeding the threshold amounts should submit evidence of financial assurance. Licensees may follow the guidance provided in NUREG-1757, Volume 3, "Consolidated NMSS [Office of Nuclear Material Safety and Safeguards] Decommissioning Guidance—Financial Assurance, Recordkeeping and Timeliness."

NRC regulations also require that licensees maintain records important to decommissioning in identified locations. All licensees must maintain records of structures and equipment where irradiators are used or stored. As-built drawings showing modifications to structures and equipment fulfill this requirement. If drawings are not available, licensees may substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the areas and locations. In addition, irradiator licensees that have experienced unusual occurrences (e.g., leaking sources or other incidents that involve spread of contamination) also must maintain records about contamination that remains after cleanup or contamination that may have spread to inaccessible areas. Leak-test results of sealed sources, records of radiation monitors on a pool water recirculation system, and records of analysis of pool water samples are part of the decommissioning records.

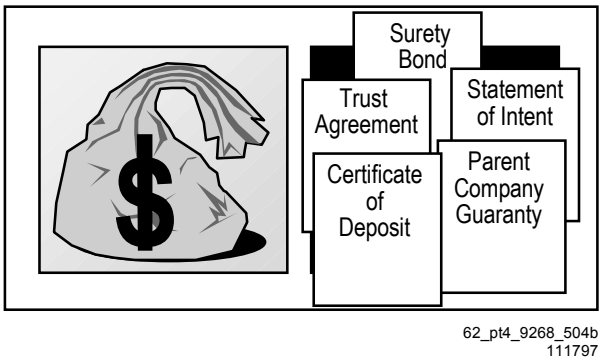

Figure 8.2 Financial assurance for decommissioning

Most 10 CFR Part 36 irradiator licensees must provide financial assurance for decommissioning and can use one of several approved financial mechanisms.

Table 8.1 Minimum Inventory Quantity Requiring Financial Assurance

Radionuclide (sealed sources)	Activity in Gigabecquerels	Activity in Curies
Co-60	3.7×10^5	10,000
Cs-137	3.7×10^6	100,000

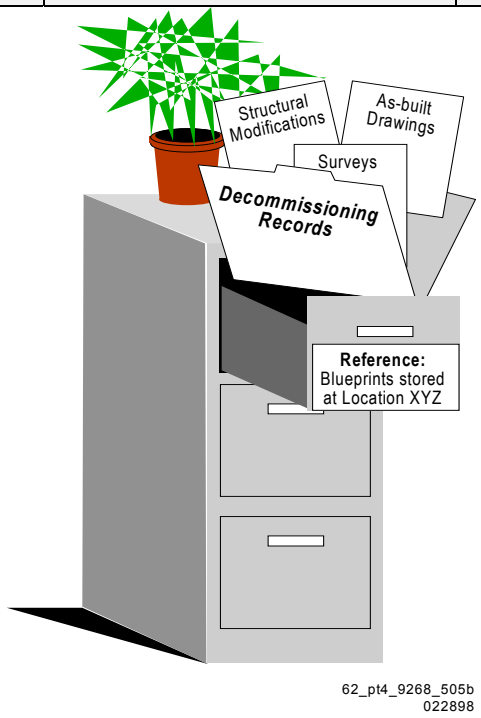

Figure 8.3 Records important to decommissioning

All irradiator licensees must maintain records important to decommissioning, regardless of whether they need financial assurance for decommissioning.

Response from Applicants:

State the following:
Pursuant to 10 CFR 30.35(g), we shall transfer records important to decommissioning to the new licensee before licensed activities are transferred or assigned in accordance with10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, each licensee shall forward the records required by 10 CFR 30.35(g) to the appropriate NRC Regional Office.

AND

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

Reference: NUREG-1757, Volume 3

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

Regulation: 10 CFR 30.33(a)(1), 10 CFR 36.69, 10 CFR 51.22(c)(14)

Criteria: Sources and devices will be used only for the purposes for which they were designed and in accordance with the manufacturer's recommendations for use as specified in an approved SS&D registration certificate.

Unless special circumstances are present, the issuance of an irradiator license is categorically excluded from the need for the applicant to develop an environmental assessment or an environmental impact statement in accordance with 10 CFR 51.22(c)(14)(vii).

Discussion: Requests to use sealed sources in irradiators for purposes not listed in the SS&D registration certificate will be reviewed on a case-by-case basis. Examples might include greater than small quantities of flammable materials with a flash point below 60 degrees (C) (140 degrees F), irradiation of explosive material, or cryogenic material.[5]

If an applicant wants to irradiate greater than small quantities of flammable materials with a flash point below 60 degrees C (140 degrees F), see Appendix D In addition, irradiation of explosives is generally prohibited; however, if an applicant wants to request irradiation of explosives, see Appendix D.

Applicants need to submit sufficient information to demonstrate that the proposed use will not compromise the integrity of the source or source shielding, or other radiation safety-critical components of the device. The NRC will evaluate the radiation safety program for each type and use of sealed sources in each irradiator requested.

[5] Under certain conditions, particular irradiated cryogenic material can explode.

Irradiation of food and certain other products intended for commercial distribution to the public also is subject to the regulations of the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). Contact these agencies for further information. An NRC licensee also must comply with applicable FDA or USDA regulations.

Response from Applicant: Provide either of the following:

- A specific description of use for each type of irradiator requested, (e.g., "for use in irradiation of products or food). There will be no irradiation of explosives and no irradiation of more than small quantities of flammable materials with a flash point below 60 degrees C (140°degrees F) without specific written authorization from the NRC."

OR

- If the irradiator will be used for purposes other than irradiation of food or products for human consumption or research purposes, a description of these purposes and safety analyses (and procedures) should be provided to support safe use.

Note:

- Allowed uses of irradiators normally include the irradiation of food or products for human or animal consumption, medical sterilization, or research purposes.

- Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

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

8.7.1 Radiation Safety Officer (RSO) Training and Experience

Regulations: 10 CFR 30.33(a)(3), 10 CFR 36.13(d)

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

Discussion: The person responsible for the radiation protection program is called the RSO. The NRC believes the RSO is the key to overseeing and ensuring safe operation of the licensee's irradiator program. The RSO must have independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Licensee management should identify and designate a responsible, qualified person as RSO. The named individual should agree, in writing, to assume the duties of RSO. Appendix F contains a model RSO delegation of authority.

Figure 8.4 and Appendix F illustrate typical RSO duties. The NRC requires the name of the RSO on the license to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.
In accordance with 10 CFR 36.13(d), the applicant must provide the NRC with a description of the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the RSO and those management personnel who have important radiation safety responsibilities or authorities. The applicant must specify who within the management structure has the authority to stop unsafe operations. The applicant must also describe the training and experience required for the RSO.

To be considered eligible for the RSO position, an individual should complete a radiation safety course. Training should include approximately 40 hours covering the following topics:

- radioactivity and radioactive decay
- interactions of radiation with matter
- biological effects of radiation
- radiation detection using radiation detection instruments and personnel dosimeters
- basic radiation protection principles and good safety practices (including time, distance, and shielding)
- radiation protection regulations and regulatory requirements

The course should include a written test or evaluation of the individual's comprehension of these topics. See Appendix E for a detailed description of RSO training courses and exam requirements.

In addition to the above general course, if the RSO was previously an RSO at a similar licensee site or was trained as an irradiator operator but has not had experience working at an irradiator, he or she should have the equivalent of at least 40 hours in self study or directed study on information directly applicable to radiation safety at irradiators. This should include applicable regulations (10 CFR Part 20, "Standards for Protection Against Radiation," and 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators") and reports or studies describing case histories of accidents or problems at irradiators (see Appendix F). The license application should list the documents studied or to be studied in the description of the training of the proposed RSO and should describe how the applicant will evaluate the individual's comprehension of the information studied.

The RSO should have at least 3 months (full-time equivalent) of experience at the applicant's irradiator or at another irradiator of a similar type. The 3 months of experience may include pre-operational involvement, such as acceptance testing, while the irradiator is being constructed.

However, to allow flexibility, the NRC will determine the adequacy of the RSO's training and experience on a case-by-case basis, looking at his or her actual qualifications and drawing on the NRC staff's experience in reviewing such qualifications.

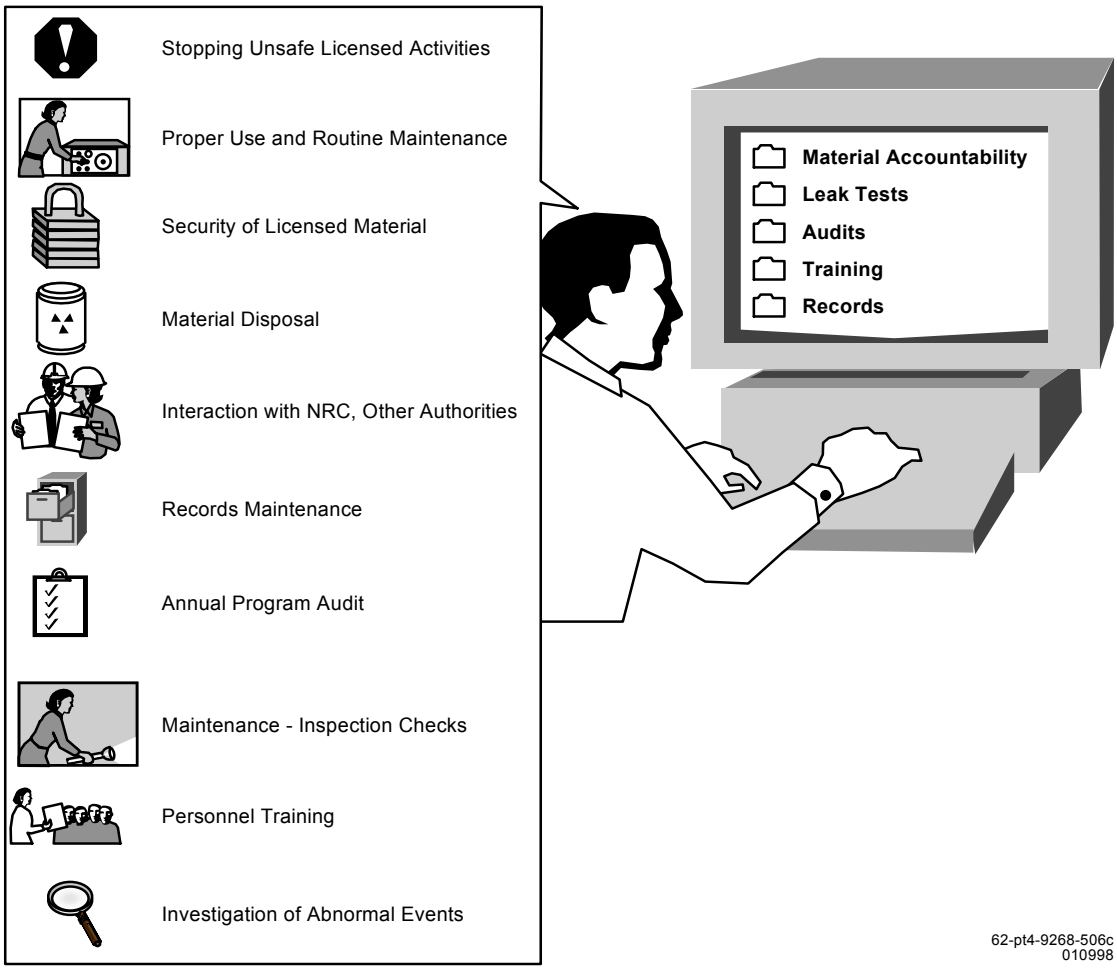

Figure 8.4 Typical duties and responsibilities of RSOs

Note: The NRC will consider individuals with alternative training and experience as RSOs. For example, a person certified in health physics or industrial hygiene with previous experience in managing a radiation safety program of comparable size and scope could be considered as an individual case. The qualifications, training, and experience required of the RSO may vary depending upon the complexity of the applicant's operations and number of irradiator personnel.

Response from Applicant: Provide the following:

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

AND

- Demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart, by position, demonstrating day-to-day oversight and coordination with management in radiation safety activities.

AND

- The specific training and experience of the RSO. Include the specific dates of certification or training, or both, in radiation safety.
- Documentation showing the RSO's training and experience specific to the irradiator that the applicant intends to use.
- Documentation to show that the RSO has obtained training in the regulatory requirements applicable to Part 36 irradiators.

OR

- Alternative information demonstrating that the proposed RSO is qualified by training and experience (e.g., certification by the American Board of Health Physicists, completion of a bachelor's or master's degree in the sciences with at least 1 year of experience in the conduct of a radiation safety program of comparable size and scope).
- Documentation to show that the RSO has obtained training and experience applicable to the regulatory requirements of Part 36 irradiators.

Note: It is important to notify the NRC and obtain a license amendment before making changes in the designation of the RSO responsible for the radiation safety program.

8.8 Item 8: Individuals Working in or Frequenting Restricted Areas

8.8.1 Initial Training and Experience for Irradiator Operators

Regulations: 10 CFR 19.12, 10 CFR 30.7, 10 CFR 30.9, 10 CFR 30.10, 10 CFR 30.33, 10 CFR 36.13(b), 10 CFR 36.23(b),10 CFR 36.51(a), 10 CFR 36.51(b), 10 CFR 36.51(c)

Criteria: Irradiator operators must have adequate training and experience. Successful completion of one of the following is evidence of adequate training and experience:

- irradiator manufacturer's course for operators specific to the irradiator that the applicant intends to use

AND

- description of the initial training program for irradiator operators that demonstrates compliance with the requirements of 10 CFR 36.51(a), (b), and (c)

OR

- training course as described in Appendix E.

The training provided to individuals to qualify them to be irradiator operators must include:

- instruction
- on-the-job or simulator training (i.e., supervised experience)
- means employed by the applicant to test each individual's understanding of the Commission's regulations and licensing requirements and the irradiator safety, security, operating, and emergency procedures
- minimum training and experience of personnel who may provide training

In addition, instruction must be provided to at least one other individual who will be on site during operations on how to respond to the independent backup access control alarm and to promptly render or summon assistance.

Nonroutine operations, including activities such as loading and unloading of sources in an irradiator, are typically performed by the source manufacturer or by an NRC or Agreement State licensee specifically authorized to perform such activity. Applicants requesting to perform nonroutine operations, must provide additional training. For more information see Appendix G.

Discussion: Irradiator operators have the responsibility to ensure the proper use and security of irradiators containing licensed material. Irradiator operators must receive training and instruction and be tested before being permitted to operate an irradiator.

Training should be commensurate with the complexity of the irradiator design and potential radiation hazard (e.g., approximately 40 hours of instruction for pool-type panoramic irradiators and approximately 20 to 30 hours of instruction for underwater irradiators). Up to 50 percent of that instruction may be self study or reading. The written test should cover the range of topics covered in the instruction.

On-the-job training should be supervised by an experienced operator and should last at least 1 month on a full-time basis (approximately 160 hours). If an approved operator does not operate the irradiator for more than a year, his or her performance during operation should:

- be audited for at least 1 day before he or she is permitted to operate the irradiator independently

- receive a safety review regarding the irradiator

The requirements in 10 CFR 36.51(a), (b), and (c) are for an individual to become qualified initially as an irradiator operator. They do not apply to individuals qualified to be operators before July 1, 1993, the effective date of 10 CFR Part 36. The safety reviews and evaluation requirements of 10 CFR 36.51(d) and (e), however, apply to all irradiator operators. Current licensees should conduct safety reviews to discuss 10 CFR Part 36 regulations and any resulting changes in operating and emergency procedures. Licensees also should conduct safety reviews at intervals not to exceed 12 months thereafter. Individuals must be trained in the following subjects to become an irradiator operator:

- The fundamentals of radiation safety as they apply to irradiators
  - The goal is to provide the individual with the necessary foundation to perform his or her task safely and to help the individual worker understand the basis for the safety requirements and procedures that will be taught.

- The requirements of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," and 10 CFR Part 36
  - The operator is not expected to be an authority on NRC regulations or to be able to determine whether a given procedure is adequate to meet NRC regulations. Instead, operators should be instructed on NRC requirements that are directly applicable to their responsibilities.

- The operation of the licensee's irradiator
  - The objective is to help the person understand the operating and emergency procedures, not to become an engineer.

- Licensee operating and emergency procedures that the individual will be required to perform
  - This is the most important part of the training because operating the irradiator safely depends on following these procedures correctly. The objective is that the operator correctly perform his or her assigned tasks. The training does not have to include procedures that the individual will not perform.

  - Safety and security requirements: The individual should be trained and competent in all safety and security procedures.

- Case histories of accidents and problems involving irradiators
  - The individual should be taught about situations that could lead to problems associated with irradiator operations. Instruction material on accidents or events is often difficult to obtain. See Appendix A for a list of NRC Information Notices (IN) describing irradiator events.

Additional training is required for irradiator operators if they will perform nonroutine operations. For more information see Appendix G.

Response from Applicant: Provide the following:

- The statement: "Before using licensed materials, irradiator operators will have successfully completed one of the training courses described in criteria in the section entitled 'Initial Training and Experience for Irradiator Operators' in NUREG-1556, Volume 6, Revision 1, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses,'."

AND

- A description of the initial training program for irradiator operators that demonstrates compliance with the requirements of 10 CFR 36.51(a), (b), and (c).

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

8.8.2 Annual Safety Reviews and Performance Evaluations for Irradiator Operators

Regulations: 10 CFR 19.12, 10 CFR 30.33, 10 CFR 36.51(d), 10 CFR 36.51(e)

Criteria: Licensees must conduct safety reviews for irradiator operators annually. Licensees also must evaluate the safety performance of each irradiator operator annually.

Discussion: Licensees must provide refresher training, called safety reviews, to irradiator operators as well as evaluate the safety aspects of each irradiator operator's performance (i.e., performance evaluation).

Annual Safety Reviews

Safety reviews must include, as appropriate, each of the following areas:

- changes in operating and emergency procedures since the last review
- changes in regulations and license conditions since the last review
- reports on recent accidents, mistakes, or problems that have occurred at irradiator facilities
- relevant results of inspections[6] of operator safety performance
- relevant results of the facility's inspection and maintenance checks
- a drill to practice an emergency or abnormal event procedure

[6] The word "inspections" in 10 CFR 36.51(d)(4) means the "evaluations" performed under 10 CFR 36.51(e).

Also, each operator must be given a brief written test on the information covered during the safety review (See 10 CFR 36.51(d)).

The duration of safety reviews should be commensurate with the complexity of the irradiator's design and potential radiation hazard (e.g., approximately 4 hours for panoramic wet-source-storage irradiators and 2 hours for dry-source-storage and underwater irradiators). Safety reviews may be conducted at intervals not to exceed 12 months or throughout the calendar year on an as-needed basis.

The "drill" referenced in 10 CFR 36.51(d)(6) means actually going through a procedure using the actual equipment in as realistic a manner as practical. For example, for a drill on the response to a fire alarm it is not necessary that the alarm actually be enunciated if sounding the alarm would be disruptive. Each operator should take an active part in the drill. Individuals who must be prepared to respond to alarms required by 10 CFR 36.23(b), 10 CFR 36.23(i), 10 CFR 36.27(a), 10 CFR 36.29(a), 10 CFR 36.29(b), and 10 CFR 36.59(b) shall be trained and tested on how to respond.

Annual Performance Evaluations

The safety performance of each irradiator operator must be evaluated and reviewed at least every 12 months to ensure that regulations, license conditions, and operating and emergency procedures are followed. In addition, the results of the evaluation must be discussed with each operator along with instructions on how to correct any mistakes or deficiencies observed.

Individuals (e.g., the RSO or trained operators, conducting these reviews must have adequate training and experience to direct such evaluations). The applicant should identify these individuals by position if the position requires the qualifications, or by name of the qualified individual.

Response from Applicant: Describe the program for annual safety reviews and performance evaluations of irradiator operators that demonstrates compliance with 10 CFR 36.51(d) and (e).

8.8.3 Training for Individuals Who Require Unescorted Access

Regulations: 10 CFR 19.12, 10 CFR 30.7, 10 CFR 30.9, 10 CFR 30.10, 10 CFR 30.33, 10 CFR 36.51(f),

Criteria: Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for irradiator operators and the RSO, must be instructed and tested in precautions to avoid radiation exposure, procedures listed in 10 CFR 36.53, "Operating and Emergency Procedures," that they must perform or comply with, and their proper response to alarms.

Note: Refer to Section 8.10.13, "Security Program" and NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2

Quantities of Radioactive Material," for information regarding an individual who requires unescorted access to category 1 or category 2 quantities of radioactive material.

Discussion: According to 10 CFR 19.12, "Instructions to Workers," all individuals who, in the course of employment, are likely to receive an occupational dose in excess of 100 millirem (mrem) (1 millisievert (mSv)) in a year must receive appropriate instruction on radiation safety. However, in some facilities, certain individuals other than irradiator operators may require unescorted access to the radiation room of an irradiator. The applicant should identify those individuals (e.g., individuals who perform inspection and maintenance checks) and train them according to 10 CFR 36.51(f).

Training may include the subjects described in Appendix E. In accordance with 10 CFR 36.51(f), individuals who will be permitted unescorted access must be instructed and tested in any precautions or procedures listed in 10 CFR 36.53.

Response from Applicant: The applicant's program for instructing and testing unescorted individuals (other than irradiator operators) will be examined during inspections, but should not be submitted in the license application.

8.8.4 Training for Individuals Who Must be Prepared To Respond to Alarms

Regulations: 10 CFR 19.12, 10 CFR 30.33, 10 CFR 36.23(b), 10 CFR 36.23(i), 10 CFR 36.27(a), 10 CFR 36.29(a), 10 CFR 36.29(b), 10 CFR 36.51(g), 10 CFR 36.59(b)

Criteria: Individuals who must be prepared to respond to an activation of an alarm shall be trained and tested on how to respond to such an alarm to promptly render or summon assistance following the licensee's operating and emergency procedures. Each individual shall be retested at least once a year. Tests may be oral.

Discussion: In accordance with 10 CFR 36.51(g), individuals who will respond to any of the following alarms shall be trained and tested at least once a year:

- Activation of an access control alarm (visible and audible alarm) indicating the detection of a personnel entry to the irradiation room while the sources are exposed.
- Activation of an intrusion alarm (personnel access barrier around the pool to prevent access when the irradiator is not attended) to detect unauthorized entry into the pool when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual who may not necessarily be onsite. This intrusion alarm system is specific to underwater irradiators.
- Activation of heat and smoke detector alarm (audible alarm) indicating the presence of a fire.
- Activation of a radiation monitor alarm (audible alarm) in an irradiator with an automatic product conveyor system indicating the presence of a loose radioactive source that is being carried toward the product exit.

- Activation of a radiation monitor alarm (audible alarm and visible indicator) that is located at entrances to the personnel access barrier around the pool irradiator to detect abnormal radiation levels. This radiation monitor alarm system is specific to underwater irradiators that are not in a shielded radiation room.

- Activation of a radiation monitor alarm on a pool water circulating system in an irradiator indicating above normal radiation levels.

Response from Applicant: The applicant's program for instructing and testing, as applicable, individuals designated to respond to alarms, will be examined during inspections, but should not be submitted in the license application.

8.9 Item 9: Facilities and Equipment

8.9.1 General Description of the Facility and Site

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.13(e), 10 CFR 36.39, 10 CFR 36.61

Criteria: Facilities and equipment must be adequate to protect public health and safety and to minimize danger to life or property. The application must include a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

Discussion: A diagram of the facility must be submitted for review with enough detail designating the location of required interlocks, radiation monitors, alarms and other required systems to be used at the facility (e.g., blueprints with interlock and radiation monitor locations identified) (see Figure 8.5). In addition, the diagram should include a general layout of the entire facility, identifying areas surrounding the irradiator room.

The irradiator must meet the design requirements that are described in 10 CFR 36.39, "Design Requirements." These requirements are summarized below. In addition, the licensee must describe the site-specific testing frequency of all required systems as described in 10 CFR 36.61, "Inspection and Maintenance."

For panoramic irradiators:

- Shielding design to ensure that radiation dose rates in unrestricted areas will not exceed 0.02 mSv (2 mrem) in any 1 hour at any location 30 centimeters from the exterior of the shielding walls.

- Effects of heating on shielding walls if the irradiator will use more than 2×10^{17} Bq (5 million Ci) of licensed material.

- Foundation design to demonstrate that there is adequate support for the weight of the facility shield walls.

- Design of the source rack to ensure that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources.

- Design of the source rack to ensure that the mechanism that moves the sources assures that the likelihood of a stuck source is low, and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

- Design and logic diagram for the access control system to ensure that it meets the requirements of 10 CFR 36.23(g), “Access Control.”

- Design of the fire extinguishing system and locations of smoke and heat detectors to ensure that the system is appropriate to detect fires, and that the system is protected from mechanical and radiation damage.

- Design of the source return mechanism to ensure that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

- Design of the reinforced concrete radiation shields following appropriate building codes to ensure their integrity in the event of an earthquake.

- Design of the electrical wiring and electrical equipment in the irradiation room to ensure minimization of failures caused by prolonged exposure to radiation.

For pool irradiators:

- Pool design to ensure that pool integrity is strong enough to bear the weight of the pool water and shipping cask, to ensure that a dropped cask will not fall on sealed sources, that the pipes and metal components are metallurgically compatible with other components in the pool, and that the pool is leak resistant.

- Design of the water handling and purification system to ensure that water leaking from the system does not drain to unrestricted areas without being monitored.

- Design of the location and sensitivity of the radiation monitor system to ensure that the system includes sensitive detectors located close to where contamination is likely to occur.

- Design of the source rack to ensure that there are no crevices on the source or between the source and the source holder that would promote corrosion on a critical area of the source.

For all irradiators:

- Design of the location and sensitivity of the radiation monitors to ensure that the product conveyor system stops operating before a source on the conveyor would cause a radiation overexposure to any person.

An applicant should provide a schedule for construction activities associated with the irradiator. This will allow the NRC to inspect and ensure construction activities meet design requirements as described in NRC Manual Chapter 2815, entitled “Construction and Preoperational Inspection of Panoramic, Wet-Source-Storage Gamma Irradiators” and Appendix P to this Volume, “Interim Staff Guidance on Construction .”

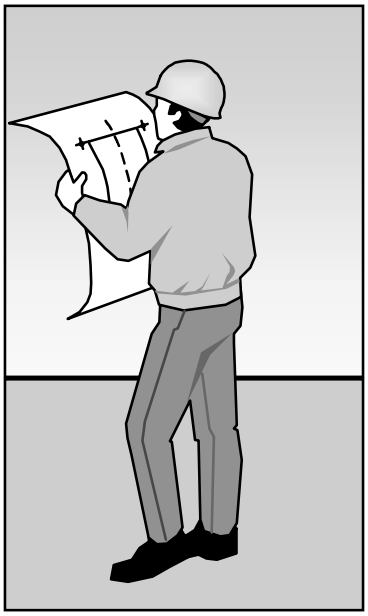

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Figure 8.5 General description of facility

Diagrams, drawings, sketches, or blueprints of facilities are needed for a clear understanding of the facility’s design and its relationship to adjacent properties.

Response from Applicant:

- Describe the irradiator design by including information, drawings, diagrams, sketches, and photographs, as appropriate.
- Show locations of safety-related equipment and features as required in 10 CFR Part 36.
- Provide a construction schedule for the irradiator.
- Describe the site-specific testing frequency of all systems listed in 10 CFR 36.61.

Reference: NRC Manual Chapter 2815, entitled “Construction and Preoperational Inspection of Panoramic, Wet-Source-Storage Gamma Irradiators,” can be found under “Inspection Manual” at: http://www.nrc.gov/reading-rm/doc-collections/.

8.9.2 Access Control

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.13(e), 10 CFR 36.23, 10 CFR 36.31(b), 10 CFR 36.39(g), 10 CFR 36.41(g), 10 CFR 36.61

Criteria: Irradiator facilities must have access controls to prevent inadvertent entry into the radiation room, as required by 10 CFR 36.23.

Discussion: This section discusses two categories of irradiators:

- panoramic irradiators (dry-source-storage, wet-source-storage)
- underwater irradiators

Panoramic Irradiators

The door or barrier that serves as the primary access control system must have devices that will: 1) prevent the source from being moved out of its shielded position if the door or barrier were open, and 2) cause the source to return to its shielded position if the door or barrier were opened while the source was exposed.

Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

The backup access control system must be able to detect entry while the source is exposed. If entry is detected, the system must: 1) automatically cause the source to return to its shielded position, and 2) activate audible and visible alarms.

Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and also must activate a visible and audible alarm to alert any individual entering the room to the hazard. The alarm must alert at least one other individual who is onsite and prepared to render or summon assistance promptly.

A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted entry while the monitor measures high radiation levels must activate the alarm described in 10 CFR 36.23(b). The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam (e.g., an area of the maze that may expose the instrument directly to the irradiator sources when in the unshielded position).

The requirement in 10 CFR 36.23 for a door or other physical barrier applies to each entrance of the radiation room, whether intended for personnel or product entrance or exit. A conveyor

system could meet the requirement by providing a clearance large enough for a package, but too small for a person by using barriers that would require unusual exertion to bypass.

A photoelectric system cannot be considered a physical barrier. The purpose of this requirement is to prevent someone from carelessly or accidentally entering the radiation room while the sources are exposed.

This section also requires an independent backup access control system to provide a redundant means of preventing a person from being accidentally exposed to the source. In case of a failure of the interlocks on the door or barrier combined with a failure to follow operating procedures, the backup system should warn the person entering the radiation room of the danger and automatically cause the sources to return to their shielded position. The backup system could use photoelectric cells in an entrance maze, pressure mats on the floor, or similar means of detection. The backup system also can disengage the pneumatic system that controls the source rack movement by releasing all the compressed air from the system if an unauthorized entry is detected, causing the source to return to its shielded position by force of gravity. The system must alert another trained person, not inside the irradiator radiation area or maze, who is onsite and prepared to render or summon assistance.

The mechanism that moves the sources must require a key to actuate it. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any one time, and only irradiator operators or facility management may have access to it. The key must be attached to a calibrated portable radiation survey meter by a chain or cable. In addition, the lock for source control movement must be designed so that the key may not be removed if the sources are in an unshielded position. Also, the door to the radiation room must require the same key to open it. This redundant feature will ensure that the sources are in the shielded position prior to an individual entering the radiation room. It will also ensure that any individual entering the radiation room will have in his or her possession a calibrated portable radiation survey instrument for monitoring radiation levels in the radiation room in the event the sources were not in the shielded position. In addition, the console of a panoramic irradiator must have a source position indicator that signals when the sources are in fully shielded position, when they are in transit, and when the sources are exposed.

Irradiators can produce ozone in concentrations exceeding those permitted by regulations of the Occupational Safety and Health Administration (OSHA) at 29 CFR 1910.1000, “Air Contaminants.” Nitrogen oxides can also be produced, although concentrations would not be expected to exceed OSHA’s limits. To control these gases, irradiators with large sources typically are equipped with ventilation systems to exhaust the gases before personnel entry.

OSHA regulates exposure to ozone and other noxious gases in the workplace, and the U.S. Environmental Protection Agency regulates emissions offsite. If NRC personnel observe problems with noxious gases at an irradiator during an inspection, NRC will notify OSHA of the problem under the terms of the “Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration; Worker Protection at NRC-Licensed Facilities,” signed October 21, 1988.

The radiation room must be equipped with a device integrated with the control system ensuring that the sources cannot be exposed unless the access door and other interlocks are engaged within a preset time of activating the control. The irradiator must be equipped with a safety timer that will automatically generate visible and audible warnings to alert personnel in the radiation room that the startup sequence has begun, provide sufficient time to leave the area and be equipped with at least one clearly identified emergency stop device that will abort the startup sequence. The safety timer must be integrated with the control system so that the source cannot be exposed unless the startup sequence is complete within the preset time and the control console indicates that it is safe to expose the source.

For panoramic irradiators whose construction began after July 1, 1993, the licensee must verify from the design and logic diagram that the access control system meets the requirements of 10 CFR 36.23. Before loading sources, the licensee must test the completed access control system to ensure that it functions as designed and that all alarms, controls, and interlocks work properly. For more information, see Appendix H, "Construction Monitoring and Acceptance Testing."

Underwater Irradiators

The pool must be within an area surrounded by a personnel access barrier with an intrusion alarm when the facility is not operating. Only operators and facility management may have access to keys to the personnel access barrier. The intrusion alarm must be able to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance when the alarm is activated.

Response from Applicant:

- Submit specific information describing the access control system and how it works, which demonstrates compliance with the requirements of 10 CFR 36.23. Specific drawings or sketches should be submitted, as appropriate. Refer to Appendix O regarding exemptions that can be requested for teletherapy units converted to non-human use.

- For panoramic irradiators, describe the facility alarm systems.

- For panoramic irradiators, describe the lock and key system for controlling source movement and discuss how it meets the requirements of 10 CFR 36.31(a).

- Describe the site-specific testing frequency of access control systems.

References: The "Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration," signed October 21, 1988, can be found on the NRC Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html

8.9.3 Shielding

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.25, 10 CFR 36.39(a), 10 CFR 36.41(a), 10 CFR 36.61

Criteria: Irradiator shielding must meet the requirements as described in 10 CFR 36.25, "Shielding," and the requirements of local building codes or other appropriate sources.

Discussion: The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 mSv (2 mrem) per hour at any location 30 cm or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. The maximum dose rate of 0.02 mSv (2 mrem) per hour is considered practical to achieve. Areas where the radiation dose rate exceeds 0.02 mSv (2 mrem) per hour must be locked, roped off, or have appropriate warnings posted. These may include areas not normally occupied, such as the equipment access area on the roof of the irradiator.

The radiation dose at 30 cm over the edge of the pool of a pool irradiator may not exceed 0.02 mSv (2 mrem) per hour when the sources are in the fully shielded position.
The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 mSv (2 mrem) per hour and at 5 cm from the shield may not exceed 0.2 mSv (20 mrems) per hour.

For panoramic irradiators:

- If not built in seismic areas, it is acceptable that shielding meet generally accepted building code requirements for reinforced concrete, with walls, wall penetrations, and entranceways designed to meet the radiation shielding requirements of 10 CFR 36.25.
- If built in seismic areas, the applicant must design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source, such as American Concrete Institute (ACI) Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.
- American National Standards Institute (ANSI) Standard 43.10, "Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV) and Dry Source Storage Gamma Irradiators (Category II)" discusses geologic and seismic site considerations, which should be evaluated prior to building a panoramic irradiator.
- The licensee must monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete (see Appendix H).
- If the irradiator will use more than 2×10^{17} Bq (5 million Ci) of activity, the applicant must evaluate the effects of heating of the shielding walls by the irradiator sources (e.g., thermal effects on concrete).

Response from Applicant:

- **For panoramic irradiators:**
  - Describe the shielding to be used and its composition.
  - Submit a diagram showing the configuration of shielding, including walls and the ceiling, and indicate the thickness of each and penetrations in the shielding.
  - If any accessible areas outside the shield are expected to have a dose rate exceeding 0.02 mSv (2 mrem) per hour, identify the areas and explain how access will be controlled for radiation safety purposes.
  - For requests to possess more than 2×10^{17} Bq (5,000,000 Ci), submit an evaluation of the effects of heating of the shielding walls by the irradiator sources.
  - Describe the testing frequency of the irradiator shielding as required by 10 CFR 36.57, "Radiation Surveys."

For underwater irradiators: No response is required from the applicant in a license application.

Note:

- The NRC does not approve irradiator shield designs. Instead, the NRC conducts inspections to ensure that the maximum dose rate outside the completed shield is according to NRC requirements.

- The applicant should identify building code requirements to which shielding walls will be built and inspections of the construction will be performed by local authorities so that the license reviewer can confirm that they do not adversely impact the NRC requirements.

Reference: See the notice of availability (on the inside front cover of this report) to obtain a copy of the ACI Standard 318-89. This standard is also available for purchase from ACI (248-848-3700, http://www.aci-int.org).

8.9.4 Fire Protection

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.27, 10 CFR 36.39(h), 10 CFR 36.41(h), 10 CFR 36.61

Criteria: Panoramic irradiators must have smoke and heat detectors to detect a fire, to activate alarms and to cause the source rack to automatically become fully shielded to meet the requirements as described in 10 CFR 36.27, "Fire Protection," and 10 CFR 36.39(h).

Discussion: The radiation room must have heat and smoke detectors that activate an audible alarm capable of alerting a person who can summon assistance promptly. The sources must become fully shielded automatically if a fire or smoke is detected.

The radiation room must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

The fire extinguishing system is required because a fire could disable the access control system or could prevent the sources from being shielded, thereby lowering the margin of safety. The fire extinguishing system must be operable without entry into the room. During a fire, there would be no means of ensuring that the access control systems and source position indicators or the mechanism that returns the source to the shielded position had operated properly.

For panoramic irradiators:

- The applicant must verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The applicant must verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and low characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

- The licensee must test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. In addition, the licensee must test the operability of the fire extinguishing system. It is not required that licensees turn on extinguishers (i.e., water or chemicals) during tests of the operability of their fire protection systems. For more information see "Radiation Safety Program - Inspection and Maintenance Checks" and Appendix H, "Construction Monitoring and Acceptance Testing."

Response from Applicant:

- For panoramic irradiators, describe:

  – the type and location of the heat and smoke detectors to be used to detect a fire in the radiation room (Refer to Appendix O regarding exemptions that can be requested for teletherapy units converted to non-human use)

  – the alarms to alert personnel trained to summon assistance

  – how the sources will automatically become fully shielded if a fire is detected

  – how the heat and smoke detectors will be tested and the testing frequency

For underwater irradiators: No response is required since the sources are always underwater and not subject to damage by fire.

8.9.5 Radiation Monitors

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.13(e), 10 CFR 36.23(c), 10 CFR 36.29, 10 CFR 36.39(e), 10 CFR 36.41(e), 10 CFR 36.59(b), 10 CFR 36.61

Criteria: Irradiator facilities must have radiation monitors to detect radiation levels and the presence of sources as described in 10 CFR Part 36.

Discussion: This section will only discuss the evaluation of the location of radiation monitors. For information regarding the calibration, sensitivity, and testing of monitors, see "Radiation Safety Program - Instruments."

For irradiators with automatic product conveyor systems:

The irradiator must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting a trained individual in the facility who is prepared to summon assistance.

For panoramic irradiators:

A monitor must be provided to detect the radiation level in the radiation room when the source is indicated to be in the fully shielded position. The monitor must be integrated with the personnel access door interlocks, as applicable, to prevent room access when the monitor detects an elevated radiation level for which the alarm set point is as low as practical but high enough to avoid false alarms. Room access must also be prevented if the monitor malfunctions or is turned off.

For underwater irradiators that are not in a shielded radiation room:

There must be a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut off. The alarm must be capable of alerting an individual who is prepared to respond promptly (e.g., prevent movement of irradiated product out of pool in the event water is contaminated, or in the event that a loose source is embedded in the product carrier).

For all irradiators:

- The licensee must ensure that the location and sensitivity of the monitor used to detect sources carried by the product conveyor system are appropriate.
- The licensee must verify that the product conveyor is designed to stop before a source on it could cause a radiation overexposure to any person.

For pool irradiators:

- If the licensee uses radiation monitors to detect contamination under 10 CFR 36.59(b), the licensee must verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to be concentrated.

For all irradiators, the licensee must verify the operability of radiation monitors and related alarms and interlocks prior to loading sources. For more information, see Appendix I.

Response from Applicant:

- Describe the location and type of radiation monitors that will be used to meet the requirements of 10 CFR 36.23(c), 10 CFR 36.29, "Radiation Monitors," and 10 CFR 36.59(b).
- Describe the location and types of alarms and those individuals who are trained to respond to those alarms. Diagrams and sketches should be used, as appropriate.
- Discuss the alarm set points or the methods for establishing the alarm set points.
- For all irradiators, describe the evaluation performed to meet 10 CFR 36.39(e) on detector location and sensitivity and the acceptance testing that will be performed to meet 10 CFR 36.41(e).
- Describe the testing frequency of radiation monitors.

8.9.6 Irradiator Pools

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.23(i), 10 CFR 36.33, 10 CFR 36.39(c), 10 CFR 36.39(d), 10 CFR 36.41(c), 10 CFR 36.41(d), 10 CFR 36.61

Criteria: Irradiator facilities with pools must be designed and equipped as described in 10 CFR Part 36.

Discussion: The NRC requires that irradiator pools must either:

Have a water-tight stainless steel liner (or a liner metallurgically compatible with other components in the pool),

OR

Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination.

The purpose of the requirement is to reduce the likelihood of the pool leaking water that may be contaminated or used for shielding purposes. Therefore, the design of the water handling and purification system must ensure that water leaking from the system does not drain to unrestricted areas without being monitored.

In either case, the licensee must have a method to store the sources safely during repairs of the irradiator pool.

Irradiator pools must have no outlets more than 0.5 meters below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meters below the normal low water level that could act as siphons must have breakers to prevent siphoning. Irradiator pools must have a means to replenish water that is lost. The means to

replenish the water does not have to be automatic. Irradiator pools also must have a clearly visible indicator to show if the pool water level is above or below the normal low water level.

For all pool irradiators:

- A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations. Also, this ensures compatibility with OSHA requirements and ANSI standards.

- The pool shall be designed to ensure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirement of 10 CFR 36.33(b), and that metal components are metallurgically compatible with other components in the pool.

- Irradiator pools must be equipped with a purification system capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with enough clarity to allow for inspection of the source and source rack for damage and proper position. The water purification system is needed to minimize the probability of corrosion of the sealed sources and the source rack.

- The 0.02 mSv (2 mrem) per hour limit on the dose rates for poles and long-handled tools to be used in irradiator pools is imposed to prevent radiation streaming. Hollow and low-density poles and tools can have either vent holes to allow shielding water to enter or sufficient bends to prevent radiation levels at handling areas of the tools from exceeding 0.02 mSv (2 mrem) per hour.

The licensee must verify that the pool design ensures its integrity as required by 10 CFR 36.39(c) and that the design of the water purification system is adequate. The licensee must also conduct inspections and tests of the pool and water handling systems to meet the requirements of 10 CFR 36.41(c) and (d) (see Appendix I).

Response from Applicant: Provide the following:

- **For all pool irradiators, describe:**

  – The pool water- liner. If no water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool is used, explain why the pool has a low likelihood of substantial leakage and how decontamination could be accomplished if necessary.

  – The high and low water-level indicators and their locations.

  – The purification system for the pool with an explanation of why it is capable of maintaining pool water conductivity less than 20 microsiemens per centimeter.

– The means to replenish pool water.

– The barrier used during normal operation to prevent personnel from falling into the pool.

– How high radiation doses will be minimized when using long-handled tools or poles (use sketches if appropriate).

– The pool outlets. If the pool has outlets more than 0.5 meters below the surface that could allow water to drain out of the pool, the means of preventing inadvertent excessive loss of pool water (in this context, outlets do not include transfer tubes between adjacent pools because the transfer tubes do not provide a means to allow water to drain out of the pools).

– The testing frequency of multiple regulatory required systems as listed in 10 CFR 36.61, "Inspection and Maintenance."

8.9.7 Source Rack

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.35, 10 CFR 36.39(f), 10 CFR 36.41(f), 10 CFR 36.61

Criteria: Systems must be in place to protect the source rack.

Discussion: An important element in a radiation safety program is providing systems to protect the source rack and the mechanism that raises and lowers the sources from the pool.

For all irradiators, 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.

- For pool irradiators, the licensee must verify that there are no crevices on the source or between the source and source rack that would promote corrosion on a critical area of the source (e.g., crevice corrosion, an inaccessible location in or around the sources or rack with low oxygen concentrations).

- For panoramic irradiators, the licensee must determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. In addition, licensees should review the potential of sealed sources to become dislodged from the source rack when dropped as a result of loss of power, failure of cables, or other alternate means of support.

- For panoramic irradiators, the licensee must review the design of the mechanism that moves the sources to ensure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

- For panoramic irradiators, the licensee must test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power.

- For all irradiators with product conveyor systems, the licensee must observe and test the operation of the conveyor system to ensure that the requirements in 10 CFR 36.35 "Source Rack Protection," are met for protection of the source rack and the mechanism that moves the rack. Testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

See Appendix H, "Construction Monitoring and Acceptance Testing."

Response from Applicant: Submit procedures for ensuring source rack protection and testing frequency of the source rack protection system. If the product moves on a product conveyer system, describe the source rack protection to be provided to prevent products and product carriers from touching the source rack or mechanism that moves the rack. Provide diagrams or sketches of those systems, if appropriate. For panoramic irradiators: Describe any safety and emergency actions to be taken if source is stuck or if a rack sticks. Explain how and how often observation and testing of the conveyor system will occur to ensure that the requirements in 10 CFR 36.35 are met.

8.9.8 Power Failures

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.37, 10 CFR 36.39(i), 10 CFR 36.41(i), 10 CFR 36.41(j), 10 CFR 36.61

Criteria: If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position. In addition, the lock on the door of the radiation room of a panoramic irradiator must not be deactivated by a power failure.

Discussion: Automatic source retraction in case of power loss must be accomplished without offsite power. The loss of offsite power may occur at irradiator facilities due to means outside the control of the licensee. In those cases where loss of offsite power occurs, the licensee is responsible for ensuring that the sources automatically return to the shielded position in accordance with 10 CFR 36.37(a). This is normally accomplished by an irradiator design that does not need electrical energy to return the sources to their shielded position. In addition, 10 CFR 36.37(b) requires that the lock on the door of the radiation room may not be deactivated as the result of a power failure. It also requires that during a power failure, the licensee must ensure that anyone entering the area of any irradiator where sources are located must use an operable and calibrated radiation survey meter.

The licensee needs to demonstrate how the source rack would return into the shielded position in the event of a power outage and what effects the loss of power would have on the lock of the door to the radiation room that contains the sources. If the locks on the doors did not function as designed and allowed entry into the radiation room, the licensee would need to have procedures in place to ensure that safety features would prevent an individual from being

exposed to the sources if they did not return to the shielded position. Backup power is not required as long as loss of power will cause the source to return to its shielded position (e.g., the source returns to the shielded position due to gravity).

For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

The licensee must test the ability of the source rack to return to its shielded position during a power loss greater than 10 seconds. For more information; see Appendix I.

Response from Applicant:

- **For panoramic irradiators:** Describe how the sources are automatically returned to the shielded position if offsite power is lost for longer than 10 seconds.

- For panoramic irradiators: Describe how loss of power will affect the lock on the doors in the radiation room.

- For panoramic irradiators that use a computer system to control access, describe how the licensee will ensure that the access control system will operate properly if offsite power is lost. Describe how the licensee will ensure that computer security features prevent an irradiator operator from commanding the computer to override the access control system.

- Describe the site-specific testing frequency to ensure that sources are returned to the shielded position if offsite power is lost for longer than 10 seconds.

- **For underwater irradiators:** No response is required from the applicant in a license application.

8.10 Item 10: Radiation Safety Program

8.10.1 Audit Program

Regulations: 10 CFR 20.1101, 10 CFR 20.2102

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

- compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license

- occupational doses and doses to members of the public are ALARA (10 CFR 20.1101)

- records of audits and other reviews of program content are maintained for 3 years

Discussion: Applicants must develop and implement an audit program. Appendix I contains a suggested audit program that is specific to the use of irradiators and is acceptable to the NRC. All areas indicated in Appendix I may not be applicable to every licensee and all items may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit need not be reviewed at the next audit.

Currently, the NRC's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of irradiator operators to determine if, for example, operating and emergency procedures are available and are being followed.

It is essential that once identified, problems be corrected comprehensively and in a timely manner. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," provides guidance on this subject. The NRC will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, the NRC can exercise discretion and may elect not to cite a violation. The NRC's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. The NRC has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Response From Applicant: The applicant is not required to, and should not, submit its audit program to the NRC for review during the licensing phase. See Appendix I for a sample radiation safety audit program. Audits will be reviewed during inspections to determine compliance with NRC regulations.

References: IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, can be found under "Generic Communications" at http://www.nrc.gov/reading-rm/doc-collections/.

8.10.2 Instruments

Regulations: 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2), 10 CFR 36.23(c), 10 CFR 36.27(a), 10 CFR 36.29, 10 CFR 36.39(e), 10 CFR 36.57(c), 10 CFR 36.57(e), 10 CFR 36.59(b), 10 CFR 36.63(b), 10 CFR 36.81(f)

Criteria: The NRC requires specific types of instruments to perform radiation surveys and to monitor certain activities.

Survey Instruments

Surveys that are required before and during operation of all types of irradiators require using survey instruments, which:

- measure the type of radiation expected
- are calibrated:
  - at least annually using a source of radiation similar to that found in the irradiator
  - after any servicing or repair (other than a battery exchange)
  - to ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than ± 20 percent on each scale
  - by the instrument manufacturer or person specifically authorized by the NRC or an Agreement State to calibrate survey instruments
- do not saturate and read zero at high radiation dose rates

Radiation Monitors

The requirements for use of radiation monitors are shown in Table 8.2.

Table 8.2 Requirements for Radiation Monitors

Type of Irradiator	Monitor Required	Purpose of Monitor	Required Checks
Panoramic pool	Gamma sensing integrated with personnel access locks. Must activate alarm if entry is attempted while sensing radiation. 10 CFR 36.23(c)	Detects presence of high radiation in radiation room to prevent room access when radiation levels are high	Periodic checks with radioactive check source to confirm operability
All pool types (required unless water is checked daily by analysis of a sample of pool water)	Gamma sensing of pool circulating system. Must activate an alarm set point as low as practical when pool is contaminated. 10 CFR 36.59(b)	Detects a possible leaking sealed source	Periodic checks with radioactive check source to confirm operability and sensitivity
Underwater type not in a shielded radiation room	Gamma sensing mounted over the pool. Must have an audible alarm capable of alerting an authorized individual. 10 CFR 36.29(b)	Detects abnormal radiation levels	Periodic checks with radioactive check source to confirm operability and sensitivity
Any irradiator using a product conveyor system	Gamma sensing to detect and stop the product conveyor if a source is present. 10 CFR 36.29(a) 10 CFR 36.39(e)	Must stop conveyor before a source on the conveyor can cause a radiation overexposure to any person	Periodic checks with radioactive check source to confirm operability. The location and sensitivity of the monitor to detect sources carried by the product conveyor must be evaluated.

Discussion: Irradiator licensees must have survey instruments and radiation monitors as shown in Figure 8.6.

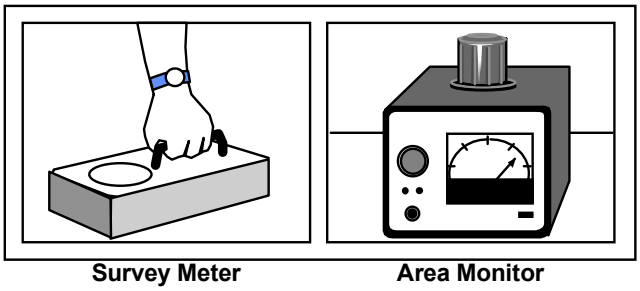

Figure 8.6 Radiation detection instruments

Irradiator licensees must have a variety of radiation detection instruments, including portable survey instruments and fixed radiation monitors.

Survey Instruments

The survey instruments should measure at least 0.05 mR through 200 mR per hour (2 mSv) and be checked for functionality with a source of radiation at the beginning of each day of use (e.g., with a check source). Plans to conduct nonroutine operations, such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the irradiator, sealed source relocation, replacement, and disposal of sealed sources, alignment or removal of a sealed source from service must include an evaluation of the type of survey instrument to be used because some of these operations may increase the individual's risk of radiation exposure. These operations should be carefully monitored with an appropriate survey meter. Furthermore, proper calibration of a survey meter is important for initial surveys since they can be used as a basis for public dose estimates. For those licensees requesting authorization to calibrate their own survey instruments, Appendix J contains calibration procedures acceptable to the NRC.

Nonroutine operations are typically performed by the source manufacturer or distributor, or a service provider licensee that is specifically authorized to perform such services. Applicants requesting authorization to perform nonroutine operations should submit operating and emergency procedures that are specific for the type of operation that is being proposed. The NRC will review these procedures to determine if the procedures are adequate to protect the workers and members of the public. See Appendix G, "Information Needed to Support Applicant's Request to Perform Nonroutine Operations," for further guidance.

Radiation Monitors

Fixed radiation monitors are used to detect the presence of radiation for various purposes at irradiator facilities. They are vital to access control systems because they provide electronic signals used to activate both audible and visual alarms when radiation is present. Monitors that

warn individuals of the presence of high radiation or which are integrated with personnel access door locks to prevent room access under high radiation conditions should be designed to

provide fail-safe operation (i.e., if the radiation monitor for any reason fails to respond to radiation), the system should provide for a backup warning system.

Response from Applicant:

For Survey Instruments: Provide one of the following:

- A statement that, "We will use survey instruments that meet the criteria in the section entitled 'Radiation Safety Program - Instruments' in NUREG-1556, Volume 6, Revision 1, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses.'"

AND ONE OF THE FOLLOWING:

- A statement that, "Each survey meter will be calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations."

OR

- A statement that, "We will implement the model survey meter calibration program published in Appendix J entitled 'Model Survey Instrument Calibration' in NUREG-1556, Volume 6, Revision 1, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses.'"

OR

- Submit alternative calibration procedures for NRC review.

For Radiation Monitors: Describe the type of monitors used to meet the requirements of 10 CFR 36.23(c), 10 CFR 36.29, 10 CFR 36.39(e), and 10 CFR 36.59(b). (The location of these monitors and alarm set-points were described in the response to "Facilities and Equipment - Radiation Monitors.")

Notes:

- Alternative responses will be evaluated using the criteria listed above.
- The NRC license, will state that survey meter calibrations will be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State to calibrate instruments, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must submit additional information for review. See Appendix J for more information.
- Regardless of whether an applicant is authorized to calibrate survey meters or contract a

licensed entity authorized to perform calibrations, the licensee must retain calibration records for at least 3 years.

8.10.3 Material Receipt and Accountability

Regulations: 10 CFR 20.1501(a), 10 CFR 20.1801, 10 CFR 20.1802, 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

Criteria: Licensees must do the following:

- Develop, maintain, and implement a procedure to account for licensed material.
- Maintain records of receipt, transfer, and disposal of sources and devices.
- Update transactions in the NSTS, including the annual inventory reconciliation required by 10 CFR 20.2207(g).

Discussion: While loss, theft, or misplacement of licensed material at most irradiator facilities is unlikely because of limited access to sealed sources and the hazards involved with approaching unshielded sources, accountability for licensed materials must be ensured. As illustrated in Figure 8.7, licensed materials must be tracked from “cradle to grave” to ensure accountability and ensure that possession limits listed on the license are not exceeded. Furthermore, if source activity exceeds the activities listed in Appendix E, “Nationally Tracked Source Thresholds,” to 10 CFR Part 20, the transfer transaction (receipt, transfer, and disposal) must be reported in accordance with 10 CFR 20.2207, “Reports of Transactions Involving Nationally Tracked Sources.”

The regulations in 10 CFR 20.2207 require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking System Transaction Report. The NSTS is a secure, accessible, and easy-to-use computer system that tracks high-risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay below threshold levels.

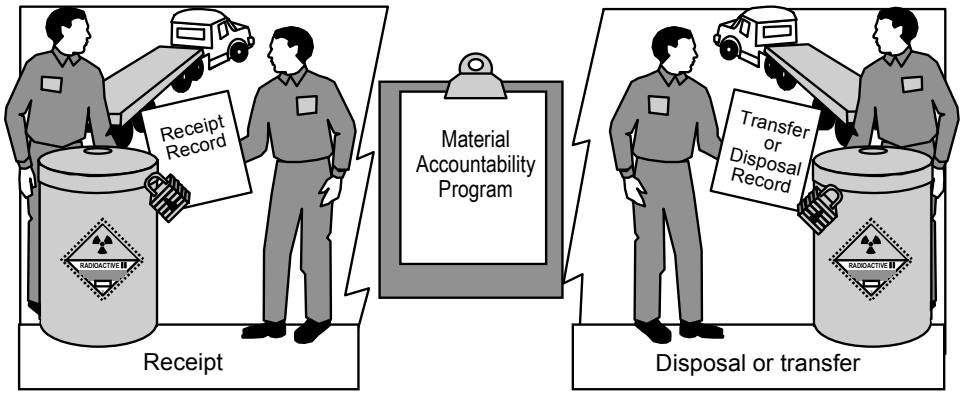

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Figure 8.7 Material receipt and accountability

Licensees must maintain records of receipt, transfer, and disposal and implement an accountability procedure.

Because this report covers various types of irradiators, it is not possible to prescribe a specific procedure for material accountability that will apply to every situation. In developing a licensed material accountability program, the applicant should take into consideration the specific conditions at its facility. Table 8.3 includes elements that may be included in the accountability procedure for various facilities.

Table 8.3 Elements of Accountability Procedure

Irradiator Type	Items to be Addressed in Accountability Procedure
Pool irradiator	Verify that no sources have been lost when sources are added to, removed from, or moved within the irradiator. Maintenance of records that include sealed source serial numbers and location of each source.
Panoramic dry-source-storage irradiator (including teletherapy units converted to irradiators)	Leak tests. Verify that no sources have been lost when sources are added to, removed from, or moved within the irradiator. Maintenance of records that include sealed source serial numbers and location of each source.

Receipt, transfer, and disposal records must be maintained for the times specified in Table 8.4. Typically, these records contain the following types of information:

- Radionuclide, amount (in units of becquerels or curies) of byproduct material, and date of measurement of each sealed source.
- Manufacturer's (or distributor's) name, model number, and serial number of each sealed source containing byproduct material.

- Location of each sealed source.
- For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's (or distributor's) name and model number, and serial number).
- Date when accountability evaluation was performed.
- Name with signature of individual performing accountability.

In addition, the transfer transactions must be reported to NSTS in accordance with 10 CFR 20.2207.

Table 8.4 Receipt, Transfer, and Disposal 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

*See the section entitled, "Financial Assurance and Recordkeeping for Decommissioning."

Response from Applicant: Provide the following:

- Procedure(s) for ensuring material accountability.

AND

A statement declaring that, "We will comply with the NSTS reporting requirements as described in 10 CFR 22.2207."

AND

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

8.10.4 Occupational Dosimetry

Regulations: 10 CFR 20.1201, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1501(c), 10 CFR 20.1502, and 10 CFR 36.55

Criteria: The requirements for occupational dosimetry are shown in Table 8.5.

Discussion: The regulations in 10 CFR 36.55(a) require that irradiator operators shall wear a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. Regulations in 10 CFR 36.55(b)

require, in part, that other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter.

The requirements for most individuals are described in Table 8.5. Other individuals who perform certain nonroutine operations (e.g., source loading, unloading, and repositioning, troubleshooting the control console, clearing stuck source racks, investigating and remediating removable contamination and leaking sources, (re)installing source cables, and any other activity during which personnel could receive radiation doses exceeding NRC limits) are likely to exceed 10 percent of the limits as shown in Figure 8.8 (see Appendix G, "Information Needed to Support Applicant's Request to Perform Nonroutine Operations"). Applicants also will be required to provide dosimetry (whole body and perhaps extremity monitors) to individuals performing such services.

When personnel monitoring is needed, most licensees use either film badges, thermoluminescent dosimeters (TLDs), or optically stimulated luminescence dosimeters (OSLDs) that are supplied by a NVLAP-approved processor. The exchange frequency for film badges is usually monthly due to technical concerns about film fading. The exchange frequency for TLDs and OSLDs are usually quarterly. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Some workers (e.g., package handlers, shipping personnel, and custodial personnel) may work near the irradiator but are not likely to exceed 10 percent of the limits. Refer to Appendix K for guidance for demonstrating that an unmonitored individual will not exceed 10 percent of the limits.

Table 8.5 Requirements for Occupational Dosimetry

Type of Irradiator	Category of Personnel	Type of Dosimetry	When Dosimetry Must Be Worn
Panoramic	Irradiator operators	Film, TLD, or OSLD	When operating irradiator
Underwater	Irradiator operators	Film, TLD, or OSLD	When in area around pool
Panoramic	Other individuals, including visitors (for groups of visitors, only two must be monitored)	Pocket dosimeter, film, TLD, or OSLD	When entering or in radiation room
All	Anyone who could receive, in one year, a radiation dose in excess of 10% of the allowable limits as shown in Figure 8-8.*	Pocket dosimeter, film, TLD, or OSLD	As directed by the RSO based on 10 CFR 20.1502

* The licensee must maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10 percent of the allowable limits, as shown in Figure 8.8.

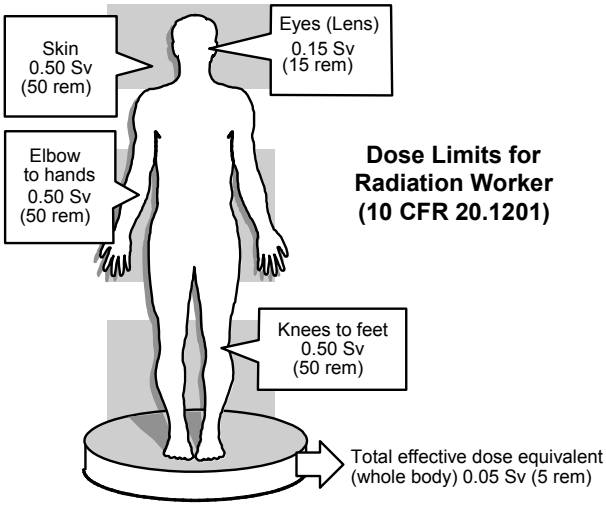

Figure 8.8 Annual dose limits for radiation workers

Response from Applicant: The applicant's occupational dosimetry program required by 10 CFR Part 20 and 10 CFR Part 36 will be examined during inspection, but should not be submitted in the license application.

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, 10 CFR 36.25.

Criteria: Licensees must do the following:

- Ensure that irradiators and their sealed sources will be used, transported, and stored in such a way that individual members of the public will not receive more than 1 mSv (100 mrem) in 1 year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour, from licensed operations.

- Control and maintain constant surveillance over licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

Discussion: Members of the public include all persons who are not radiation workers. This includes persons who work or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where licensed material is used or stored.

Security procedures described in "Facilities and Equipment - Access Control," "Radiation Safety Program - Operating Procedures," and "Radiation Safety Program - Emergency Procedures," should be sufficient to limit the exposure to the public during use or storage. Public dose is

controlled, in part, by ensuring that irradiators are secure (e.g., irradiator is locked or located in a locked area) to prevent unauthorized access or use. Irradiator use is usually restricted by

controlling access to the keys needed to operate the irradiator and to keys to the locked irradiator area. Only authorized users should have access to these keys.

Public dose also is affected by the choice of storage and use locations and conditions. Since an irradiator produces a radiation field, it must be located and constructed so that the dose in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 0.02 mSv (2 mrem) in any 1 hour and the dose to an individual member of the public does not exceed 1 mSv (100 mrem) in a year. Use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time spent near an irradiator, increasing the distance from the irradiator, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure. Licensees must determine the radiation levels in unrestricted areas that are normally occupied during operation of an irradiator as specified in Table 8.6.

Table 8.6 Radiation Limits Specified in 10 CFR 36.25

Irradiator Type	Limit	Where Measured	Source Position
Panoramic	0.02 mSv (2 mrem) per hour	30 centimeters or more from the wall (of the room where the sources are exposed) in areas normally occupied	Exposed
Pool irradiator (including panoramic pool irradiators and underwater irradiators)	0.02 mSv (2 mrem) per hour	30 centimeters over the edge of the pool irradiator	Shielded
Dry-source-storage panoramic irradiator	0.02 mSv (2 mrem) per hour	1 meter from the shield	Shielded
Dry-source-storage panoramic irradiator	0.2 mSv (20 mrem) per hour	5 centimeters from the shield	Shielded

Doses adjacent to the irradiator location can be determined by direct measurements and calculations using the “inverse square” law to evaluate the effect of distance on radiation levels, and occupancy factors to account for the actual presence of the member of the public.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., changes the shielding of the irradiator, increases the source strength, changes the type or frequency of irradiator use, or changes the occupancy of adjacent areas), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement or a combination of measurement and 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. See Appendix L for examples of methods to demonstrate compliance.

Response from Applicant: The applicant's program to control doses received by individual members of the public will be examined during inspection, but should not be submitted in a license application.

8.10.6 Operating Procedures

Regulations: 10 CFR 19.11(a)(3),10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201-2207, 10 CFR 21.21,10 CFR 30.50, 10 CFR 36.13(c), 10 CFR 36.51, 10 CFR 36.53

Criteria: The applicant must have and follow written operating procedures for items listed in 10 CFR 36.53(a). Refer to Table 8.9 for a description of the items.

Discussion: Operating procedures must be developed, maintained, and implemented to ensure that irradiators are used only as they were designed to be used, and radiation doses received by occupational workers and members of the public are ALARA. Copies of operating procedures should be provided to all irradiator operators. In addition, the applicant must post current copies of operating procedures applicable to licensed activities at each site. If posting of procedures is not practicable, the licensee may post a notice which describes the documents and states where they may be examined.

Improper operation could lead to the damage or malfunction of an irradiator and potentially lethal radiation overexposures to individuals. The applicant will provide summaries of the written operating procedures describing their important radiation safety aspects. The level of detail should be sufficient to demonstrate that regulatory requirements have been addressed.

Table 8.7 lists the procedures that must be developed, maintained, and implemented, as well as important radiation safety aspects that should be submitted in the application.

Table 8.7 Operating Procedures

Required Procedures	Items to be Addressed in Procedures Summary
Operation of the irradiator, including entering and leaving the radiation room	The procedure summary should be detailed enough to show how the licensee will comply with 10 CFR 36.67, "Entering and Leaving the Radiation Room," and should describe the initial entry and survey after an irradiation. Describe how the applicant will prevent access to keys by individuals who have not been qualified to be operators, as required by 10 CFR 36.51(a). For panoramic irradiators, when product movement is occurring, the summary should address the required presence (10 CFR 36.65, "Attendance During Operation,") of an irradiator operator and another person who is trained on how to respond and prepared to render or summon assistance if the access alarm sounds. For static irradiations (no movement of product), a person who is trained to respond to alarms must be onsite.‡
Use of personnel dosimeters	See "Radiation Safety Program - Occupational Dosimetry"
Surveying the shielding of panoramic irradiators	See "Facilities and Equipment - Shielding"
Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas	See "Facilities and Equipment - Radiation Monitors"
Leak testing of sources	See "Model Leak Test Program for Dry-Source-Storage Irradiator Sealed Sources," Appendix M
Inspection and maintenance checks required by 10 CFR 36.61, "Inspection and Maintenance"	See "Radiation Safety Program - Inspection and Maintenance Checks"
Loading, unloading, and repositioning sources, if the operations will be performed by the licensee	If these procedures will be performed by the applicant, see Appendix G.
Inspection of movable shielding required by 10 CFR 36.23(h), if applicable.*	Describe inspection of roof plugs or other movable shielding required by 10 CFR 36.23(h), if applicable.*

‡ In 10 CFR 36.65, the term "onsite" is intended to give flexibility to licensees. For example, for a research irradiator at a university, the person onsite could be a guard located on campus but not in the building containing the irradiator, provided the guard would hear the alarm and was trained as required by 10 CFR 36.51(g). The guard would not have to be trained as an irradiator operator.

* If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an *operating procedure requiring inspection of shielding before operating.*

Normally, the manufacturer or a person specifically authorized by the NRC or an Agreement State will perform nonroutine operations involving source loading, unloading and repositioning, troubleshooting the control console, clearing stuck source racks, investigating and remediating removable contamination or leaking sources, (re)installing source cables, and other critical operations requiring special skills or the potential for radiation overexposures. If these operations are not performed properly with attention to good radiation safety principles, the irradiator may not operate as designed and personnel performing the operations could receive potentially lethal exposures. If the applicant wishes to perform nonroutine operations, the information in Appendix G should be provided.

Repair and Preventive Maintenance

Applicants are not required to submit outlines of maintenance, service, and repair procedures with a license application. However, routine preventive maintenance and repairs should be done according to the manufacturer's written instructions, where applicable, by qualified licensee personnel using their knowledge, experience, judgment, and skills to respond to each particular situation.

Improper repairs or maintenance not being performed in a timely fashion was identified as a contributing cause of many incidents. Therefore, malfunctions and defects found during inspection and maintenance checks must be repaired *without undue delay*. It is understood that it may be necessary to obtain a special part, piece of equipment, or particular skilled type of labor that may not be readily available. Licensees are allowed some flexibility in making *noncritical* repairs. As long as a reasonable effort is made, the licensee will meet the intent of the requirement. However, some repairs are *critical* and *not* subject to the latitude in 10 CFR 36.61(b). For example, licensees must make repairs to the access control system before operating the irradiator to ensure compliance with 10 CFR 36.23.

Preventive maintenance should be performed according to the manufacturer's written instructions. If the manufacturer's written instructions are not available, the applicant should perform a review of the systems comprising the irradiator in consultation with knowledgeable individuals and determine and implement an appropriate schedule for preventive maintenance.

Security of Licensed Material

Security of NRC-licensed materials is a priority of the NRC. A licensee that fails to comply with applicable security requirements may be subject to enforcement action. Although it is generally difficult to access sealed sources used in most 10 CFR Part 36 irradiators, the applicant should develop, maintain, and implement procedures to prevent unauthorized access, removal, or use of the licensed material. Also, procedures should require that all areas associated with irradiator operations, particularly control and interlock systems, be locked and secured against unauthorized access.

See Section 8.10.13, “Security Program,” for more information about an irradiator security program.

Revision of Procedures

The licensee may revise operating procedures without NRC approval only if all of the following conditions are met:

- The revisions do not reduce the safety of the facility.
- The revisions are consistent with the procedure summary submitted with the license application.
- The revisions have been reviewed and approved by the RSO.
- The users or operators are instructed and tested on the revised procedures before they are put into use.

Response from Applicant:

For routine operations: Provide operating procedure summaries describing the radiation safety aspects for those items listed in 10 CFR 36.53(a). For items in which other sections of this guide are referenced, respond to the applicable section.

For nonroutine operations: Submit either of the following:

- A statement that: “The irradiator manufacturer or other person authorized by the NRC or an Agreement State will perform non-routine operations such as source loading, unloading and repositioning, electrical troubleshooting of the control console, clearing stuck source racks, investigating and remediating removable contamination or leaking sources, (re)installing source cables, and other critical operations requiring special skills or the potential for radiation overexposures.”

OR

- The information listed in Appendix G supporting a request to perform this work “in-house.”

Note: Information requested in Appendix G will be reviewed on a case-by-case basis; if approved, the license will contain a condition authorizing the licensee to perform nonroutine operations.

Reference: See IN 83-09: “Safety and Security of Irradiators,” dated March 9, 1983, IN 04-18, “Recent Safety-Related Event at Panoramic Wet-Source-Storage Irradiator,” dated October 26, 2004.

8.10.7 Procedure for Identifying and Reporting Defects and Non-Compliance as Required by 10 CFR Part 21

Regulations: 10 CFR Part 21, 10 CFR 30.50, 10 CFR 36.83

Criteria: Licensees must notify NRC if defects and failures are found in a basic component that could create a substantial safety hazard.

Discussion: Equipment defects that could create a substantial safety hazard, or equipment failures involving NRC-regulated activities must be reported to the NRC. For example, a failure of an access control system such that a person could enter the radiation room during a time when the sources are exposed in a panoramic irradiator, or a defect in an interlock that prevents the operation of a panoramic irradiator in the event a roof plug or other movable shielding is not in place. Operating personnel should be instructed to report any malfunction or defect in irradiator equipment to management so that management can take appropriate action, and make the required notifications to the NRC or appropriate regulatory authority.

Response from the Applicant: None required.

8.10.8 Emergency Procedures

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201-2207, 10 CFR 21.21, 10 CFR 30.50, 10 CFR 36.13(c), 10 CFR 36.37(c), 10 CFR 36.53, 10 CFR 36.67, 10 CFR 36.83

Criteria: The licensee must have and follow emergency or abnormal event procedures, appropriate for items listed in 10 CFR 36.53(b). Emergency procedures should include notifying the NRC during and after emergencies and abnormal events.

Discussion: Emergency procedures must be developed, maintained, and implemented to ensure that radiation doses received by occupational workers and members of the public during an emergency or abnormal events are ALARA. Copies of emergency procedures should be provided to all irradiator operators. In addition, the applicant must post current copies of emergency procedures applicable to licensed activities at each site. If posting of procedures is not practicable, the licensee may post a notice which describes the documents and states where they may be examined.

In accordance with 10 CFR 36.13(c), the applicant must provide an outline of written emergency procedures describing important radiation safety aspects. The level of detail should be sufficient to demonstrate that regulatory requirements have been addressed.

Figure 8.9 illustrates proper handling of one type of incident (i.e., broken source rack cable).

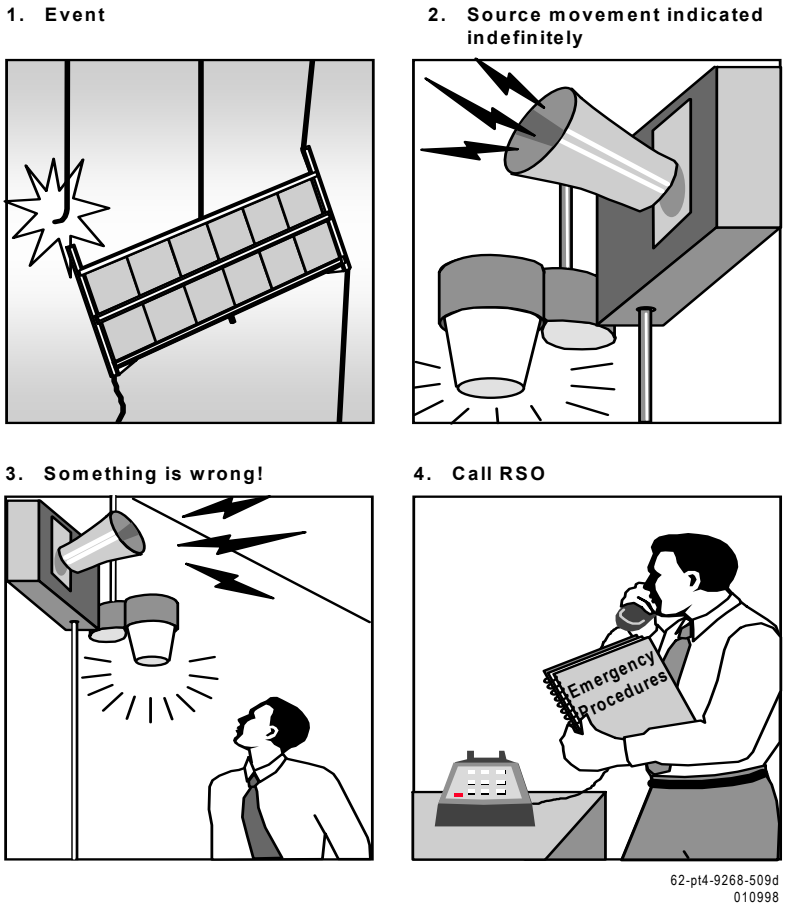

Figure 8.9 Proper handling of an incident

Licensee personnel implement emergency procedures when a source rack cable breaks.

Licensees must have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

- sources stuck in the unshielded position
- personnel overexposures
- a radiation alarm from the product exit portal monitor or pool monitor
- detection of leaking sources, pool contamination, or alarm caused by contamination of pool water (include 10 CFR 36.59(c) requirements)
- a low- or high-water level indicator, an abnormal water loss, or leakage from the source storage pool
- a prolonged loss of electrical power (include 10 CFR 36.37, “Power Failures,” and 10 CFR 36.67(c) requirements)

- a fire alarm or explosion in the radiation room
- an alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area
- natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility
- the jamming of automatic conveyor systems

The applicant should consider other events that may require emergency or abnormal event procedures (e.g., abnormally high radiation levels indicated by the area radiation monitor, collision with the source(s) or source rack).

Emergency and abnormal event procedures should include who will be notified of the event, the role of the RSO, and what records of the event will be kept. The procedures should clearly identify telephone numbers of the RSO or other individuals who can provide assistance including the irradiator manufacturer (or distributor) and State and local agencies. The procedures should include actions to be taken immediately after discovering the emergency or abnormal event. Emergency procedures should also include notifying the NRC when events specified in Table 8.8 shown below occur.

The RSO should be proactive in evaluating whether NRC notification is required. Refer to Table 8.8 shown below and the regulations (10 CFR 20.2201-20.2207, 10 CFR 30.50, "Reporting Requirements," and 10 CFR 36.83, "Reports") for descriptions of when and where notifications are required.

Table 8.8 Typical NRC Incident Notifications Required for Irradiator Licensees

Event Telephone Notification and Written Report Regulatory Requirement			
	Telephone report	Written report	
Theft or loss of material	immediate	Within 30 days	10 CFR 20.2201(a) & (b)
Whole body dose greater than 0.25 Sv (25 rems) per event	immediate	Within 30 days	10 CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Sv (250 rems) per event	immediate	Within 30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)

Event Telephone Notification and Written Report Regulatory Requirement			
	Telephone report	Written report	
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	Within 24 hours	Within 30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	Within 24 hours	Within 30 days	10 CFR 20.2202(b)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv (5 rems) in a year	none	Within 30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv (100 mrems) in a year	none	Within 30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	Within 2 days	Within 30 days	10 CFR 21.21(d)(3)(i) & (ii)
Filing petition for bankruptcy under Title 11 of the United States Code	none	immediately after filing petition	10 CFR 30.34(h)
Expiration of license	none	Within 60 days	10 CFR 30.36(d)(1)
Decision to permanently cease licensed activities at entire site	none	Within 60 days	10 CFR 30.36(d)(2)
Decision to permanently cease licensed activities in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	Within 60 days	10 CFR 30.36(d)(2)
No principal activities conducted for 24 months at the entire site	none	Within 60 days	10 CFR 30.36(d)(3)
No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	Within 60 days	10 CFR 30.36(d)(4)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	Within 30 days	10 CFR 30.50(a)

Event Telephone Notification and Written Report Regulatory Requirement			
	Telephone report	Written report	
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	Within 24 hours	Within 30 days	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	Within 24 hours	Within 30 days	10 CFR 30.50(b)(4)

Note: Telephone notifications shall be made to the NRC Operations Center at (301) 816-5100 or by facsimile to (301) 951-0550.

Emergency procedures generally should not include post-emergency corrective actions and repairs since there will be time to carefully consider such actions on a case-by-case basis after the situation is under control.

Emergency procedures for personnel overexposures, fire alarms, explosion in the radiation room, and natural phenomena may involve emergency responders outside the applicant's organization. The applicant should inform and train individuals in these organizations regarding the unique concerns and hazards associated with emergencies at the irradiator facility. For instance, hospitals should be informed about the different radiation accidents that could occur at the facility (i.e., overexposure vs. personnel contamination incident).

The licensee may revise emergency procedures without NRC approval only if all of the following conditions are met:

- The revisions do not reduce the safety of the facility.
- The revisions are consistent with the procedures submitted with the license application.
- The revisions have been reviewed and approved by the RSO.
- The users or operators are instructed and tested on the revised procedures before they are put into use.

Response from Applicant: Provide emergency procedures or summaries, as requested, describing the radiation safety aspects for those items listed in 10 CFR 36.53(b).

8.10.9 Leak Tests

Regulations: 10 CFR 36.59, 10 CFR 36.81(h), 10 CFR 36.83

Criteria: The NRC requires testing to determine whether there is any radioactive leakage from the sources in the irradiator. Records of the test results must be maintained.

Discussion:

Dry-Source-Storage Sealed Sources

Each dry-source-storage sealed source must be tested for leakage at 6-month intervals. 10 CFR 36.59(a) prohibits sources from being used unless the licensee tests the sources for leaks or has a certificate from a transferor that leak tests have been performed within 6 months before the transfer.

The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 200 becquerels (0.005 microcurie)[7] of radioactivity and must be performed by a person approved by the NRC or an Agreement State to perform the analysis. In general, the sensitivity required can be obtained with a thin-window G-M probe.

Manufacturers, consultants, and other organizations may be authorized by the NRC or an Agreement State to either perform the entire leak test sequence (sample collection and analysis) for other licensees or provide leak test kits (sample collection kit) to dry-source-storage licensees. In the latter case, the licensee is expected to take the leak test sample according to the irradiator manufacturer's (or distributor's) and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. See Figure 8.10 below. Licensees may also be authorized to conduct the entire leak test sequence themselves. Appendix M contains a model leak test program.

[7] 10 CFR Part 36 uses one significant figure in converting becquerels to microcurie.

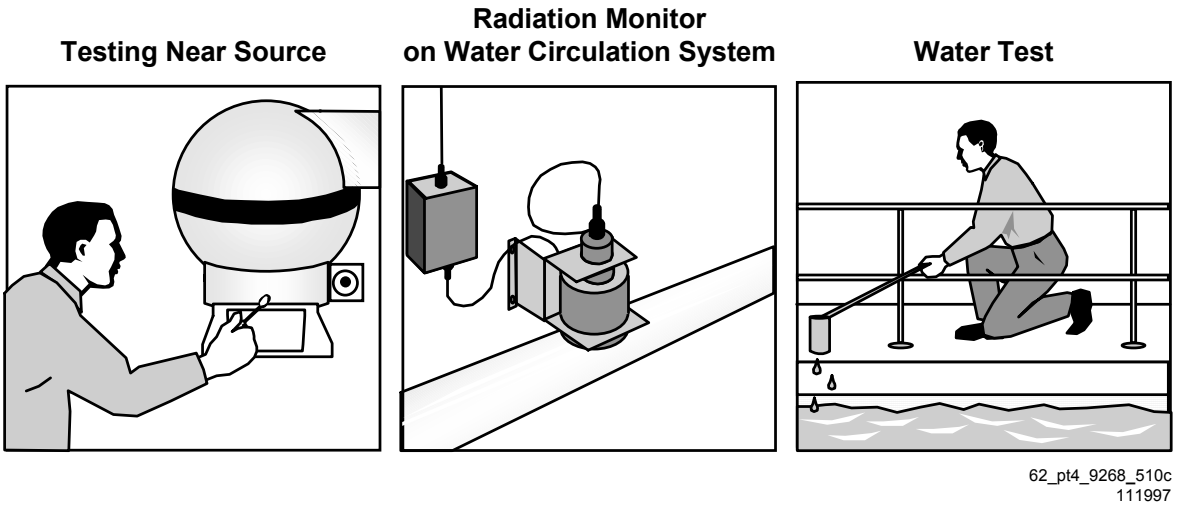

Figure 8.10 Leak testing

The panel on the far left illustrates leak testing a dry-source-storage irradiator source, while the other two panels illustrate two ways of monitoring pool water to determine if wet-source-storage sources are leaking.

Pool Irradiators

For pool irradiators, 10 CFR 36.59(b) prohibits sources from being put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak tests have been performed within 6 months before the transfer. After placing sources in the pool, the water must be checked for contamination each day the irradiator operates. For pool irradiators, leak testing sources by wipe testing is not highly sensitive or effective. The check may be done either by using a radiation monitor on a pool water circulating system or by analyzing a sample of pool water. If analyzing a sample of pool water, the results must be available within 24 hours. Whether the applicant desires to check for contamination by analyzing a pool water sample daily or by continuous monitoring, the procedures and sensitivity of the equipment to be used should be detailed in the application. If collecting a pool sample, use a sensitive detector, such as a sodium iodide detector, to verify the absence of detectable contamination in the sample. If using the continuous monitoring method, applicants may use a less sensitive detector such as a G-M detector affixed to a filter or demineralizer where radioactive material would be concentrated.

If the licensee detects a leaking source, the licensee must promptly check personnel, equipment, facilities, and irradiated products for contamination. If any personnel or product are found to be contaminated, decontamination must be performed immediately. If a source is found to be leaking, the licensee must arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. If the pool is contaminated, the licensee must arrange to clean the pool until the concentration levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations

(DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to 10 CFR Part 20. See 10 CFR 30.50 for reporting requirements.

Upon detection of leaking sources, licensees should consider immediately stopping irradiator operations to minimize the spread of contamination. In addition, the licensee must make a telephone report within 24 hours as described in 10 CFR 30.50(c)(1), followed by a written report within 30 days as described in 10 CFR 30.50(c)(2).

Response from Applicant:

For dry-source-storage irradiators: Submit one of the following three alternatives:

- A statement that, "Leak tests will be performed at intervals not to exceed 6 months. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by the NRC or an Agreement State to provide leak test kits to other licensees and according to the irradiator manufacturer's (or distributor's) and kit supplier's instructions. Records of leak test results will be maintained."

OR

- A statement that, "We will implement the model leak test program published in Appendix M to the current version of NUREG-1556 Volume 6, 'Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses,'"

OR

- A description of alternative equipment and procedures for determining whether there is any radioactive leakage from sources contained in the irradiator.

For pool irradiators: Submit either of the following:

- A description of equipment, procedures, and sensitivity of method that will be used to check for contamination by *analysis of a sample* of pool water.

OR

- A description of equipment, procedures, and sensitivity of method that will be used to check for contamination by *continuous monitoring.*

Note: Requests for authorization to perform leak testing and sample analysis will be reviewed and, if approved, NRC staff will authorize these requests via a license condition.

8.10.10 Inspection and Maintenance Checks

Regulations: 10 CFR 20.1101, 10 CFR 36.13(c) and (h), 10 CFR 36.53(a)(6), 10 CFR 36.61

Criteria: The applicant must have and follow written procedures for inspection and maintenance checks for items specified in 10 CFR 36.61.

Discussion: Applicants must periodically make inspection and maintenance checks to ensure proper operation of the irradiator. The frequency of checks is not stated in the regulations because it will be site-specific depending on the design of the facility. However, the frequency of checks must be specified in the application. In the applicant's description of the procedures, specify the inspection and maintenance check frequency of the following items:

- operability of each aspect of the access control system required by 10 CFR 36.23
- functioning of the source position indicator as required by 10 CFR 36.31(b)
- operability of the radiation monitor for radioactive contamination in pool water required by 10 CFR 36.59(b), using a radiation check source, if applicable
- operability of the over-pool radiation monitor at underwater irradiators as required by 10 CFR 36.29(b)
- operability of the product exit monitor required by 10 CFR 36.29(a)
- operability of the emergency source return control required by 10 CFR 36.31(c)
- leak-tightness of systems through which pool water circulates (visual inspection)
- operability of the heat and smoke detectors and extinguisher system required by 10 CFR 36.27 (but without turning extinguishers on)
- operability of the means of pool water replenishment required by 10 CFR 36.33(c)
- operability of the indicators of high and low pool water levels required by 10 CFR 36.33(d)
- operability of the intrusion alarm required by 10 CFR 36.23(i), if applicable
- functioning and wear of the system, mechanisms, and cables used to raise and lower sources
- condition of the barrier to prevent products from hitting the sources or source mechanism as required by 10 CFR 36.35
- amount of water added to the pool to determine whether the pool is leaking
- electrical wiring on required safety systems for radiation damage

- pool water conductivity measurements as required by 10 CFR 36.63

The applicant should keep in mind that these are the minimum items to be checked based on requirements in 10 CFR 36.61, and that the licensee should develop and implement procedures for other necessary checks as appropriate (e.g., as recommended by the manufacturer). For instance, if applicable, the applicant should have and follow written procedures for inspection and maintenance checks to ensure that all product positioning system components, product boxes, or carriers continue to meet design specifications and are not likely to cause an irradiator malfunction.

Response from Applicant: Describe inspection and maintenance checks, including the frequency of the checks, listed in the "Discussion" section (10 CFR 36.61).

8.10.11 Transportation

Regulations: 10 CFR 71.5, 10 CFR 71.17, 10 CFR 71.19, 10 CFR 71.21, 10 CFR 71.37, 10 CFR 71.38, Subpart H of 10 CFR Part 71, 49 CFR Parts 171-178, 10 CFR 20.1101, 10 CFR 30.41, 10 CFR 30.51

Criteria: Applicants must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with NRC and DOT regulations.

Discussion: The general license in 10 CFR 71.17, "General License: NRC-approved Package," and 10 CFR 71.21, "General License: Use of Foreign Approved Package," provides

the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Regulations in 10 CFR 71.17 contain the general license provisions for NRC-approved packages. Regulations in 10 CFR 71.21 contain the general license provisions for packages approved in a foreign national competent authority certificate. Transporting licensed materials originating at irradiator facilities normally involves quantities of radioactive material that require a Type B package. Because of the special requirements involved in shipping Type B packages, most irradiator licensees have chosen to transfer possession of radioactive materials to an irradiator manufacturer (or service provider licensee) with an NRC or Agreement State license that then acts as the shipper. The manufacturer (or service provider licensee) subject to the provisions of 10 CFR 71.17 or 10 CFR 71.21, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations. Licensees that do this must ensure that the manufacturer (or service provider licensee):

- is authorized to possess the licensed material at temporary job sites (i.e., at the irradiator location)
- actually takes possession of the licensed material under its license
- uses an approved Type B package
- is registered with the NRC as a user of the Type B package

- has an NRC-approved quality assurance (QA) plan.

For each shipment, it must be clear who possesses the licensed material and is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

If a licensee plans to make shipments of licensed materials in Type B packages on its own, the licensee must notify the NRC before the first use of an approved package (user registration) and have an NRC-approved QA plan, incorporating two of the requirements under the 10 CFR 71.17 general license. For information about QA plans, see Revision 2 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," (issued March 2005). The guide can be found under "Regulatory Guides" on the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/. For further information about registering as a user of a package or submitting a QA program for review, contact the NRC's Office of Nuclear Material Safety and Safeguards, Division of Spent Fuel Storage and Transportation by calling the NRC's toll free number 1-800-368-5642. For information about any associated fees, contact the NRC's Office of the Chief Financial Officer, by calling the NRC's toll free number 1-800-368-5642 and asking for extension 415-7554.

During an inspection, the NRC uses the provisions of 10 CFR 71.5, "Transportation of Licensed Material," and a "Memorandum of Understanding with DOT on the Transportation of Radioactive Material" (signed June 8,1979) to examine and enforce various DOT requirements applicable to irradiator licensees. The MOU between the NRC and DOT can be found on the NRC public Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance. Appendix N lists major DOT regulations applicable to the shipment and transportation of radioactive material.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials on its own in Type B packages, a licensee must ensure that it is in compliance with the general license requirements in 10 CFR 71.17. Transportation issues will be reviewed during inspection.

References: "Radioactive Material (RAM) Regulations Review 2008" can be found on DOT's Pipeline and Hazardous Materials Safety Administration public Web site at http://phmsa.dot.gov/hazmat.

8.10.12 Minimization of Contamination

Regulations: 10 CFR 20.1406.

Criteria: Applicants for new licenses must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities so as to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during

decontamination. Irradiator applicants usually do not need to address these issues as a separate item since they are included in responses to other items of the application.

Sealed sources and devices that are approved by the NRC or an Agreement State and located and used according to their respective SS&D registration certificates usually pose little risk of contamination. Leak tests performed as specified in 10 CFR 36.59, "Detection of Leaking Sources," should identify defective sources. Leaking sources must be withdrawn from use and decontaminated, repaired, or disposed of according to NRC requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant: The applicant does not need to provide a response to this item under the following condition. The NRC will consider that the above criteria have been met if the applicant's responses meet the criteria for the following sections: "Radioactive Material - Sealed Sources and Devices," "Facilities and Equipment - Irradiator Pools" (if applicable), "Radiation Safety Program - Operating Procedures," "Radiation Safety Program - Emergency Procedures," "Radiation Safety Program - Leak Tests," and "Waste Management - Sealed Source Transfer and Disposal."

8.10.13 Security Program

Regulations: 10 CFR 20.2207, 10 CFR Part 37

Criteria: Licensees must ensure the security and control of licensed 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

8.11.1 Sealed Source Disposal and Transfer

Regulations: 10 CFR 20.2001, 10 CFR 20.2207, 10 CFR 30.41, 10 CFR 30.51, 10 CFR 30.36, 10 CFR 36.59

Criteria: Licensed materials must be disposed of according to NRC requirements by transfer to an authorized recipient. Appropriate records must be maintained.

Discussion: When disposing of sealed sources or contaminated items (caused by leaking sources), licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer (or distributor) of the sources, a commercial firm licensed by the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., its license specifically authorizes the same radionuclide, form, and use).

If a product of the irradiator that may have been inadvertently contaminated has been shipped, the licensee must arrange for locating and surveying the product for contamination. If contaminated equipment, facilities, or products are found, the licensee must arrange to have them decontaminated or properly disposed of by an NRC or Agreement State licensee authorized to provide these services. If the pool is contaminated, the licensee must arrange to clean up the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B to 10 CFR Part 20 (10 CFR 36.59(c)).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the methods described in 10 CFR 30.41, "Transfer of Byproduct Material." In addition, all packages containing radioactive sources must be prepared and shipped according to NRC and DOT regulations. Furthermore, if source activity exceeds activities listed in Appendix E, "Nationally Tracked Source Thresholds," to 10 CFR Part 20, the transfer transaction must be reported in accordance with 10 CFR 20.2207. Records of the transfer must be maintained as required by 10 CFR 30.51, "Records."

Response from Applicant: The applicant does not need to provide a response to this item during the licensing process. However, the licensee should establish and include waste disposal procedures in its radiation safety program and a decommissioning funding plan and cost estimate, if applicable. These issues will be addressed during inspection.

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

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

8.12 Item 12: Fees

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

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

8.13 Item 13: Certification

Individuals acting in a private capacity are required to date and sign NRC Form 313. Otherwise, a representative of the corporation or legal entity filing the application must sign and date NRC Form 313 and include his or her title. 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 the management's commitment to and responsibility for the radiation protection program. The NRC will return all unsigned applications for proper signature.

Notes:

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

9. AMENDMENTS AND RENEWALS TO A LICENSE

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

Applicants for license amendment or renewal should do the following:

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

9.1 Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b)

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

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

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

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

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

10. APPLICATIONS FOR EXEMPTIONS

Regulations: 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 30.11, 10 CFR 36.17

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 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"; and 10 CFR 36.17, "Applications for 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.

The Regulations in 10 CFR 36.17(b) permits teletheraphy licensees to propose alternatives to the requirements of 10 CFR Part 36 provided that there is an adequate rationale and that the alternatives provide an adequate level of safety for workers and the public.

For converted teletherapy units, Appendix O lists specific sections of the regulations, the rationale and acceptable alternatives, and the wording of the license condition granting the exemption. The regions may grant exemption requests shown in Appendix O without consulting the Office of Federal and State Materials and Environmental Management Programs (FSME).

Exemption requests other than those described in Appendix O must be coordinated with FSME.

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)

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 cease licensed activities permanently at the entire site.

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

  – No principal activities having been conducted at the entire site under the license for a period of 24 months.

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

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

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

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

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

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

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."

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 AND LIST OF NRC INFORMATION NOTICES PERTAINING TO PART 36 IRRADIATORS

Regulatory Guides

NUREG-1345 "Review of Events at Large Pool-Type Irradiators," March 1989.

NUREG-1757 "Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees: Final Report," Volume 1, Revision 2, September 2006.

NUREG-1757 "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness: Final Report," Volume 3, September 2003.

NUREG-2155 "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material", February 2013

Information Notices (INs)

IN 83-09 "Safety and Security of Irradiators," March 9, 1983.

IN 85-01 "Continuous Supervision of Irradiators," January 10, 1985.

IN 85-36 "Malfunction of a Dry-Storage, Panoramic, Gamma Exposure Irradiator," May 9, 1985.

IN 89-25 "Unauthorized Transfer of Ownership or Control of Licensed Activities," Rev. 1, December 7, 1994.

IN 89-82 "Recent Safety-Related Incidents at Large Irradiators," December 7, 1989.

IN 91-14 "Recent Safety-Related Incidents at Large Irradiators," March 5, 1991.

IN 94-89 "Equipment Failures at Irradiator Facilities," December 28, 1994.

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

IN 96-54 "Vulnerability of Stainless Steel to Corrosion When Sensitized," October 17, 1996.

IN 97-30 "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," June 3, 1997.

IN 04-13 "Registration, Use, and Quality Assurance Requirements for NRC-Certified Transportation Packages," June 30, 2004 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML041810535).

IN 04-18 "Recent Safety-Related Event at Panoramic Wet-Source-Storage Irradiator," October 26, 2004.

IN 11-11 “Reporting Requirement for Heat and Smoke Detector Failure,” April 27, 2011.

NRC Information Notices (IN) can be found under “Generic Communications” at: http://www.nrc.gov/reading-rm/doc-collections/.

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/nrc313.pdf

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. maximum amount which will be possessed at any one time.

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

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING 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 COMMISSION FORM 313

Item No.	Title and Criteria	Yes	Description Attached
5	**RADIOACTIVE MATERIAL**		
	Sealed Sources and Devices		
	• Identify each radionuclide that will be used in each irradiator.		[ ]
	• Identify the manufacturer (or distributor) and model number of each sealed source.		[ ]
	• Identify the manufacturer (or distributor) and model number of each irradiator, if applicable.		[ ]
	• Specify the maximum activity per source.		[ ]
	• Specify the maximum activity per irradiator.		[ ]
	• If depleted uranium is used as shielding material, specify the total amount (in kilograms).		[ ]
	Financial Assurance and Recordkeeping for Decommissioning		
	• If financial assurance is required (possession greater than 10,000 curies cobalt-60 or 100,000 curies cesium-137), submit documentation required by Title 10 of the Code of Federal Regulations (10 CFR) 30.35, "Financial Assurance and Recordkeeping for Decommissioning." (NUREG-1757, Volume 3, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," provides further guidance on the types of financial assurance instruments that the U.S. Nuclear Regulatory Commission (NRC) finds acceptable.)		[ ]

Item No.	Title and Criteria	Yes	Description Attached
6	**PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED** Provide either of the following: • A specific description of use for each type of irradiator requested (e.g., for use in irradiation of products or food). There will be no irradiation of explosives and no irradiation of more than small quantities of flammable materials with a flash point below 60 degrees Celsius © (140 degrees Fahrenheit (F)) without specific written authorization from the NRC." **OR** • If the irradiator will be used for purposes other than irradiation of food or products for human or research purposes, description of these purposes and safety analyses (and procedures, if needed) to support safe use.		[ ] [ ]
7	**INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM** **Radiation Safety Officer (RSO)** **Training and Experience** • State the name of the proposed RSO. • Describe the proposed RSO's training and experience specific to the irradiator that the applicant intends to use. **Responsibilities and Authorities** • Describe the organizational structure for managing the irradiator. • Specify the radiation safety responsibilities and authorities of the RSO. • Specify other management personnel who have important radiation safety responsibilities and authorities. • Describe who has the authority to stop unsafe operations.		[ ] [ ] [ ] [ ] [ ] [ ]

Item No.	Title and Criteria	Yes	Description Attached
8	**INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS**		
	Initial Training for Irradiator Operators		
	• Before using licensed materials, irradiator operators will have successfully completed one of the training courses described in criteria in the section entitled, "Initial Training for Irradiator Operators," in the current version of NUREG-1556, Vol. 6.	[ ]	
	AND		
	• Provide a description of the initial training program for irradiator operators that demonstrates compliance with the requirements of 10 CFR 36.51(a), (b), and (c).		[ ]
	Annual Training Regarding Safety Reviews for Irradiator Operators		
	• Describe the program for annual safety reviews and performance evaluations of irradiator operators that demonstrates compliance with 10 CFR 36.51(d) and (e).		[ ]
	Training for Individuals Who Require Unescorted Access		
	• The applicant's program for instructing and testing unescorted individuals (other than irradiator operators) will be examined during inspections, but should not be submitted in the license application.	N/A	N/A
	Training for Individuals Who Must be Prepared To Respond to Alarms		
	The applicant's program for instructing and testing, as applicable, individuals designated to respond to alarms will be examined during inspections, but should not be submitted in the license application.	N/A	N/A

Item No.	Title and Criteria	Yes	Description Attached
9	**FACILITIES AND EQUIPMENT**		
	General Description		
	• Describe the irradiator design by including information, diagrams, sketches, and photographs, as appropriate.		[ ]
	• Show locations of safety-related equipment and features as required in 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators."		[ ]
	• Provide a construction schedule for the irradiator, as applicable, and updates as necessary.		[ ]
	• Describe the site-specific testing frequency of all systems listed in 10 CFR 36.61, "Inspection and Maintenance."		[ ]
	Access Control		
	• Submit specific information describing the access control system sufficient to demonstrate compliance with the requirements of 10 CFR 36.23, "Access Control." Applicants should submit specific drawings or sketches, as appropriate.		[ ]
	• For panoramic irradiators, describe the facility alarm systems.		[ ]
	• For panoramic irradiators, describe the lock and key system for controlling source movement and discuss how it meets the requirements of 10 CFR 36.31(a).		[ ]
	• Describe the site-specific testing frequency of access control systems.		[ ]
	Shielding for Panoramic Irradiators		
	• Describe the shielding to be used and its composition.		[ ]
	• Submit a diagram showing the configuration of shielding, including walls and the ceiling, and indicate the thickness of each and penetrations in the shielding		[ ]
	• If any accessible areas outside the shield are expected to have a dose rate exceeding 0.02 millisieverts (mSv) (2 millirem (mrem)) per hour, identify the areas and tell how access to those areas will be controlled.	N/A	[ ]
	• For requests to possess more than 2 x 10^{17} becquerels (5,000,000 curies), submit an evaluation of the effects of heating of the shield walls by the irradiator sources (see 10 CFR 36.39(a).		[ ]
	• Describe the site-specific testing frequency of the irradiator shielding.		[ ]
	Note: For underwater irradiators, no response is required from the applicant in a license application.		N/A

Item No.	Title and Criteria	Yes	Description Attached
9	**FACILITIES AND EQUIPMENT *(Cont'd)***		
	Fire Protection for Panoramic Irradiators		
	Describe:		
	• Type and location of the heat and smoke detectors to be used to detect a fire in the radiation room.		[ ]
	• Alarms to alert personnel who will be trained to summon assistance.		[ ]
	• How the sources will automatically become fully shielded if a fire is detected.		[ ]
	• How the heat and smoke detectors will be tested and the site-specific testing frequency.		[ ]
	***Note*:** For an underwater irradiator, no response is required since the sources are always underwater and not subject to damage by fire.	N/A	N/A
	Radiation Monitors		
	• Describe the location and type of radiation monitors that will be used to meet the requirements of 10 CFR 36.23(c), 10 CFR 36.29, "Radiation Monitors," and 10 CFR 36.59(b).		[ ]
	• Describe the location and types of alarms and those individuals who are trained to respond to those alarms. Use diagrams and sketches, as appropriate.		[ ]
	• Discuss the alarm set-points or the methods for establishing the alarm set-points.		[ ]
	• For all irradiators, describe the evaluation performed to meet 10 CFR 36.39(e) on detector location and sensitivity and the acceptance testing that will be performed to meet 10 CFR 36.41(e).		[ ]
	• Describe the site-specific testing frequency of radiation monitors.		[ ]

Item No.	Title and Criteria	Yes	Description Attached
9	**FACILITIES AND EQUIPMENT *(Cont'd)***		
	Irradiator Pools		
	Describe:		
	• The water-tight stainless pool liner. (If no water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool is used, explain why the pool has a low likelihood of substantial leakage and how decontamination could be accomplished, if necessary.)		[ ]
	• The high and low water-level indicators and their locations.		[ ]
	• The purification system for the pool and explain why the purification system is considered capable of maintaining pool water conductivity less than 20 microsiemens per centimeter		[ ]
	• The means to replenish pool water.		[ ]
	• The barrier used during normal operations to prevent personnel from falling into the pool.		[ ]
	• How high radiation doses from radiation streaming will be avoided when using long-handled tools or poles (use sketches if appropriate).		[ ]
	• If the pool has outlets more than 0.5 meters below the surface that could allow water to drain out of the pool, the means of preventing inadvertent excessive loss of pool water (in this context outlets do not include transfer tubes between adjacent pools because the transfer tubes do not provide a means to allow water to drain out of the pools).		[ ]
	• Describe the site-specific testing frequency of multiple regulatory required systems as listed in 10 CFR 36.61.		[ ]

Item No.	Title and Criteria	Yes	Description Attached
9	**FACILITIES AND EQUIPMENT *(Cont'd)***		
	Source Rack		
	• Submit procedures for ensuring source rack protection and testing frequency of the source rack protection system. If the product moves on a product conveyer system, describe the source rack protection to be provided to prevent products and product carriers from touching the source rack or mechanism that moves the rack. Provide diagrams or sketches of those systems, if appropriate.		[ ]
	Power Failures for Panoramic Irradiators		
	• Describe how the sources are automatically returned to the shielded position if offsite power is lost for longer than 10 seconds.		[ ]
	• Describe how loss of power will affect the lock on the doors in the radiation room.		[ ]
	• Describe how the licensee will ensure that the access control system will operate properly if offsite power is lost. Describe how the licensee will ensure that computer security features prevent an irradiator operator from commanding the computer to override the access control system.		[ ]
	• Describe the site-specific testing frequency to ensure that sources are returned to the shielded position if offsite power is lost for longer than 10 seconds.		[ ]
	Note: For underwater irradiators, no response is required from the applicant in a license application.	N/A	N/A
10	**RADIATION SAFETY PROGRAM**		
	Audit Program	Need not be submitted with application	
	The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections, but should not be submitted in the license application.		

Item No.	Title and Criteria	Yes	Description Attached
10	**RADIATION SAFETY PROGRAM**		
	Instruments		
	Survey Instruments		
	State the following:	[ ]	
	• We will use survey instruments that meet the criteria in the section entitled "Radiation Safety Program - Instruments" in the current version of NUREG-1556, Vol. 6, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses."		
	AND ONE OF THE FOLLOWING	[ ]	
	• Each survey meter will be calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations.		
	OR	[ ]	
	• We will implement the model survey meter calibration program published in Appendix J entitled "Model Survey Instrument Calibration Program" in the current version of NUREG-1556, Vol.6.		[ ]
	OR		
	• Submit alternative calibration procedures for NRC review.		[ ]
	OR, IN LIEU OF ALL OF THE ABOVE, SUBMIT		
	• A description of an alternative method to perform surveys pursuant to 10 CFR 20.1501, "General.".		[ ]
	Radiation Monitors		
	• Describe the type of monitors used to meet the requirements of 10 CFR 36.23(c), 10 CFR 36.29, "Radiation Monitors," and 10 CFR 36.59(b).		

Item No.	Title and Criteria	Yes	Description Attached
10	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Material Accountability** • Submit a description of procedure(s) for ensuring material accountability.		[ ]
	Occupational Dosimetry The applicant's occupational dosimetry program required by 10 CFR Parts 20, "Standards for Protection Against Radiation," and 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators," will be examined during inspection, but should not be submitted in a license application.	Need not be submitted with application	
	Public Dose The applicant's program to control doses received by individual members of the public will be examined during inspection, but should not be submitted in a license application.	Need not be submitted with application	
10	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Operating Procedures** **Routine Operations** • Provide operating procedures summaries describing the radiation safety aspects for those items listed in 10 CFR 36.53(a). **Non-Routine routine Operations** Submit either of the following: • The irradiator manufacturer or other person authorized by NRC or an Agreement State will perform non-routine operations such as source loading, unloading and repositioning, electrical troubleshooting of the control console, clearing stuck source racks, investigating/ and remediating removable contamination/ or leaking sources, (re)installing source cables, and other critical operations requiring special skills or having the potential for radiation overexposures.	[ ]	[ ]

Item No.	Title and Criteria	Yes	Description Attached
	OR • The information listed in Appendix H in the current version of NUREG-1556, Volume 6. **Emergency Procedures** • Provide emergency procedures summaries describing the radiation safety aspects for those items listed in 10 CFR 36.53(b).		[ ] [ ]
10	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Leak Tests** **For Dry-Source-Storage Irradiators** Provide one of the following three alternatives: • Leak tests will be performed at intervals not to exceed 6 months. Leak tests will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by the NRC or an Agreement State to provide leak test kits to other licensees and according to the irradiator manufacturer's (or distributor's) and the kit supplier's instructions. Records of leak test results will be maintained. **OR** • We will implement the model leak test program published in Appendix M in the current version of NUREG-1556, Vol. 6. **OR** • A description of alternative equipment and/or procedures for determining whether there is any radioactive leakage from sources contained in the irradiator.	[ ] [ ]	[ ]

Item No.	Title and Criteria	Yes	Description Attached
10	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Leak Tests** **For Pool Irradiators** Submit either of the following: • A description of equipment, procedures, and the capability to detect the contamination of the pool water in accordance with 10 CFR 36.59(b) by *analysis of a sample of pool water*.		[ ]
	OR		
	• A description of equipment, procedures, and the capability to detect the contamination of the pool water in accordance with 10 CFR 36.59(b) by *continuous monitoring*.		[ ]
	Inspection and Maintenance Describe inspection and maintenance checks, including the frequency of the checks, listed in 10 CFR 36.61.		[ ]
	Transportation No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials on its own in Type B packages, a licensee must ensure that it is in compliance with the general license requirements in 10 CFR 71.17. Transportation issues will be reviewed during inspection.	Need not be submitted with application	

Item No.	Title and Criteria	Yes	Description Attached
10	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Minimization of Contamination** No response need be submitted and the NRC will consider that the criteria have been met if the applicant's responses meet the criteria for the following sections: "Radioactive Material - Sealed Sources and Devices," "Facilities and Equipment - Irradiator Pools" (if applicable), "Radiation Safety Program - Operating Procedures," "Radiation Safety Program - Emergency Procedures," "Radiation Safety Program - Leak Tests," and "Waste Management - Sealed Source Transfer and Disposal."	Need not be submitted with application	
10	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Security Program** 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	
11	**WASTE MANAGEMENT** **Sealed Source Disposal and Transfer** The applicant does not need to provide a response to this item during the licensing process. However, the licensee should establish and include waste disposal procedures in its radiation safety program.	Need not be submitted with application	

APPENDIX D

IRRADIATION OF EXPLOSIVE MATERIALS OR GREATER THAN SMALL QUANTITIES OF FLAMMABLE MATERIALS

Explosive Materials

Irradiation of explosive materials is prohibited under 10 CFR 36.69, "Irradiation of explosive or flammable materials," unless the applicant has received prior written authorization from the U.S. Nuclear Regulatory Commission (NRC). If an applicant requests authorization to irradiate explosive materials, he or she must be able to demonstrate that detonation of the explosive would not rupture the irradiator sealed sources, injure personnel, damage safety systems, or cause radiation overexposure of personnel.

Greater Than Small Quantities of Flammable Materials

Prior written authorization from the NRC is required by 10 CFR 36.69(b) before irradiation of more than small quantities of flammable materials with a flash point below 60 degrees Celsius (C) (140 degrees Fahrenheit (F) in a panoramic irradiator. As defined in the National Fire Code NFPA 30, "Flammable and Combustible Liquids Code," published by the National Fire Protection Association (NFPA),[6] the flash point is "the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid…" According to the NFPA 30 classification system, Class I and Class II liquids have flash points below 60 degrees C (140 degrees F). The flash points of many substances are tabulated in NFPA 325, "Fire Hazard Properties of Flammable Liquids, Gases, and Volatile Solids."[8] Flash points are also specified on the material safety data sheets for industrial chemicals, when applicable. Examples of common flammable liquids with a flash point below 60 degrees C (140 degrees F) are acetone, benzene, most alcohols, number two fuel oil, gasoline, kerosene, toluene, turpentine, and any flammable gas.

The NRC is concerned about irradiating flammable materials that may cause an explosion. If the flash point of a flammable liquid is exceeded, the concentration of the vapor in air could exceed the flammable limit and the potential for an explosion could exist.

The NRC considers that compliance with the requirements in 10 CFR 36.21, "Performance Criteria for Sealed Sources," 10 CFR 36.27, "Fire Protection," 10 CFR 36.35," Source Rack Protection," 10 CFR 36.39(h), 10 CFR 36.41(h), and 10 CFR 36.53(b)(7) will provide adequate protection against radiological impacts arising from a fire. With an energetic explosion, however, applicants should consider the possibility of direct damage to the source encapsulation or to the source rack preventing it from being lowered to the shielded position.

A "small quantity" of flammable material can be defined as a quantity of flammable material that, when dispersed evenly throughout the radiation room with no loss to ventilation, would have a concentration below the lower flammable limit concentration. Although local concentrations could exceed the average room concentration, the movement of air into and out of the radiation room provides a margin of safety. In addition, the time required to vaporize all the material also adds to the margin of safety. Further, small pockets of flammable vapor will contain quantities of energy too small to provide a force strong enough to significantly damage the irradiator. Given these factors, the definition of small quantity is considered to be conservative enough to ensure safe operation of an irradiator.

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[8] Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169 7471 (Telephone No. 1-800-344-3555).

Special precautions must be taken when irradiating cryogenic material. The hazard from cryogenic irradiation occurs when air condenses or freezes (possibly insidiously without detection) on cold surfaces during irradiation. While the exact details are uncertain, oxygen in the air is converted by the radiation to ozone. Under certain circumstances (often during a subsequent warmup), the ozone decomposes or reacts with other agents explosively. If cryogenic material is to be irradiated, the applicant must submit procedures for ensuring the safe handling of such material.[9]

Example of determining a small quantity of flammable material:

This example considers the irradiation of isopropyl alcohol in a radiation room whose total volume is 100 m^3. NFPA 325 states that the lower flammable limit at atmospheric temperature and pressure for isopropyl alcohol is 2 percent by volume, the specific gravity of the liquid is 0.8, and the vapor density relative to that of air is 2.1. The density of air is 1.293 kilograms (kg) per millimeters cubed(m/3) ($kg/m^{3)}$. The volume of isopropyl alcohol in the room at the lower flammable limit will be 2 percent of 100 m^3, which is equal to 2 m^3. The weight will be $2m^3$ x 1.293 kg/m^3 x 2.1 (density relative to air) = 5.43 kg. With a specific gravity of 0.8, the volume of the liquid isopropyl alcohol would be 6.79 liters. If the liquid mixture were 70 percent isopropyl alcohol and 30 percent water, the volume of a small quantity would be 6.79/0.7 = 9.7 liters. Thus, in a radiation room with a volume of 100 m^3, a volume less than 9.7 liters of 70 percent isopropyl alcohol (exposed to the direct radiation beam) can be considered a small quantity because the flammable limit could not be reached in any significant volume, even if there were no ventilation.

If the applicant irradiates small quantities of flammable material, the licensee's records should demonstrate that the above criterion for small quantities has been met, including how the licensee limited the quantity of flammable material in the radiation room at one time.

If the quantity to be exposed to the direct beam at any one time would exceed a small quantity, it is necessary to consider whether the concentration of flammable vapor in the room air could exceed the lower flammable limit. If product movement through the irradiator stopped, and the radiation sources could not be returned to the shielded position, the temperature of the irradiated product would rise. This could cause the vapor pressure of the flammable material to increase, and that pressure might cause the containers to leak and release flammable vapor into the room air. If ventilation were insufficient, the flammable vapor concentration might exceed the lower flammable limit and a spark could cause the mixture to explode.

Requests for approval to irradiate more than small quantities of flammable material:

The applicant must demonstrate that it is unlikely that the concentration of flammable vapor in the air in a significant volume of the room would exceed the lower flammable limit. There are two methods to do this. The first method requires demonstrating that no single failure would be likely to cause the product to become immobilized in the radiation room and prevent the sources from being returned to the shielded position. Such a situation theoretically might arise if the product carriers became jammed and pushed into the source rack preventing its return to the

[9] This information was taken from Oak Ridge National Laboratory Report ORNL/M-260, DE87 002877, "Safety Analysis Report for the National Low-Temperature Neutron Irradiation Facility (NLTNIF) at the ORNL Bulk Shielding Reactor (BSR)," June 1986.

shielded position. The second method is to demonstrate that even if the product became immobilized and the source rack could not be returned to the shielded position, the ventilation system would prevent the concentration of flammable vapor in a significant volume of the room air from reaching the lower flammable limit.

If an applicant is applying for authorization to irradiate more than a small quantity of flammable material, the application should include all of the following information:

- name of the flammable material that has a flash point below 60°C (140°F) and its flash point
- its flammable limit as percent by volume in air
- its specific gravity as a liquid
- its vapor density relative to that of air
- maximum quantity to be in the direct radiation beam in the radiation room at any one time
- description of the packaging for the product

In addition, the application should:

EITHER

Describe why a single failure is unlikely to cause immobilization of the product being irradiated with the simultaneous inability to return the sources to the shielded position.

OR

Describe why the ventilation system will prevent the concentration of vapor in air from exceeding the lower flammable limit in a significant volume of the room if the product is immobilized and the sources cannot be returned to the shielded position. If this second approach is taken, the applicant should also provide a procedure to return the source to the shielded position and remove the product from the radiation room if the ventilation system fails. The procedure should identify the means to detect ventilation system failure.

APPENDIX E

TRAINING FOR RADIATION SAFETY OFFICERS AND IRRADIATOR OPERATORS

Course Content

Didactic training for radiation safety officers (RSOs) will be provided by a qualified instructor and may be in the form of lecture, videotape, or self study emphasizing the following practical subjects important to safe use of irradiators:

- Principles of radiation safety (20 hours):
  - radioactivity and radioactive decay
  - interactions of radiation with matter
  - external radiation vs. radioactive contamination
  - internal vs. external exposure
  - biological effects of radiation (e.g., why large radiation doses must be avoided)
  - units of radiation dose
  - types and relative hazards of radioactive material possessed
  - as low as is reasonably achievable (ALARA) concept
  - use of time, distance, and shielding to minimize exposure (e.g., how shielding and access controls prevent large doses)
  - radiation detection and measurement using survey meters, monitors and personnel dosimeters
- Regulatory requirements (20 hours):
  Applicable regulations (i.e., Title 10 of the *Code of Federal Regulations* (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 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators.")
  - NRC dose limits
  - license conditions, amendments, renewals
  - locations of use and storage of radioactive materials
  - material control, accountability, and security requirements
  - annual audit of radiation safety program
  - transfer and disposal

- record keeping
- case histories of accidents or problems involving irradiators
- handling incidents
- recognizing and ensuring that radiation warning signs are visible and legible
- licensing and inspection by regulatory agency
- need for complete and accurate information (10 CFR 30.9, “Completeness and Accuracy of Information”)
- employee protection (10 CFR 30.7, “Employee Protection”)
- deliberate misconduct (10 CFR 30.10, “Deliberate Misconduct”)

- Practical explanation of the theory and operation of irradiators (40 hours):
  - basic function of the irradiator
  - radiation safety features of an irradiator (including alarms)
  - operating and emergency procedures, which the individual is responsible for performing
  - routine vs. nonroutine maintenance
  - lock-out procedures
  - how an irradiator is designed to prevent contamination

- On-the-job training for an RSO also should include at least 3 months (full-time equivalent) of experience at the applicant’s irradiator or at another irradiator of a similar type. The 3 months of experience may include preoperational involvement, such as acceptance testing, while the irradiator is being constructed.

Course Examination

- Written examination designed to verify an individual’s competency and understanding of the subject matter (e.g., 25 to 50 questions, closed-book written test with 80 percent as the passing grade).

Training for Irradiator Operators

Course Content

Didactic training for operators will be provided by a qualified instructor and may be in the form of lecture, videotape, or self study emphasizing the following practical subjects important to safe use of irradiators:

- Radiation safety (20 hours):
  - external radiation vs. radioactive contamination
  - internal vs. external exposure
  - biological effects of radiation (e.g., why large radiation doses must be avoided)
  - units of radiation dose
  - types and relative hazards of radioactive material possessed
  - ALARA concept
  - use of time, distance, and shielding to minimize exposure (e.g., how shielding and access controls prevent large doses)
  - proper use of survey meters and personnel dosimeters.
- Regulatory requirements (20 hours):
  - applicable regulations
  - NRC dose limits
  - case histories of accidents or problems involving irradiators
  - handling incidents
  - recognizing and ensuring that radiation warning signs are visible and legible
- Practical explanation of the theory and operation of irradiators (40 hours):
  - basic function of the irradiator
  - radiation safety features of an irradiator
  - operating and emergency procedures which the individual is responsible for performing
  - routine vs. nonroutine maintenance
  - lock-out procedures
  - how an irradiator is designed to prevent contamination

Before an individual is permitted to operate an irradiator without a supervisor present, in accordance with 10 CFR 36.51(c) , the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and

emergency procedures that he or she is to perform. On-the-job or simulator training must be done under the supervision of a qualified irradiator operator:

- Supervised hands-on experience performing:
  - — operating procedures, which the individual is responsible for performing
  - — test runs of emergency procedures that the individual is responsible for performing
  - — routine maintenance
  - — lock-out procedures

Course Examination

- Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision. The written examination will be designed to verify an individual's competency and understanding of the stated subject matter (e.g., 25 to 50 questions, closed-book written test with 80 percent as the passing grade). In addition, the licensee shall conduct safety reviews for operators at least annually and each operator shall be given a brief written test.

Training Assessment

Management will ensure that potential RSOs and authorized operators are qualified to work independently with irradiators. This must be demonstrated by written examination and by direct observations.

Course Instructor Qualifications

Instructors should have either:

- bachelor's degree in a physical or life science or engineering,
- successful completion of an irradiator manufacturer's course for users (or equivalent),
- successful completion of a 40-hour radiation safety course, AND
- hands-on experience with irradiators of at least 40 hours.

OR

- successful completion of an irradiator manufacturer's course for users (or equivalent),
- successful completion of 40-hour radiation safety course, AND
- hands-on experience with irradiators for at least 12 months.

Note:

- Licensees must maintain records of training (10 CFR 36.81(b)).
- Additional training is required for those applicants intending to perform nonroutine operations, such as source loading and unloading. See Appendix G, “Information Needed to Support Applicant’s Request to Perform Nonroutine Operations.”

APPENDIX F

TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

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

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

- maintaining an up-to-date license and timely submission of amendment and renewal requests
- ensuring that when the licensee identifies violations of regulations or license conditions or program weaknesses, corrective actions are developed, implemented, and documented

Model Delegation of Authority

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

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

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

_____ _____
Signature of Radiation Safety Officer Date

cc: Affected department heads

APPENDIX G

INFORMATION NEEDED TO SUPPORT APPLICANT'S REQUEST TO PERFORM NONROUTINE OPERATIONS

Nonroutine operations may include, but are not limited to, the following:

- source loading, unloading, and repositioning
- troubleshooting the control console
- clearing stuck source racks
- investigating and remediating removable contamination and leaking sources
- (re)installing source cables
- any other activity during which personnel could receive radiation doses exceeding NRC limits.

If these operations are not performed properly with attention to radiation safety principles, the irradiator may not operate as designed and personnel performing these tasks could receive lethal radiation doses.

Applicants wishing to perform nonroutine operations must use personnel with special training and follow appropriate procedures consistent with the manufacturer's written instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, personnel dosimetry). Accordingly, provide the following information:

- Describe which nonroutine operations will be performed. The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.
- Identify who will perform nonroutine operations and their training and experience applicable to these operations. Acceptable training would include manufacturers' courses for nonroutine operations or equivalent.
- Submit procedures for nonroutine operations. These procedures should ensure the following:
  - Doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielding and adequate planning when working with unshielded sources).
  - Manufacturer's written instructions and recommendations are followed.
  - Planned special exposure requirements (Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1206, "Planned Special Exposures"), if applicable, are met.
  - Operations involving source loading, unloading, and repositioning include recording the rack position of each source and surveying all empty or loaded source transport containers for removable contamination to prevent the introduction of radioactive contaminants into the irradiator.

- Confirm that individuals performing nonroutine operations will wear whole body radiation dosimetry, if appropriate.

- Describe steps to be taken to ensure that radiation levels in areas where nonroutine operations will take place do not exceed the limits in 10 CFR 20.1301, "Dose Limits for Individual Members of the Public." For example, applicants can do the following:

  – Commit to performing surveys with a survey instrument.

  – Specify where and when surveys will be conducted during nonroutine operations.

  – Commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by 10 CFR 20.2103, "Records of Surveys."

APPENDIX H

CONSTRUCTION MONITORING AND ACCEPTANCE TESTING

To ensure that irradiators and their components are built and installed as designed, 10 CFR 36.41, “Construction Monitoring and Source Testing,” requires that licensees conduct monitoring and acceptance testing before loading sealed sources into an irradiator. Figure H.1 illustrates this point and Table H.1 correlates the components to be checked and the types of tests with the type of irradiator to which the requirement applies.

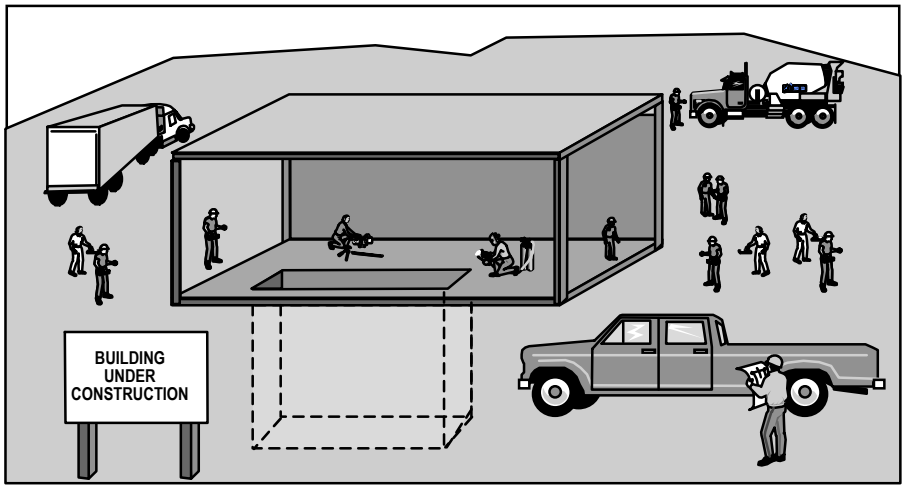

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Figure H.1 Construction monitoring and acceptance testing

Before loading sealed sources, irradiator licensees must ensure that the as-built irradiator meets design criteria.

Table H.1 Construction Monitoring and Acceptance Testing

Irradiator Elements	Irradiator Type	Licensee Requirement
Shielding	Panoramic	Monitor the construction of the shielding to ensure that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.
Foundations	Panoramic	Monitor the construction of the foundations to verify that their construction meets design specifications.
Pool integrity	Pool	Verify that the pool meets design specifications including requirements in 10 CFR 36.33(a) and test the integrity of the pool. Verify that outlets and pipes meet the requirements of 10 CFR 36.33(b).
Water handling system	Pool	Verify that the water purification system, the conductivity meter, and the water level indicators operate properly (water level controls should be checked, if installed).

Irradiator Elements	Irradiator Type	Licensee Requirement
Radiation monitors	All	Verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 10 CFR 36.29(a).
	Pool	Verify the proper operation of the radiation monitors and the related alarm if used to meet 10 CFR 36.59(b).
	Underwater	Verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 10 CFR 36.29(b).
Source rack	Panoramic	Test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power.
	Irradiator with product conveyor systems	Observe and test the operation of the conveyor system to ensure that the requirements in 10 CFR 36.35, "Source Rack Protection," are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.
Access control	Panoramic	Test the completed access control system to ensure that it functions as designed and that all alarms, controls, and interlocks work properly.
Fire protection	Panoramic	Test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee must test the operability of the fire extinguishing system. It is not necessary that licensees turn on extinguishers (i.e., water or chemicals) during tests of the operability of their fire protection systems.
Source return	Panoramic	Demonstrate that the source racks can be returned to their fully shielded positions without offsite power.
Computer systems	Panoramic, that use a computer system to control the access control system	Verify that the access control system will operate properly if offsite power is lost and verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.
Wiring	Panoramic	Verify that the electrical wiring and electrical equipment that were installed meet the design specifications (e.g., radiation-resistant wiring installed in appropriate locations and according to code).

APPENDIX I

SUGGESTED AUDIT CHECKLIST FOR 10 CFR PART 36 IRRADIATORS

Note: **All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit**. For example, licensees do not need to address areas which do not apply to their activities and activities which have not occurred since the last audit need not be reviewed at the next audit.

Licensee's name: _____ License No. _____

Date of This Audit _____

_____ Date _____
(Auditor Signature)

_____ Date _____
(Management Signature)

Audit History

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

B. Were previous audits conducted at intervals not to exceed at least every 12 months? (Title 10 to the *Code of Federal Regulations* (10 CFR) 20.1101, "Radiation Protection Programs.")

C. Were records of previous audits maintained? (10 CFR 20.2102, "Records of Radiation Protection Programs.")

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

E. Were corrective actions taken? (Look for repeated deficiencies).

Organization And Scope of Program

A. If the mailing address or places of use changed, was the license amended?

B. If ownership changed or bankruptcy was filed, was the U.S. Nuclear Regulatory Commission's (NRC's) prior consent obtained or was the NRC notified?

C. Radiation Safety Officer (RSO)

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

2. Does the new RSO meet the licensee's training requirements?

3. Is the RSO fulfilling his or her duties?

4. To whom does the RSO report?

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

E. Sealed Sources and Devices (SS&D)

1. Does the license authorize all of the regulated radionuclides contained in irradiators?

2. Have copies of (or access to) SS&D certificates been provided?

3. Are the sealed sources, and if applicable, devices in accordance with the description in SS&D registration certificates? (10 CFR 32.210, "Registration of Product Information.")

4. Are there manufacturers' manuals for operation and maintenance?

5. Are the actual uses of the irradiator consistent with the authorized uses listed on the license?

6. Are the sealed sources used under conditions specified in the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SS&D registration certificates?

F. Commensurate security program implemented

Training and Instructions to Workers

A. Were all workers who are likely to exceed 1 mSv (millisievert) (100 mrem) in a year instructed per (10 CFR 19.12, "Instructions to Workers"")? Refresher training provided, as needed? Records maintained?

B. Did each individual permitted to operate the irradiator without a supervisor present, receive instructions according to the license commitments and 10 CFR 36.51, "Training" before operating the irradiator?

C. Are records of training, tests, safety reviews, and annual evaluations maintained for each authorized irradiator operator? (10 CFR 36.81(b), (c))

D. Did individuals who perform nonroutine operations receive training before performing these operations?

E. Did interviews reveal that individuals know the emergency procedures?

F. Did this audit include observations of irradiator operations?

G. Do workers have familiarity with requirements for the following:

1. the radiation safety program
2. annual dose limits
3. Form NRC 4 and 5 (or equivalent)
4. 10 percent monitoring threshold
5. dose limits to embryo and fetus and declared pregnant worker
6. grave danger posting?

Radiation Survey Instruments and Radiation Monitors

A. Are all portable survey meters calibrated at least annually to an accuracy of ± 20 percent for the gamma energy of the sources in use? (10 CFR 36.57(c))

B. Are portable survey meters of a type that does not saturate and read zero at high dose rates? (10 CFR 36.57(c))

C. Are calibration records maintained?

D. Are all operable survey instruments able to detect 0.5 microsievert (0.05 mrem) per hour?

E. Has the licensee evaluated the location and sensitivity of the radiation monitor to detect sources carried by the product conveyor system for automatic conveyor systems? (10 CFR 36.29(a))

F. Has the licensee tested the operability and sensitivity of monitor used to detect the presence of high radiation levels in the radiation room before personnel entry at frequency specified in license application?

G. Has the licensee tested the operability and sensitivity of monitors used to detect contamination of pool water due to leaking sources? (Frequency of checks as specified in license application?)

H. For underwater irradiators not in a shielded radiation room, has the licensee tested the operability and sensitivity of monitors used to detect abnormal radiation levels? (Frequency of checks as specified in license application?)

Conductivity Meters

A. Are appropriate operable conductivity meters possessed and used?

B. Are conductivity meters calibrated at least annually? (10 CFR 36.63(b))

Sealed Source Accountability Program

A. Are records maintained showing the receipt, location, transfer, and disposal of each sealed source? (10 CFR 30.51(a)(1))

B. Is the material accountability program as described in the application being implemented?

C. Transactions entered into the National Source Tracking System, including annual reconciliation? (20.2207)

Personnel Radiation Protection

A. Are as-low-as-is-reasonably-achievable (ALARA) considerations incorporated into the radiation protection program? (10 CFR 20.1101(b))

B. Is documentation kept showing that unmonitored individuals receive ≤10 percent of the limit? (10 CFR 20.1502(a))

C. Did unmonitored individuals' activities change during the year that could put them over 10 percent of the limit?

D. If yes to C above, was a new evaluation performed?

E. Is external dosimetry provided to individuals, as required by 10 CFR 36.55, "Personnel Monitoring," and to individuals likely to receive >10 percent of the limit?

1. Irradiator operators: Is the dosimetry supplier National Voluntary Laboratory Accreditation Program," approved? (10 CFR 20.1501(c))

2. Are the dosimeters exchanged monthly for film badges and quarterly for thermoluminescence dosimeter?

3. Are dosimetry reports reviewed by the RSO upon receipt?

4. Are dosimeters provided to persons who enter the radiation room of a panoramic irradiator? (10 CFR 36.55(b))

5. Are annual checks of accuracy of pocket dosimeters performed? (10 CFR 36.55(b))

6. Are the records NRC forms or the equivalent? (10 CFR 20.2104(d), 10 CFR 20.2106(c))

   a. NRC Form 4 "Cumulative Occupational Exposure History" completed?

   b. NRC Form 5 "Occupational Exposure Record for a Monitoring Period" completed?

7. Declared pregnant worker, embryo, or fetus

a. If a worker declared her pregnancy, did the licensee comply with (10 CFR 20.1208, “Dose Equivalent to an Embryo/Fetus”)?

b. Were records kept of embryo/fetus dose per (10 CFR 20.2106(e))?

F. Are records of exposures, surveys, monitoring, and evaluations maintained (10 CFR 20.2102, “Records of Radiation Protection Programs,” 10 CFR 20.2103,”Records of Surveys,” 10 CFR 20.2106, “Records of Individual Monitoring Results,”, 10 CFR 36.57(a)]?

Public Dose

A. Is public access controlled in a manner to keep doses below 1 mSv (100 mrem) in a year? (10 CFR 20.1301(a)(1))

B. Has a survey or evaluation been performed according to 10 CFR 20.1501(a)? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

C. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour? (10 CFR 20.1301(a)(2))

D. Is access to sealed sources controlled in a manner that would prevent unauthorized use or removal? (10 CFR 20.1801)

E. Records maintained? (10 CFR 20.2103, 10 CFR 20.2107, “Records of Dose to Individual Members of the Public.”)

Operating and Emergency Procedures

A. Have operating and emergency procedures been developed? (10 CFR 36.53, “Operating and Emergency Procedures.”)

B. Do they addressthe required itemsin 10 CFR 36.53(b)?

C. Does each individual working with the sealed sources have access to a current copy of the operating and emergency procedures (including emergency telephone numbers)?

D. Did any emergencies occur?

1. If so, were they handled properly?

2. Were appropriate corrective actions taken?

3. Was NRC notification or reporting required? (10 CFR 20.2201, “Reports of Theft or Loss of Licensed Material,” 10 CFR 2202, “Notification of Incidents,” 10 CFR 2203, “Reports of Exposures, Radiation Levels, and Concentrations of

Radioactive Material Exceeding the Constraints or Limits," 10 CFR 30.50, "Reporting Requirements," and 10 CFR 36.83, "Reports.")

Leak Tests

A. Were sealed sources leak tested at prescribed intervals? (10 CFR 36.59, "Detection of Leaking Sources."

B. Was the leak test performed according to regulatory requirements? (10 CFR 36.59)

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

D. Were any sealed sources found leaking and, if yes, were appropriate actions taken and was the NRC notified? (10 CFR 20.2201,10 CFR 20.2203, 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect or its Evaluation," 10 CFR 30.50, 10 CFR 36.59, and 10 CFR 36.83)

Inspection and Maintenance Checks

A. Are all procedures for maintenance of the irradiator being followed where applicable?

B. Are all checks to determine proper functioning and wear of the source movement systems performed at frequencies as specified in the license application?

C. Are labels, signs, and postings clean and legible?

D. Are checks for operability as required by 10 CFR 36.61(a) (not included in item 4.) performed at frequencies and according to procedures described in the license application, including for:

1. Each aspect of the access control system

2. Emergency source return control

3. Heat and smoke detectors, extinguisher system

4. Pool water replacement system high and low water indicators

5. For underwater irradiators, was the intrusion alarm tested for operability? (Frequency of checks as specified in license application?)

E. Are checks for functioning and condition of equipment performed at required frequencies and according to procedures described in license application, including:

1. Assessment of the condition and operability of the source rack protector are performed at the required frequencies (10 CFR 36.61(a)).

2. Assessment of water added to the pool to determine if there is pool leakage are performed at required frequencies as required by (10 CFR 36.61(a)(14)).

3. Assessment of radiation damage to electrical wiring are performed at required frequencies as required by (10 CFR 36.61(a)(15)).

4. Water conductivity and analysis are performed at required frequencies (10 CFR 36.63).

5. Confirmation that water circulation system is leak tight. (10 CFR 36.61(a)(7)).

6. Functioning of the source position indicator (10 CFR 36.61(a)(2)).

7. Assessment of leak tightness of water circulation system, visual inspection (10 CFR 36.61(a)(7)).

Repair and Preventive Maintenance

A. Are repair and maintenance of components related to the radiological safety of the irradiator performed by the manufacturer or person specifically authorized by the NRC or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument, compliance with 10 CFR 20.1301, "Radiation Dose Limits for Individual Members of the Public," limits)?

B. Are malfunctions and defects found during inspection and maintenance checks are repaired without undue delay?

Transportation

Note: This section will not apply if you have not transported sealed sources during the period covered by this audit.

A. Were sources shipped since the last audit?

B. If so, were 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," requirements followed?

C. Were U.S. Department of Transportation Type A or Type B packages used? (10 CFR Part 71, 49 CFR 173.415, 49 CFR 173.416) If Type B, was the NRC certificate of compliance granted before shipment or shipper is registered as a user of the Type B package? Does the shipper have an NRC-approved quality assurance program?

D. Are the package performance test records on file? (49 CFR 173.415(a))

E. Is there special form sources documentation? (49 CFR 173.476(a))

F. Does the package have two labels (ex. Yellow II) with TI, Nuclide, Activity, and Hazard Class? (49 CFR 172.403, 49 CFR 173.441)

G. Is the package properly marked? (49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324)

H. Are packages closed and sealed during transport? (49 CFR 173.475(f))

I. Are shipping papers prepared, used, and maintained? [49 CFR 172.200(a))

J. Do shipping papers contain proper entries? (Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)) (49 CFR 172.200, 49 CFR 172.201, 49 CFR 172.202, 49 CFR 172.203, 49 CFR 172.204, 49 CFR 172.604)

K. Is the package secured against movement? (49 CFR 177. 834)

L. Is it placarded on vehicle, if needed? (49 CFR 172.504)

M. Are there proper overpacks, if used? (49 CFR 173.25)

N. Are any incidents reported to the U.S. Department of Transportation? (49 CFR 171.15, 49 CFR 171.16)

Auditor's Independent Survey Measurements

A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits (10 CFR 20.1501(a) and 10 CFR 1502(a))?

Notification and Reports

A. Was a telephone report made within 24 hours as described in 10 CFR 36.83(b),10 CFR 30.50(c)(1), and a written report within 30 days as described in 10 CFR 30.50(c)(2) of any of the following:

1. source stuck in an unshielded position
2. any fire or explosion in a radiation room
3. damage to the source rack
4. failure of the cable or drive mechanism used to move the source racks
5. inoperability of the access control system
6. detection of radioactive contamination attributable to licensed radioactive material
7. detection of radioactive contamination attributable to licensed radioactive material
8. structural damage to the pool liner or walls

9. abnormal water loss or leakage from the source storage pool

10. pool water conductivity exceeding 100 microsiemens per centimeter

B. Was any radioactive material lost or stolen? Were reports made? (10 CFR 20.2201, 10 CFR 30.50)

C. Did any reportable incidents occur? Were reports made? (10 CFR 20.2202, 10 CFR 30.50)

D. Did any overexposures and high radiation levels occur? Were they reported? (10 CFR 20.2203, 10 CFR 30.50)

E. If any events (as described in items A through C above) did occur, what was the root cause? Were corrective actions appropriate?

F. Is the management/RSO/shift foreman licensee aware of the telephone number for the NRC Emergency Operations Center? (301-816-5100)

Posting and Labeling

A. Is NRC Form 3 "Notice to Workers" posted? (10 CFR 19.11, "Posting of Notices to Workers.")

B. Are NRC regulations and license documents posted or a notice posted? (10 CFR 19.11, 10 CFR 21.6, "Posting Requirements.")

C. Is there other posting and labeling? (10 CFR 20.1902, "Posting Requirements," 10 CFR 20.1904, "Labeling Containers.")

Radiation dose rates in the radiation room of a panoramic irradiator room will exceed 500 rad (5 Gray) per hour when the sources are exposed. Therefore, the radiation room should be posted as a very high radiation area in accordance with 10 CFR 20.1902. Please note that the signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

Record Keeping for Decommissioning

A. Are records kept of information important to decommissioning? (10 CFR 30.35(g))

B. Do records include all information outlined in (10 CFR 30.35(g))?

Bulletins And Information Notices

A. Are NRC bulletins, NRC information notices, and Office of Federal and State Materials and Environmental Management Programs newsletters received?

B. Is appropriate training and action taken in response?

Special License Conditions or Issues

A. Did an auditor review special license conditions or other issues (e.g., nonroutine operations)?

Deficiencies Identified in Audit; Corrective Actions

A. Summarize problems or deficiencies identified during audit.

B. If problems or deficiencies are identified in this audit, describe corrective actions planned or taken. Are corrective actions planned or taken at ALL licensed locations (not just the location audited)? Include the date(s) when corrective actions are implemented.

C. Provide any other recommendations for improvement.

Evaluation of Other Factors

A. Is senior licensee management appropriately involved with the radiation protection program and radiation safety officer (RSO) oversight?

B. Does the RSO have sufficient time to perform his or her radiation safety duties?

C. Does the licensee have sufficient staff to support the radiation protection program?

APPENDIX J

MODEL SURVEY INSTRUMENT CALIBRATION PROGRAM

Training

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

- Classroom training may be in the form of lecture, videotape, or self study and will cover the following subject areas:
  - — principles and practices of radiation protection
  - — radioactivity measurements, monitoring techniques, and the use of instruments
  - — mathematics and calculations basic to using and measuring radioactivity
  - — biological effects of radiation
- On-the-job-training will be considered complete if the individual has:
  - — Observed authorized personnel performing survey instrument calibration, and
  - — Conducted survey meter calibrations under the supervision, and in the physical presence of, an individual already authorized to perform calibrations.

Facilities and Equipment

- 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.

Model Procedure for Calibrating Survey Instruments

1. A radioactive sealed source(s) will be used for calibrating survey instruments, and this source will:
   - approximate a point source
   - have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within ± 5 percent accuracy by the National Institutes of Standards and Technology
   - contain a radionuclide which emits photons of identical or similar energy as the sealed sources that the instrument will measure

- be strong enough to give an exposure rate of at least 30 mR/hour (7.7 microcoulomb/kilogram per hour) at 100 cm (e.g., 3.1 gigabecquerels) (85 millicuries) of cesium-137 or 780 megabecquerels (21 millicuries) of cobalt-60.

2. Inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.

3. A record must be made of each survey meter calibration.

4. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than ±20 percent.

5. There are three kinds of scales frequently used on radiation survey meters. They are calibrated as follows:

   - Meters on which the user selects a linear scale must be calibrated at not fewer than two points on each scale. The points will be at approximately 1/3 and 2/3 of the decade.

   - Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade.

   - Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

6. Readings above 200 mR/hour (50 microcoulomb/kilogram per hour) need not be calibrated. However, higher scales should be checked for operation and the approximately correct response.

7. Survey meter calibration reports will indicate the procedure used and the results of the calibration. The reports will include:

   - The owner or user of the instrument.

   - A description of the instrument that includes the manufacturer's name, model number, serial number, and type of detector

   - A description of the calibration source, including the exposure rate at a specified distance on a specified date, and the calibration procedure.

   - For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument.

- The exposure reading indicated with the instrument in the “battery check” mode (if available on the instrument).
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular).
- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument.
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure.
- The exposure rate from a check source, if used.
- The signature of the individual who performed the calibration and the date on which the calibration was performed.

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

- date of most recent calibration
- initials or other specific identifying mark of calibrator
- date that the primary calibration is again required
- special-use or limited calibration label (if applicable)
- serial number of the instrument or other unique identification number used by the facility to identify a specific instrument

References: Detailed information about survey instrument calibration may be obtained by referring to American National Standards Institute (ANSI) N323A-1997, “Radiation Protection Instrumentation Test and Calibration.” Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered online at http://www.ansi.org.

APPENDIX K

GUIDANCE FOR DEMONSTRATING THAT UNMONITORED INDIVIDUALS ARE NOT LIKELY TO EXCEED 10 PERCENT OF THE ALLOWABLE LIMITS

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the applicable regulatory limits in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201, "Occupational Dose Limits for Adults.". However, irradiator operators are required by 10 CFR 36.55(a) to wear a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. As discussed in Item 8.10.4, these personnel dosimeters may be film badges, thermoluminescence dosimeters (TLDs) or optically stimulated luminescence dosimeters. Also, other individuals who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be a pocket dosimeter. When groups of visitors enter the radiation room at least two people must wear dosimeters. In those instances where pocket chambers are used instead of film badges or TLDs, a check of the response of the dosimeters to radiation must be made at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose. To demonstrate that dosimetry is *not* required for other workers, a licensee needs to have available, for inspection, an evaluation to demonstrate that its workers are not likely to exceed 10 percent of the applicable annual limits.

The most common way that individuals might exceed 10 percent of the applicable limits is by performing work near the irradiator shield or areas of cable or equipment penetration of the shield of the irradiator. However, for most irradiators even these activities result in the individual receiving minimal doses. A licensee will need to evaluate the doses which its workers might receive in performing these tasks to assess whether dosimetry is required. The evaluation may be done by carefully measuring the dose rates when the source is in the irradiate position using techniques similar to those as described in Appendix L. An evaluation of the actual time workers spend in the area can provide the information needed to estimate the annual dose of the workers.

The applicable total effective dose equivalent (whole body) limit is 50 millisievert (mSv) (5 rems) per year and 10 percent of that value is 5 mSv (500 millirems) per year.

Example: A careful measurement of the highest dose rate at the face of the shield of a panoramic irradiator is found to be 0.015 mSv/hr (millisievert per hour) (1.5 mrem/hr). An individual is expected to spend no more than 3 hours per week in the area near the shield. Based on the dose rate, assuming the source is continuously in the irradiate position while the work is being performed, the annual dose is expected to be less than 2.34 mSv (234 mrem) (i.e., 3 hr/wk x 1.5 mrem/hr x 52 wk/yr). Based on the above specific information, no dosimetry is required if the individual performs work in the area less than 6.4 hours per week.

APPENDIX L

GUIDANCE FOR DEMONSTRATING THAT INDIVIDUAL MEMBERS OF THE PUBLIC WILL NOT RECEIVE DOSES EXCEEDING THE ALLOWABLE LIMITS

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) (100 millirem (mrem)) in one calendar year resulting from the licensee's possession and use of licensed materials.

Members of the public include persons who live, work, or may be near locations where an irradiator is used or where the sealed sources for the irradiator are stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or sources stored.

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

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials. However, the licensee may control access to these areas for other reasons such as security.

Licensees must show compliance with both portions of the regulation. For areas around irradiator facilities, a combination of calculations and measurements (e.g., using an environmental thermoluminesence dosimeter(TLD) or optically stimulated luminescence dosimeter (OSLD)) is often used to prove compliance.

Combined Measurement – Calculational Method[10]

These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making these measurements, and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2,080 hours (i.e., a "work year" of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

[10] For ease of use, the examples in this appendix use conventional units. The conversions to SI units are as follows: 1 ft = 0.305 m; 1 mrem = 0.01 mSv.

Licensees may also choose to use environmental TLDs[11] in unrestricted areas next to the irradiator area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

The combined measurement-calculational method may be used to estimate the maximum dose to a member of the public. Since Title 10 of the Code of Federal Regulations (10 CFR) Part 36, "Licenses and Radiation Safety Requirements for Irradiators," irradiators are designed so that the maximum dose rate in any public area is less than 0.02 mSv (2 mrem) in any one hour, the licensee will generally be able to show by calculation that the maximum dose to an individual will be less than the 1 mSv/yr (100 mrem/yr) limit. The combined measurement-calculational method takes a tiered approach, going through a two-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each irradiator is a point source, (2) typical radiation levels encountered when the source is in the unshielded position, and (3) no credit is taken for any shielding found between the irradiator shield and the unrestricted areas. The method is only valid for the source activity at the time of measurement and must be repeated if the source strength or shielding is changed.

Even though most large irradiators approximate a planar source, the results obtained from a point source assumption will be conservative and therefore may be used.

Part 1 of the combined measurement-calculational method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the irradiator and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

Example

To better understand the combined measurement-calculational method, we will examine Food-Safe, Inc., an irradiator licensee. Yesterday, the company's president noted that the shield of the new irradiator area is close to an area used by workers whose assigned duties do not include the use of licensed materials and he asked the radiation safety officer (RSO), to determine if the company is complying with NRC's regulations.

[11] TLDs and OSLDs used for personnel monitoring (e.g., lithium fluoride) may not have sufficient sensitivity for this purpose. For example, there may be a TLD with a minimum reportable level of 10 mrem that is used to monitor doses received, and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could reach 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs/OSLDs to evaluate compliance with the public dose limits, they should consult with their TLD/OSLD supplier and choose TLDs/OSLDs with a sufficient sensitivity, such as those that are used for environmental monitoring.

The area in question is near the wall, which constitutes the primary shield of the irradiator. The RSO measures the distance from the shield to the center of the area in question and, using a calibrated survey instrument, measures the highest dose rate at one foot from the shield, to be 2 mrem per hour.

Table L.1 summarizes the information the RSO has on the irradiator.

Table L.1 Information Known About Dose at the Shield of the Irradiator

Description of Known Information	Co-60 Panoramic Irradiator
Dose rate encountered at 1 foot from the face of the shield, in mrem/hr.	2 mrem/hr.
Distance from the face of the shield to the nearest occupied work area, in ft.	4 ft

Example: Part 1

The RSO's first thought is that the distance between the irradiator shield and the area in question may be sufficient to show compliance with the regulation in 10 CFR 20.1301, "Dose Limits for Individual Members of the Public." So, taking a worst case approach, he assumes: 1) the irradiator is constantly in use (i.e., 24 hr/d), and 2) the workers are constantly in the unrestricted work area (i.e., 24 hr/d). The RSO proceeds to calculate the dose the workers might receive hourly and yearly from the irradiator as shown in Table L.2 below.

Table L.2 Calculational Method,
Part 1: Hourly and Annual Dose Received from Irradiator

Step No.	Description	Input Data	Results
1	Multiply the measured dose rate measured at 1.0 ft from the face of the shield wall in mrem/hr by the square of the distance (ft) at which the measurement was made (e.g., 1 foot from the face of the shield)	$2 \times (1)^2$	2
2	Square of the distance (ft) from the face of the shield to the nearest unrestricted area, in ft^2	$(4)^2$	16
3	Divide the result of Step 1 by the result of Step 2 to calculate the dose received by an individual in the area near the shield. **HOURLY DOSE RECEIVED FROM IRRADIATOR**, in mrem in an hour	2/16	**0.125**
4	Multiply the result of Step 5 by 40 hr/work week x 52 weeks/year = **MAXIMUM ANNUAL DOSE RECEIVED FROM IRRADIATOR**, in mrem in a year	0.125 x 40 x 52	**260**

Note: The result in Step 3 demonstrates compliance with the 2 mrem in any one hour limit. Reevaluate if assumptions change. If the result in Step 4 exceeds 100 mrem/yr, proceed to Part 2 of the calculational method.

At this point, the RSO is pleased to see that the total dose that an individual could receive in any one hour is only 0.125 mrem in an hour, less than the 2 mrem in any one hour limit but notes that an individual could receive a dose of 260 mrem in a year, higher than the 100 mrem limit.

Example: Part 2

The RSO reviews the assumptions and recognizes that the workers are not in area near the shield all of the time. A realistic estimate of the number of hours the workers spend in the area is made, keeping the other assumptions constant (i.e., the irradiator is in constant use (i.e., 24 hours per day (hr/day)). The annual dose received is then recalculated.

Table L.3 Calculational Method,
Part 2: Annual Dose Received from a 10 CFR Part 36 Irradiator

Step No.	Description	Results
5	A. Average number of hours per day an individual spends in area of concern (e.g., a non-radiation worker spends 1.5 hr/day in the area near the shield; the remainder of the day the workers are away from the area assigned to jobs unrelated to radiation. (painting, groundskeeping, desk jobs, etc.)	1.5
	B. Average number of days per week in area	5
	C. Average number of weeks per year in area (e.g., full-time workers)	52
6	Multiply the results of Step 5.A. by the results of Step 5.B. by the results of Step 5.C. = **AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR**	1.5 x 5 x 52 = **390**
7	Multiply the results in Step **3** by the results of Step 6 = **ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN**, in mrem in a year	0.125 x 390 = **49**

The RSO is pleased to note that the calculated annual dose received is significantly lower, and does not exceed the 100 mrem in a year limit.

Since most irradiators are in use a majority of the time, and down time is usually unpredictable, generally no additional allowance for irradiator duty cycle is made.

The RSO is glad to see that the results in Step 7 show compliance with the 100 mrem in a year limit. Had the result in Step 7 been higher than 100 mrem in a year, then the RSO could have done one or more of the following:

- considered whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions

- calculated the effect of any shielding[12] located between the irradiator shield and the public area—such calculation is beyond the scope of this appendix
- taken corrective action (e.g., change work patterns to reduce the time spent in thearea near the shield) and perform new calculations to demonstrate compliance.

- designated the area inside the use area as a restricted area and the workers as occupationally exposed individuals. This would require controlling access to the area for purposes of radiation protection and training the workers as required by 10 CFR 19.12, "Instructions to Workers."

Note that in the example, the RSO evaluated the unrestricted area outside only one wall of the irradiator area. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the as low as reasonably achievable principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., adding sources to the irradiator, changing the work habits of the workers, or otherwise changing the estimate of the portion of time spent in the area in question) and to perform additional evaluations, as needed.

RECORDKEEPING: 10 CFR 20.2107, "Records of Dose to Individual Members of the Public," requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

[12] National Council on Radiation Protection and Measurements Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV," contains helpful information. It is available from NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814. NCRP's telephone numbers are: 301-657-2652 or 1-800-229-2652.

APPENDIX M

MODEL LEAK TEST PROGRAM FOR DRY-SOURCE-STORAGE IRRADIATOR SEALED SOURCES

Training

Before allowing an individual to perform leak testing, the radiation safety officer (RSO) will ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

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

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and the use of instruments
- mathematics and calculations basic to the use and measurement of radioactivity
- biological effects of radiation

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples.

- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests.

Facilities and Equipment

- To ensure achievement of the required sensitivity of measurements, leak tests will be analyzed in a low-background area.

- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.

- A NaI(Tl) well counter system with a single or multichannel analyzer will be used to count samples from sealed sources containing gamma-emitters (e.g., cesium-137, cobalt-160).

Frequency for Conducting Leak Tests of Sealed Sources

- Leak tests will be conducted at least every six months.

Model Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as serial number, radionuclide, and activity.

- Use an appropriately sensitive survey meter to monitor exposure.

- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.[13]

[13] Prepare one swipe per irradiator, if more than one source is contained in the same enclosure.

- Number each wipe to correlate with identifying information for each source.

- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.

- Select an instrument that is sensitive enough to detect 200 becquerels (0.005 microcurie) of the radionuclide.

- Using the selected instrument, count and record background count rate.

- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ±5 percent of the stated value and traceable to a primary radiation standard such as those maintained by the National Institutes of Standards and Technology

- Calculate efficiency.

  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 = Becquerel

- 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 three years.

- If the wipe test activity is 200becquerels (0.005 microcurie) or greater, notify the radiation safety officer, so that the source can be withdrawn from use and disposed of properly. Also notify NRC.

APPENDIX N

TRANSPORTATION

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

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

A. Table of Hazardous Materials and Special Provisions—49 CFR 172.101
   1. Title 49 of the Code of Federal Regulations (49 CFR) 172.101—Purpose and Use of Hazardous Materials Table

B. Shipping Papers
   1. 49 CFR 172.201—Preparation and Retention of Shipping Papers
   2. 49 CFR 172.202—Description of Hazardous Material on Shipping Papers
   3. 49 CFR 172.203—Additional Description Requirements
   4. 49 CFR 172.204—Shipper's Certification (if applicable)

C. Package Markings
   1. 49 CFR 172.301—General Marking Requirements for Non-Bulk Packages
   2. 49 CFR 172.304—Marking Requirements
   3. 49 CFR 172.310—Class 7 (radioactive) Materials
   4. 49 CFR 172.324—Hazardous Substances in Non-bulk Packaging (designation of "reportable quantities" with the letters "RQ")

D. Package Labeling
   1. 49 CFR 172.400(a)—General Labeling Requirements
   2. 49 CFR 172.403—Class 7 (radioactive) Material
   3. 49 CFR 172.406—Placement of Labels

E. Placarding of Vehicles
   1. 49 CFR 172.504—General Placarding Requirements
   2. 49 CFR 172.516—Visibility and Display of Placards
   3. 49 CFR 172.556—RADIOACTIVE Placard

F. Emergency Response Information
   1. 49 CFR 172.600—Applicability and General Requirements
   2. 49 CFR 172.602—Emergency Response Information
   3. 49 CFR 172.604—Emergency Response Telephone Number

G. Training
   1. 49 CFR 172.702—Applicability and Responsibility for Training and Testing (for HAZMAT employees)
   2. 49 CFR 172.704—Training Requirements (includes types of training, when it must be conducted, need for refresher training every three years, recordkeeping)

H. Safety and Security Plans
   1. 49 CFR 172.800—Purpose and Applicability
   2. 49 CFR 172.802—Components of a Security Program

I. Shippers—General Requirements for Shipments and Packaging
   1. 49 CFR 173.25—Authorized Packaging and Overpacks
   2. 49 CFR 173.403—Definitions
   3. 49 CFR 173.413—Requirements for Type B Packages
   4. 49 CFR 173.416—Authorized Type B Packages (includes packaging certification requirements)
   5. 49 CFR 173.441—Radiation Level Limitations and Exclusive Use Provisions
   6. 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission approved packages
   7. 49 CFR 173.476—Approval of Special Form Class 7 (radioactive) Materials (includes requirement for documentation of special form status)

J. Carriage by Public Highway
   1. 49 CFR 177.817—Shipping Papers (location of shipping papers during transport)
   2. 49 CFR 177.842—Class 7 (radioactive) Material (includes requirement for blocking and bracing during transport)

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

1. Minimum Required Packaging for Class 7 (Radioactive) Material[1] (49 CFR 173 and 10 CFR 71)[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.

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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.

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.

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

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

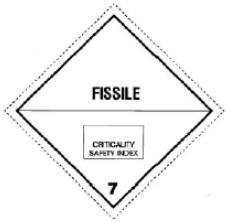
6. Hazard Communications for Class 7 (Radioactive) Materials:

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]			Other Labels[2]	
				
White-I	**Yellow-II**	**Yellow-III**	**Fissile**	**Empty**
Radiation Surface Level (RSL):			Fissile labels required for each package containing fissile material, other than fissile-excepted material; and labels must be affixed adjacent to radioactive category labels.	Empty labels required for shipments of empty Class 7 (radioactive) packages satisfying §173.428; and any previously-used labels cannot be visible
mSv/h: **RSL** ≤ 0.005	0.005 < **RSL** ≤ 0.5	0.5 < **RSL** ≤ 2[4]		
mrem/h: **RSL** ≤ 0.5	0.5 < **RSL** ≤ 50	50 < **RSL** ≤ 200[4]		
Transport Index (TI):[4]				
TI = 0[4]	0[4] < **TI** ≤ 1	1 < **TI** ≤ 10[4, 5]		

Contents on Labels

- Each radioactive category label must contain: (a) Except for LSA-I material, the names of the radionuclides in the package where, for mixtures of radionuclides, the names listed must be in accordance with the 95% rule specified in §172.433(g); and, for LSA-I material, the term "LSA-I"; (b) activity in appropriate SI units (*e.g.* Bq, TBq), or appropriate customary units (e.g. Ci, mCi) in parentheses following SI units; and (c) for Yellow-II or Yellow-III labels the Transport Index (TI). Abbreviations and symbols may be used. Except for Pu-239 and Pu-241, the weight in g or kg of fissile radionuclides may be inserted instead of activity units; for Pu-239 and Pu-241, the weight in g of fissile radionuclides may be inserted in addition to the activity units.
- Each fissile label must contain the relevant Criticality Safety Index (CSI).

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

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

[3] The category of the label must be the higher of the two values specified for RSL and TI; see §172.403(b).

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

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

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

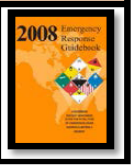
- Except for a road vehicle used solely for transporting Class 7 (radioactive) material, if radioactive material has been released in a road, rail, or air transport conveyance, the conveyance must be taken out of and remain out of service until the radiation dose rate at every accessible surface is less 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).

APPENDIX O

EXEMPTIONS FOR TELETHERAPY UNITS CONVERTED TO NONHUMAN USE

The following are technical justifications and commitments, which are acceptable to exempt licensees from specific sections of Title 10 of the Code of Federal Regulations (10 CFR) Part 36, "Licenses and Radiation Safety Requirements for Irradiators." The regions may grant the exemptions shown below without prior coordination with the Office of Federal and State Materials and Environmental Management Programs (FSME). Acceptable license conditions are also shown below.

1. 10 CFR 36.23(a) - "The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources."

   For converted teletherapy units, the use of a single key or even several keys on a key-ring may be impractical. The key switch on many control panels is a three-position switch, which controls electrical power to the teletherapy unit. The key can only be inserted and removed in the "off" position, and in this position the main power and control circuits are without electrical power. Power is required to conduct such activities as move collimators, activate field lights, and align systems.Requiring a single key would not allow the licensee to operate these powered systems.

   Therefore, a licensee may be exempted from this requirement, provided that the licensee commits to have the operator present for the entire period of time that the key is in the control panel.

   The following license condition should be used:

   > "Notwithstanding the requirements of 10 CFR 36.23(a), the licensee may use separate keys to operate the lock on the personnel entrance door or barrier and to move the sources in accordance with procedures described in the letter/application dated _____."

2. 10 CFR 36.23(b) - "Each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while sources are exposed."

   The licensee may be granted an exemption from this requirement provided that the licensee has an electrical interlock system meeting all of the conditions specified in 10 CFR 35.615(b) on each entrance to the radiation room. Alterations of the electrical interlocks of the teletherapy unit to meet the requirements of 10 CFR 36.23(b) may cause the interlock system to function incorrectly. A working electrical interlock system on each entrance suffices to prevent personnel entry while the source is exposed. The licensee should commit in its application to each of the conditions of 10 CFR 35.615(b). In addition, the licensee should commit to having an operator present during the entire irradiation who can visually observe the entrance, and to having a radiation monitor that can be read before entering the radiation area.

The following license condition should be used:

> "Notwithstanding the requirements of 10 CFR 36.23(b), the licensee is exempt from having an independent backup access control to detect personnel entry while sources are exposed based on the commitments described in the letter/application dated _____."

3. 10 CFR 36.23(c) - "The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high."

   Alteration of the interlock system to meet this requirement would prevent entry to the treatment room to remove a patient in the event of a stuck source. The region may grant the licensee an exemption from this requirement provided that the licensee has an electrical interlock system, which will retract the source, upon opening access doors to the radiation room and commits to its use. In addition, the licensee must commit to having an operator present and having a radiation monitor in the room as described above.

   The following license condition should be used:

> "Notwithstanding the requirements of 10 CFR 36.23(c), the licensee is exempt from having the monitor integrated with personnel access door locks to prevent room access when radiation levels are high based on the commitments described in the letter/application dated _____."

4. 10 CFR 36.23(d) - "Visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position."

   An acceptable justification is that an audible alarm within the treatment room may cause undue distress to non-human subjects. If the licensee commits to having a visual alarm provided on the outside of the treatment room, and to having the operator visually check the room before starting treatments, the regions may grant the licensee an exemption.

   The following license condition should be used:

> "Notwithstanding the requirements of 10 CFR 36.23(d), the licensee is exempt from having an audible alarm within the treatment area, based on the commitments described in the letter/application dated _____."

5. 10 CFR 36.23(f) - "Each radiation room at a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door…has been closed within a preset time…"

   Exemptions may be granted to licensees having teletherapy units that are being used for irradiation of materials only (no patients), provided that the licensee commits to the operator visually verifying that the room is not occupied before closing the door, and that the converted teletherapy unit (irradiator) activates a visual and audible alarm in the

teletherapy room for at least 15 seconds before moving the source from the shielded position. This visual or audible alarm must be interlocked with the teletherapy unit such that the source will not move to the exposed position until the visual or audible alarm has been activated and is finished alarming. The following license condition should be used:

> "Notwithstanding the requirements of 10 CFR 36.23(f), the licensee is exempt from having a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time based on the commitments described in the letter/application dated _____."

6. 10 CFR 36.27(a) - "The sources must automatically become shielded if a fire is detected."

10 CFR 36.27(b) - "The radiation room at a panoramic irradiator must be equipped with a fire extinguishing systems capable of extinguishing a fire without entry of personnel. The system must have a shutoff valve to control flooding into unrestricted areas."

The statements of consideration state that the purpose of the fire extinguishing system is to prevent a fire from damaging the access control system or preventing the sources from being shielded. Most converted teletherapy units are designed to retract the source when the electrical power fails, as may occur during a fire. The licensee may be granted an exemption from these requirements provided that the licensee commits to the following:

- having smoke detectors, fire extinguishers, and a fire alarm at the site to detect and fight small fires
- alerting authorities of the fire
- having a means of measuring the radiation levels in the radiation room during an electrical failure.
- instructing the operators to retract the source before exiting for a fire involving major portions of the facility, provided this action does not jeopardize the operator's safety.

The following license condition should be used:

> "Notwithstanding the requirements of 10 CFR 36.27(a) and (b), the licensee is exempt from (*as requested by the licensee*) based on the commitments described in letter/application dated _____."

7. 10 CFR 36.31(a) - "The key must be attached to a portable radiation survey meter by a chain or cable……The door to the radiation room must require the same key."

Converted teletherapy units require that the source activation key be inserted in the console to provide power to the unit to activate field lights and align the head. Therefore, the region may grant the licensee an exemption from this requirement

provided that the licensee commits to having administrative controls in place to ensure that personnel entering the radiation room use a portable survey meter to verify that the source has retracted. The licensee must also commit to attach the survey meter to the exposure room door key.

The following license condition should be used:

> "Notwithstanding the requirements of 10 CFR 36.31(a), the licensee is exempt from the requirement to have console key attached to a portable survey meter by a chain or cable and that the door to the radiation room require the same key, based on the commitments described in the letter/application dated _____. The radiation room door key shall be attached to the portable survey meter."

8. 10 CFR 36.31(b) - "The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in…transit."

   In converted teletherapy units the source is moved nearly instantaneously from the shielded to the exposed position. Most teletherapy units are designed with two indicator lights — green indicates the source is in the fully shielded position, red indicates the source is exposed. During transit both lights are "on" indicating that the source is in transit. To require that the licensee install an electronic system to indicate "in transit" for the period of time the source is in transit, less than a second, does not provide any additional protection. Therefore, the region may grant this exemption provided the licensee submits a description of its device indicators.

   The following license condition should be used:

   > "Notwithstanding the requirements of 10 CFR 36.31(b), the licensee is exempt from the requirement to have a separate position indicator to indicate when the source is in transit, in accordance with letter/application dated _____."

9. 10 CFR 36.67(b)(2) - "The irradiator operator…must activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control."

   Because of the risk of malfunction associated with alterations to the existing electrical interlocks of the teletherapy unit, and considering the licensee's commitment to administratively control access to the room to meet the intent of this regulation, the region may grant this exemption, if the licensee demonstrates that a retrofit to install such a control would not be possible with the teletherapy unit and a licensee commits to the following:

   The operator will close the doors immediately upon completion of the visual inspection required by 10 CFR 36.67(b)(1).

The operator will verify that each door has locked automatically before stepping to the control panel.

The following license condition should be used:

> "Notwithstanding the requirements of 10 CFR 36.67(b)(2), the licensee is exempt from the requirement to have a control in the radiation room which must be activated prior to irradiation which would not allow the source to be moved from the shielded position unless the door to the radiation room is locked within a preset time, based on the commitments described in the letter/application dated _____."

APPENDIX P

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.
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APPENDIX Q

SAFETY CULTURE STATEMENT OF POLICY

Safety Culture

The safety culture policy statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011 and can be found at: http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf. It is also posted in the U.S. Nuclear Regulatory Commission's (NRC's) Agencywide Documents Access and Management System (ADAMS) Accession No. ML11146A047.

Safety Culture Policy Statement

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

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

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

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

The following are traits of a positive safety culture:

(1) *Leadership Safety Values and Actions*—Leaders demonstrate a commitment to safety in their decisions and behaviors,

(2) *Problem Identification and Resolution*—Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance,

(3) *Personal Accountability*—All individuals take personal responsibility for safety,

(4) *Work Processes*—The process of planning and controlling work activities is implemented so that safety is maintained,

(5) *Continuous Learning*—Opportunities to learn about ways to ensure safety are sought out and implemented,

(6) *Environment for Raising Concerns*—A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination,

(7) *Effective Safety Communication*—Communications maintain a focus on safety,

(8) *Respectful Work Environment*—Trust and respect permeate the organization, and

(9) *Questioning Attitude*—Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

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

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

NRC FORM 335
(12-2010)
NRCMD 3.7

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER
(Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)
NUREG-1556, Volume 6, Revision 1
DRAFT

2. TITLE AND SUBTITLE
Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses (NUREG-1556, Volume 6, Revision 1) - Draft Report for Comment

3. DATE REPORT PUBLISHED

MONTH	YEAR
August	2013

4. FIN OR GRANT NUMBER

5. AUTHOR(S)
Colleen C. Casey, Anine Grumbles, Willie Lee, Randolph Ragland, Roberto J. Torres

6. TYPE OF REPORT
Technical

7. PERIOD COVERED (Inclusive Dates)
January 1999 to May 2013

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)
Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above", if contractor, provide NRC Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address.)
Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)
This technical report contains information intended to provide program-specific guidance and to assist applicants and licensees in preparing applications for irradiator licenses under Title 10 of the Code of Federal Regulations (10 CFR) Part 36, "Licenses and Radiation Safety Requirements for Irradiators." In particular, the report describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)
NUREG-1556
Volume 6
Irradiators
Panoramic Irradiators
10 CFR Part 36
Underwater Irradiators

13. AVAILABILITY STATEMENT
unlimited

14. SECURITY CLASSIFICATION
(This Page)
unclassified
(This Report)
unclassified

15. NUMBER OF PAGES

16. PRICE

Printed
on recycled
paper

Federal Recycling Program

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

OFFICIAL BUSINESS