

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Self-Shielded Irradiator Licenses

Draft Report for Comment

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Program-Specific Guidance About Self-Shielded Irradiator Licenses

Draft Report for Comment

Manuscript Completed: January 2017
Date Published: January 2017

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ABSTRACT

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

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FOREWORD

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

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

The current document, NUREG-1556, Volume 5, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses," is intended for use by applicants, licensees, and NRC staff. This revision provides a general update to the previous information contained in NUREG-1556, Volume 5, dated October 1998.

1 This report takes a risk-informed, performance-based approach to licensing self-shielded
2 irradiators. A team composed of staff from NRC Headquarters, NRC regional offices, and
3 Agreement States prepared this document, drawing on their collective experience in radiation
4 safety in general and as specifically applied to self-shielded irradiators.

5 NUREG-1556, Volume 5, Revision 1, is not a substitute for NRC or Agreement State
6 regulations. The approaches and methods described in this NUREG are provided for
7 information only. Methods and solutions different from those described in this NUREG may be
8 acceptable if they include a basis for the staff to make the determinations needed to issue or
9 renew a license.

10 _____

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

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- ## ACKNOWLEDGMENTS

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

The working group also thanks Lisa Dimmick, Joseph Nick, John O'Donnell, Monica Ford, Tara Weidner, Tomas Herrera, and Duane White for developing the formatting and language used in many parts of the report. In addition, the Working Group thanks Celimar Valentin-Rodriguez for her creative graphic designs, editing assistance, and proof-reading skills.

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ABBREVIATIONS

2	ACMUI	Advisory Committee on the Medical Uses of Isotopes
3	ADAMS	Agencywide Documents Access and Management System
4	AEA	Atomic Energy Act
5	ALARA	as low as is reasonably achievable
6	ANSI	American National Standards Institute
7	AU	authorized user
8	bkg	background
9	Bq	Becquerel
10	C/kg	coulomb per kilogram
11	CFR	<i>Code of Federal Regulations</i>
12	Ci	curie
13	Co-60	cobalt-60
14	cpm	counts per minute
15	Cs-137	cesium-137
16	d	day
17	DHS	Department of Homeland Security
18	DOE	United States Department of Energy
19	DOJ	United States Department of Justice
20	DOT	United States Department of Transportation
21	DVD	digital versatile disc
22	EPAct	Energy Policy Act
23	FR	<i>Federal Register</i>
24	ft	foot
25	GM	Geiger-Mueller
26	GBq	gigabecquerel
27	GPO	Government Printing Office
28	GTRI	Global Threat Reduction Initiative
29	HPS	Health Physics Society
30	h	hour
31	IN	Information Notice
32	IP	Inspection Procedure
33	ISMP	Integrated Source Management Portfolio
34	kg	kilogram
35	L/C	License Condition
36	LVS	License Verification System
37	m	meter
38	MBq	megabecquerel
39	mCi	millicurie
40	MDA	minimum detectable activity
41	MeV	million electron volts
42	mo	month
43	MOU	memorandum of understanding
44	mR	milliroentgen
45	mrem	millirem
46	mSv	millisievert
47	NA	National Academies
48	NCRP	National Council on Radiation Protection and Measurements
49	NIST	National Institute of Standards and Technology
50	NMSS	Office of Nuclear Material Safety and Safeguards

1	NNSA	National Nuclear Security Administration
2	NRC	United States Nuclear Regulatory Commission
3	NSTS	National Source Tracking System
4	NSTTR	National Source Tracking Transaction Reports
5	NVLAP	National Voluntary Laboratory Accreditation Program
6	OCFO	Office of the Chief Financial Officer
7	OCR	optical character reader
8	OEM	original equipment manufacturer
9	OMB	Office of Management and Budget
10	OSL	optically stimulated luminescent
11	PII	Personally Identifiable Information
12	Q	quality factor
13	QA	quality assurance
14	R	roentgen
15	rad	radiation-absorbed dose
16	RED	radiological exposure device
17	Rem	roentgen equivalent
18	Rev.	revision
19	RDD	radiological dispersal device
20	R.G.	Regulatory Guide
21	RIS	Regulatory Issue Summary
22	RQ	reportable quantities
23	RSO	radiation safety officer
24	SA	State Agreement
25	SDE	shallow-dose equivalent
26	SI	International System of Units (abbreviated “SI” from the French “le Système
27		Internationale d’Unités”)
28	Sr-90	strontium-90
29	SSD	sealed source and device
30	std	standard
31	Sv	sievert
32	TAR	technical assistance request
33	TBq	terabecquerel
34	TEDE	total effective dose equivalent
35	TI	transportation index
36	TLD	thermoluminescent dosimeters
37	U.S.C.	United States Code
38	U.S.	United States
39	URL	Uniform Resource Locator
40	wk	week
41	yr	year

1 PURPOSE OF REPORT

This report provides guidance to an applicant in preparing an application and applying for a self-shielded irradiator license and also provides the U.S. Nuclear Regulatory Commission (NRC) with criteria for evaluating such applications. This NUREG uses the terms “byproduct material,” “licensed material,” “staff,” and “radioactive material” interchangeably. Some licensees use an irradiator to calibrate instruments and dosimetry, and they use the word “calibrator” when referring to the irradiator. Within this NUREG, the terms “self-shielded irradiator,” “self-contained irradiator,” “calibrator,” and “irradiator” are used interchangeably.

This report addresses the variety of radiation safety issues associated with self-shielded irradiators of different types. Self-shielded irradiators are of many different designs and may contain different sealed sources based, in part, on their intended use (e.g., for purposes in research, industry, medicine, and other fields). Typical uses include:

- irradiating blood or blood products
- sterilizing or reducing microbes in or on media, supplies, and products
- studying radiation effects on materials
- researching, synthesizing, and modifying chemicals and polymers
- eradicating insects through sterile male release programs
- conducting botanical and horticultural research
- conducting biomedical research, including the irradiation of small animals
- performing dosimetry applications, including calibration of dosimeters
- performing calibration of survey instruments

Because of differences in design, manufacturers can provide appropriate instructions and recommendations for proper operation and maintenance. In addition, with irradiators of varying designs, the sealed sources may be oriented in different locations within the devices, resulting in different radiation safety challenges. Applicants should obtain this information from the manufacturers or suppliers if such information is not provided with the self-shielded irradiator.

The American National Standards Institute (ANSI) has developed and published safety standards for gamma irradiators. In determining basic safety requirements, ANSI divided all gamma irradiators into four general categories. This NUREG deals with the type of irradiator discussed in ANSI/Health Physics Society (HPS) Standard N43.7-2007, “Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (ANSI Category I).”¹ This NUREG also uses the same definition of a self-shielded irradiator as the ANSI definition for a Category I irradiator: “[a]n irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume undergoing irradiation is not physically possible in its designed configuration.”

¹Copies may be ordered electronically at the following URL: <http://www.ansi.org> or by writing to ANSI, 25 West 43rd St., New York, NY 10036 (212-642-4900). Copies are also available from the Health Physics Society (HPS) at the following URL: <http://www.hps.org> or by writing to HPS, 1313 Dolley Madison Blvd., Suite 402, McLean, VA 22101 (703-790-1745).

1 This NUREG does not address the other three ANSI Categories of gamma irradiators that are
2 regulated by the requirements of 10 CFR Part 36: (i) panoramic dry-source storage
3 (ANSI Category II); (ii) self-contained wet-source storage (ANSI Category III); and
4 (iii) panoramic wet-source storage (ANSI Category IV). These categories of irradiators are
5 addressed in NUREG-1556 Volume 6, "Program Specific Guidance About 10 CFR Part 36
6 Irradiator Licenses."

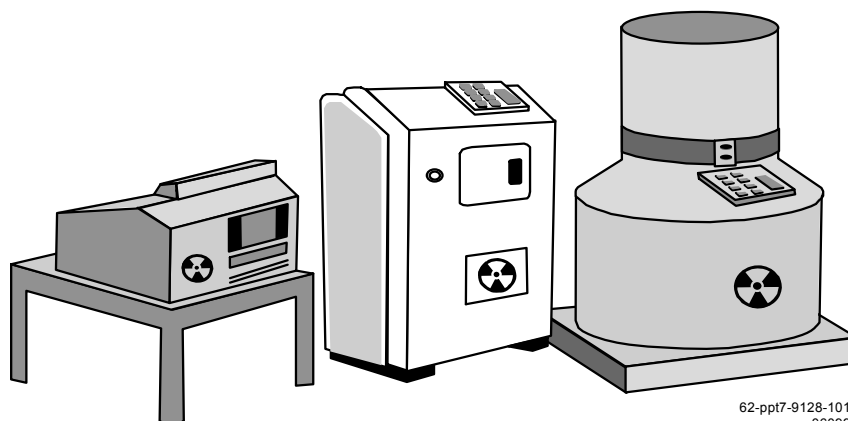
7 This NUREG does not address the manufacture, distribution, and service of self-shielded
8 irradiators. The applicant for these types of activities may wish to refer to other NUREG-1556
9 volumes, including: Volume 3, "Applications for Sealed Source and Device Evaluation and
10 Registration;" Volume 12, "Program-Specific Guidance About Possession Licenses for
11 Manufacturing and Distribution;" and Volume 18, "Program-Specific Guidance About Service
12 Provider Licenses."

13 For the self-shielded irradiators covered by this NUREG, the radionuclides most commonly used
14 are cesium-137 and cobalt-60. On July 25, 2011, the NRC issued a statement of policy on the
15 protection of cesium-137 chloride sources, such as those typically used in self-shielded
16 irradiators. The statement sets forth the NRC's policy regarding secure uses of these sources
17 and provides the NRC's expectations for the security and safety of these sources. The full text
18 of the policy statement can be found in the *Federal Register* (76 FR 44378) on July 25, 2011,
19 and can be found at <http://www.gpo.gov/fdsys/pkg/FR-2011-07-25/pdf/2011-18767.pdf>.

20 Depending on the design, the radiation source within the irradiator may be in a fixed position or
21 may be movable within the unit. In the latter case, interlocks are used to ensure that the source
22 does not move into a position that, during normal use of the irradiators, may cause a radiation
23 hazard to any individual. Bypassing or failure of an interlock could cause persons to be
24 exposed to high levels of radiation.

25 Applicants can request that an existing NRC license be amended to authorize the possession
26 and use of a self-shielded irradiator or can request that a separate license be issued to
27 authorize the possession and use of a self-shielded irradiator.

Examples of Self-Shielded Irradiators



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Figure 1-1. Types of Irradiators. The Irradiator on the Far Left is Used to Calibrate Dosimetry Devices, While the Center Unit Can be Used to Sterilize Blood, and the Unit on the Right is Typically Used for Research.

Chapter 8 of this NUREG, "Contents of an Application," identifies the information needed to complete NRC Form 313, "Application for Materials License" (see Appendix A of this NUREG), for the use of sealed sources containing byproduct material in self-shielded irradiators. The Office of Management and Budget (OMB) has approved the information collection requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and NRC Form 313 under OMB Clearance Nos. 3150-0017 and 3150-0120, respectively.

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

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

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

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11, as indicated on the form. Applicants should address those items on separate sheets of paper and submit them along with the completed NRC Form 313. For the convenience and streamlined handling of self-shielded irradiator applications, Appendix B of this NUREG, "Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313," may be used to provide supporting information.

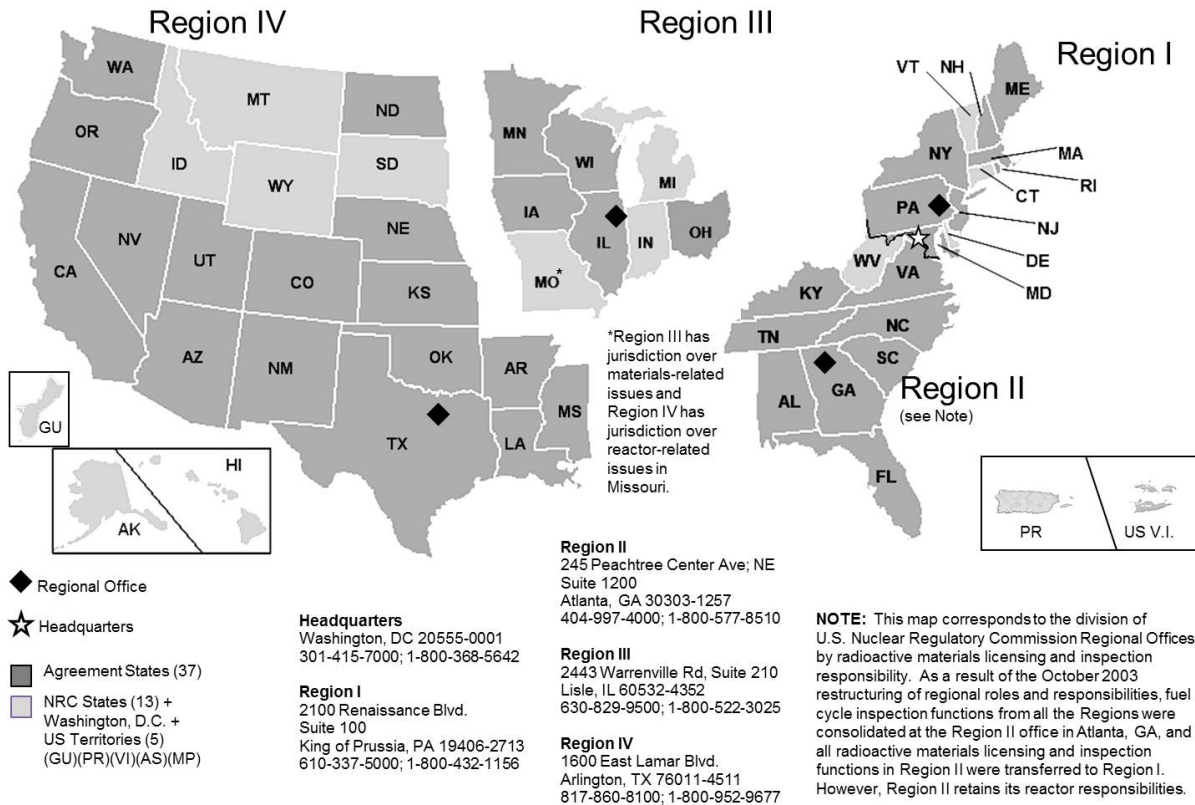
In this NUREG, "dose" or "radiation dose" means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE), as defined in 10 CFR Part 20, "Standards for Protection Against Radiation." To describe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

2 AGREEMENT STATES

2.1 Jurisdiction Determination

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

¹Locations of NRC Offices and Agreement States



¹Current regional office addresses can be verified at <http://www.nrc.gov/about-nrc/locations.html>

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

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

1 State has regulatory authority. These areas can also include Tribal lands of federally
2 recognized Indian Tribes².

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

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

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	Regulatory Agency
Federal agency, regardless of location (except that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with Title 10 of the <i>Code of Federal Regulations</i> (CFR) 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

²For 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.

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

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	Regulatory Agency
Non-Federal entity in Agreement State	Agreement State ⁴
Non-Federal entity in Agreement State at federally controlled site not subject to exclusive Federal jurisdiction	Agreement State ⁴
Non-Federal entity in Agreement State at federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	NRC
Non-Federal entity in Agreement State using radioactive materials not directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	Agreement State ⁴

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

4 **2.2 Reciprocal Recognition of Specific Licenses**

- 5 Performing licensed activities in other jurisdictions is possible through reciprocal recognition of
6 specific licenses (i.e., reciprocity). Agreement States have reciprocity provisions that permit
7 NRC licensees to perform licensed activities under circumstances when an Agreement State is
8 the regulatory authority (See Section 2.1). NRC licensees and Agreement State licensees are
9 subject to the regulations of the regulatory authority as indicated in Section 2.1. To ensure
10 compliance with an Agreement State's reciprocity requirements, licensees are advised to
11 request authorization from the appropriate Agreement State radiation control program office well
12 in advance of the scheduled use of licensed material.
- 13 Agreement State licensees that wish to conduct licensed activities in areas under NRC
14 jurisdiction must either obtain a specific NRC license or file for reciprocity with the appropriate
15 NRC regional office for the Agreement State that issued their license. Failure to file for
16 reciprocity or obtain a specific NRC license before working in areas under NRC jurisdiction can

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

1 result in NRC enforcement action, which may include civil penalties. The reciprocity filing must
2 be renewed annually.

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

3 MANAGEMENT RESPONSIBILITY

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

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

3.1 Commitments and Responsibilities

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

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

- prevention of discrimination 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, “Employee protection” and 10 CFR 30.10, “Deliberate misconduct”
- commitment to obtain the NRC’s prior written consent before transferring control of the license (see Section 9.1, “Timely Notification of Transfer of Control,” of this NUREG)
- notification of the appropriate NRC regional administrator, in writing, immediately following the filing of a petition for voluntary or involuntary bankruptcy [10 CFR 30.34(h)], as discussed further in Section 8.2.1, “Notification of Bankruptcy Proceedings,” of this NUREG.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of the NRC’s Enforcement Policy and Inspection Manual available in the NRC’s online library, under “Document Collections,” 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.

Table 3-1. Traits of a Positive Safety Culture		
Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.	All individuals take personal responsibility for safety.
Work Processes	Continuous Learning	Environment for Raising Concerns
The process of planning and controlling work activities is implemented so that safety is maintained.	Opportunities to learn about ways to ensure safety are sought out and implemented.	A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.
Effective Safety Communications	Respectful Work Environment	Questioning Attitude
Communications maintain a focus on safety.	Trust and respect permeate the organization.	Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

1 The NRC, as the regulatory agency with an independent oversight role, reviews the
2 performance of individuals and organizations to determine compliance with requirements and
3 commitments through its existing inspection and assessment processes. However, NRC's
4 safety culture policy statement and traits are not incorporated into the regulations. Safety
5 culture traits may be inherent to an organization's existing radiation safety practices and
6 programs. For instance, if an irradiator operator notices that an irradiator chamber door is not
7 properly latching, the operator should immediately cease using the irradiator and inform
8 management so that the Radiation Safety Officer (RSO) is notified. The RSO should call the
9 manufacturer, distributor, or service provider for repair and alert all irradiator operators not to
10 use the irradiator until the door latch is fixed. If the door latch completely fails, so that the door
11 can be opened with the source in the unshielded position, the licensee is required to notify the
12 NRC Headquarters Operations Center within 24 hours of discovery of an event involving
13 licensed material in which equipment is disabled or fails to function when it is required to be
14 available and operable to prevent exposures exceeding regulatory limits. The need to
15 recognize an equipment failure and make a 24-hour report may correspond with the safety

1 culture trait specified in Table 3-1 “Problem Identification and Resolution” (issues potentially
2 impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected
3 commensurate with their significance).

4 However, licensees should be aware that this is just an example, and should consider reviewing
5 their radiation safety programs in order to develop and implement a safety culture program
6 commensurate with the nature and complexity of their organizations and functions.

7 Refer to Appendix C of this NUREG for the NRC’s safety culture policy statement. More
8 information on NRC activities relating to safety culture can be found at
9 <http://www.nrc.gov/about-nrc/safety-culture.html>.

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* (CFR) contain regulations applicable to self-shielded 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 10 CFR regulations can be found under the "Basic References" link at the U.S. Nuclear Regulatory Commission's (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 Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- [10 CFR Part 33](#) "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- [10 CFR Part 36](#) "Licenses and Radiation Safety Requirements for Irradiators"
- [10 CFR Part 37](#) "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- [10 CFR Part 71](#) "Packaging and Transportation of Radioactive Material"
- [10 CFR Part 110](#) "Export and Import of Nuclear Equipment and Material"
- [10 CFR Part 150](#) "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters under Section 274"
- [10 CFR Part 170](#) "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services under the Atomic Energy Act of 1954, as Amended"

- [10 CFR Part 171](#) “Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC”

Copies of the above documents may be obtained by calling the Government Publishing Office Customer Contact Center toll-free at 866-512-1800, in Washington, DC, at 202-512-1800, or online at <http://bookstore.gpo.gov>. In addition, 10 CFR Parts 1 through 199 can be found on the NRC’s Web site at <http://www.nrc.gov/reading-rm/doc-collections/> under “Regulations (10 CFR).”

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

5 HOW TO FILE

5.1 Application Preparation

Applicants for a materials license should do the following:

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

5.2 Where to File

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

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

5.3 Paper Applications

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

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

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

5.4 Electronic Applications

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

6 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

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

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

- **Proprietary Information and Trade Secrets:** If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Appendix D of this NUREG provides a checklist for requests for withholding proprietary information from public disclosure.
- **Personally Identifiable Information:** Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII, and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice (IN) 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" and "Information Notices," respectively, at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.
- **Security-Related Information:** Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information and the top of every page of a document that contains such information should be clearly marked: "Security Related 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 Web page under "Regulatory Issue Summaries" at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>. Additional

1 information on procedures and any updates is available at [http://www.nrc.gov/reading-
rm/sensitive-info.html](http://www.nrc.gov/reading-
2 rm/sensitive-info.html).

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

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

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

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

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

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

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

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

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

7 APPLICATION AND LICENSE FEES

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

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

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

8 CONTENTS OF AN APPLICATION

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

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

Title 10 of the *Code of Federal Register* (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 ALARA." Regulatory Guide 8.10, Rev. 2, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," discusses the ALARA concepts and philosophy. The application should document ALARA considerations, including establishing administrative action levels and monitoring programs.

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

The application should include information on how the licensee will implement the security requirements in 10 CFR 20.1801, "Security of stored material," 10 CFR 20.1802, "Control of material not in storage," and 10 CFR Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

The majority of self-shielded irradiator licensing actions will fall under the categorical exclusion in 10 CFR 51.22(c)(14)(vii). This means that the licensing action will not require an environmental assessment or environmental impact statement in accordance with 10 CFR 51.22(b), because the NRC has already determined that this type of licensing action does not have a significant impact on the environment.

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

8.1 Item 1: License Action Type

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

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

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

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

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

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

6 **8.2 Item 2: Name and Mailing Address of Applicant**

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

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

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

18 **8.2.1 Notification of Bankruptcy Proceedings**

19 **Regulation:** 10 CFR 30.34(h)

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

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

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

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

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

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

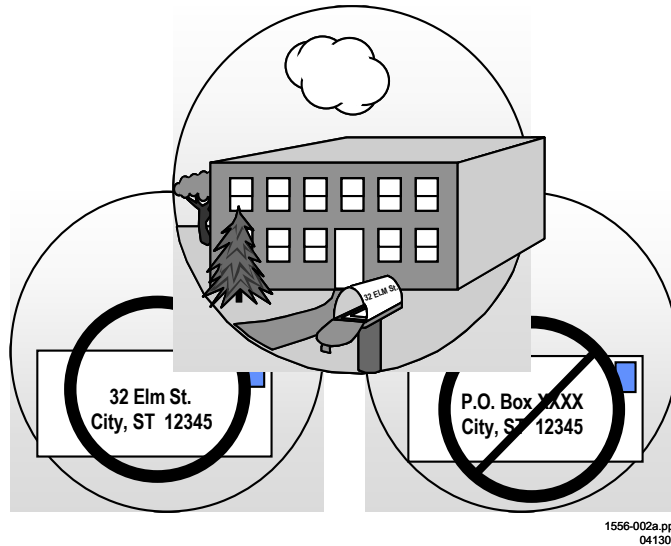
For security purposes, applicants are discouraged from identifying the self-shielded irradiator physical location by room number or providing drawings of the location within the facility. The acceptability of the irradiator’s location may be reviewed during an onsite visit as part of the licensing process and would also be subject to inspection following the issuance of a license. See Section 8.9, “Facilities and Equipment” for additional information.

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

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

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

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



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

Figure 8-1. Location of Use or Possession

8.4 Item 4: Person To Be Contacted about This Application

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

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

8.5 Item 5: Radioactive Material

8.5.1 Sealed Sources and Devices

Regulations: 10 CFR 20.1003, 10 CFR 20.2207, 10 CFR 30.32(g), 10 CFR 30.33(a)(2), 10 CFR 32.201, 10 CFR 32.210, 10 CFR Part 37

Criteria: Applicants should provide the manufacturer's or distributor's name and model number for each requested sealed source and device (e.g., irradiator unit). Licensees will be authorized to possess and use only those sealed sources and devices specifically registered with the NRC under 10 CFR 32.210, "Registration of product information," or the equivalent regulations of an

1 Agreement State. Licensees must also protect aggregated Category 1 and Category 2
2 quantities of radioactive material, as defined in 10 CFR 37.5, from theft, diversion, and
3 sabotage.

4 **Discussion:** The NRC or an Agreement State performs a safety evaluation of self-shielded
5 irradiators and the sealed sources contained in self-shielded irradiators under 10 CFR 32.210 or
6 equivalent regulations of an Agreement State before authorizing a manufacturer or distributor to
7 distribute the irradiators or sealed sources to specific licensees. The safety evaluation is
8 documented in a Sealed Source and Device (SSD) registration certificate issued to the
9 manufacturer or distributor. Applicants should provide the manufacturer's or distributor's name
10 and model number for each requested sealed source and device so that the NRC can verify that
11 they have been evaluated and registered with NRC under 10 CFR 32.210 or the equivalent
12 regulations of an Agreement State.

13 Before the formalization of the SSD registration process, some older irradiators might have
14 been specifically approved by the NRC on a license. Existing NRC licensees can continue to
15 use those units that are specifically approved and listed on their licenses. Possession and use
16 of sealed sources and devices that have been specifically approved on a license must adhere to
17 the commitments made in the license application and incorporated into the license.

18 Applicants that request to possess or use sealed sources or a device that contains sealed
19 sources that do not have SSD certificates and are not already approved on their existing license
20 should provide the NRC with the information contained in 10 CFR 32.210(c). This will allow the
21 NRC to perform an evaluation and make a determination as to whether the source or device can
22 be approved for possession or use by the applicant. Such an evaluation will increase the time
23 needed to process the licensing action.

24 Self-shielded irradiators typically contain one or more sealed sources. Applicants should
25 consult with the proposed manufacturer or distributor to ensure that requested sources and
26 devices conform to the sealed source and device designations registered with the NRC or an
27 Agreement State. Only authorized and approved sealed sources may be installed and used in
28 the selected self-shielded irradiator model(s). Licensees may not make any changes to the
29 sealed source, device, or source/device combination that would alter the description or
30 specifications from those indicated in the respective registration certificates, without obtaining
31 the NRC's prior permission in a license amendment. Such changes might necessitate a custom
32 registration review of the sealed source, device, or source/device combination, increasing the
33 time needed to process a licensing action.

34 In addition to the acceptable sealed sources that can be used in a device, the SSD registration
35 certificates provide the leak test frequency and the ANSI Category of the irradiator. The SSD
36 registration certificates also contain sections on "Conditions of Normal Use" and "Limitations
37 and Other Considerations of Use." These sections may include information about the sealed
38 source/device from the manufacturer or distributor about particular conditions of use that are
39 important to the radiation safety of the device, or by circumstances unique to the sealed source
40 or device. For example, the working life of the device or an appropriate operating temperature
41 and other environmental conditions may be specified. Except as specifically approved by the
42 NRC, possession and use of sealed sources and devices must adhere to the conditions and
43 limitations of the SSD registration certificate and the commitments made in the license
44 application. Accordingly, applicants should acquire a copy of the SSD registration certificate(s)
45 from the manufacturer or distributor, review it, and maintain it for future reference.

1 Information provided by the applicant/licensee regarding manufacturers, model numbers, and
2 possession limits is considered sensitive information and should be marked accordingly (see
3 Chapter 6, "Identifying and Protecting Sensitive Information").

The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated "Category 1 quantity of radioactive material" or "Category 2 quantity of radioactive material." These terms are defined in 10 CFR 37.5, and the radionuclides referenced in these 10 CFR 37.5 definitions are listed in Appendix A to 10 CFR Part 37. See Section 8.10.6.2, "Security Program for Category 1 and Category 2 Radioactive Material," of this NUREG for more information on the applicability and requirements of 10 CFR Part 37.

4 **Response from Applicant:**

- 5 • Identify each radionuclide that will be used in each source in the self-shielded irradiators.
- 6 • Provide the manufacturer's or distributor's name and model number for each sealed
7 source and device requested.
- 8 • For each source model, identify the radionuclide, activity per source, and maximum
9 possession limit. The activity per source and maximum activity in each irradiator cannot
10 exceed the maximum activity listed on the approved certificate of registration issued by
11 NRC or by an Agreement State.
- 12 • State that each sealed source, device, and source/device combination is registered as
13 an approved sealed source or device by the NRC or an Agreement State and will be
14 possessed and used in accordance with the conditions specified in the SSD registration
15 certificate. Obtain a copy of the SSD certificate from the manufacturer/distributor and
16 provide the SSD registry number with the application.

Mark the section of your application in which you identify sealed sources and devices with manufacturers' model numbers and maximum possession limits with, "Security-Related Information—Withhold from Public Disclosure Under Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 2.390." In accordance with 10 CFR 2.390(b)(ii), the NRC is waiving the affidavit requirements. To the extent possible, your application should not include any personally private, proprietary, or safeguards information.

17 **8.5.2 Financial Assurance and Recordkeeping for Decommissioning**

18 **Regulations:** 10 CFR 30.34(b), 10 CFR 30.35, 10 CFR 30.51(f)

19 **Criteria:** Self-shielded irradiator licensees authorized to possess sealed sources containing
20 radioactive material in excess of the limits specified in 10 CFR 30.35, "Financial assurance and
21 recordkeeping for decommissioning," must provide evidence of financial assurance for
22 decommissioning. Pursuant to 10 CFR 30.35(g), licensees must transfer records important to
23 decommissioning to new proposed licensees before licensed activities are transferred, in
24 accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), before license
25 termination, each licensee shall forward the records required by 10 CFR 30.35(g) to the
26 appropriate NRC regional office.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, records important to decommissioning. These records include as-built drawings and modifications of structures and equipment where irradiators are used or stored, as well as records related to leaking sources.

Discussion:

Financial Assurance

The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most self-shielded irradiator applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the limits in 10 CFR 30.35. The limits for typical self-shielded irradiator sealed sources are shown in Table 8-1. Applicants requesting more than one radionuclide need to use the sum-of-the-ratios method to determine whether financial assurance is needed. See Appendix E of this NUREG for additional information.

Table 8-1. Minimum Inventory Quantity Requiring Financial Assurance		
Radionuclide in a Sealed Source	Activity	
	Gigabecquerel (GBq)	Curie (Ci)
Cs-137	3.7×10^6	100,000
Co-60	3.7×10^5	10,000
Sr-90	3.7×10^4	1,000

Licensees may use the worksheet in Appendix E of this NUREG to determine whether they need to establish financial assurance if the only radioactive materials possessed are sealed sources in self-shielded irradiators. NRC licenses will indicate a maximum radionuclide possession limit. In most cases, a licensee would need to possess several irradiators before the financial assurance requirements would apply. Therefore, a self-shielded irradiator licensee can reduce the maximum possession limit to quantities not requiring financial assurance for decommissioning.

Applicants and licensees wanting to possess sealed sources in self-shielded irradiators or other licensed materials exceeding the limits in 10 CFR 30.35 must submit evidence of financial assurance or a decommissioning funding plan [10 CFR 30.35 (b)]. Licensees may follow the guidance provided in NUREG-1757, Volume 3, "Consolidated Decommissioning Guidance - Financial Assurance, Recordkeeping, and Timeliness," on the various financial assurance mechanisms authorized by the regulations to guarantee or secure funds.

NRC may authorize possession exceeding the limits shown in Table 8-1 without requiring decommissioning financial assurance, for the purpose of normal source exchange for no more than 30 days. However, under no circumstances, including source exchange, should a licensee exceed the possession limits authorized by its license without NRC approval.

Recordkeeping for Decommissioning

The regulations in 10 CFR 30.35(g) also require that licensees maintain records important to decommissioning in an identified location. 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 new licensees 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.

All self-shielded irradiator licensees need to maintain records of structures and equipment where each irradiator was used or stored. As-built drawings, with modifications of structures and equipment shown as appropriate, fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the room or building or a description of the area) concerning the specific areas and locations. If no records exist regarding structure and equipment where self-shielded irradiators were used or stored, licensees shall make all reasonable efforts to create such records based on historical information (e.g., employee recollections). In addition, self-shielded irradiator licensees that have experienced unusual occurrences (e.g., leaking sources or other incidents that involve spread of contamination) also need to maintain records about contamination that remains after cleanup or that might have spread to inaccessible areas.

For self-shielded irradiator licensees whose sources have never leaked, acceptable records important to decommissioning are leak test results and sketches or written descriptions of the specific locations where each irradiator was used or stored. In addition, any transfer or disposal records shall be retained in accordance with 10 CFR 30.51(a)(3).

Response from Applicant:

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

AND

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

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

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

Regulations: 10 CFR 30.33(a)(1), 10 CFR 32.210

Criteria: An application for a license will be approved if the proposed activity is authorized by the Atomic Energy Act of 1954, as amended, and devices will be used only for the purposes for which they were designed and according to the manufacturer's recommendations for use, as specified in an approved SSD registration certificate.

Discussion: Allowed uses normally include the irradiation of blood, insects, animals, biological samples, and inanimate objects. Uses that are usually prohibited are the irradiation of flammable, corrosive, and explosive materials that might damage the integrity of the shielding or

1 the sealed source containment or the irradiation of other materials that might interfere with the
2 safe operation of the device.

3 Specific requirements related to the irradiation and distribution of food for human consumption
4 are subject to regulations of the Food and Drug Administration and the U.S. Department of
5 Agriculture and are not discussed in this document. Applicants should contact these agencies
6 for further information.

7 Requests to irradiate items prohibited or not listed in the SSD registration certificate will be
8 reviewed on a case-by-case basis. Applicants need to submit enough information to
9 demonstrate that irradiation of the proposed items will not compromise the integrity of the
10 source, source shielding, or other components critical to the radiation safety of the device.
11 Contact the appropriate NRC Regional Office (see Figure 2-1) for additional case-specific
12 guidance. Being granted an NRC license does not relieve a licensee from complying with other
13 applicable Federal, State, or local regulations.

14 **Response from Applicant:**

15 State the following: "We will not irradiate flammable, corrosive, or explosive materials."

For this purpose, "flammable" will mean any material with a flash point at a temperature below the temperature one would expect irradiated products to reach during irradiation. However, in no case should any material with a flash point below 62.78 degrees Celsius (145 degrees Fahrenheit) be irradiated.

For this purpose, "corrosive" will mean any material with a pH less than 4.0 or greater than 10.0.

Applicants may propose different definitions if justification is provided.

17 **AND**

18 For all self-shielded irradiators that will be used for the purposes listed on the SSD registration
19 certificate, state the following:

20 If there is only a single irradiator, state: "This self-shielded irradiator will be used for the
21 purposes described in its SSD registration certificate."

22 **OR**

23 If there are multiple irradiators, state: "These self-shielded irradiators will be used for the
24 purposes described in their respective SSD registration certificates."

25 **OR**

26 For all self-shielded irradiators that will be used for purposes other than those listed on
27 the SSD registration certificate, specify these purposes and submit safety analyses,
28 including operating and emergency procedures and training, as necessary, to support
29 safe use. The safety analyses should include enough information to demonstrate that

irradiation of the proposed items will not compromise the integrity of the source, source shielding, or other components critical to the radiation safety of the device.

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

8.7.1 Radiation Safety Officer (RSO)

Regulations: 10 CFR 30.33(a)(3), 10 CFR Part 37

Criteria: RSOs must have training and experience that are adequate to ensure that the licensee's radiation safety program is implemented in accordance with regulatory requirements, the terms and conditions of the license, and licensee procedures. Successful completion of training as described in Appendix F of this NUREG is evidence of adequate training and experience.

Discussion: The person responsible for the radiation protection program is the RSO. The RSO is key to overseeing and ensuring safe operation of the licensee's radiation protection program. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO should have independent authority to stop operations that he or she considers unsafe. He or she should have sufficient time and commitment from management to fulfill his or her duties and responsibilities to ensure that radioactive materials are used in a safe manner, approved radiation safety procedures are being implemented, and the required records of licensed activities are maintained. Typical RSO duties are illustrated in Figure 8-2 and described in Appendix G of this NUREG. The NRC requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and that the named individual knows of his or her designation as RSO. Appendix H of this NUREG also provides a model Delegation of Authority, which should be used to further emphasize the agreement on duties and responsibilities of the RSO by management and the designated RSO.

The RSO may delegate certain day-to-day tasks of the radiation protection program to other responsible individuals, sometimes referred to as "alternate RSOs" or "site RSOs." For example, a licensee with multiple permanent locations of use or use at temporary jobsites may appoint "site RSOs," who assist the RSO and are responsible for the day-to-day activities at these locations. Licensees may also appoint "alternate RSOs" who may "step in" as an emergency contact when the RSO is unavailable. Such "alternate RSOs" or "site RSOs" do not need to meet all RSO qualifications; however, they should be qualified, experienced authorized users who have adequate knowledge of the activities to which they are assigned. These individuals should have the same management support and decisionmaking authority as the RSO that is necessary to accomplish the tasks to which they have been assigned. Please note that only the primary RSO is named on an NRC license.

For all broad scope licenses, the RSO must ensure that the licensee's radioactive material is used and stored safely and securely according to approved policies and procedures and that all regulatory requirements are met.

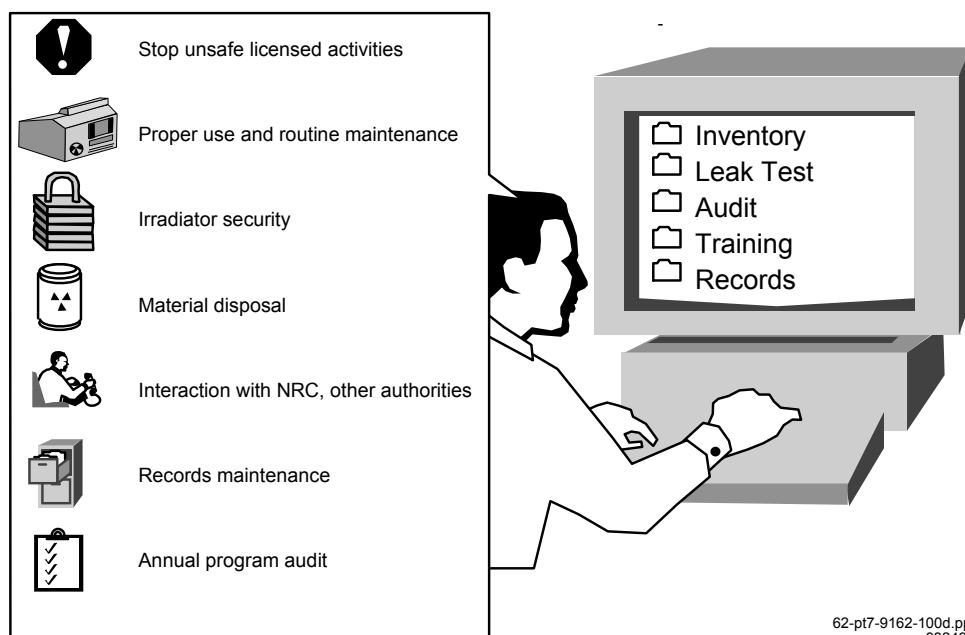


Figure 8-2. Typical Duties and Responsibilities of RSOs

For licensees possessing an aggregated amount of Category 1 or Category 2 quantity of radioactive material, the RSO should participate in the development and implementation of a security program for radioactive material in accordance with 10 CFR Part 37. A "Category 1 quantity of radioactive material" and a "Category 2 quantity of radioactive material" are defined terms in 10 CFR 37.5, and the radionuclides referenced in these 10 CFR 37.5 definitions are listed in Appendix A to 10 CFR Part 37.

Response from Applicant: Submit the following:

- the name of the proposed RSO

AND EITHER

- this statement: "Before obtaining licensed materials, the proposed RSO will have successfully completed training described in Appendix F of NUREG-1556, Volume 5, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses.'"

OR

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

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

8.7.2 Authorized Users (AUs)

Regulations: 10 CFR 30.33(a)(3)

Criteria: Authorized users (AUs) must have adequate training and experience. Successful completion of training as described in Appendix F of this NUREG is evidence of adequate training and experience.

Discussion: An AU is a person whose training and experience meet NRC criteria, who is named either explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material or devices containing licensed material. AUs must ensure the proper use, security, and routine maintenance of self-shielded irradiators containing licensed material. They must have appropriate training to provide reasonable assurance that they will use the irradiator safely, maintain security of and access to the irradiator, and respond appropriately to accidents and malfunctions.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material or device. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for the safe use and security of licensed material.

Response from Applicant: Provide the name(s) of the AUs and submit either of the following:

- this statement: "Before using licensed material, authorized users will receive the training described in Appendix F of NUREG-1556, Volume 5, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses.'"

OR

- alternative information demonstrating that the proposed AUs are qualified by training and experience

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

8.8.1 Instructions to Occupationally Exposed Radiation Workers

Regulations: 10 CFR 19.12, 10 CFR 19.13, 10 CFR 30.33(a)(3), 10 CFR 37.43

Criteria: For those individuals who are not AUs but are likely to receive in a year an occupational dose of radiation over 1 millisievert (mSv) [100 millirem (mrem)], the licensee must provide training as required by 10 CFR 19.12, "Instructions to workers." The extent of this training must be commensurate with potential radiological health protection problems present in the workplace. Any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material (as defined in 10 CFR 37.5) must implement a training program for those individuals implementing the security program.

Discussion: Personnel who will use the irradiator have the responsibility to ensure the proper use and security of irradiators containing licensed material and will need to be trained in the operating and emergency procedures to ensure the safe use of the licensed material.

1 Licensees need to perform a prospective evaluation to determine radiation doses likely to be
2 received by different individuals or groups (see Section 8.10.3, "Occupational Dose"). AUs,
3 individuals performing routine maintenance, and individuals performing installations, relocations,
4 nonroutine maintenance, or repairs would be most likely to receive doses in excess of 1 mSv
5 [100 mrem] in a year. See the previous section for a discussion of training and experience
6 for AUs.

7 Individuals other than AUs (e.g., biomedical engineers, radiation safety personnel, researchers)
8 may perform routine maintenance on irradiators. However, they must either be trained in
9 radiation safety and in the irradiator manufacturers' or distributors' operating and emergency
10 procedures, or they must work under the supervision and in the direct physical presence of
11 someone who has this training. Such individuals may also require escorting to comply with
12 security requirements related to access to radioactive materials or devices containing
13 radioactive materials.

14 Some licensees might have specific individuals trained to perform installations, relocations,
15 nonroutine maintenance, or repairs. Authorizations for these functions are separate from those
16 for an AU or an individual who performs routine maintenance and will be specifically stated in a
17 license condition. Appendix F of this NUREG contains suggested training for individuals who
18 will conduct nonroutine maintenance.

19 In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or
20 Category 2 quantity of radioactive material must implement a training program in accordance
21 with 10 CFR 37.43, "General security program requirements," to ensure that those individuals
22 who may have a responsibility to implement portions of the security program possess and
23 maintain the knowledge, skills, and abilities to carry out their assigned duties and
24 responsibilities effectively. For additional guidance on implementing 10 CFR Part 37
25 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical
26 Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional
27 information regarding best practices for protection of risk-significant radioactive material is
28 available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-
29 Significant Radioactive Material."

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

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

Response from Applicant: The applicant's training program will be examined during inspections and should not be submitted in the license application.

8.8.2 Instructions to Ancillary Workers

Regulations: 10 CFR 19.12, 10 CFR 19.13, and 10 CFR 30.33(a)(3)

Criteria: Those individuals who are not AUs or radiation workers but whose duties might require entry into the irradiator room (e.g., housekeeping, security, laboratory workers who do not use the irradiator) will need training commensurate to their duties. Personnel who might respond to alarms or work in the vicinity of the irradiator should be familiar with the emergency procedures.

Discussion: Licensees need to perform a prospective evaluation to determine radiation doses likely to be received by different individuals or groups (see Section 8.10.3, "Occupational Dose"). While performing prospective evaluations, a licensee might recognize that some ancillary personnel, although not likely to receive doses over 1 mSv [100 mrem], should receive training commensurate with their involvement with licensed material. For example, housekeeping staff should receive training on the meaning of the radiation symbol and instructions on how to respond if the irradiator door was found open and the irradiator unattended.

Response from Applicant: The applicant's training program will be examined during inspections and should not be submitted in the license application.

8.9 Item 9: Facilities and Equipment

Regulations: 10 CFR 30.33(a)(2), 10 CFR Part 37, 10 CFR 37.5, 10 CFR 37.49, 10 CFR 37.53

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property and provide enhanced physical protection of aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5.

Discussion: Self-shielded irradiators incorporate many engineering features to protect individuals from unnecessary radiation exposure. These devices are usually designed for use in a controlled environment, such as a laboratory, where the device is inside a building, protected from the weather, and not subject to wide variations of temperature and humidity. For information to help applicants determine the proper location of irradiators, applicants should refer to the device's SSD registration certificate, paying close attention to the sections entitled "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use."

If a proposed location for a self-shielded irradiator is not within the conditions of normal use or the limitations of use specified in the SSD registration certificate, the applicant should provide adequate justification for this deviation. In addition, the applicant might need to take compensatory measures (e.g., increased surveillance and maintenance) to ensure that the irradiator operates as designed and provides the intended level of protection. Information Notice (IN) 96-35, "Failure of Safety Systems on Self-Shielded Irradiators Because of Inadequate Maintenance and Training," dated June 11, 1996, discusses an irradiator failure incident in which the lack of a climate-controlled environment (i.e., on the loading dock) might have accelerated the degradation of internal components leading to a failed interlock and an excessive dose received by an irradiator operator.

1 Self-shielded irradiators vary in weight from several hundred to several thousand pounds. As a
2 comprehensive safety measure, before installing an irradiator, licensees should evaluate
3 whether the floor in the proposed location can support the weight of the irradiator. If the
4 irradiator will be moved between floors using an elevator, the licensee should evaluate whether
5 the elevator can support the weight of the irradiator. Often licensees locate self-shielded
6 irradiators on a ground floor. Based on the radioactivity of the licensed material, self-shielded
7 irradiators require additional security measures to prevent unauthorized removal or access to
8 the licensed materials or the device. For more information, see Section 8.10.2, "Radiation
9 Safety Program - Operating and Emergency Procedures," and Section 8.10.8, "Security
10 Program for Category 1 and Category 2 Materials."

11 The fire-resistant properties of most irradiators should provide adequate radioactive material
12 containment and shielding integrity in most situations; however, additional protection might be
13 desirable for some situations. For example, the room housing the irradiator could be equipped
14 with an automatically operated fire detection and control system (sprinkler, chemical, or gas).
15 As an alternative, the self-shielded irradiator could be located under conditions (e.g., a ground-
16 floor location in a fire-resistant building with little combustible material) and other controls
17 (e.g., coordination with and training of firefighting personnel) that help ensure a low level of
18 radiation risk attributable to fires.

19 As explained in an "Urgent Notice" with an enclosed Order, both dated July 3, 1984
20 (see Appendix I of this NUREG), an NRC licensee identified a malfunction that could have
21 resulted in a radiation overexposure. The malfunction involved an interlock mechanism, which
22 would have failed to prevent a shielded door from being opened after the source had moved out
23 of the shielded position. The Order, which remains in effect, modifies existing licenses that
24 authorize J. L. Shepherd Mark I or Model 81-22 irradiators. Applicants wishing to use either of
25 these models must comply with the Order's requirements. The requirements of the Order will
26 be imposed on the licensee through the use of a standard license condition on all licenses
27 authorizing possession and use of J. L. Shepherd Mark I or Model 81-22 irradiators.

28 Irradiators are equipped with electrical and mechanical safety interlocks to ensure that irradiator
29 users are not exposed to the radiation. As noted above, these safety features might no longer
30 function over time and need to be checked on a periodic basis. The irradiator user's manual
31 has instructions on how to perform these safety interlock checks.

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

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

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

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

1 **Response from Applicant:**

2 Submit the following:

- 3 • this statement: "We will conduct electrical and mechanical safety interlock checks of
4 each irradiator at least quarterly, in accordance with the irradiator's user's manual."

5 **AND EITHER**

- 6 • this statement: "We will ensure that each area where a self-shielded irradiator is located
7 corresponds to the 'Conditions of Normal Use' and 'Limitations and/or Other
8 Considerations of Use' on the applicable irradiator's Sealed Source and Device
9 registration certificate; the floor beneath the self-shielded irradiator is adequate to
10 support the weight of the irradiator; each self-shielded irradiator is secured to prevent
11 unauthorized access or removal; and each area where a self-shielded irradiator is
12 located is equipped with an automatically operated fire-detection and -control system
13 (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low
14 level of radiation risk attributable to fires."

15 **OR**

- 16 • alternative information; be sure to include justification for placing an irradiator in an area

that does not correspond to the “Conditions of Normal Use” and the “Limitations and/or Other Considerations of Use”

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

References: Information Notices are available in the “NRC Library / Document Collections / Generic Communications” on NRC’s Home Page at <http://www.nrc.gov>. For hard copies, see the Notice of Availability on the inside front cover of this report.

8.10 Item 10: Radiation Safety Program

Regulations: 10 CFR 20.1101, 10 CFR 20.2102, 10 CFR 30.33

Criteria: A radiation safety program should be established by the applicant. The program should be commensurate with the scope and extent of activities for the use of licensed materials in self-shielded irradiators. Each applicant for a self-shielded irradiator license should develop, document, and implement a radiation protection program containing the following elements:

- steps to keep radiation exposures ALARA
- description of equipment and facilities adequate to protect personnel, the public, and the environment
- conduct of licensed activities by individuals qualified by training and experience
- written operating and emergency procedures to address all likely scenarios
- description of the organizational structure and of the individuals responsible for ensuring implementation of the radiation safety and security program
- records management
- implementation of an audit program to ensure that the radiation safety and security program are reviewed at least annually

Discussion: The specific components of the applicant’s radiation safety and security program are detailed as separate topics in the remainder of this section. Some topics do not require a response from an applicant but are intended to provide guidance to the applicant on acceptable methods of compliance with specific NRC requirements.

8.10.1 Audit and Review of Program

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

Criteria: Licensees must review the content and implementation of their radiation protection programs at least annually to ensure compliance with the provisions of NRC regulations, Orders, and the terms and conditions of the license in accordance with 10 CFR 20.1101(c). Licensees that are subject to the requirements in 10 CFR Part 37 must annually review their access authorization program and security program. Records of audits and other reviews of program content are maintained for 3 years after the record is made and in accordance with 10 CFR 20.2102(b), 10 CFR 37.33(c), and 10 CFR 37.55(c).

1 **Discussion:** Appendix J of this NUREG contains a suggested annual audit program that is
2 specific to the use of self-shielded irradiators and is acceptable to the NRC. Since all areas
3 indicated in Appendix J may not be applicable to every licensee and all items may not need to
4 be addressed during each audit, licensees may wish to develop a program-specific audit
5 checklist.

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

10 It is essential that once problems are identified, comprehensive corrective actions are taken in a
11 timely manner. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development
12 and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this
13 subject. The NRC routinely reviews licensee's records to verify whether appropriate corrective
14 actions were implemented in a timely manner to address recurrence. It is in the best interest of
15 the licensee to identify potential violations of regulatory requirements and take necessary steps
16 to correct them. The NRC can opt to exercise discretion and may elect not to cite the licensee
17 for these violations if prompt and effective corrective actions are implemented. The NRC's
18 Enforcement Policy may be found online at [http://www.nrc.gov/about-](http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html)
19 [nrc/regulatory/enforcement/enforce-pol.html](http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html), and the Enforcement Manual may be found online
20 at <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html>. For examples of the
21 NRC's use of discretion in issuing a notice of violation, refer to the most recent version of NRC's
22 enforcement documents at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

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

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

- in accordance with 10 CFR 37.33, review its access authorization programs at least annually to confirm compliance with the requirements of Subpart B of 10 CFR Part 37 and ensure that comprehensive actions are taken to correct any noncompliance that is identified; and
- in accordance with 10 CFR 37.55, review its security program at least annually to confirm compliance with the requirements of Subpart C of 10 CFR Part 37 and ensure that comprehensive actions are taken to correct any noncompliance that is identified.

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

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

Response from Applicant: The applicant's program for reviewing the content and implementation of its radiation protection program, access authorization program, and security program will be examined during inspections and should not be submitted with the license application.

References:

NRC's Enforcement Policy may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html> and the Enforcement Manual may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html>.

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

- NRC Inspection Procedure 87122, "Irradiator Programs

8.10.2 Radiation Monitoring Instruments

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

Criteria: Pursuant to 10 CFR 20.1501, "General," licensees must possess, or have access to, radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: All licensees possessing self-shielded irradiators should have, or have access to, calibrated radiation detection instruments to determine radiation levels in areas adjacent to the irradiator. Usually it is not necessary for a licensee to have a radiation survey meter solely for use during irradiator operations, because it is not expected that a survey be performed each time a sample is irradiated. In these cases, it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

As explained in an "Urgent Notice" with an enclosed Order, both dated July 3, 1984 (see Appendix I of this NUREG), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism, which would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses that authorize J. L. Shepherd Mark I or Model 81-22 irradiators and requires licensees to provide either a calibrated and operable radiation survey meter or a room monitor for use with either of these irradiators. Although not required for all licensees possessing moving-source irradiators, it would be prudent for these licensees to use either a calibrated radiation survey meter or room monitor to ensure that the sources are in the shielded position whenever a sample is not undergoing irradiation.

The NRC requires that radiation survey meter calibrations be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests authorization to do this themselves. Applicants seeking

1 authorization to perform survey-meter calibrations should submit additional information for
2 review. See Appendix K of this NUREG for more information. Regardless of whether an
3 applicant is authorized to calibrate radiation survey meters or contracts an authorized firm to
4 perform calibrations, the licensee must retain records of the calibration of instruments and
5 equipment used for quantitative radiation measurements for 3 years after the record is made in
6 accordance with 10 CFR 20.2103(a).

7 **Response from Applicant:**

8 Submit one of the following:

- 9 • this statement: "We will use instruments that meet the radiation-monitoring instrument
10 specifications published in Appendix K of NUREG-1556, Volume 5, Revision 1,
11 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About
12 Self-Shielded Irradiator Licenses.'" Additionally, each radiation survey meter will have
13 been calibrated by the manufacturer or other person authorized by the NRC or an
14 Agreement State to perform radiation survey meter calibrations no more than 12 months
15 before the date the meter is used."

16 **OR**

- 17 • this statement: "We will use instruments that meet the radiation-monitoring instrument
18 specifications published in Appendix K of NUREG-1556, Volume 5, Revision 1,
19 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About
20 Self-Shielded Irradiator Licenses.'" Additionally, we will implement the model radiation
21 survey meter calibration program published in Appendix K of this NUREG-1556, and we
22 will ensure that each radiation survey meter will have been calibrated no more than
23 12 months before the date the meter is used."

24 **OR**

- 25 • a description of alternative equipment and/or procedures for (1) ensuring that interlocks
26 function as required to return moving self-shielded irradiator sources to the shielded
27 position, and (2) determining source shielding integrity after an incident involving the
28 self-shielded irradiator.

29 **Notes:**

- 30 • Alternative responses will be reviewed using the criteria listed above.
- 31 • Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will contain license
32 conditions to require compliance with the terms of the Order in Appendix I of this
33 NUREG. Applicants requesting these irradiators must ensure that their radiation
34 detection instruments meet these requirements.
- 35 • Applicants who plan to perform nonroutine maintenance that will affect safety-critical
36 components (e.g., sealed source, radiation shielding, source movement control or
37 mechanism, or interlocks) will need to possess and use appropriate calibrated radiation
38 survey meters. Refer to the section on "Radiation Safety Program - Maintenance" and
39 Appendices M and N of this NUREG for more information.

- Required calibration records must be retained for a minimum of 3 years.

8.10.3 Material Receipt and Accountability

Regulations: 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)(2), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 37.49, 10 CFR 37.71, 10 CFR 37.75, 10 CFR 37.77, 10 CFR 110.28, 10 CFR 110.29, 10 CFR 110.31, 10 CFR 110.32, 10 CFR 110.42, 10 CFR 110.43, 10 CFR 110.44

Criteria: Licensees must do the following:

- Conduct physical inventories at intervals not to exceed 6 months (or some other interval justified by the applicant and approved by the NRC) to account for all sealed sources in accordance with license condition.
- Maintain records of receipt, transfer, and disposal of licensed material.
- Update transactions in the National Source Tracking System (NSTS), including performing annual inventory reconciliation, if applicable.
- Before transferring aggregated Category 1 or Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37, use NRC's license verification system to verify that the recipient licensee is authorized to possess the radioactive material.
- Preplan, coordinate, and provide advance notification of shipment of Category 1 quantities of radioactive material and coordinate shipment of Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37.

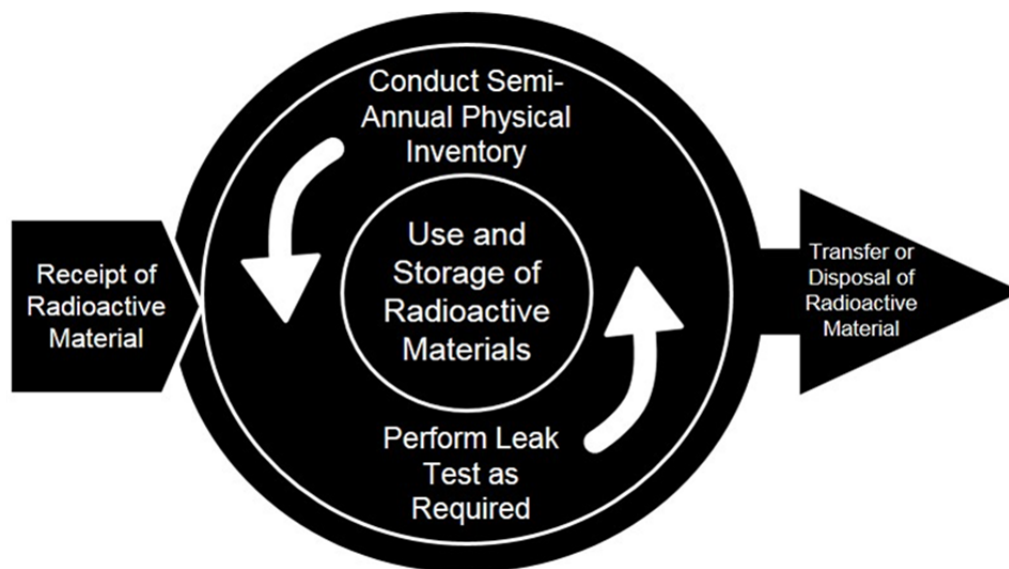
Discussion:

8.10.3.1 Inventory

While loss, theft, or misplacement of most self-shielded irradiators is unlikely because of their size and weight, accountability for licensed materials must be ensured; see Figure 8-3. Many licensees record use of self-shielded irradiators in a log book. Licensees are also required to conduct leak tests of irradiator sealed source(s) at the frequency specified in the SSD registration certificate. Because both of these activities require that an individual approach the irradiator, records of use and leak tests may be used as part of an accountability program. For more information, see Section 8.10.6, "Radiation Safety Program – Operating, Emergency, and Security Procedures," and Section 8.10.7, "Radiation Safety Program - Leak Tests," in this NUREG. However, because some irradiators might not be in use or are used rarely, licensee shall continue to physically approach and account for all sealed sources at least every 6 months. For aggregated Category 1 and Category 2 quantities of radioactive material, licensees must, according to 10 CFR 37.49(a)(1), continuously monitor and detect, without delay, all unauthorized entries into security zones. Additionally, for Category 1 quantities of radioactive material, 10 CFR 37.49(a)(3)(i) requires immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. For Category 2 quantities of radioactive material, 10 CFR 37.49(a)(3)(ii) requires weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

Licensees are required under 10 CFR 20.1801 and 20.1802 to secure radioactive materials from unauthorized removal or access while in storage in controlled or unrestricted areas and to control and maintain constant surveillance over licensed material that is in a controlled or unrestricted area and is not in storage. Applicants should establish policies and procedures for ensuring accountability of licensed materials. Licensed materials should be tracked from receipt to transfer to ensure accountability at all times; to identify when licensed material may be lost, stolen, or misplaced; and to ensure that the possession limit stated on the license is not exceeded.

Receipt to Disposal (Life Cycle)



Licensees must maintain records of receipt, transfer, and disposal and conduct semiannual physical inventories.

Figure 8-3. Material Receipt and Accountability

8.10.3.2 National Source Tracking System (NSTS)

As illustrated in Figure 8-3, licensed materials must be tracked from receipt to disposal, 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."

Pursuant to 10 CFR 20.1003, "Definitions," a "nationally tracked source" is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E to 10 CFR Part 20. For example, the Category 2 value provided for cesium-137 is 1 TBq [27 Ci]. The cesium-137 sources used in self-shielded irradiators are usually at or above the Category 2 quantities listed in Appendix E to 10 CFR Part 20.

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

8.10.3.3 Decommissioning Records

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

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

Information on locations where irradiators are used or stored are records important to decommissioning and are required by 10 CFR 30.35(g)(2).

Table 8-2. Record Maintenance	
Type of Record	How Long Record Must Be Maintained
Receipt	For as long as the material is possessed and for 3 years following the transfer or disposal of the material
Inventory	For 5 years from the date of the inventory in accordance with license conditions
Transfer	For 3 years after <u>each</u> transfer, <u>unless a specific requirement dictates otherwise</u>
Disposal	Until NRC terminates the license
Important to decommissioning*	Until the site is released for unrestricted use
* See Section 8.5.2 entitled, "Financial Assurance and Recordkeeping for Decommissioning," for more details.	
NOTE: If the sealed source(s) will be procured from a company outside the U.S., the NRC licensee must comply with the import regulations listed in 10 CFR Part 110. The same applies for exports of byproduct material.	

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

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

1 **Response from Applicant:**

2 Submit the following:

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

5 **AND**

- 6 • the statement: "Physical inventories will be conducted and documented at intervals not
7 to exceed 6 months to account for all sealed sources and devices received and
8 possessed under the license."

9 **AND**

- 10 • If applicable, provide the following statement: "We will comply with the National Source
11 Tracking System (NSTS) reporting requirement as described in 10 CFR 20.2207."

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

13 **8.10.4 Occupational Dose**

14 **Regulations:** 10 CFR 19.13, 10 CFR 20.1101, 10 CFR 20.1201, 10 CFR 20.1202,
15 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.2104,
16 10 CFR 20.2106

17 **Criteria:** Applicants must do either of the following:

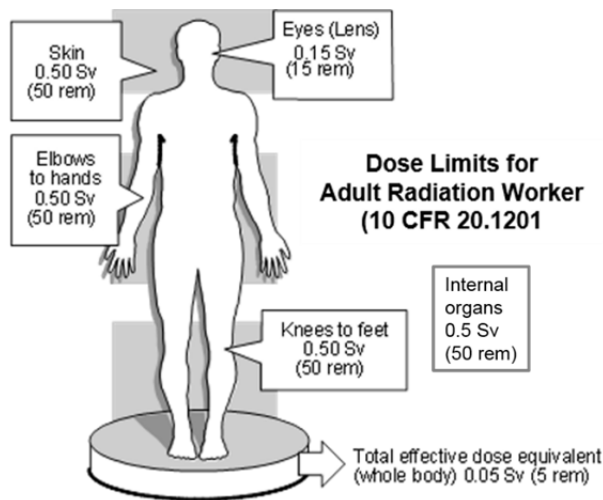
- 18 • Perform a prospective evaluation demonstrating that unmonitored individuals are not
19 likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a), and
20 maintain a record of this evaluation for inspection by the NRC.

21 **OR**

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

Discussion: Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure. When personnel monitoring is required, for all personnel dosimeters that require processing to determine the radiation dose, licensees must use dosimeters supplied by an NVLAP-approved processor. The exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their NVLAP-approved processor for its recommendations for exchange frequency and proper use of the dosimeter.

The annual dose limits for adult radiation workers are shown in Figure 8-4. Note that in accordance with 10 CFR 20.1207, the annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers. Also, 10 CFR 20.1208 requires the licensee to ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem [5 mSv].



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

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

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

- adults who are likely to receive an annual dose from sources external to the body in excess of any of the following (each evaluated separately)
 - 5 mSv [0.5 rem] deep-dose equivalent
 - 15 mSv [1.5 rems] lens (of the eye) dose equivalent

- 50 mSv [5 rems] shallow-dose equivalent to the skin
 - 50 mSv [5 rems] shallow-dose equivalent to any extremity
 - minors who are likely to receive an annual dose from sources external to the body in excess of any of the following (each evaluated separately)
 - 1.0 mSv [0.1 rem] deep-dose equivalent
 - 1.5 mSv [0.15 rem] lens (of the eye) dose equivalent
 - 5 mSv [0.5 rem] shallow-dose equivalent to the skin
 - 5 mSv [0.5 rem] shallow-dose equivalent to any extremity
 - declared pregnant women who are likely to receive a dose from radiation sources external to the body during the entire pregnancy in excess of 1.0 mSv [0.1 rem] deep-dose equivalent
 - individuals entering a high or very high radiation area
- Under conditions of routine use, typically a worker does not require an individual monitoring device (dosimetry). A worker also may not require dosimetry when proper emergency procedures are followed. Appendix L of this NUREG provides guidance on performing a prospective evaluation demonstrating that workers are not likely to exceed the limits in 10 CFR 20.1502(a) and thus are not required to have personnel dosimetry.
- Workers who perform nonroutine maintenance such as any repair, removal, replacement, or alteration involving (i) electrical and mechanical systems that control source or shielding movement, (ii) the irradiator's shielding or sealed source, (iii) safety interlocks, or (iv) any component that may affect safe operation of the irradiator, are more likely than workers who only engage in routine activities to exceed the limits in 10 CFR 20.1502(a). Applicants must provide dosimetry (whole body and perhaps extremity monitors) to workers who perform nonroutine operations or must perform a prospective evaluation demonstrating that unmonitored workers who perform nonroutine operations are not likely to receive radiation doses in excess of the limits in 10 CFR 20.1502(a).

Response from Applicant: Provide any one of the following:

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

OR

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

OR

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

Notes:

- Alternative methods for demonstrating compliance with the referenced regulations will be evaluated against the previously listed criteria.
- Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with NRC requirements (e.g., to respond to worker requests or to maintain records of personal exposure).

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

8.10.5 Public Dose

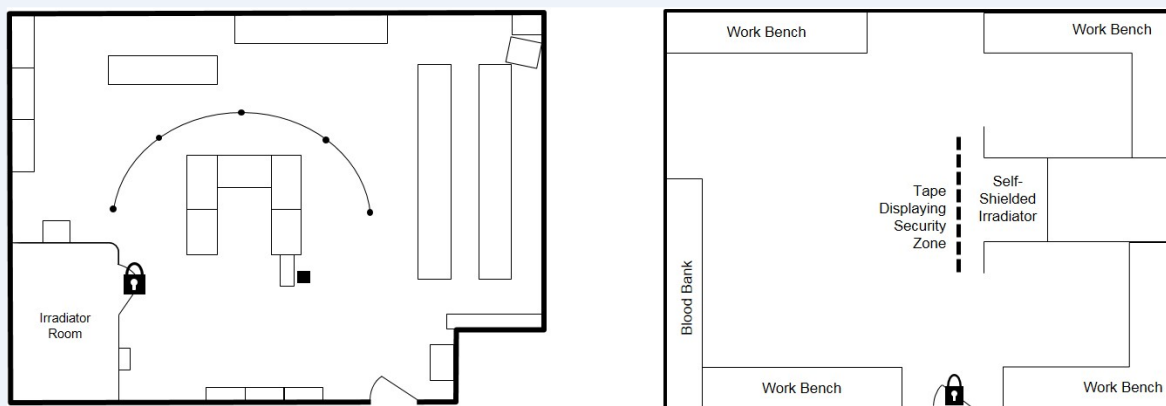
Regulations: 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.2107

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

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

In the case of self-shielded irradiators, members of the public include persons who work or may be near locations where self-shielded irradiators are used or 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 stored.

The licensee’s operating and emergency procedures should be effective in limiting the exposure to the public during use or storage. See Figure 8-5. Public dose is controlled, in part, by ensuring that irradiators are secure (e.g., located in a locked area) to prevent unauthorized access or use. Irradiator use is usually restricted by controlling access to (i) the keys needed to operate the irradiator and/or (ii) the keys or other access-control devices (e.g., keycards, biometric identification, cipher locks, proximity readers) to the locked irradiator area. Only authorized users should have access to these keys and other access-control devices.



Irradiators should be located away from occupied areas and secured to prevent unauthorized use or removal.

Figure 8-5. Proper Location of Irradiator

Public dose is also affected by the choice of storage and use locations and conditions. Because a self-shielded irradiator presents a radiation field, it must be located so that the radiation level in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 100 mrem [1 mSv] in a year or 2 mrem [0.02 mSv] in any 1 hour. 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.

Licenses can determine the radiation levels adjacent to the irradiator location either by calculations or a combination of direct measurements and calculations using some or all of the following: (i) typical known radiation levels provided by the irradiator manufacturer or distributor, (ii) the inverse square law to evaluate the effect of distance on radiation levels, (iii) the occupancy factor to account for the actual presence of members of the public, and (iv) limits on the use of the self-shielded irradiator(s). See Appendix M of this NUREG for an example.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., changes the location of irradiators, changes the type or frequency of irradiator use, adds self-shielded irradiators, or changes the occupancy of adjacent areas), the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action as needed in accordance with 10 CFR 20.1302, "Compliance with dose limits for individual members of the public."

During NRC inspections, licensees must be able to provide documentation in accordance with 10 CFR 20.2107, "Records of dose to individual members of the public," demonstrating, by measurement or calculation, that the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See Appendix M of this NUREG for examples of methods to demonstrate compliance.

Response from Applicant: No response is required from the applicant in a license application, but documentation demonstrating compliance will be examined during inspection.

8.10.6 Operating, Emergency, and Security Procedures

Regulations: 10 CFR 30.34(e); 10 CFR 20.1101; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2202; 10 CFR 20.2203; 10 CFR 20.2207; 10 CFR 30.50; 10 CFR 21.21; 10 CFR 19.11(a)(3); 10 CFR 37 (Subpart B); 10 CFR 37.21(a); 10 CFR 37.45; 10 CFR 37.49

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

8.10.6.1 Operating and Emergency Procedures

Before using an irradiator, licensees must:

- Commit to implement the manufacturer's or distributor's operating and emergency procedures.

OR

- Develop, implement, and maintain model-specific operating and emergency procedures that contain these elements:

- an analysis of each type of material to be placed in the irradiator to ensure that it is compatible with the irradiator's design as described in the irradiator's SSD registration certificate
- special safety procedures (if materials to be irradiated are not compatible and special safety procedures are determined to be needed)
- instructions for using the self-shielded irradiator and performing routine maintenance according to the manufacturer's or distributor's written recommendations and instructions
- instructions for maintaining security to prevent unauthorized use, access, or removal of self-shielded irradiators and the associated sealed sources
- steps to take to keep radiation exposures ALARA
- steps to maintain accountability
- steps to control access to a malfunctioning or damaged irradiator
- emergency procedures that include which steps to take and whom to contact (e.g., RSO, local officials, regulatory agency). These should address the following relatively likely scenarios:
 - leaking source
 - failure of safety interlocks

- 1 – alarming radiation monitor inside irradiator room
- 2 – toppled-over irradiator (during movement to another location)
- 3 – natural disaster (flood, tornado, earthquake, etc.)
- 4 – security alarm for unauthorized access

5 AND

- 6 • Train personnel in the operating and emergency procedures and make copies available
7 to all users.

8 AND

- 9 • Keep a current copy of operating and emergency procedures at each irradiator's control
10 panel (or, if this is not practicable, post a notice describing the procedures and stating
11 where they may be examined).

Discussion: When used as designed, properly functioning self-shielded irradiators pose little radiation safety risk. However, improper maintenance, irradiating material incompatible with an irradiator's design, or operating an irradiator in an environment other than that recommended by the manufacturer or distributor could lead to damage or malfunction of an irradiator and elevated exposure rates in the irradiator's immediate vicinity. Operating and emergency procedures should be developed to minimize these risks while keeping radiation exposures ALARA. These procedures should be model-specific to account for potentially significant differences in irradiator design and construction that lead to manufacturers (or distributors) providing different instructions and recommendations for operating and maintaining irradiators.

21 Sources contained in many self-shielded irradiators are designed to deliver significant radiation
22 doses in short periods of time. Although self-shielded irradiators are safe when used correctly,
23 unauthorized access to the irradiator or the irradiator's sources by untrained individuals could
24 lead to a life-threatening situation. Therefore, operating procedures will also need to address
25 access control and accountability. Many licensees achieve access control by permitting only
26 AUs or the RSO to have access to the keys for the irradiator and/or the irradiator area.
27 Accountability of an operating irradiator may be ensured by using a log book to record irradiator
28 use, maintenance, service calls, and sealed-source leak tests. Each activity requires an
29 individual to interact in some way with the irradiator and thereby verify its presence. For
30 sources contained in irradiators that are not actively used, licensees would need to find other
31 methods to maintain accountability, such as conducting inventories.

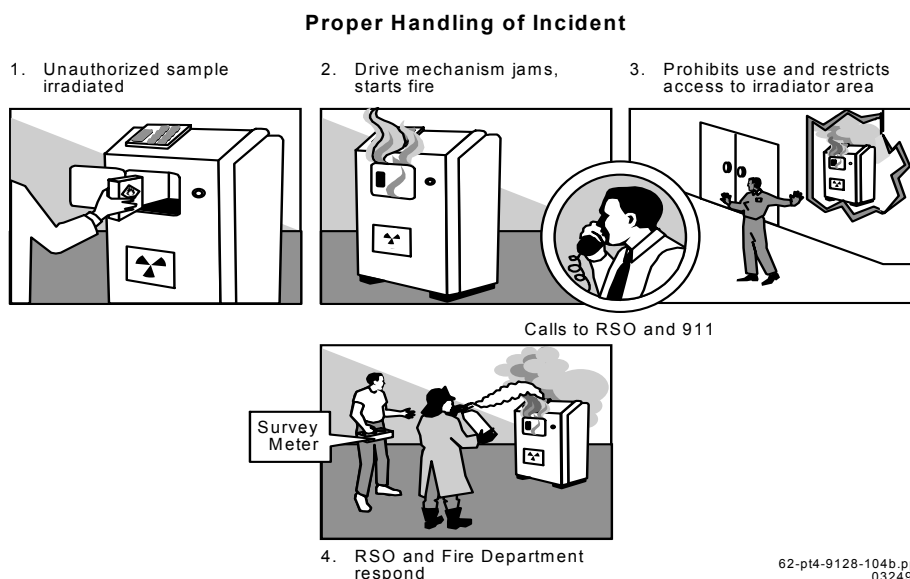
Licensees should post current copies of the operating procedures applicable to licensed activities (e.g., at the irradiator control panel). If posting of a document is not practicable, the licensee may post a notice that describes the document and states where it may be examined.

Figure 8-6 illustrates a proper response to a fire in an irradiator. Emergency procedures should be developed to address a spectrum of incidents (e.g., interlock failure, flood, tornado, earthquake, leaking source, radiation monitor sounding an alarm inside the irradiator room, security-system alarm). Emergency response procedures should include the following elements:

- Leave the irradiator room to reduce radiation exposure.
- Control access (e.g., lock the door).

- 1 • Contact the RSO for further instructions and to initiate emergency response.
2 (Telephone numbers for the RSO, other responsible individuals, the irradiator
3 manufacturer or distributor or its representative, the local law enforcement agency, the
4 fire department or other emergency response organization, and the NRC should be
5 posted or easily accessible.)
- 6 • Survey areas outside the irradiator room to determine whether further restriction of the
7 area is necessary to ensure that no one can enter the area if the radiation level exceeds
8 0.02 mSv [2 mrem] per hour.
- 9 • Require timely reporting to the NRC, according to 10 CFR 20.2201, "Reports of theft or
10 loss of licensed material," 20.2202, "Notification of incidents," and 20.2203, "Reports of
11 exposures, radiation levels, and concentrations of radioactive material exceeding the
12 constraints or limits;" 10 CFR 30.50, "Reporting requirements;" and 10 CFR 21.21,
13 "Notifications of failure to comply or existence of a defect and its evaluation."

The NRC must be notified when a self-shielded irradiator is lost, stolen, or other conditions occur. The RSO must be proactive in evaluating whether NRC notification is required. Refer to Appendix N and the relevant regulations (10 CFR 20.2201 through 20.2203, 10 CFR 30.50, and 10 CFR 21.21) for a description of when and where notifications are required.



Licensee personnel implement emergency procedures when a flammable sample catches fire.

Figure 8-6. Proper Handling of Incident

- 14 Appendix O of this NUREG provides information for applicants to consider when developing
15 their procedures for self-shielded irradiators.

- 1 Licensees may change or revise their operating and emergency procedures if:
- 2 • the changes are reviewed, approved, and documented by licensee management and
3 the RSO
 - 4 • affected licensee staff is trained in the revised procedures before they are implemented
 - 5 • the changes are consistent with applicable license conditions and the procedures or
6 commitments submitted in the license application
 - 7 • the changes do not degrade the safety or security of the program

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

- in accordance with 10 CFR 37.21(a), establish, implement, and maintain its access authorization program in accordance with the requirements of 10 CFR Part 37, Subpart B;
- in accordance with 10 CFR 37.45, coordinate with their local law enforcement agency (LLEA) for responding to threats to a licensee's facility; and
- in accordance with 10 CFR 37.49, be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones, including those surrounding mobile devices.

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

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

8 **Response from Applicant:** Submit the following:

- 9 • A statement that: "If we change our operating, emergency, or security procedures
10 without amending our license, we will ensure that (i) the changes are reviewed and
11 approved by licensee management and the RSO; (ii) affected licensee staff are trained
12 in the procedures before they are implemented; (iii) the changes are consistent with
13 applicable license conditions and the procedures or commitments submitted in the
14 license application; and (iv) the changes do not degrade the safety of the program."

15 **AND EITHER**

- 16 • A statement that: "Operating, emergency, and security procedures will be developed,
17 implemented, maintained, and distributed and will meet the Criteria in the section entitled
18 'Radiation Safety Program - Operating and Emergency Procedures' in NUREG-1556,

Volume 5, Revision 1, ‘Consolidated Guidance About Materials Licenses:
Program-Specific Guidance About Self-Shielded Irradiator Licenses.’”

OR

- alternative operating and emergency procedures

Notes:

- Alternative procedures will be reviewed using the criteria listed above. Do not submit your security procedures. Security procedures will be reviewed during the prelicense visit and subsequent inspections.
- Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will include license conditions to require compliance with the terms of the Order in Appendix I of this NUREG. Applicants requesting these irradiators must ensure that their operating and emergency procedures address these requirements.

8.10.6.2 Security Program for Category 1 and Category 2 Radioactive Material

Regulations: 10 CFR Part 37

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

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

Discussion:

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

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

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

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

- 1 In accordance with 10 CFR 37.41(b), licensees must establish a security program designed to
2 monitor and, without delay, detect, assess, and respond to any actual or attempted
3 unauthorized access to Category 1 or Category 2 quantities of radioactive material.
- 4 Per 10 CFR Part 37, Subpart D, licensees must provide for physical protection of Category 1 or
5 Category 2 quantities of radioactive materials in transit. These requirements apply to licensees
6 delivering such material to a carrier for transport, as well as cases in which licensees are
7 transporting such material. Please note that the Subpart D requirements applicable to the
8 transport of Category 1 quantities of radioactive material are more stringent than those
9 applicable to Category 2 quantities.

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

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

- 10 For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155,
11 "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category
12 2 Quantities of Radioactive Material." Additional information regarding best practices for
13 protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security
14 Best Practices for the Protection of Risk-Significant Radioactive Material."

15 **Response from Applicant:**

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

18 **8.10.7 Leak Tests**

19 **Regulations:** 10 CFR 30.53, 10 CFR 20.1501, 10 CFR 20.2103

- 20 **Criteria:** The NRC requires testing to determine whether there is any radioactive leakage from
21 the source in the self-shielded irradiator. The NRC finds testing to be acceptable if it is
22 conducted by an organization licensed by the NRC or an Agreement State to perform leak
23 testing or if it is conducted in accordance with procedures submitted by the applicant and
24 approved by the NRC. Licensees must maintain records of leak test results in accordance with
25 license conditions or, if applicable, NRC regulations.

- 26 **Discussion:** Based on the conditions of the license, a licensee must leak test sealed sources
27 at intervals approved by the NRC or as specified in the SSD registration certificate. The
28 measurement of the leak test sample is a quantitative analysis requiring that instrumentation
29 used to analyze the sample be capable of detecting 185 Bq [0.005 Ci] of radioactivity.

- 30 Manufacturers, distributors, consultants, and other organizations may be authorized by the NRC
31 or an Agreement State to either perform the entire leak test sequence on behalf of licensees or

provide leak test kits to licensees. In the latter case, the licensee takes the leak test sample according to the manufacturer's and/or the kit supplier's instructions and returns it to the leak test service provider for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. The NRC or an Agreement State may, in a license condition, specifically authorize self-shielded irradiator licensees to conduct the entire leak test sequence themselves.

Response from Applicant:

Submit one of the following:

- the statement: "Leak tests will be performed at intervals approved by the NRC or as specified in the Sealed Source and Device registration certificate. Leak tests will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test kit supplied by an organization authorized by the NRC or an Agreement State to provide leak test kits to other licensees; and according to the self-shielded irradiator manufacturer's or distributor's instructions and kit supplier's instructions."

OR

- the statement: "Leak testing and analysis will be done by the applicant." Provide the information in Appendix P of this NUREG supporting a request to perform leak testing and sample analysis and either state that you will follow the model procedures in Appendix P of NUREG-1556, Volume 5, Revision 1, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiators or submit alternative procedures."

Notes:

- Alternative responses will be reviewed using the criteria listed above.
- Requests for authorization to perform leak testing and sample analysis will be reviewed on a case-by-case basis and, if approved, the NRC staff will authorize these activities through a license condition.

8.10.8 Maintenance

Regulations: 10 CFR 20.1101, 10 CFR 30.32(g)(2), 10 CFR 30.34(e), 10 CFR 32.210

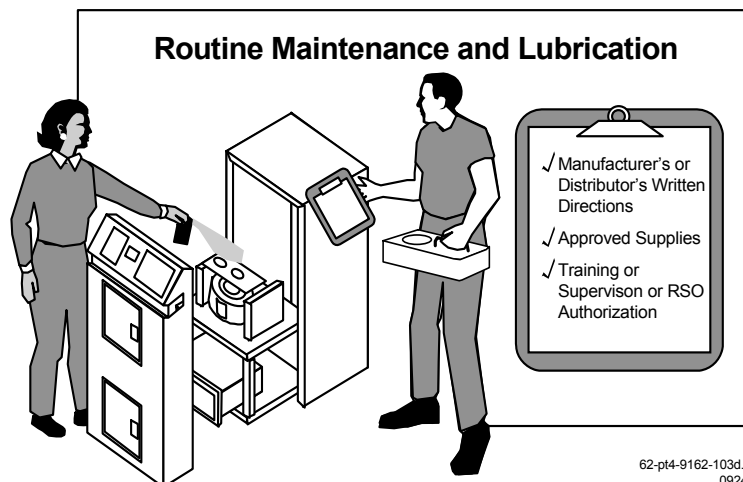
Criteria: Self-shielded irradiators should be maintained according to the manufacturer's or distributor's written recommendations and instructions and in accordance with the SSD registration certificate; see Figure 8-7. For self-shielded irradiators, writers of the radiation safety procedures for maintenance must consider the ALARA criterion and ensure that the irradiator functions as designed and that source integrity is not compromised.

Discussion: NRC Information Notice 96-35, "Failure of Safety Systems on Self-Shielded Irradiators Because of Inadequate Maintenance and Training," dated June 11, 1996, emphasizes the importance of proper maintenance and describes two incidents in which safety interlocks on self-shielded irradiators failed to prevent inadvertent exposure. Generally, before

any maintenance or repair work is done, licensees need to determine (and assure themselves of the adequacy of) the following:

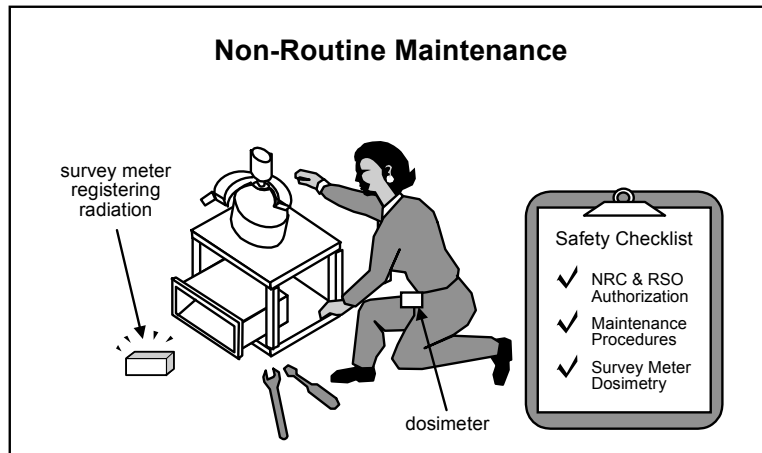
- the training and experience of the personnel performing the work
- the tasks to be performed
- the protocol or procedures to be followed (e.g., from the manufacturer's and/or distributor's procedures or instruction manual) for the particular task to be performed
- the radiation safety procedures, including any possible need for compensatory (emergency) measures (such as steps taken to compensate for lack of or reduced shielding)
- considerations for keeping exposures ALARA
- the qualification of parts, components, and other materials to be used in the irradiator
- use of an operable and calibrated radiation survey meter
- the tests to be performed before the irradiator is returned to routine use to ensure that it functions as designed

The NRC permits self-shielded irradiator licensees to perform routine maintenance of the irradiator, provided that they follow the self-shielded irradiator manufacturer's or distributor's written recommendations and instructions.



To ensure proper operation of the unit, self-shielded irradiator licensees need to perform routine maintenance according to the manufacturer's or distributor's written instructions and recommendations.

Figure 8-7. Routine Maintenance and Lubrication



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For nonroutine maintenance, most licensees rely on the manufacturer, distributor, or other service-provider companies.

Figure 8-8. Nonroutine Maintenance

In this NUREG, “routine maintenance” includes cleaning, lubrication, and changing batteries, relays, or fuses.

AND

“Nonroutine maintenance” means any repair, removal, replacement, or alteration involving electrical and mechanical systems that control source or shielding movement, the irradiator’s shielding or sealed source, safety interlocks, any component that may affect safe operation of the irradiator, or any other activities during which personnel could receive radiation doses exceeding NRC limits.

Nonroutine maintenance must be performed by the self-shielded irradiator manufacturer, distributor, service provider, or a person specifically authorized by the NRC or an Agreement State; see Figure 8-8.

Applicants seeking authorization to perform nonroutine maintenance should submit specific operating and emergency procedures to the NRC for review. See Appendix Q of this NUREG for more information.

Note: When replacement parts are required, and neither the irradiator licensee nor its service provider can obtain the replacement part from the manufacturer or distributor, the irradiator licensee and/or service provider may obtain a part from another vendor or fabricate the part. If the original equipment manufacturer (OEM) part cannot be obtained, the irradiator licensee and/or the service provider should verify that the replacement part will have the same form, fit, and function as the original component. If the maintenance involves work on

- the shielding of any sealed sources
- the driving unit of any sources
- safety interlocks

1 • any other electrical or mechanical component that:

2 — could expose any sources

3 — would reduce the shielding around any sources

4 — could compromise the radiation safety of the device or any sources

5 The irradiator licensee should provide the technical information to the NRC for a safety review
6 before nonroutine maintenance activities occur in accordance with the SSD registry, as
7 described in 10 CFR 32.210 and 10 CFR 30.32(g)(2), to ensure compliance with the radiation
8 safety measures that apply to the original equipment.

9 Equipment defects that could create a substantial safety hazard or equipment failures involving
10 NRC-regulated activities must be reported to the NRC in accordance with 10 CFR Part 21. For
11 example, a safety interlock failure for an irradiator/calibrator is a defect that must be reported to
12 the NRC. IN 91-39, "Compliance with 10 CFR Part 21, Reporting of Defects and
13 Noncompliance," dated June 17, 1991, provides additional guidance on determining whether a
14 safety hazard exists and sample procedures for identifying and reporting defects. The
15 information notice can be found on the NRC's Generic Communications Web page under
16 Information Notices at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>. For guidance
17 on the use of sources that have not been directly supplied by the manufacturer and/or
18 distributor, see RIS 2013-01, "Use of Aftermarket Sealed Sources Registered Under
19 10 CFR 32.210" dated March 12, 2013 (ADAMS Accession No. ML12313A147).

20 The NRC issued RIS 2008-23, "The Global Threat Reduction Initiative (GTRI) Domestic Threat
21 Reduction Program & Federally Funded Voluntary Security Enhancements for High-Risk
22 Radiological Material," on October 3, 2008 (ADAMS Accession No. ML082540256). This
23 voluntary initiative has been coordinated with the Department of Energy's National Nuclear
24 Security Administration (NNSA). Please note that once an irradiator has undergone these
25 security enhancements (also known as being "hardened"), it is much more difficult to access the
26 cesium chloride sources, and this could affect servicing (e.g., source exchange, transportation).
27 Irradiator licensees with GTRI-hardened irradiators should confirm that the service provider
28 licensee can perform the activity. Licensees should review their NRC or Agreement State
29 licenses or contact the regulatory agency to confirm that service providers are authorized to
30 perform the requested hardened-irradiator services. GTRI irradiator hardening was done to
31 ensure the continued safe use and operation of the irradiator in keeping with the sealed source
32 and device registration. If a service provider informs the irradiator licensee that they will remove
33 any aspect of the GTRI irradiator-hardening hardware, the irradiator licensee should discuss this
34 matter with its regulatory agency before allowing the service provider to initiate this service.

35 **Response from Applicant:**

36 For all **maintenance**, submit:

37 • this statement: "We will maintain documentation of the use of all non-OEM replacement
38 parts and components. If OEM replacement parts cannot be used for the shielding of
39 any sealed sources, the driving unit of any sources, safety interlocks, or other electrical
40 or mechanical component that could expose the source, reduce the shielding around the
41 source(s), or compromise the radiation safety of the device or any sources, we will
42 obtain and document NRC approval before beginning the nonroutine maintenance
43 activity. In addition, if a service provider plans to remove any aspect of the GTRI

1 irradiator-hardening hardware, we will discuss this matter with the NRC before allowing
2 this service to be initiated.”

3 For **routine maintenance**, submit either of the following:

- 4 • this statement: “We will implement and maintain procedures for routine maintenance of
5 our self-shielded irradiators according to each manufacturer’s or distributor’s written
6 recommendations and instructions.”

7 **OR**

- 8 • alternative procedures for the NRC’s review

9 For **nonroutine maintenance**, submit either of the following:

- 10 • this statement: “We will have the self-shielded irradiator manufacturer, distributor,
11 service provider, or another person authorized by the NRC or an Agreement State
12 perform nonroutine maintenance.”

13 **OR**

- 14 • alternative procedures for the NRC’s review addressing the information listed in
15 Appendix Q of NUREG-1556, Volume 5, Revision 1, ‘Consolidated Guidance About
16 Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator
17 Licenses.’”

18 **Notes:**

- 19 • Alternative procedures for performing routine maintenance will be reviewed using the
20 criteria listed above.
- 21 • Information requested in Appendix Q will be reviewed on a case-by-case basis. If
22 approved, the license will contain a condition authorizing the licensee to perform
23 nonroutine maintenance.

24 **References:** IN 91-39, “Compliance with 10 CFR Part 21, Reporting of Defects and
25 Noncompliance,” dated June 17, 1991, can be found on the NRC’s Generic Communications
26 Web page under Information Notices at [http://www.nrc.gov/reading-rm/doc-collections/gen-](http://www.nrc.gov/reading-rm/doc-collections/gen-comm/)
27 [comm/](http://www.nrc.gov/reading-rm/doc-collections/gen-comm/).

28 RIS 2013-01, “Use of Aftermarket Sealed Sources Registered under 10 CFR 32.210,” issued
29 March 12, 2013 (ADAMS Accession No. ML12313A147).

30 **8.10.9 Transfer and Transportation**

31 **Regulations:** 10 CFR 20.1101, 10 CFR 30.41, 10 CFR 30.51, 10 CFR Part 37 (Subpart D),
32 10 CFR 71.5, 10 CFR 71.12, 10 CFR 71.37, 10 CFR 71.38, 10 CFR 71.101, 10 CFR 110.23,
33 10 CFR 110.27, 10 CFR 110.28, 10 CFR 110.29, and 49 CFR Parts 171-178

34 **Criteria:** Licensees and applicants must develop, implement, and maintain procedures for
35 transport of radioactive material to ensure compliance with NRC and U.S. Department of

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

5 **Discussion:** All packages containing radioactive sources must be prepared and shipped
6 according to NRC and DOT regulations.

7 Some irradiator licensees who rarely ship radioactive material have chosen to transfer
8 possession of radioactive materials to a contracted irradiator manufacturer, irradiator distributor,
9 or service provider licensee (contractor) with an NRC or Agreement State license who then acts
10 as the shipper. The contractor, who is subject to the provisions of 10 CFR 71.12 or
11 10 CFR 71.14, as appropriate, then becomes responsible for proper packaging of the
12 radioactive materials and compliance with NRC and DOT regulations. Licensees who do this
13 should ensure that the contractor

- 14 • is authorized to possess the irradiator at temporary jobsites (e.g., at the irradiator
15 location)
- 16 • actually takes possession of the irradiator under its license
- 17 • provides documentation of the transfer of possession to the licensee
- 18 • uses an approved Type B package
- 19 • is registered with NRC as a user of the Type B package
- 20 • has an NRC-approved QA plan

For each shipment, it must be clear (i) when the transfer of possession from the licensee to the contractor takes place, (ii) who possesses the licensed material and is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations, (iii) who is responsible for security of the radioactive materials, and (iv) who is responsible for decontamination and cleanup, if necessary.

21 During an inspection, the NRC uses the provisions of 10 CFR 71.5, "Transportation of licensed
22 material," and a Memorandum of Understanding (MOU) with DOT on the Transportation of
23 Radioactive Material (signed June 6, 1979) to examine and enforce various DOT requirements
24 applicable to irradiator licensees. Appendix R of this NUREG lists major DOT regulations.

25 For secure transport of radioactive material quantities of concern, the shipper (either the
26 licensee or the service provider, as appropriate) must comply with the security measures
27 described in Subpart D of 10 CFR Part 37. Additional information regarding secure transport
28 can be found in Section 8.10.6.2, "Security Program for Category 1 and Category 2 Radioactive
29 Material," of this NUREG.

30 If the irradiator to be moved or transported has been hardened, as described in the
31 Maintenance Section above, the irradiator may be transported in an approved Type B shipping
32 cask in its entirety. If the licensee or service provider wishes to remove the hardening for
33

1 transport, the licensee should discuss this matter with the NRC before allowing this service to
2 be initiated.



Figure 8-9. Illustrations for Import and Export

Note: If the sealed source(s) will be procured from a company outside the U.S., the NRC licensee must comply with the import regulations listed in 10 CFR Part 110. The same applies for exports of byproduct material, as illustrated in Figure 8-9. Also be aware of the list of embargoed and restricted destinations.

3 **Irradiators Built Before 10 CFR Part 71 Regulation Implementation/Exemption Request**

4 Before the adoption of the requirements of 10 CFR Part 71 in 1966, irradiators could be
5 transported without being evaluated under the hypothetical accident conditions now
6 incorporated in 10 CFR Part 71. Unlike most post-1966 irradiators, pre-1966 irradiators are not
7 certified shipping packages. Transport of pre-1966 units may require transferring the sealed
8 source from the irradiator to a Type B package or the use of a certified package for the irradiator
9 containing the sealed sources. NRC will consider a licensee's request for an exemption for a
10 one-time shipment, according to 10 CFR 71.12, *only* if the options above are not viable.

11 An exemption may be granted if the request is authorized by law and will not endanger life or
12 property or the common defense and security. A request for such an exemption should
13 demonstrate the need for the exemption, describe why alternatives considered are not viable,
14 specify from what requirement(s) an exemption is requested and the period for which the
15 exemption is requested, and describe steps taken to ensure that the shipment will not endanger
16 life or property or the common defense and security (for example, steps to minimize accident
17 risk and to respond to a transportation accident). Typically, exemption requests that the NRC
18 approves are for a limited period, such as 30 days.

19 Additional information supporting an exemption request should include the following:

- 20 • the manufacturer's or distributor's name and the model number of the irradiator, the type
21 and activity of radioactive material to be transported, and a brief description of the
22 proposed trip (including at least its starting and ending points and approximate distance)
- 23 • the planned date of the shipment
- 24 • engineering drawings of the irradiator
- 25 • consideration of the following:

- 1 — DOT's hazardous material routing requirements
- 2 — transport during time of low road usage
- 3 — use of good roads and avoidance of residential areas to the maximum
- 4 — extent possible
- 5 — accompaniment of the shipment by an escort knowledgeable in the use of
- 6 — radiation survey instruments
- 7 — providing the escort with appropriate survey instruments and supplies to permit
- 8 — the establishment of a radiation exclusion area
- 9 — written procedures to be followed by the escort in an emergency situation
- 10 — use of an exclusive-use vehicle and shoring to limit movement of the package
- 11 — during transport
- 12 — notification of state radiological health officials and the local fire department of
- 13 — the time and route of the shipment
- 14 — how the material will be secured to meet the requirements of Subpart D of
- 15 — 10 CFR Part 37

16 NRC Headquarters staff must review these exemption requests, which are typically requests to
17 amend materials (10 CFR Part 30) licenses. Licensees should address their requests to the
18 appropriate Regional Office. The Regional Office will refer the request to NRC Headquarters
19 staff for review by NMSS. If the exemption is approved, NRC Headquarters staff will provide the
20 language for the license condition. There may be an additional fee associated with these
21 special reviews. In addition to an NRC exemption, the licensee may also need a DOT
22 exemption; contact DOT's Office of Hazardous Materials Safety at 202-366-4535 for additional
23 information.

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

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

24 **Response from Applicant:** No response is needed from applicants during the licensing phase.
25 However, before offering a Type B package for shipment, a licensee needs to have registered
26 with the NRC as a user of the package and obtained NRC's approval of its QA program.
27 Transportation issues will be reviewed during inspection.

To request an exemption from the regulations for the transportation of an irradiator built before 1966, submit the following:

- Establish that the irradiator was built before 1966.
- Explain why an approved package cannot be used, what alternatives have been considered, and why each alternative is not viable.
- Specify from what requirement(s) an exemption is requested and the period for which the exemption is requested.
- Describe procedures, controls, and other actions to be taken to ensure that the shipment will not endanger life or property or the common defense and security.
- Demonstrate that the request is authorized by law and will not endanger life or property or the common defense and security.

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at 202-366-4425.

8.11 Item 11: Waste Management

8.11.1 Self-Shielded Irradiator Transfer and Disposal

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

Criteria: Licensed materials must be disposed of according to NRC requirements by transfer to an authorized recipient in accordance with 10 CFR 30.41, "Transfer of byproduct material." Appropriate records must be maintained in accordance with 10 CFR 30.51.

The NRC's Lost Source Policy states that a civil penalty may be issued for violations resulting in regulated material being out of the control of the licensee, regardless of the use, license type, quantity, or type of regulated material (e.g., through loss, abandonment, improper transfer, or improper disposal of regulated material). The Lost Source Policy is described in Section 2.3.4 of NRC's Enforcement Policy and in Section 3.1 in NRC's Enforcement Manual.

Discussion: 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. In addition, under 10 CFR 37.71(a) and (b), "Physical Protection of Byproduct Material Category 1 and Category 2 Quantities of Radioactive Material," any licensee, before transferring Category 1 or Category 2 quantities of radioactive material, shall verify that the recipient is authorized to possess the radioactive material. This verification can be completed in one of two ways:

- using the NRC's License Verification System (LVS)

OR

- contacting the license-issuing authority

1 In either case, the licensee must verify that the transferee's license authorizes the receipt of the
2 type, form, and quantity of radioactive material to be transferred and that the licensee is
3 authorized to receive radioactive material at the location requested for delivery. If the
4 verification is conducted by contacting the license-issuing authority, the transferor shall
5 document the verification. For transfers within the same organization, the licensee does not
6 need to verify the transfer.

7 When the licensee is unable to use the LVS to complete the license verification requirement,
8 they may use a manual process to verify the license with the regulatory agency that issued the
9 license. Verification information is collected from both the transferring licensee and the issuing
10 agency using NRC Form 749, "Manual License Verification Report." Information about LVS can
11 be found on the NRC Web page under Nuclear Security and Safeguards/Radioactive Material
12 Security at <http://www.nrc.gov/security/byproduct/ismplvs.html>.

13 When disposing of self-shielded irradiators, licensees must transfer them to an authorized
14 recipient. Authorized recipients are the original manufacturer or distributor of the irradiator,
15 a commercial firm licensed by the NRC or an Agreement State to accept radioactive waste from
16 other persons, or another specific licensee authorized by NRC or an Agreement State to
17 possess the licensed material (i.e., its license specifically authorizes the same radionuclide,
18 form, and use). Licensees should promptly dispose of irradiators that are no longer in service or
19 not being used by the licensee in order to minimize potential problems of access by
20 unauthorized individuals, use for inappropriate purposes, or improper disposal. Because of the
21 difficulties and costs associated with disposal of sealed sources, applicants should preplan the
22 disposal. Applicants might want to consider contractual arrangements with the source supplier
23 as part of a purchase agreement.

24 If source activity exceeds activities listed in Appendix E, "Nationally Tracked Source
25 Thresholds," to 10 CFR Part 20, the transfer transaction must be reported in accordance with
26 10 CFR 20.2207.

The Conference of Radiation Control Program Directors (CRCPD) maintains a list of "Outlets for Common Radioactive Materials" and "Radioactive Waste Broker & Decontamination Services" on their Web site at http://www.crcpd.org/StateServices/Comm_Svcs.aspx .

27 Appendix S of this NUREG contains helpful information related to the Radiation Source Use and
28 Replacement Study, which can also be found on the NRC Web page under Nuclear Security
29 and Safeguards/Radioactive Material Security at [http://www.nrc.gov/security/nas-facts-](http://www.nrc.gov/security/nas-facts-sheet.pdf)
30 [sheet.pdf](http://www.nrc.gov/security/nas-facts-sheet.pdf).

31 **Response from Applicant:** The applicant does not need to provide a response to this item
32 during the licensing phase. However, the licensee should develop, implement, and maintain
33 self-shielded irradiator transfer and waste disposal procedures, including updates to the NSTS,
34 in its radiation safety program.

35 **References:**

36 The NRC's Enforcement Policy may be found online at
37 <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>, and the Enforcement
38 Manual may be found online at
39 <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html>.

8.12 Item 12: License Fees

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

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

8.13 Item 13: Certification

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

Notes:

- It is a criminal offense to knowingly and willfully make a false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, those items will be incorporated into the license and, therefore, will become binding regulatory requirements.

9 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or will change, 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 Title 10 of the *Code of Federal Register* (CFR) [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 U.S. Nuclear Regulatory Commission (NRC) Form 313 or a letter requesting amendment or renewal.
- Provide the license number and docket number.
- For renewals, provide a complete and up-to-date application, including all required program elements outlined in Appendix B of this NUREG. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application.

9.1 Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b)

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

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

- radioactive materials are possessed, used, or controlled only by persons who have valid NRC or Agreement State licenses
- materials are properly handled and secured
- persons using these materials are capable, competent and committed to implementing appropriate radiological controls
- a clear chain of custody is established to identify who is responsible for disposition of records and licensed material
- public health and safety are not compromised by the use of such materials
- adequate financial assurance is provided for compliance with the applicable NRC requirements, if required

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

6 **Reference:** For further information, see Regulatory Issue Summary (RIS) 2014-08, Rev. 1,
7 “Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials
8 Licenses,” dated May 5, 2016. This RIS can be found on the NRC’s Generic Communications
9 Web page under “Regulatory Issue Summaries”:

10 <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.

10 APPLICATIONS FOR EXEMPTIONS

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

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

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

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

Unless the NRC has granted an exemption in writing, licensees must comply with all applicable regulations.
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Some licensees with self-shielded irradiators built before 1966 may need an exemption from the requirements in 10 CFR Part 71 in order to transport these irradiators. Section 8.10.9, "Transportation," provides more detailed information about this special situation.

11 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 20.1401, 10 CFR 20.1402, 10 CFR 20.1403, 10 CFR 20.1404, 10 CFR 20.1405, 10 CFR 20.1406, 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36, 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 U.S. Nuclear Regulatory Commission (NRC), in writing, within 60 days of the occurrence of any of the following:
 - expiration of its license
 - a decision to permanently cease principal activities¹ at the entire site
 - a decision to permanently cease principal activities¹ in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements
 - no principal activities¹ under the license have been conducted for a period of 24 months
 - no principal activities¹ 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 (j)
- submit, to the appropriate NRC regional office, a completed NRC Form 314, "Certificate of Disposition of Materials" (or equivalent information) and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final surveys and results of leak tests of sealed sources).
- Before a license is terminated, send records important to decommissioning that are required by 10 CFR 30.35(g) to the appropriate NRC regional office in accordance with 10 CFR 30.51(f).

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

1 **Discussion:** Typically, a self-shielded irradiator termination request will meet the previously
2 listed criteria if the licensee has performed the following steps:

- 3 • The licensee must dispose of or transfer the sealed sources to an NRC or Agreement
4 State licensee authorized to possess these devices, as described in Section 8.11,
5 “Waste Management.”
- 6 • The licensee must copy applicable decommissioning records as described in Section
7 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning.” Typically, this
8 includes transfer of records and final leak test records to the appropriate NRC regional
9 office. See Section 8.5.2 for additional recordkeeping requirements if leaking sealed
10 sources or other incidents that involve the spreading of contamination have occurred.
- 11 • The licensee must submit a completed NRC Form 314 and a copy of the applicable
12 decommissioning records to the appropriate NRC regional office.

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

19 **References:**

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

21 NUREG-1757, “Consolidated Decommissioning Guidance,” Volume 1, “Decommissioning
22 Process for Materials Licensees,” can be found at [http://www.nrc.gov/reading-rm/doc-](http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/)
23 [collections/nuregs/staff/sr1757/](http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/).

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

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APPENDIX A

U.S. NUCLEAR REGULATORY COMMISSION FORM 313

U.S. Nuclear Regulatory Commission Form 313

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

NRC FORM 313 <small>(06-2016)</small> <small>10 CFR 30, 32, 33, 34</small> <small>35, 36, 37, 39, and 40</small>	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE	APPROVED BY OMB: NO. 3150-0120 <small>Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</small>																								
EXPIRES: 06/30/2019																										
INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.																										
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NRC FORM 313 (06-2016)

1

APPENDIX B

2

SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN

3

ITEMS 5 THROUGH 11 OF NRC FORM 313

1
2

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

Table B-1. Items 5 & 6: Materials to Be Possessed and Proposed Uses						
Yes	No	Radioisotope	Manufacturer or Distributor Model No.	Quantity	Use as Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Cesium-137	<p>Each of the following requested sealed sources, devices, and source/device combinations is the subject of an approved SSD registration certificate number(s). State the SSD certificate number(s):</p> <p>_____</p> <p>Sealed source manufacturer's or distributor's name and model number:</p> <p>_____</p> <p>Device manufacturer's or distributor's name and model number:</p> <p>_____</p>	<p>_____ Ci</p> <p>per source and maximum possession limit (based on number of sources requested):</p> <p>_____ Ci total</p> <p>Not to exceed either the maximum activity per source or maximum activity per device as specified in SSD registration certificate</p>	Yes []	<p>[] Not applicable</p> <p>_____</p> <p>[] Uses are:</p> <p>_____</p> <p>(Submit safety analysis, including procedures and training, supporting safe use)</p>

Table B–1. Items 5 & 6: Materials to Be Possessed and Proposed Uses (Continued)

Yes	No	Radioisotope	Manufacturer or Distributor Model No.	Quantity	Use as Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Cobalt-60	<p>Each of the following requested sealed sources, devices, and source/device combinations is the subject of an approved SSD Registration Certificate numbers. State the SSD certificate number(s):</p> <p>_____</p> <p>Sealed source manufacturer's or distributor's name and model number:</p> <p>_____</p> <p>Device manufacturer's or distributor's name and model number:</p> <p>_____</p>	<p>_____ Ci</p> <p>per source and maximum possession limit (based on number of sources requested):</p> <p>_____ Ci total</p> <p>Not to exceed either the maximum activity per source or maximum activity per device as specified in SSD registration certificate</p>	Yes []	<p>[] Not applicable</p> <p>_____</p> <p>[] Uses are:</p> <p>_____</p> <p>(Submit safety analysis, including procedures and training, supporting safe use)</p>

Table B–1. Items 5 & 6: Materials to Be Possessed and Proposed Uses (Continued)

Yes	No	Radioisotope	Manufacturer or Distributor Model No.	Quantity	Use as Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Strontium-90	<p>Each of the following requested sealed sources, devices, and source/device combinations is the subject of an approved SSD Registration Certificate numbers. State the SSD certificate number(s):</p> <p>_____</p> <p>Sealed source manufacturer's or distributor's name and model number:</p> <p>_____</p> <p>Device manufacturer's or distributor's name and model number:</p> <p>_____</p>	<p>_____ Ci</p> <p>per source and maximum possession limit (based on number of sources requested):</p> <p>_____ Ci total</p> <p>Not to exceed either the maximum activity per source or maximum activity per device as specified in SSD registration certificate</p>	Yes []	<p>[] Not applicable</p> <p>[] Uses are:</p> <p>_____</p> <p>(Submit safety analysis, including procedures and training, supporting safe use)</p>

Table B–1. Items 5 & 6: Materials to Be Possessed and Proposed Uses (Continued)

Yes	No	Radioisotope	Manufacturer or Distributor Model No.	Quantity	Use as Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Other (specify)	Sealed source manufacturer or distributor name and model number: _____ Device manufacturer or distributor name and model number: _____ SSD Registration Certificate numbers: _____	_____ Ci per source and maximum possession limit (based on number of sources requested): _____ Ci total Not to exceed either the maximum activity per source or maximum activity per device as specified in SSD registration certificate	Yes []	[] Not applicable _____ [] Uses are: _____ (Submit safety analysis, including procedures and training, supporting safe use)
					Yes	Description Attached
Financial Assurance and Recordkeeping For Decommissioning State the following: “In accordance with 10 CFR 30.35(g), we shall maintain drawings and records important to decommissioning and shall transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or forward the records to the appropriate NRC regional office before the license is terminated.” <p style="text-align: center;">AND</p> If financial assurance is required, submit evidence of financial assurance following the guidance of NUREG-1757, Volume 3, “Consolidated Decommissioning Guidance - Financial Assurance, Recordkeeping, and Timeliness.”					[]	[]

Table B-2. Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal			
Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
<p>7. Individual(s) Responsible for Radiation Safety Program and Their Training and Experience</p> <p>7.1 Radiation Safety Officer (RSO) Name of RSO: _____ (As you would like it to appear on the license)</p>	<p>State the following: “Before obtaining licensed materials, the proposed RSO will have successfully completed training described in Appendix F of NUREG-1556, Volume 5, Revision 1, ‘Consolidated Guidance About Materials License: Program-Specific Guidance About Self-Shielded Irradiator Licenses.”</p> <p style="text-align: center;">OR</p> <p>Provide alternative information demonstrating that the proposed RSO is qualified by training and experience.</p>	[]	[]
<p>7. Individual(s) Responsible for Radiation Safety Program and Their Training and Experience</p> <p>7.2 Authorized Users (AUs) Names of AUs: _____ _____ _____ _____ (As you would like them to appear on the license)</p>	<p>State the following: “Before using licensed materials, authorized users will receive the training described in Appendix F of NUREG-1556, Volume 5, Revision 1, ‘Consolidated Guidance About Materials License: Program-Specific Guidance About Self-Shielded Irradiator Licenses.”</p> <p style="text-align: center;">OR</p> <p>Provide alternative information demonstrating that the proposed AUs are qualified by training and experience.</p>	[]	[]

Table B–2. Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)		
Item No. and Title	Suggested Response	Yes
8. Training for Individuals Working in or Frequenting Restricted Areas	The applicant's training program will be examined during inspections but should not be submitted in the license application.	Need Not Be Submitted with Application
9. Facilities and Equipment	<p>State the following: "We will conduct electrical and mechanical safety interlock checks of each irradiator at least quarterly, in accordance with the irradiator's user's manual."</p> <p style="text-align: center;">AND EITHER</p> <p>State the following: "We will ensure that each area where a self-shielded irradiator is located corresponds to the 'Conditions of Normal Use' and 'Limitations and/or Other Considerations of Use' on the applicable irradiator's Sealed Source and Device registration certificate; the floor beneath the self-shielded irradiator is adequate to support the weight of the irradiator; each self-shielded irradiator is secured to prevent unauthorized access or removal; and each area where a self-shielded irradiator is located is equipped with an automatically operated fire-detection and -control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low level of radiation risk attributable to fires."</p> <p style="text-align: center;">OR</p> <p>Provide alternative information; be sure to include justification for placing an irradiator in an area that does not correspond to the "Conditions of Normal Use" and the "Limitations and/or Other Considerations of Use."</p>	<p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p>

Table B–2. Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)		
Item No. and Title	Suggested Response	Yes
10. Radiation Safety Program		
10.1 Audit and Review of Program	The applicant's program for reviewing the content and implementation of its radiation protection program, access authorization program, and security program will be examined during inspections and should not be submitted with the license application.	Need Not Be Submitted with Application
10.2 Radiation Monitoring Instruments	<p>Submit one of the following:</p> <ul style="list-style-type: none"> • this statement: "We will use instruments that meet the radiation-monitoring instrument specifications published in Appendix K of NUREG-1556, Volume 5, Revision 1, 'Consolidated Guidance About Materials License: Program-Specific Guidance About Self-Shielded Irradiator Licenses.'" Additionally, each radiation survey meter will have been calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform radiation survey meter calibrations no more than 12 months before the date the meter is used." 	[]

Table B-2. Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)

Item No. and Title	Suggested Response	Yes
	<p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • this statement: “We will use instruments that meet the radiation-monitoring instrument specifications published in Appendix K of NUREG-1556, Volume 5, Revision 1, ‘Consolidated Guidance About Materials License: Program-Specific Guidance About Self-Shielded Irradiator Licenses.’ Additionally, we will implement the model radiation survey meter calibration program published in Appendix K of this NUREG-1556, and we will ensure that each radiation survey meter will have been calibrated no more than 12 months before the date the meter is used.” <p style="text-align: center;">OR</p> <p>a description of alternative equipment and/or procedures for (1) ensuring that interlocks function as required to return moving self-shielded irradiator sources to the shielded position, and (2) determining source shielding integrity after an incident involving the self-shielded irradiator.</p>	<p style="text-align: center;">[]</p> <p style="text-align: center;">[]</p>

Table B–2. Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)			
Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
10. Radiation Safety Program			
10.3 Material Receipt and Accountability	State the following: “We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times.”	[]	
10.3.1 Inventory	State the following: “Physical inventories will be conducted and documented at intervals not to exceed 6 months to account for all sealed sources and devices received and possessed under the license.” AND	[]	
10.3.2 National Source Tracking System (NSTS)	State the following: “We will comply with the NSTS reporting requirement as described in 10 CFR 20.2207.”	[]	
10.4 Occupational Dose	Provide any one of the following: <ul style="list-style-type: none"> the statement: “We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a).” OR <ul style="list-style-type: none"> the statement: “We will provide and require the use of individual monitoring devices (dosimetry). All personnel dosimeters that require processing to determine the radiation dose will be processed by a NVLAP-approved processor.” 	[] []	

Table B–2. Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)			
Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
10. Radiation Safety Program	<p style="text-align: center;">OR</p> <p>a description of an alternative method for demonstrating compliance with the referenced regulations.</p>		[]
10.5 Public Dose	No response is required from the applicant in a license application, but documentation demonstrating compliance will be examined during inspection.		
10.6 Operating, Emergency, and Security Procedures	<p>Submit the following:</p> <ul style="list-style-type: none"> this statement: “If we change our operating, emergency, or security procedures without amending our license, we will ensure that (i) the changes are reviewed and approved by licensee management and the RSO; (ii) affected licensee staff are trained in the procedures before they are implemented; (iii) the changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application; and (iv) the changes do not degrade the safety of the program.” 	[]	

Table B–2. Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)			
Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
	<p style="text-align: center;">AND EITHER</p> <ul style="list-style-type: none"> this statement: “Operating, emergency, and security procedures will be developed, implemented, maintained, and distributed and will meet the Criteria in the section entitled ‘Radiation Safety Program - Operating and Emergency Procedures’ in NUREG-1556, Volume 5, Revision 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses.’” <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> alternative operating and emergency procedures 	[]	[]
10. Radiation Safety Program 10.7 Leak Tests	Submit one of the following: <ul style="list-style-type: none"> this statement: “Leak tests will be performed at intervals approved by the NRC or as specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by the NRC or an Agreement State to provide leak-testing services to other licensees; or by using a leak-test kit supplied by an organization authorized by the NRC or an Agreement State to provide leak-test kits to other licensees and according to the self-shielded irradiator manufacturer’s or distributor’s instructions and kit supplier’s instructions.” 	[]	

Table B–2. Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)

Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
	<p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • this statement: “Leak testing and analysis will be done by the applicant.” Provide the information in Appendix P of this NUREG supporting a request to perform leak testing and sample analysis and either state that you will follow the model procedures in Appendix P of NUREG-1556, Volume 5, Revision 1, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiators or submit alternative procedures.” 	[]	
<p>10. Radiation Safety Program</p> <p>10.8 Maintenance</p>	<p>For all maintenance, submit:</p> <ul style="list-style-type: none"> • this statement: “We will maintain documentation of the use of all non-OEM replacement parts and components. If OEM replacement parts cannot be used for the shielding of any sealed sources, the driving unit of any sources, safety interlocks, or other electrical or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or any sources, we will obtain and document NRC approval before beginning the nonroutine maintenance activity. In addition, if a service provider plans to remove any aspect of the GTRI irradiator-hardening hardware, we will discuss this matter with the NRC before allowing this service to be initiated.” 	[]	

Table B-2. Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)			
Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
	<p>For routine maintenance, submit either of the following:</p> <ul style="list-style-type: none"> this statement: "We will implement and maintain procedures for routine maintenance of our self-shielded irradiators according to each manufacturer's or distributor's written recommendations and instructions." <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> alternative procedures for the NRC's review <p>For nonroutine maintenance, submit either of the following:</p> <ul style="list-style-type: none"> this statement: "We will have the self-shielded irradiator manufacturer, distributor, service provider, or another person authorized by the NRC or an Agreement State perform nonroutine maintenance." <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> alternative procedures for the NRC's review addressing the information listed in Appendix Q of NUREG-1556, Volume 5, Revision 1, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiators or submit alternative procedures.' 	<p>[]</p> <p>[]</p>	<p>[]</p> <p>[] The information listed in Appendix Q of this NUREG supporting a request to perform non-routine maintenance in-house is attached.</p>

Table B–2. Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal (Continued)			
Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
10. Radiation Safety Program 10.9 Transfer and Transportation	No response is needed from applicants during the licensing phase. However, before offering a Type B package for shipment, a licensee needs to have registered with NRC as a user of the package and obtained NRC's approval of its quality assurance (QA) program. Transportation issues will be reviewed during inspection.	Need Not Be Submitted with Application	
11. Waste Management 11.1 Self-Shielded Irradiator Disposal & Transfer	The applicant does not need to provide a response to this item during the licensing phase. However, the licensee should develop, implement, and maintain self-shielded irradiator transfer and waste disposal procedures, including updates to the National Source Tracking System, in its radiation safety program.	Need Not Be Submitted with Application	

1

APPENDIX C

2

SAFETY CULTURE POLICY STATEMENT

Safety Culture

The safety culture policy statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011 and can be found at: <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 Accession Number ML11146A047.

Safety Culture Policy Statement

The purpose of this Statement of Policy is to set forth the Commission's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. The Commission encourages the Agreement States, Agreement State licensees and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture, as articulated in this Statement of Policy.

Nuclear Safety Culture is defined as *the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment*. Individuals and organizations performing regulated activities bear the primary responsibility for safety and security. The performance of individuals and organizations can be monitored and trended and, therefore, may be used to determine compliance with requirements and commitments and may serve as an indicator of possible problem areas in an organization's safety culture. The NRC will not monitor or trend values. These will be the organization's responsibility as part of its safety culture program.

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

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations (e.g., production, schedule, and the cost of the effort versus safety). It should be noted that although the term "security" is not expressly included in the following traits, safety and security are the primary pillars of the NRC's regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

1 The following are traits of a positive safety culture:

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

20 There may be traits not included in this Statement of Policy that are also important in a positive
21 safety culture. It should be noted that these traits were not developed to be used for
22 inspection purposes.

23 It is the Commission's expectation that all individuals and organizations, performing or
24 overseeing regulated activities involving nuclear materials, should take the necessary steps to
25 promote a positive safety culture by fostering these traits as they apply to their organizational
26 environments. The Commission recognizes the diversity of these organizations and
27 acknowledges that some organizations have already spent significant time and resources in
28 the development of a positive safety culture. The Commission will take this into consideration
29 as the regulated community addresses the Statement of Policy.

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APPENDIX D

2

CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)

3

Checklist For Requests to Withhold Proprietary Information from Public Disclosure (Under 10 CFR 2.390)

In order to request that the U.S. Nuclear Regulatory Commission (NRC) withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:

<input type="checkbox"/>	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
<input type="checkbox"/>	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary.
<input type="checkbox"/>	An affidavit that:
<input type="checkbox"/>	Is signed under oath and affirmation (notarization may suffice).
<input type="checkbox"/>	Clearly identifies (such as by name or title and date) the document to be withheld.
<input type="checkbox"/>	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information the organization is seeking to withhold and is authorized to apply for withholding on behalf of the organization.
<input type="checkbox"/>	States that the organization submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
<input type="checkbox"/>	Provides a rational basis for holding the information in confidence.
<input type="checkbox"/>	Fully addresses the following issues:
<input type="checkbox"/>	Is the information submitted to, and received by, the NRC in confidence? Provide details.
<input type="checkbox"/>	To the best of the applicant's knowledge, is the information currently available in public sources?
<input type="checkbox"/>	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
<input type="checkbox"/>	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your organization, the amount of effort or money expended in developing the information, and the ease or difficulty for others to acquire the information.

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APPENDIX E

2

GUIDANCE ON FINANCIAL ASSURANCE

Guidance on Financial Assurance

Determining Need for Financial Assurance

If the only radioactive materials possessed are sealed sources in self-shielded irradiators, use Table E–1 to determine whether financial assurance is required.

Table E–1. Worksheet for Determining Need for Financial Assurance for Self-Shielded Irradiators				
Step No.	Description	Cobalt-60	Cesium-137	Strontium-90
1	Activity possessed, in Curies*			
2	Activity requiring financial assurance, in Curies	10,000	100,000	1,000
3	Divide data in Step 1 by data in Step 2 = FRACTION			
4	Add the fractions determined in Step 3			

*For ease of use by most irradiator licensees, this table uses only conventional units. The conversion to SI units is 1 Ci = 37 GBq.

If the sum of the fractions is greater than or equal to 1, the applicant will need to submit certification of financial assurance or a decommissioning funding plan [10 CFR 30.35(e)]. Licensees may follow the guidance provided in NUREG-1757 Volume 3, “Consolidated Decommissioning Guidance - Financial Assurance, Recordkeeping, and Timeliness,” on the various Financial Assurance Mechanisms authorized by the regulations to guarantee or secure funds.

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APPENDIX F

2

MODEL TRAINING PROGRAM

Model Training Program

To ensure the control and security of licensed material, licensees should provide individuals with training commensurate with their assigned duties.

Course Content

Training may be in the form of a lecture, digital versatile disc (DVD) or other video, webinar, hands-on activity, or self-study; training emphasizes practical subjects important to the safe use of the self-shielded irradiator:

- Radiation Safety
 - characteristics of types of radiation
 - units of radiation dose and quantity of radioactivity
 - radiation vs. contamination
 - internal vs. external exposure
 - biological effects of radiation
 - types and relative hazards of radioactive material possessed
 - “as low as reasonably achievable” (ALARA) philosophy
 - use of time, distance, and shielding to minimize exposure
 - use of radiation detection instruments
- Regulatory Requirements
 - applicable parts of Title 10 of the *Code of Federal Regulations* (CFR), “Energy,” of 10 CFR Parts 19, 20, 21, and 30
 - locations of use and storage of radioactive materials and devices containing radioactive materials
 - material control and accountability
 - security of radioactive materials and devices containing radioactive materials
 - annual reviews of radiation safety program content and implementation
 - license conditions, amendments, and renewals
 - occupational and public dose limits
 - transfer and disposal
 - applicable U.S. Department of Transportation regulations and 10 CFR 71

- 1 — recordkeeping
- 2 — reporting requirements for nationally tracked sources
- 3 — reporting requirements for theft or loss, incidents, exposures, etc.
- 4 — licensing and inspection by regulatory agency
- 5 — need for complete and accurate information (10 CFR 30.9)
- 6 — employee protection (10 CFR 30.7)
- 7 — deliberate misconduct (10 CFR 30.10)
- 8 — security (10 CFR 37)
- 9 • Practical Explanation of the Theory and Operation of Each Irradiator Possessed by
10 the Licensee
- 11 — routine vs. nonroutine maintenance
- 12 — operating and emergency procedures
- 13 — prior events involving self-shielded irradiators

14 **Instructor's Qualifications**

15 The individual preparing and conducting training is qualified as an radiation safety officer (RSO)
16 or authorized user (AU) on a self-shielded irradiator license before giving training.

17 **Training Assessment**

18 Management will ensure that potential RSOs and AUs are qualified to work independently with
19 each type of the licensee's irradiators. This may be demonstrated by written or oral examination
20 or by observation.

21 **Training Documentation**

22 Training should be documented, including course outlines and materials and results of testing.
23 Maintain records of training for 3 years after the last use of licensed material by the user.

24 **Training Frequency**

25 Refresher training should be provided any time there is a significant change to the radiation
26 safety program (e.g., new make and model of irradiator, new location).

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APPENDIX G

2

TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

3

Typical Duties and Responsibilities of the Radiation Safety Officer

Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped immediately;
- Radiation exposures are as low as reasonably achievable (ALARA);
- Notices to workers are posted as required by 10 CFR 19.11, "Posting of notices to workers;"
- Development, distribution, implementation, and maintenance of up-to-date operating and emergency procedures to cover all likely scenarios;
- Investigating incidents and responding to any emergencies;
- Serving as a point of contact for the NRC's, Agreement State's, and licensee's, management during routine operations, emergencies, or incidents;
- Proper authorities are notified of incidents such as damage to sealed sources, loss of licensed material, fire, theft, etc.
- Unusual occurrences are investigated, cause(s) and appropriate corrective actions(s) are identified, and timely corrective action(s) are taken to prevent recurrence;
- Self-shielded irradiators are properly secured from unauthorized access, as described in 10 CFR Part 37;
- Possession, installation, relocation, use, storage, repair, and maintenance of self-shielded irradiators are consistent with the limitations in the license, the sealed source and device Registration Certificate(s), and manufacturer's specific recommendations and instructions;
- Potential safety and security consequences are analyzed before conducting any activities involving repair, use, maintenance, installation, or relocation that were never previously analyzed;
- Individuals installing, relocating, using, maintaining, or repairing self-shielded irradiators are trained and authorized as described in the license application;
- Evaluations of occupationally exposed individuals are performed to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits or personnel monitoring devices are provided;
- When necessary, National Voluntary Laboratory Accreditation Program (NVLAP)-approved personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;

- 1 • Licensed material is transported in accordance with all applicable NRC and DOT
2 requirements.
- 3 • Transaction reports are prepared for nationally tracked sources.
- 4 • Documentation is maintained to demonstrate, by measurement or calculation, that the
5 total effective dose equivalent to the individual member of the public likely to receive the
6 highest dose from the licensed operation does not exceed the annual limit in
7 10 CFR 20.1301, "Dose limits for individual members of the public."
- 8 • Up-to-date license is maintained and amendment and renewal request are submitted in
9 a timely manner;
- 10 • Radiation safety, access authorization, and security program reviews (audits) are
11 performed at least annually and documented;
- 12 • Ordering, receipt, surveys, and delivery of licensed material;
- 13 • Monitoring and surveys of all areas in which radioactive material is used;
- 14 • Performing/overseeing the inventory and leak testing of sealed sources;
- 15 • Training personnel;
- 16 • Licensed material is transferred or disposed of properly;
- 17 • Overseeing decontamination activities;
- 18 • Maintaining required records that are necessary to support the license and satisfy
19 NRC regulations.

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APPENDIX H

2

MODEL DELEGATION OF AUTHORITY FOR RADIATION SAFETY OFFICER

3

Model Delegation of Authority for Radiation Safety Officer

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

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

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads

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APPENDIX I

2

J. L. SHEPHERD ORDER

3

ADAMS Accession No. [ML15210A628](#)

J. L. Shepherd Order

JULY 3, 1984

UNITED STATES

NUCLEAR REGULATORY COMMISSION

URGENT NOTICE

TO ALL LICENSEES WHO POSSESS J. L. SHEPHERD IRRADIATORS

An NRC licensee recently identified a malfunction in the lock mechanism of its J. L. Shepherd self-shielded irradiator which could have resulted in a radiation overexposure. Although no overexposure appears to have occurred, the potential hazard warrants immediate preventive action. Therefore, we have prepared the enclosed Order which requires the use of radiation survey equipment when the irradiators are being used.

If you possess a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator, do not use it unless you provide appropriate radiation monitoring as specified in the Order. If you do not currently possess the appropriate equipment, you must obtain it before you resume use of your irradiator. Also, you should report any problems to your nearest NRC regional office immediately. Do not attempt to repair an irradiator, or allow anyone else to attempt repairs, unless specific authorization for repair of the irradiator which you possess is provided in an NRC license.

We suggest that you review who has access to your irradiator, and establish strict controls to assure that no untrained personnel have access. Trained persons who continue to use the irradiator should conduct careful radiation surveys as specified in the Order. Irradiator doors should be opened slowly, to minimize any accidental exposure and to avoid “blinking out” of instruments due to high exposure rates. Any unusual meter reading should be taken as evidence of a problem.

We are including in this mailing certain licensees about which we are uncertain whether they possess J. L. Shepherd irradiators. If you do not possess a J. L. Shepherd irradiator, please disregard this notice.

Because this Order is effective immediately, it is important that you notify your radiation safety personnel immediately, and retain this Order with your license records. Questions and comments may be directed to your nearest NRC regional office.

Sincerely,

/RA/

Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Enclosure: Order Modifying License

1 UNITED STATES OF AMERICA
2 NUCLEAR REGULATORY COMMISSION
3 OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
4 WASHINGTON, D.C. 20555
5 ORDER MODIFYING CERTAIN LICENSES (EFFECTIVE IMMEDIATELY)

6 I

7 Recently, the Nuclear Regulatory Commission (NRC) staff was notified by a licensee of the
8 failure of a locking mechanism on a self-shielded irradiator which could have resulted in a
9 radiation overexposure. ("Self-shielded" irradiators are designed so that the radioactive source
10 remains in a shielded position at all times, both during storage and during irradiations.
11 Therefore, the irradiators need not be placed in a shielded room.)

12 The irradiator is a J. L. Shepherd Mark I, containing about 6,000 curies of cesium 137. The unit
13 is operated as follows: (1) With the source in its shielded storage position, the shielded door is
14 opened, (2) materials to be irradiated are placed inside the irradiator chamber, (3) the shielded
15 door is closed, (4) the radioactive source is raised into the irradiation chamber, (5) after
16 irradiation is complete, the source is lowered, and (6) the door is opened for removal of
17 irradiated materials.

18 The shielded door is interlocked so that it should not open when the radioactive source is in the
19 irradiation chamber. However, in the case reported to NRC, the lock mechanism failed. In such
20 a situation, an operator who opens the shielded door with the source raised could be subjected
21 to substantial radiation exposure. The J. L. Shepherd Model 81-22 irradiator employs an
22 interlock similar to the Mark I.

23 The NRC staff has examined the irradiator in question and confirmed the defect. Furthermore,
24 a New York City inspector checking a J. L. Shepherd Mark I irradiator in New York reported a
25 malfunctioning interlock system. NRC and the Agreement States are studying the problem
26 further to assess its generic implications.

27 Based on the foregoing, I have concluded that the possibility of failure of locking mechanisms
28 and/or mechanical timers on J. L. Shepherd Mark I and Model 81-22 irradiators represents a
29 potential radiation hazard warranting immediate preventive action pending further investigation.
30 I have determined, therefore, that the public health, safety, and interest require that the
31 restrictions on the use of such irradiators as prescribed in Section II of this Order should be
32 made immediately effective.

33 II

34 Accordingly, pursuant to Sections 81, 116 I, 162 o, and 182 of the Atomic Energy Act of 1954,
35 as amended, and 10 CFR Parts 2 and 30 of the Commission's regulations, IT IS HEREBY
36 ORDERED, EFFECTIVE IMMEDIATELY, THAT:

37 Each license that authorizes possession of byproduct material in a J. L. Shepherd Mark I or
38 Model 81-22 self-shielded irradiator is hereby amended to add the following conditions:

- 39 1. The J. L. Shepherd irradiator shall not be used unless the licensee provides a calibrated
40 and operable radiation survey meter or room monitor for use with the irradiator.

2. The irradiator door shall not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
3. Each room monitor (a) shall be operable at all times when the irradiator is in use, (b) shall activate a visible and audible alarm when radiation levels exceed 2 millirems per hour, (c) shall be located to detect any radiation escaping from the irradiator door, and (d) shall be located so that it is visible to the irradiator user when he is next to the irradiator.
4. If a room monitor is not installed, a radiation survey meter shall be used (a) to determine the radiation level at the irradiator door when the door is closed, and (b) to check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators shall position themselves so as to minimize exposure to any radiation escaping from the open door.
5. If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee shall stop use of the irradiator and immediately notify the appropriate NRC regional office by telephone.
6. The licensee shall not attempt repair or authorize others to attempt repair of the irradiator except as specifically authorized in a license issued by NRC.

III

Any affected licensee may request a hearing on this Order. A request for a hearing shall be submitted within twenty (20) days of the date of this Order to Mr. R. E. Cunningham, Director, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. ANY REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

IV

If a hearing is requested, the Commission will issue an Order designating the time and place of any such hearing. If a hearing is held the issue to be considered at such a hearing will be: Whether, on the basis of the matters set forth in Section 1 and II of this Order, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards

Dated at Bethesda, Maryland
this 3rd day of July, 1984

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APPENDIX J

2

SUGGESTED SELF-SHIELDED IRRADIATOR AUDIT CHECKLIST

3

Suggested Self-Shielded Irradiator Audit Checklist

Note: Not all areas indicated in audit notes are necessarily applicable to every license, and some areas might not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit _____ Date of Last Audit _____

Next Audit _____

Auditor _____ Date _____
(Signature)

Management Review _____ Date _____
(Signature)

Audit History

- A. Were previous audits conducted annually? [10 CFR 20.1101]
- B. Were records of previous audits maintained? [10 CFR 20.2102]
- C. Were any deficiencies identified during last two audits or two years, whichever is longer?
- D. Were corrective actions taken? Were corrective actions sufficient to prevent recurrence of the deficiency? (Look for repeated deficiencies.)

Organization and Scope of Program

- A. Radiation Safety Officer (RSO) [License Condition (L/C)]
 - 1. If the RSO was changed, was the license amended?
 - 2. Does the new RSO meet U.S. Nuclear Regulatory Commission (NRC) training requirements? [Section 8.7.1]
 - 3. Is the RSO fulfilling his or her duties? [Appendix E of this NUREG]
 - 4. To whom does the RSO report?
- B. Licensed Material
 - 1. Does the license authorize all of the NRC-regulated radioactive material contained in the licensee's self-shielded irradiators? [L/C]
 - 2. Does the total amount of radioactive material possessed by the licensee require financial assurance? [10 CFR 30.35(a)]

- 1 C. Are the self-shielded irradiators as described in the Sealed Source and Device (SSD)
2 Registration Certificate? Does the licensee have copies of (or access to) the SSD
3 Certificates? Does the licensee have the manufacturer's or distributor's manuals for
4 operation and maintenance? [10 CFR 32.210]
- 5 D. Are the licensee's actual uses of their self-shielded irradiators consistent with the
6 authorized uses listed on the license? [L/C]
- 7 E. If the mailing address or places of use changed, was the license amended? [L/C]
- 8 F. If control of the license was transferred or bankruptcy was filed, was NRC prior consent
9 obtained or notification made, respectively? [10 CFR 30.34(b)(1)]

10 **Training and Instructions to Workers**

- 11 A. Were all workers who are likely to exceed 1 mSv [100 mrem] in a year instructed
12 according to 10 CFR 19.12? Was refresher training provided as needed?
13 [10 CFR 19.12]
- 14 B. Did each authorized user and person independently performing routine or nonroutine
15 maintenance attend license-required training before working with self-shielded
16 irradiators? [Sections 8.7.2 and 8.8; Appendix D of this NUREG]
- 17 C. Are training records maintained for each individual? [10 CFR 20.2102]
- 18 D. Did interviews with workers reveal that they know the emergency procedures and repair,
19 maintenance, and relocation limitations?
- 20 E. Did this audit include observations of operators using the self-shielded irradiators? Did it
21 include observations of persons performing routine or other authorized maintenance?
- 22 F. Did the audit identify any operator error in reporting maintenance and repair or operation
23 issues to the RSO for review before starting work?

24 **Radiation Survey Instruments**

- 25 A. Describe the survey instruments that the licensee possesses:
- 26 1. Do they meet the NRC's criteria? [Appendix K of this NUREG]
- 27 2. Are they appropriate for the source type(s)?
- 28 3. Are they checked for function before use?
- 29 4. If they are used with moving-source irradiators or during nonroutine
30 maintenance, are they calibrated as required? [10 CFR 20.1501]
- 31 B. If the licensee does not possess a radiation survey meter, are specific plans made to
32 have one available?

33 Location: _____ Location/Operation verified: _____

- 1 C. Are calibration records, if required, maintained? [10 CFR 20.2103(a)]
- 2 D. If the licensee possesses a J. L. Shepherd Mark I or Model 81-22 irradiator, is it being
- 3 used in compliance with the license condition? [L/C and Appendix F of this NUREG]

4 **Self-Shielded Irradiator Inventory and Location**

- 5 A. Is a record kept showing the receipt of each self-shielded irradiator?
- 6 [10 CFR 30.51(a)(1)]
- 7 B. Has the location of any self-shielded irradiator changed since the last audit?

8 **National Source Tracking System (NSTS)**

- 9 A. Is the information in the NSTS concerning location, manufacturer, model, isotope, and
- 10 quantity of material consistent with the inventory and with the actual information about
- 11 the irradiator? [10 CFR 20.2207]
- 12 B. Is the contact information in NSTS up to date? [10 CFR 20.2207(g)]
- 13 C. Have there been any transactions involving the irradiator, such as a transfer, receipt, or
- 14 disposal of irradiator sources? Have these transactions been reported to the NSTS
- 15 using a NSTS Report? Did this report contain all required information?
- 16 [10 CFR 20.2207(b), (c), and (e)]
- 17 D. Has the annual reconciliation of the NSTS entry been performed each January?
- 18 [10 CFR 20.2207(g)]

19 **Personnel Radiation Protection**

- 20 A. Are "as low as reasonably achievable" (ALARA) considerations incorporated in the
- 21 radiation protection program? [10 CFR 20.1101(b)]
- 22 B. Were prospective evaluations performed showing that unmonitored users receive $\leq 10\%$
- 23 of limit? [10 CFR 20.1502(a)]
- 24 C. Did unmonitored users' activities change during the year, which could put them over
- 25 10% of limit?
- 26 D. If yes to C. above, was a new evaluation performed?
- 27 E. Is external dosimetry required (for use by any user receiving $>10\%$ of limit)? Is dosimetry
- 28 provided to users?
- 29 1. If the licensee is using processed dosimetry
- 30 a. Is the dosimetry supplier National Voluntary Laboratory Accreditation
- 31 Program (NVLAP)-approved? [10 CFR 20.1501(c)]
- 32 b. Are dosimetry reports reviewed by the RSO when they are received?

- 1 2. If the licensee is using self-reading dosimeters
- 2 a. Do they have a range of zero to at least 2 mSv [200 mrem]?
- 3 b. Are they checked at periods not to exceed one year for correct response
- 4 to radiation?
- 5 c. Are they read within $\pm 20\%$ of the true radiation exposure?
- 6 d. Are they used under a program that prescribes action to evaluate the
- 7 individual's dose?
- 8 F. Are the dosimeters exchanged or read at the license-required frequency?
- 9 G. Are the records NRC Forms or their equivalent? [10 CFR 20.2104(d),
- 10 10 CFR 20.2106(c)]
- 11 1. Has NRC-4, "Cumulative Occupational Exposure History," been completed?
- 12 2. Has NRC-5, "Occupational Exposure Record for a Monitoring Period," been
- 13 completed?
- 14 H. Are there any declared pregnant workers?
- 15 1. If a worker declared her pregnancy, did the licensee comply with 10 CFR
- 16 20.1208, "Done equivalent to an embryo/fetus"? [20.1502(a)]
- 17 2. Were records kept of the dose to the embryo/fetus per 10 CFR 20.2106(e)?
- 18 I. Are records of exposures, surveys, monitoring, and evaluations maintained?
- 19 [10 CFR 20.2102, 10 CFR 20.2103, 10 CFR 20.2106]
- 20 **Public Dose**
- 21 A. Are self-shielded irradiators located and used in a manner to keep doses below 1 mSv
- 22 [100 mrem] per year? [10 CFR 20.1301(a)(1)]
- 23 B. Has a survey or evaluation been performed in accordance with 10 CFR 20.1501(a)?
- 24 C. Have there been any additions or changes to the storage or use of surrounding areas
- 25 that would necessitate a new survey or evaluation?
- 26 D. Do unrestricted area radiation levels exceed 0.02 mSv [2 mrem] in any 1 hour?
- 27 [10 CFR 20.1301(a)(2)]
- 28 E. Are self-shielded irradiators being used or stored in a manner that would prevent
- 29 unauthorized access or removal? [10 CFR 20.1801]
- 30 F. Is the licensee maintaining the records required by 10 CFR 20.2103 and
- 31 10 CFR 20.2107?

1 **Operating and Emergency Procedures**

- 2 A. Have operating and emergency procedures been developed? [Section 8.10.2 and
3 Appendix H of this NUREG]
- 4 B. Do they contain the required elements?
- 5 C. Does each operator have a current copy of the operating and emergency procedures?
6 Does the licensee keep a copy at each irradiator's control panel or post a notice
7 indicating where to obtain a copy?
- 8 D. Do emergency procedures address all likely scenarios?
- 9 E. Did any emergencies occur since the previous audit?
- 10 1. If so, were they handled properly by the operator?
- 11 2. Were appropriate corrective actions taken?
- 12 3. Was NRC notification or reporting required? If so, was it completed?
13 [10 CFR 20.2201, 10 CFR 20.2202, 10 CFR 20.2203]
- 14 F. Were operating or emergency procedures changed since last audit? If so
- 15 1. Did the licensee's management and RSO approve the new procedures before
16 they were implemented?
- 17 2. Did the affected staff receive training on the new procedures before they were
18 implemented?
- 19 3. Are the changes consistent with the license conditions and the licensee's
20 commitments?
- 21 4. Do the changes degrade safety?

22 **Leak Tests**

- 23 A. Was each sealed source leak-tested every 6 months (or at other license-prescribed
24 intervals)? [L/C]
- 25 B. Was the leak test performed as described in correspondence with the NRC and
26 according to the license? [L/C]
- 27 C. Are records of results retained with the appropriate information included? [L/C]
- 28 D. Were any sources found leaking and, if so, was the NRC notified? [L/C]

29 **Maintenance of Self-Shielded Irradiators**

- 30 A. Are the manufacturer's or distributor's written procedures followed for routine (not
31 safety-critical) cleaning and lubrication, mechanical/electrical maintenance, and repair of
32 self-shielded irradiators? [Section 8.10.7]

- 1 B. Was nonroutine maintenance performed? [Section 8.10.7 and Appendix L of this
2 NUREG]
- 3 C. If so, was the nonroutine maintenance performed according to license requirements
4 (e.g., regarding the extent of work, individuals performing the work, procedures,
5 dosimetry, survey instrument, and compliance with dose limits)? [L/C]
- 6 D. If nonroutine maintenance was performed by a service provider, was the service
7 provider authorized to perform the maintenance? Were non-OEM parts used? If so,
8 were they verified for form, fit, and function? [Section 8.10.7 and Appendix L of this
9 NUREG]
- 10 E. Since the last audit, did any operators report a need for nonroutine maintenance or
11 repair to the RSO before requesting or conducting the work?
- 12 F. Have there been any changes to the irradiator shielding or housing? Are these changes
13 in accordance with the NRC's Sealed Source and Device Registry? If not, was NRC
14 approval received before making these changes? [10 CFR 32.210]

15 **Security**

- 16 A. Is access to the irradiator controlled so that only authorized individuals can gain access
17 to the irradiator? Are personnel who have not been authorized escorted? [10 CFR
18 Part 37 Subpart B]
- 19 B. Have all personnel who have unescorted access to the irradiator been deemed
20 trustworthy and reliable, been fingerprinted, and been authorized in writing for access to
21 the irradiator? Is the list of authorized personnel up to date? [10 CFR Part 37
22 Subpart B]
- 23 C. Is a system in place so that any unauthorized access to the irradiator will be detected
24 immediately? [10 CFR 37.49]
- 25 D. Are procedures in place to ensure that any unauthorized access will be assessed to
26 determine whether further response is required? If there have been any such accesses,
27 was the procedure followed? [10 CFR 37.49(b)]
- 28 E. Is the security plan current? Is contact information for the local law enforcement agency
29 current? [10 CFR 37.43(a)]
- 30 F. Is the security system operable? [10 CFR 37.51]
- 31 G. Does the security system have a dependable means of communication to notify
32 assessment personnel? Do personnel have a dependable means of communication to
33 notify response staff or local law enforcement? [10 CFR 37.49(c)]
- 34 H. Are all documents being retained as required? [10 CFR 37.110]
- 35 I. Is all sensitive information secured and protected in accordance with the procedure?
36 Does the procedure address all required information? [10 CFR 37.31]

- 1 J. Have personnel with access to the irradiator been trained on security procedures,
2 including emergency response, notifications, and surveillance? [10 CFR 37.43(c)]
- 3 K. Are procedures in place to ensure the safe and secure transport of Category 1 and
4 Category 2 radioactive sources? Were the procedures followed for preplanning, license
5 verification, coordination, advance notification, physical protection, and reporting, as
6 applicable? [10 CFR 37.71, 37.73, 37.75, 37.77, 37.79, and 37.81]

7 **Safety Culture**

- 8 A. Do personnel who use the irradiator feel comfortable bringing safety-related or
9 security-related concerns to the attention of management? Are these concerns
10 addressed? [Section 3.1 and Appendix Q of this NUREG]
- 11 B. Have any actions been taken against personnel who bring such issues to the attention of
12 management? [Section 3.1 and Appendix Q of this NUREG]

13 **Transportation**

- 14 A. Were any self-shielded irradiators or sources shipped since the last audit?
- 15 B. If so, were 10 CFR Part 71.5 requirements followed?
- 16 1. Were DOT Type A or Type B packages used? If a Type B package was used,
17 was an NRC Certificate of Compliance granted before shipment or is the shipper
18 registered as a user of the Type B package? Is an NRC-approved QA program
19 in place? [10 CFR 71.5, 49 CFR 173.415, 49 CFR 173.416]
- 20 2. Are package performance test records on file? [49 CFR 173.415(a)]
- 21 3. Does the licensee have documentation for its special form sources?
22 [49 CFR 173.476(a)]
- 23 4. Did the package have two labels (for example, Yellow-II) with TI, Nuclide,
24 Activity, and Hazard Class? [49 CFR 172.403, 49 CFR 173.441]
- 25 5. Was the package properly marked? [49 CFR 172.301, 49 CFR 172.304,
26 49 CFR 172.310, 49 CFR 172.324]
- 27 6. Was the package closed and sealed during transport? [49 CFR 173.475(f)]
- 28 7. Were shipping papers prepared, used, and maintained? [49 CFR 172.200(a)]
- 29 8. Did shipping papers contain the proper entries [Shipping Name, Hazard Class,
30 Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ,
31 Radioactive Material, Physical and Chemical Form, Activity (SI units required),
32 Category of Label, TI, Shipper's Name, Certification and Signature, Emergency
33 Response Phone Number, and Cargo Aircraft Only (if applicable)]?
34 [49 CFR 172.200, 49 CFR 172.201, 49 CFR 172.202, 49 CFR 172.203,
35 49 CFR 172.204, 49 CFR 172.604]

9. Was the package secured against movement? [49 CFR 177.834]
10. If necessary, was the shipping vehicle placarded? [49 CFR 172.504]
11. If overpacks were used, were they the proper overpacks? [49 CFR 173.25]
12. Were any incidents reported to DOT? [49 CFR 171.15, 49 CFR 171.16]
13. Were safety and security plans documented and implemented in accordance with the plan? [49 CFR 172, Subpart I; 49 CFR 172.800; 40 CFR 172.802]
14. Does the licensee possess any irradiators manufactured before 1966? [Section 8.10.9]
 - a. If so, were any of them shipped?
 - b. If so, were NRC and DOT exemptions, if needed, received in advance?

Performance-Based Review

- A. Conduct performance-based reviews of radiation workers performing licensed activities:
 1. to assess the capability of the radiation workers to keep exposures ALARA
 2. to assess whether radiation workers follow the operating procedures
 3. to assess the effectiveness of the operating procedures and compliance with the regulations, license conditions, and the licensee's commitments submitted in support of a license (and incorporated by "tie-down" conditions)
 4. to ensure the safe and secure use of radioactive material
 5. to verify that radiation workers are cognizant of the emergency procedures and, if necessary, would be able to implement them and keep exposures ALARA
- B. Take any necessary actions to address programmatic and performance deficiencies with those radiation workers and facilitate immediate corrective measures.

Note: Performance-based reviews may include observation of licensed activities, review of records, and interviews with key personnel.

Auditor's Independent Survey Measurements (If Any Are Made)

- A. Describe the type, location, and results of these measurements. [10 CFR 20.1501]
- B. Identify the model, serial number, and calibration date of each instrument used to make these measurements.
- C. Indicate whether any radiation levels exceed regulatory limits. [10 CFR 20.1301]

1 **Notifications and Reports**

- 2 A. Was any radioactive material lost or stolen? If so, were these events reported?
3 [10 CFR 20.2201, 10 CFR 30.50, 10 CFR 37.81]
- 4 B. Did any reportable incidents occur? If so, were they reported? [10 CFR 20.2202,
5 10 CFR 30.50, 10 CFR 37.81]
- 6 C. Did any overexposures or high radiation levels occur? If so, were they reported?
7 [10 CFR 20.2203, 10 CFR 30.50]
- 8 D. If any events (as described in items 1 through 3 above) did occur, what was the root
9 cause? Were corrective actions taken? If so, were those actions appropriate?
- 10 E. Is the licensee aware of the telephone number for the NRC Emergency Operations
11 Center: (301) 816-5100?

12 **Posting and Labeling**

- 13 A. Is NRC-3, "Notice to Workers," posted? [10 CFR 19.11]
- 14 B. Are the applicable NRC regulations and license documents posted, or is a notice posted
15 about where they can be examined? [10 CFR 19.11, 10 CFR 21.6]
- 16 C. Is all other required posting and labeling present? [10 CFR 20.1902, 10 CFR 20.1904]

17 **Recordkeeping for Decommissioning**

- 18 A. Are records being kept of information important to decommissioning? [10 CFR 30.35(g)]
- 19 B. If so, do these records include all information outlined in 10 CFR 30.35(g)?

20 **NRC Correspondence**

- 21 A. Have all NRC Regulatory Issue Summaries, NRC Bulletins, NRC Information Notices,
22 and NMSS Newsletters issued since the previous audit been received?
- 23 B. If so, in response, has appropriate training been conducted and have any other
24 necessary actions been taken?

25 **License Conditions or Issues**

- 26 A. Did the auditor review the license, license conditions, and "tie-down" documents
27 (identified in the last license condition)?
- 28 B. Did auditor review any other license-related issues (e.g., non-routine maintenance)?

1 **Deficiencies Identified in Audit and Corrective Actions Taken**

2 A. Summarize any problems/deficiencies identified during the audit.

3 B. If problems/deficiencies were identified in this audit, describe all corrective actions taken
4 or planned, including their dates or prospective dates.

5 C. Provide any other recommendations for improvement.

6 **Evaluation of Other Factors**

7 A. Is senior licensee management appropriately involved with the radiation-protection
8 program and/or is there sufficient oversight from the RSO?

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

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

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APPENDIX K

2

RADIATION MONITORING INSTRUMENT SPECIFICATIONS AND MODEL

3

RADIATION SURVEY INSTRUMENT CALIBRATION PROGRAM

Radiation Monitoring Instrument Specifications and Model Radiation Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications

Any instrument used with moving-source gamma irradiators will meet the following criteria:

- the instrument is a radiation survey meter capable of detecting gamma radiation of more than 5×10^{-5} coulombs/kilogram (C/kg) [or up to several hundred milliroentgens (mR) per hour], which is
 - in the licensee's possession
 - checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation
 - calibrated with a source of radiation annually and after any servicing or repair (other than a simple battery exchange), to ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$ (Calibrations must be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State.)

OR

- the instrument is a room monitor, which
 - is installed in the irradiator room
 - is checked with a source of radiation at the beginning of each day of use to ensure that it will respond accurately to radiation and alarm at 0.02 mSv [2 mrem] per hour
 - activates a visible and audible alarm when radiation levels exceed 0.02 mSv [2 mrem] per hour
 - is positioned so that it will detect any radiation escaping from the area of the irradiator door but will still be visible to the irradiator operator when he or she is using the irradiator

The "minimum detectable activity" (MDA) for your instrument should be a fraction (10 to 50 percent) of the criteria you must meet. Any instrument used with a fixed-source gamma irradiator or beta irradiator should be

- a radiation survey meter capable of detecting gamma or beta radiation, as appropriate
- in the licensee's possession or readily accessible in the event of an accident or malfunction that could reduce the shielding for the sealed source(s)
- checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation

- calibrated with a source of radiation annually and after any servicing or repair (other than a simple battery exchange), to ensure that exposure rates indicated by the meter vary from the actual exposure rates by less than $\pm 20\%$ (Calibrations must be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State.)

Survey Instrument Calibration Program

Training

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

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:
 - principles and practices of radiation protection
 - radioactivity measurements, monitoring techniques, and the use of radiation detection instruments
 - mathematics related to the use and measurement of radioactivity
 - biological effects of radiation
- On-the-job training will consist of the following:
 - observed authorized personnel performing radiation survey instrument calibration
 - conducted radiation 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 radiation survey instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.

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

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

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

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

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

Frequency of Calibration of Radiation Measurement Instruments

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

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

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

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

Calibration Sources for Dose and Dose Rate Measuring Instruments

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

- The source should approximate a point source.
- Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 $\mu\text{Gy/h}$ [0.1 mrad/h] and 10 percent for dose rates less than 1.0 $\mu\text{Gy/h}$ [0.1 mrad/h].
- The source should contain a radionuclide that emits radiation of identical or similar type and energy as the environment in which the calibrated device will be used.
- The source should be strong enough to give an exposure rate of at least 7.7 microcoulomb per kilogram per hour (30 milliroentgen per hour) at 100 centimeters [e.g., 3.1 gigabecquerels (85 millicuries) of cesium-137 or 780 megabecquerels (21 millicuries) of cobalt-60].

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

Calibration of Dose or Dose Rate Measuring Instruments

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

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

- Background to 10 $\mu\text{Gy/h}$ [1.0 mrad/h]; $\pm x = \pm 30\%$
- 10 $\mu\text{Gy/h}$ [1.0 mrad/h] to 1.0 mGy/h [100 mrad/h]; $\pm x = \pm 20\%$
- 1.0 mGy/h [100 mrad/h] to 10 Gy/h [1,000 Rad/h]; $\pm x = \pm 10\%$
- **Logarithmic readout instruments**, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. Adjust the instrument for each scale according to site specifications or the manufacturer's specifications. After adjustment, check the calibration at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value as described for linear readout instruments.
- **Digital readout instruments** should be calibrated the same as linear readout instruments.

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

Calibration of Surface Contamination Measurement Instruments

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

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

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

- alpha measurement
 - 0.01 Bq/cm² to 2.0 Bq/cm² (60 to 12,000 dpm/100 cm²); $\pm x = \pm 20\%$
 - 2.0 Bq/cm² to 200 Bq/cm² (12,000 to 1,200,000 dpm/100 cm²); $\pm x = \pm 10\%$
- beta measurement
 - 0.05 Bq/cm² to 2.0 Bq/cm² (300 to 12,000 dpm/100 cm²); $\pm x = \pm 20\%$
 - 2.0 Bq/cm² to 200 Bq/cm² (12,000 to 1,200,000 dpm/100 cm²); $\pm x = \pm 10\%$

1 **Calibration Records**

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

- 4 • the owner or user of the radiation survey instrument
 - 5 • a description of the radiation survey instrument that includes the manufacturer's name,
6 model number, serial number, and type of detector
 - 7 • a description of the calibration source, including the exposure rate at a specified
8 distance or activity on a specified date
 - 9 • for each calibration point, the calculated exposure rate or count rate, the indicated
10 exposure rate or count rate, the deduced correction factor (the calculated exposure rate
11 or count rate divided by the indicated exposure rate or count rate), and the scale
12 selected on the radiation survey instrument
 - 13 • the exposure reading indicated with the radiation survey instrument in the "battery
14 check" mode (if available on the instrument)
 - 15 • for radiation survey instruments with external detectors, the angle between the radiation
16 flux field and the detector (i.e., parallel or perpendicular)
 - 17 • for radiation survey instruments with internal detectors, the angle between the radiation
18 flux field and a specified surface of the instrument
 - 19 • for radiation detectors with removable shielding, an indication of whether the shielding
20 was in place or removed during the calibration procedure
 - 21 • the exposure rate or count rate from a check source, if used
 - 22 • the name and signature of the individual who performed the calibration and the date on
23 which the calibration was performed
- 24 The following information will be attached to the radiation survey instrument as a calibration
25 sticker or tag:
- 26 • for dose and dose-rate measuring instruments, the source radionuclide used to calibrate
27 the radiation survey instrument (with correction factors) for each scale
 - 28 • for surface contamination measurement instruments, the efficiency of the radiation
29 survey instrument, for each radionuclide the instrument will be used to measure (if
30 efficiency is not calculated before each use)
 - 31 • for each scale or decade not calibrated, an indication that the scale or decade was
32 checked only for function but not calibrated
 - 33 • the date of calibration and the next calibration due date
 - 34 • the apparent exposure rate or count rate from the check source, if used

- 1 **Reference:** Detailed information about portable radiation survey instrument calibration may be
- 2 obtained by referring to American National Standards Institute (ANSI)-N323AB-2013,
- 3 “American National Standard for Radiation Protection Instrumentation Test and Calibration,
- 4 Portable Survey Instruments.”

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APPENDIX L

**GUIDANCE FOR DEMONSTRATING THAT UNMONITORED INDIVIDUALS
ARE NOT LIKELY TO RECEIVE EXPOSURES EXCEEDING 10 PERCENT OF
THE ALLOWABLE LIMITS**

Guidance for Demonstrating that Unmonitored Individuals are not Likely to Receive Exposures Exceeding 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in a year from sources external to the body, a dose in excess of the limits in Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 20.1502(a). To demonstrate that dosimetry is not required, a licensee is required, by a standard license condition, to perform a prospective evaluation to demonstrate that its workers are not likely to exceed these limits.

The most common way that individuals might exceed these limits is by performing frequent routine maintenance on the irradiator. However, for most self-shielded irradiators, even these activities result in individuals receiving minimal doses.

Example

The following is an example of an estimate of the dose received by the extremities and whole body of a person performing routine maintenance (cleaning and lubrication) on a self-shielded irradiator's rotating drawer drive chain. The estimate is based on observations of individuals performing the recommended procedure according to good radiation safety practices. The manufacturer can provide the following types of information:

- estimated time needed to perform the entire procedure (e.g., 20 minutes)
- expected dose rate received by the whole body of the individual, associated with the shielded source {e.g., 0.01 mSv per hour [1 mrem per hour] at 1 ft [0.3 m] from the shield}
- time the hands were exposed to the shielded source (e.g., 3 minutes)

AND

- expected dose rate received by the extremities of the individual, associated with the shielded source {e.g., 0.02 mSv per hour [2 mrem per hour] on contact with the shield}.

From this information, an estimate of the doses that the individual performing this procedure could receive is as follows:

- 3.3 μ Sv [0.33 mrem] to the whole body
- 0.001 mSv [0.1 mrem] to the hands

Adult Workers: The applicable whole body dose limit for adult workers is 50 mSv [5 rem] per year, with individual monitoring devices required when it is likely that an individual will receive 10 percent of that value {i.e. 5 mSv [500 mrem] per year}. If one of these procedures delivers 3.3 μ Sv [0.33 mrem], then an adult worker could perform 1,515 of these procedures each year and remain within 10 percent of the applicable limit.

The applicable extremity dose limit for adult workers is 500 mSv [50 rem] per year with individual monitoring devices required when it is likely than an individual will receive 10 percent of that value {i.e., 50 mSv [5 rem or 5,000 mrem] per year}. If one of these procedures delivers

0.001 mSv [0.1 mrem] to the hands, an individual could perform 50,000 of these procedures each year and remain within 10 percent of the applicable limit.

Based on the above specific situation, no dosimetry is required if a worker performs fewer than 1,515 routine maintenance procedures per year.

Minors: The applicable whole body dose limit for minors is 10 percent of the annual dose limits specified for adult workers {i.e., 5 mSv [0.5 rem] per year}, with individual monitoring devices required when it is likely that a minor will receive a deep-dose equivalent in excess of 1 mSv [0.1 rem]. If one of these procedures delivers 3.3 μ Sv [0.33 mrem], then a minor could perform 303 such procedures each year without exceeding the individual monitoring device threshold.

The applicable extremity dose limit for minors is 10 percent of the annual dose limits specified for adult workers {i.e., 50 mSv [5 rem] per year}, with individual monitoring devices required when it is likely that a minor will receive a dose to the extremities in excess of 5 mSv [0.5 rem]. If one of these procedures delivers 0.001 mSv [0.1 mrem], then a minor could perform 5,000 of these procedures each year and remain within 10 percent of the applicable limit.

Based on the above specific situation, no dosimetry is required if a minor worker performs fewer than 303 routine maintenance procedures per year.

Declared Pregnant Women: For declared pregnant women, individual monitoring devices are required when these individuals are likely to receive, during the entire pregnancy from radiation sources external to the body, a deep-dose equivalent in excess of 1 mSv [0.1 rem]. If one of these procedures delivers 3.3 μ Sv [0.33 mrem], then a declared pregnant woman could perform 303 of these procedures during her entire pregnancy without exceeding the individual monitoring device threshold.

Declared pregnant women have no requirements concerning dose to the extremities or the monitoring thereof.

Based on the above specific situation, no dosimetry is required if a declared pregnant woman performs fewer than 303 routine maintenance procedures during the entire pregnancy.

Guidance to Licensees

Licensees who wish to demonstrate that they are *not* required to provide dosimetry to their workers must prepare a written evaluation similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may *not* be appropriate to individual licensee situations. In their evaluations, licensees must use information appropriate to the various type(s) of self-shielded irradiator(s) they intend to use; this information is generally available from the irradiator manufacturer or distributor or the SSD Registration Certificate maintained by the NRC and Agreement States.

Table L–1 may be helpful in performing a prospective evaluation.¹

¹For ease of use by most irradiator licensees, this table uses conventional units. The conversion to SI units is 1 mrem = 0.01 mSv.

1 Licensees should review evaluations periodically and revise them as needed. Licensees need
 2 to check assumptions used in their evaluations to ensure that they continue to be up-to-date
 3 and accurate. For example, if workers become lax in following good radiation safety practices in
 4 the example used above, the extremities could be closer to the unshielded source, and the
 5 workers would receive correspondingly more exposure. Alternatively, workers could perform
 6 the task more slowly than the estimated 20 minutes total and 3 minutes with their hands near
 7 the unshielded source.

Table L-1. Dosimetry Evaluation			
Dosimetry Evaluation for _____ Model _____		Self-Shielded Irradiator	
A.	Time needed to perform the entire routine maintenance procedure.	_____ (minutes/60)	_____ hour
B.	Expected whole body dose rate received by the individual, determined using exposure rates measured on contact with the irradiator while the sealed source is in the shielded position.	_____ mrem/hour	
C.	Time the <i>hands</i> were exposed to the unshielded source.	_____ (minutes/60)	_____ hour
D.	Expected extremity dose rate received by the individual, determined using exposure rates measured at the typical distance that the hands would be from the sealed source during the routine maintenance procedure.	_____ mrem/hour	
Estimated Whole Body Dose Equivalent* Formula: (_____ # hours in Row A) × (_____ mrem/hour in Row B) = (_____ estimated mrem) × (_____ # of routine maintenance procedures each year) = _____ mrem Whole Body Dose*			
Estimated Extremity Dose Equivalent† Formula: (_____ # hours in Row C) × (_____ mrem/hour in Row D) = (_____ estimated mrem) × (_____ # of routine maintenance procedures each year) = _____ mrem Extremity Dose**			
*An expected whole body dose equivalent for adult workers <i>less than</i> 500 mrem requires no dosimetry. The corresponding value for minors is 100 mrem. The corresponding value for declared pregnant women during the entire pregnancy is 500 mrem. †An expected extremity dose equivalent for adult workers <i>less than</i> 5000 mrem requires no dosimetry. The corresponding value for minors is 500 mrem. There is no corresponding extremity value for declared pregnant women because the dose limit of 500 mrem over the entire gestation period is to limit dose to the fetus. Note: For ease of use by most irradiator licensees, this table uses conventional units. The conversion to SI units is 1 mrem = 0.01 mSv.			

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APPENDIX M

2

GUIDANCE FOR DEMONSTRATING THAT INDIVIDUAL MEMBERS OF THE

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PUBLIC WILL NOT RECEIVE DOSES EXCEEDING THE ALLOWABLE LIMITS

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 resulting from the licensee's possession and/or use of licensed materials does not exceed 100 mrem [1 mSv] in a calendar year

Members of the public include persons who live, work, study, or might be near locations where self-shielded irradiator devices are used or stored and licensee employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or stored.

- the radiation dose in unrestricted areas does not exceed 2 mrem [0.02 mSv] in any 1 hour

As defined in 10 CFR 20.1003, the term *unrestricted area* means "an area, access to which is neither limited nor controlled by the licensee." For purposes of this definition in 20.1003, an "unrestricted area" is an area where access is neither limited nor controlled by the licensees for purposes of limiting exposures to radiation and radioactive materials. An "unrestricted area" for purposes of 20.1003 may be controlled for other purposes, such as for security purposes (see, for ex., 10 CFR 20.1801 and 20.1802), and still be considered an "unrestricted area" as long as it is not required to be controlled for limiting exposure to radiation and radioactive materials. Typical unrestricted areas may include offices, shops, areas outside buildings, property, and storage areas for non-radioactive materials, and other facilities and laboratories where licensed materials are not normally used or stored.

Licensees must show compliance with both portions of the regulation. For areas around self-shielded irradiator facilities, calculations or a combination of calculations and measurements are often used to demonstrate compliance.

Calculation Method¹

The calculation method takes a tiered approach, going through a three-part process starting with a worst-case situation and moving toward more realistic situations. It makes the following simplifications: (i) each irradiator is a point source; (ii) typical radiation levels encountered when the source is in the shielded position are taken from either the SSD registration certificate or the manufacturer's or distributor's literature; and (iii) no credit is taken for any shielding found between the irradiator and the unrestricted areas.

Part 1 of the calculation 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

¹For ease of use by most self-shielded irradiator licensees, 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.

determine whether 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. Part 3 considers the distance and the portion of time and dose rate while the sample is moving into or out of the irradiate position, the portion of time and dose rate while the sample is in the irradiate position, and the portion of time that the affected member of the public is present. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases, licensees will need to use the calculation method through Part 1 or Part 2. The results of these calculations typically result in higher radiation levels than would exist at typical facilities but provide a conservative method for estimating doses that could be received.

Example 1

To better understand the calculation method, we will examine Glow-in-the-Dark Industries, Inc., a hypothetical self-shielded irradiator licensee. Yesterday, the company's president noted that the new irradiator area is close to his secretary's desk and he asked Tomás, the Radiation Safety Officer (RSO), to determine whether the company is complying with NRC's regulations.

The secretary's desk is near the wall separating the reception area from the designated and locked self-shielded irradiator room where the company has located its irradiator. Tomás measures the distance from the self-shielded irradiator to the wall and assumes that the irradiator would have the maximum dose rate listed in the irradiator's SSD registration certificate: 10 mrem per hour at one meter. This is the maximum dose rate permitted while the sample is in transit (i.e., moving into or out of the irradiation position). Figure M-1 is Tomás' sketch of the areas in question, and Table M-1 summarizes the information Tomás has on the irradiator.

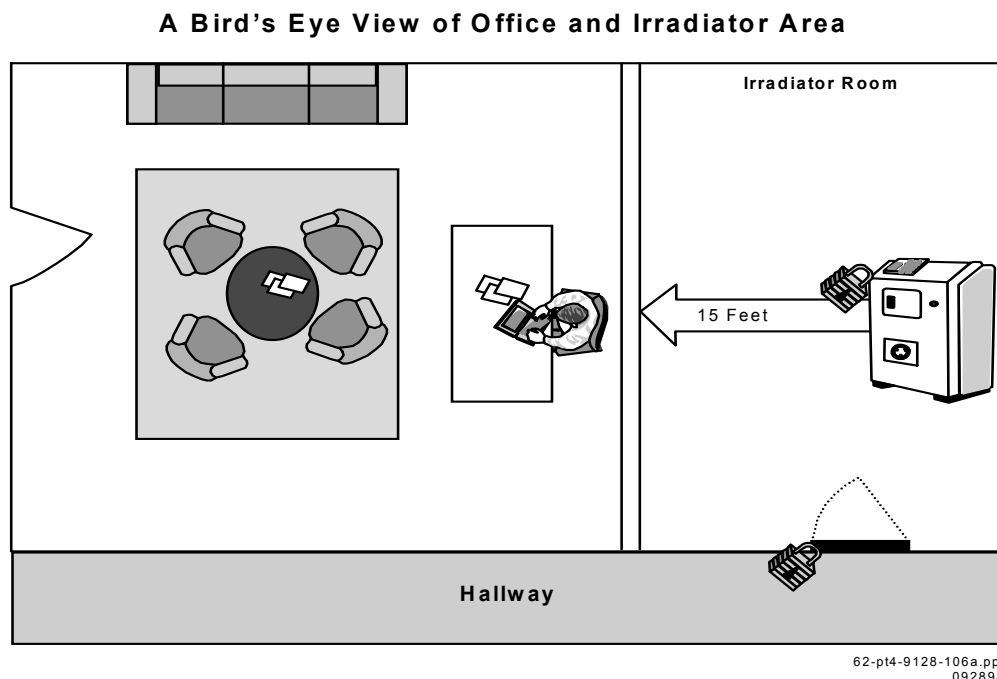


Figure M-1. Diagram of Office and Irradiator Area. This Sketch Shows the Areas Described in Examples 1 and 2.

Table M-1. Information Known About the Self-Shielded Irradiator	
Description of Known Information	Cs-137 Self-Shielded Irradiator
Dose rate in mrem/h encountered at specified distance from the irradiator	10 mrem/h at 1 meter [3.28 ft]
Distance in feet to secretary's chair	15 ft

Example 1: Part 1

Tomás' first thought is that the distance between the irradiator and the secretary's chair might be sufficient to show compliance with the regulation in 10 CFR 20.1301. So, taking a worst-case approach, he assumes (i) the self-shielded irradiator is constantly present (i.e., 24 h/d) with the samples constantly moving into and out of the irradiate position, and (ii) the secretary is constantly sitting in the desk chair (i.e., 24 h/d). Tomás proceeds to calculate the dose she might receive hourly and yearly from the self-shielded irradiator, as shown in Table M-2 below.

Table M-2. Calculation Method, Part 1: Hourly and Annual Dose Received from Self-Shielded Irradiator			
Step No.	Description	Input Data	Result
1	Dose received in an hour at known distance from irradiator, in mrem/h	10	10
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft ²	$(3.28)^2$	10.8
3	Square of the distance (ft) from the irradiator to the secretary's desk in an unrestricted area, in ft ²	$(15)^2$	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	10×10.8	108
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM SELF-SHIELDED IRRADIATOR , in mrem/h	$108/225$	0.48
6	Multiply the result of Step 5 $\times 24$ h/d $\times 365$ d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM SELF-SHIELDED IRRADIATOR , in mrem/yr	$0.48 \times 24 \times 365$	4,205
Note: The result in Step 5 demonstrates compliance with the 2 mrem in any 1 hour limit. Reevaluate if assumptions change. If the result in Step 6 exceeds 100 mrem/yr, proceed to Part 2 of the calculation method.			

At this point, Tomás is pleased to see that the total dose that an individual could receive in any 1 hour is only 0.48 mrem, but notes that an individual could receive a dose of approximately 4,200 mrem in a year, much higher than the 100-mrem limit.

Example 1: Part 2

Tomás reviews his assumptions and recognizes that the secretary is not at the desk 24 h/d. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions constant (i.e., the self-shielded irradiator is constantly present (24 h/d) with the samples constantly moving into and out of the irradiate position). He then recalculates the annual dose received.

Table M-3. Calculation Method, Part 2: Annual Dose Received from Self-Shielded Irradiator		
Step No.	Description	Result
7	A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 h/d; the remainder of the day the secretary is away from the desk area copying, filing)	5
	B. Average number of days per week in area (e.g., secretary is part time and works 3 d/wk)	3
	C. Average number of weeks per year in area (e.g., secretary works all year)	52
8	Multiply the results of Step 7.A. by the results of Step 7.B. by the results of Step 7.C = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$5 \times 3 \times 52 = 780$
9	Multiply the results in Step 5 by the results of Step 8 = ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN, in mrem/yr	$0.48 \times 780 = 374$
Note: If Step 9 exceeds 100 mrem in a year, proceed to Part 3 of the calculation method.		

Although Tomás is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the limit of 100 mrem in a year.

Example 1: Part 3

Again Tomás reviews his assumptions and recognizes that the irradiator is not constantly in use nor is the sample continuously moving into and out of the irradiating position during an irradiation cycle when the secretary is seated at the desk. As he examines the situation, he realizes he must take these factors into account.

Table M-4. Calculation Method, Part 3: Summary of Information		
Step No.	Description	Input
10	Dose rate while the irradiator is idle, in mrem/h at 3.28 ft from the irradiator	2
11	Dose rate while the sample is moving into and out of the irradiate position, in mrem/h at 3.28 ft from the irradiator	10
12	Dose rate while sample is irradiated, in mrem/h at 3.28 ft from the irradiator	2
13	Maximum number of irradiations per hour	5
14	Maximum irradiation time, in min	3
15	Time that the sample is moving into and out of the irradiate position, in min per irradiation cycle	0.20
16	From Table M-1, distance from irradiator to secretary, in ft	15
17	From Step 8, average number of hours that secretary is in area of concern, per year	780

Table M-5. Calculation Method, Part 3: Annual Dose Received from Irradiator		
Step No.	Description	Result
18	[60 minus the input from Step 13 multiplied by (the input from Step 14 plus the input from Step 15)] divided by 60 = $[60 - 5 \times (3 + 0.20)] / 60 = [60 - 16] / 60 =$ FRACTION OF TIME THE IRRADIATOR IS IDLE	0.73
19	(The input from Step 13 multiplied by the input from Step 15) divided by 60 = $(5 \times 0.20) / 60 = 1/60 =$ FRACTION OF TIME THE SAMPLE IS MOVING into and out of the irradiating position	0.017
20	1 minus the result from Step 18 minus the result from Step 19 = $1 - 0.73 - 0.017 =$ FRACTION OF TIME THE IRRADIATOR IS IN USE	0.253
21	(The input from Step 10 multiplied by the result from Step 18) plus (the input from Step 11 multiplied by the result from Step 19) plus (the input from Step 12 multiplied by the result from Step 20) = $(2 \times 0.73) + (10 \times 0.017) + (2.0 \times 0.253) = 1.46 + 0.17 + 0.506 =$ AVERAGE DOSE RATE ENCOUNTERED AT 3.28 FEET FROM THE IRRADIATOR, in mrem/h	2.136
22	The result from Step 21 multiplied by (3.28 squared divided by the input from Step 16 squared) = $2.136 \times (3.28^2 / 15^2) = 2.136 \times (10.8 / 225) =$ AVERAGE DOSE RATE ENCOUNTERED BY THE SECRETARY in mrem/h	0.10
23	The result from Step 22 multiplied by the input from Step 17 = $0.10 \times 780 =$ ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATES OF TIME SPENT IN AREA OF CONCERN, DOSE RATES, AND IRRADIATOR USAGE, in mrem/yr	78
Note: If the result in Step 23 is greater than 100 mrem/yr, the licensee must take corrective actions.		

1 Tomás is glad to see that the results in Step 23 show compliance with the 100 mrem in a year
2 limit. Had the result in Step 23 been higher than 100 mrem in a year, Tomás could have done
3 one or more of the following:

- 4 • Considered whether the assumptions used to determine occupancy are accurate, revise
5 the assumptions as needed, and recalculate using the new assumptions.

1 • Calculated the effect of any shielding² located between the irradiator area and the
2 secretarial workstation; such calculation is beyond the scope of this appendix.

3 • Take corrective action (e.g., move the irradiator within the use area, move the use
4 area, or move the secretarial workstation) and perform new calculations to
5 demonstrate compliance.

6 Note that in the example Tomás evaluated the unrestricted area outside only one wall of the
7 irradiator area. Licensees also need to make similar evaluations for other unrestricted areas
8 and to keep in mind the “as low as reasonably achievable” (ALARA) principle, taking reasonable
9 steps to keep radiation dose received below regulatory requirements. In addition, licensees
10 need to be alert to changes in situations (e.g., moving the self-shielded irradiator closer to the
11 secretarial workstation, adding a second irradiator, changing the secretary to a full-time worker,
12 or changing the estimate of the portion of time spent at the desk) and to perform additional
13 evaluations, as needed.

RECORDKEEPING: 10 CFR 20.2107 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

14 **Combination Measurement-Calculation Method**

15 This method, which allows the licensee to take credit for shielding between the irradiator and the
16 area in question, begins by measuring radiation levels in the areas, as opposed to using
17 manufacturer- or distributor-supplied rates at a specified distance from each irradiator. These
18 measurements must be made with calibrated radiation survey meters sufficiently sensitive to
19 measure background levels of radiation. However, licensees must exercise caution when
20 making these measurements, and they must use currently calibrated radiation survey
21 instruments. A maximum dose of 100 mrem [1 mSv] received by an individual over a period of
22 2080 hours (i.e., a “work year” of 40 h/wk for 52 wk/yr) is equal to less than 0.05 mrem [0.5 µSv]
23 per hour.

This rate is well below the minimum sensitivity of most commonly available GM survey instruments.

24 Instruments used to make measurements for calculations must be sufficiently sensitive. An
25 instrument equipped with a scintillation-type detector or a micro-R meter used in making very
26 low gamma-radiation measurements should be adequate.

27 Licensees may also choose to use environmental thermoluminescent dosimeters (TLDs) in
28 unrestricted areas next to the irradiator area for monitoring. This direct measurement method
29 would provide a definitive measurement of actual radiation levels in unrestricted areas without

²National Council on Radiation Protection and Measurements (NCRP) Report No. 147, “Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV,” might contain helpful information. It is available from NCRP, 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814, telephone 301-657-2652. To order electronically, access www.ncrppublications.org.

any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 100 mrem/yr [1 mSv/yr] limit.

Example 2

As in Example 1, Tomás is the RSO for Glow-in-the-Dark Industries, Inc., a hypothetical self-shielded irradiator licensee. The company has one irradiator in a designated and locked area that adjoins an unrestricted area where a secretarial work station is located. See Figure M–1 and Table M–2 for information. Tomás wants to see whether the company complies with the public dose limits at the secretarial station.

Tomás placed an environmental TLD badge in the secretarial work space for 30 days. The TLD processor sent Tomás a report indicating that the TLD received 100 mrem.

Table M–6. Combination Measurement-Calculation Method		
Step No.	Description	Input Data and Results
Part 1		
1	Dose received by TLD, in mrem	100
2	Total hours TLD exposed	24 h/d × 30 d/mo = 720
3	Divide the results of Step 1 by the results of Step 2 = HOURLY DOSE RECEIVED , in mrem in an hour	100/720 = 0.14
4	Multiply the results of Step 3 by 365 d/yr × 24 h/d = 8784 hours in a year = MAXIMUM ANNUAL DOSE RECEIVED FROM IRRADIATOR , in mrem/yr	365 × 24 × 0.14 = 8784 × 0.14 = 1226
Note: For the conditions described above, Step 3 indicates that the dose received in any 1 hour is less than the limit of 2 mrem/h. However, if there are any changes, the licensee would need to reevaluate the potential doses that could be received in any 1 hour. Step 4 indicates that the annual dose received would be much greater than the 100 mrem in a year allowed by the regulations.		
Part 2		
At this point Tomás can adjust for a realistic estimate of the time the secretary spends in the area as he did in Part 2 of Example 1.		
Part 3		
If the results of Tomás' evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, he might have to consider moving the self-shielded irradiator or the secretary's desk or adding shielding to the wall.		

1

APPENDIX N

2

ADDITIONAL NOTIFICATIONS REQUIRED FOR SELF-SHIELDED IRRADIATOR LICENSEES

3

Additional Notifications Required for Self-Shielded Irradiator Licensees

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

Typical NRC Notification and Reporting Requirements for Incidents			
Event	Telephone Notification	Written Report	Regulatory Requirement
Package received with removable radioactive surface contamination exceeding the limits of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) 71.87(i) or external radiation levels exceeding the limits of 10 CFR 71.47	immediate [NRC and final delivery carrier must be notified]	none	20.1906(d)
Theft, loss, or missing of licensed material	immediate	30 days	10 CFR 20.2201(a)(1)(i) 10 CFR 20.2201(b)(1) 10 CFR 37.81(a)
Whole body dose greater than 0.25 Sv [25 rems]	immediate	30 days	10 CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Gy [250 rads]	immediate	30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 0.5 Sv [50 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems]	none	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv [0.1 rem]	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i) & (ii)
Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a) & (c)(2)

Typical NRC Notification and Reporting Requirements for Incidents (Continued)			
Event	Telephone Notification	Written Report	Regulatory Requirement
Unplanned contamination event that requires restricted access for more than 24 hours and involves a quantity of material greater than five times the lowest annual limit on intake for the material as specified in Appendix B of 10 CFR Part 20 and requires the area to be restricted for a reason other than to allow radionuclides with half-lives less than 24 hours to decay	24 hours	30 days	10 CFR 30.50(b)(1) & (c)(2);
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits ¹	24 hours	30 days	10 CFR 30.50(b)(2) & (c)(2);
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4) & (c)(2);
Determination that any licensee that has not previously implemented the Security Orders (i.e., orders issued by the NRC to require licensees to implement interim security measures) or been subject to the provisions of 10 CFR Part 37, Subpart C will aggregate radioactive material to a quantity that equals or exceeds the Category 2 threshold	none	90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold	10 CFR 37.41(a)(3)

¹ Notifications are required when safety interlocks malfunction or other components fail resulting in the potential risk of radiation exposure.

Typical NRC Notification and Reporting Requirements for Incidents (Continued)

Event	Telephone Notification	Written Report	Regulatory Requirement
Coordination with local law enforcement agency (LLEA) has failed, either because the LLEA has not responded or because the LLEA does not plan to participate	3 business days	Submittal of a written report concerning failures of coordination with LLEA as described in 10 CFR 37.45(b) is not required; however, licensees must document their efforts to coordinate with the LLEA and keep this documentation for 3 years	10 CFR 37.45(b)
Determination that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material	As soon as possible (but not at the expense of causing delay or interfering with the LLEA response), but no later than 4 hours after discovery	30 days	10 CFR 37.57(a)&(c)
Assessment of any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material	As soon as possible, but no later than 4 hours after notifying the LLEA	none	10 CFR 37.57(b)
Determination that a shipment containing a Category 1 quantity of material is lost or missing in transport	Within 1 hour of the determination; also, notify LLEA within 1 hour of determination	30 days and periodic updates	10 CFR 37.81(a)&(g)

Typical NRC Notification and Reporting Requirements for Incidents (Continued)			
Event	Telephone Notification	Written Report	Regulatory Requirement
Determination that a shipment containing a Category 2 quantity of material is lost or missing in transport	Within 4 hours of the determination and again within 24 hours if the material has not yet been located and secured	30 days	10 CFR 37.81(b)&(g)
Discovery along the route of any actual or attempted theft or diversion, or suspicious activity, related to a Category 1 quantity of material in transport	Upon discovery, as soon as possible; also, notify LLEA as soon as possible upon discovery	30 days (except no report for suspicious activity)	10 CFR 37.81(c)&(g)
Discovery of any actual or attempted theft or diversion, or suspicious activity, related to a Category 2 quantity of material in transport	As soon as possible	30 days (except no report for suspicious activity)	10 CFR 37.81(d)&(g)
Upon recovery of any lost or missing Category 1 quantity of material	As soon as possible; also, notify the LLEA as soon as possible	To be included in the 30-day report of an event described in 10 CFR 37.81(g), if recovered during that time	10 CFR 37.81(e)&(h)
Upon recovery of any lost or missing Category 2 quantity of material	As soon as possible	To be included in the 30-day report of an event described in 10 CFR 37.81(g), if recovered during that time	10 CFR 37.81(f)&(h)

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

1 **Other Types Of Notifications Include:**

	Telephone Notification	Written Report	Regulatory Requirement
Filing petition for bankruptcy under 11 U.S.C.	none	immediately after filing petition	10 CFR 30.34(h)
Expiration of license	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities at <i>entire site</i>	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities in any <i>separate building or outdoor area</i> that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months at <i>the entire site</i>	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)

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APPENDIX O
INFORMATION FOR APPLICANTS TO CONSIDER WHEN DEVELOPING
OPERATING AND EMERGENCY PROCEDURES FOR
SELF-SHIELDED IRRADIATORS

Information for Applicants to Consider When Developing Operating and Emergency Procedures for Self-Shielded Irradiators

Elements of Operating Procedures Applicable to All Types of Self-Shielded Irradiators

- Analyze each type of material to be placed in the irradiator to ensure that it is compatible with the irradiator's design or to determine whether special procedures in addition to those given by the manufacturer or distributor are required to ensure the safe operation of the irradiator.
- Prepare model-specific instructions for routine inspections, test procedures, and maintenance to ensure that all interlocks, devices, and components critical to the safe operation of the irradiator are functioning properly. (Prohibited actions such as changing the safety control system or removing the source should be stated.)
- Develop methods to maintain accountability (e.g., use a log book to record irradiator use) and to ensure that only authorized persons will use or have access to the irradiator (e.g., control access to the irradiator's keys or control access to the area where the irradiator is located).
- Define steps to take to keep radiation exposures ALARA.
- For each model of irradiator, define step-by-step procedures on how to operate the irradiator and how to perform routine maintenance. Information may be extracted from the manufacturer's or distributor's manual.

Specific Operating Procedures Applicable to Moving-Source Irradiators¹

- The irradiator should not be used unless the licensee provides a calibrated and operable radiation survey meter or a room monitor for use with the irradiator.
- The irradiator door should not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
- Each room monitor should
 - be operable at all times when the irradiator is in use
 - activate a visible and audible alarm when radiation levels exceed 0.02 mSv [2 mrem] per hour
 - be located to detect any radiation escaping from the area of the irradiator door
 - be located so that it is visible to the irradiator user when they are next to the irradiator

¹These procedures are required for licensees authorized for a J. L. Shepherd Mark I or Model 81-22 irradiator.

- 1 • If a room monitor is not installed, a radiation survey meter should be used to
- 2 — determine the radiation level at the irradiator door when the door is closed
- 3 — check for any increase in radiation levels each time the irradiator door is opened.
- 4 (In conducting such checks, operators should position themselves to minimize
- 5 their exposure to any radiation escaping from the open door.)
- 6 • If abnormal radiation levels or any malfunction of the irradiator are detected at any time,
- 7 the licensee should stop using the irradiator, restrict access to the area housing the
- 8 irradiator, immediately notify the RSO, and determine whether a report to NRC
- 9 is required.
- 10 • The licensee should not attempt to repair or authorize others to attempt to repair the
- 11 irradiator except as specifically authorized in a license issued by NRC.

12 **Elements of Emergency Procedures Applicable to All Types of Self-Shielded Irradiators**

- 13 • Leave the irradiator area (to reduce radiation exposure).
- 14 • Control access to the area (e.g., lock its door).
- 15 • Contact responsible individuals (e.g., have ready and use the names and phone
- 16 numbers of the RSO, irradiator manufacturer or distributor, emergency response
- 17 organizations such as fire department, and the NRC).
- 18 • Take additional steps depending on the specific situation (e.g., take surveys).
- 19 • As appropriate, require timely reporting to NRC.

20 **Changes to Operating and Emergency Procedures Without a License Amendment**

21 Licensees may change their operating and emergency procedures without amending their
22 licenses if:

- 23 • The changes are reviewed and approved by licensee management and the RSO.
- 24 • Affected licensee staff are trained in the procedures before they are implemented.
- 25 • The changes are consistent with applicable license conditions and the procedures or
- 26 commitments submitted in the license application.
- 27 • The changes do not degrade the safety or security of the program.

Copies of operating and emergency procedures should be provided to all users. Post a current copy at each irradiator's control panel. If posting the procedures is not practicable, post a notice describing all such documents and where they may be examined.

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APPENDIX P

2

MODEL LEAK TEST PROGRAM

Model Leak Test Program

Training

Before allowing an individual to perform leak testing, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak testing and sample analysis independently.

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

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and instrument use
- mathematics and calculations used for measuring radioactivity
- biological effects of radiation

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

- observing authorized personnel collecting and analyzing leak test samples
- collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak testing and sample analysis

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, analyze leak tests in a low-background area.
- Use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- Analyze the leak test sample using an instrument that is appropriate for the type of radiation to be measured [e.g., NaI(Tl) well-counter system for gamma emitters, liquid scintillation for beta emitters, and gas-flow proportional counter for alpha emitters].
- If the sensitivity of the counting system is unknown, determine the minimum detectable activity (MDA). The MDA may be determined using the following formula:

$$MDA = \frac{2.71 + 4.65 \sqrt{bkg \times t}}{t \times E}$$

where: MDA = minimum detectable activity in disintegrations per minute (dpm)
 bkg = background count rate in counts per minute (cpm)
 t = background counting time in minutes
 E = detector efficiency in counts per disintegration

1 For example:

2 where: bkg = 200 cpm
3 E = 0.1 counts per disintegration (10 percent efficient)
4 t = 2 minutes

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

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

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

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

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

5 **Note:** The MDA equation shown assumes that counting times for the background measurement
6 and for the sample will be equal. MDA equations for nonequal counting times, as well as
7 derivations of equations and discussions of limitations, can be found in "Decommissioning
8 Health Physics—A Handbook for MARSSIM Users," Eric W. Abelquist, published by Taylor &
9 Francis Group, 2001.

10 **Frequency for Conducting Leak Tests of Sealed Sources**

11 Leak tests will be conducted at the frequency specified in the respective Sealed Source and
12 Device registration certificate. If a sealed source is not registered, leak tests should be
13 conducted at 6 month intervals, unless a different interval is established during the licensing
14 process. Leak testing of sealed sources may be required by license condition.

15 **Procedure for Performing Leak Testing and Analysis**

- 17 • For each source to be tested, list identifying information, such as the sealed source
18 serial number, manufacturer, model number, radionuclide, and activity.
- 19 • Use a radiation survey meter to monitor exposure.
- 20 • Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- 21 • Number each wipe to correlate with identifying information for each source.
- 22 • Wipe the most accessible area where contamination would accumulate if the sealed
23 source were leaking, but do not wipe the surface of a plated or foil source (see
24 manufacturer's instructions).

- 1 • Select instrumentation that is sensitive enough to detect 185 becquerels (Bq)
2 [0.005 microcurie] of the radionuclide contained in the sealed source.
- 3 • Using the selected instrument, count and record background count rate.
- 4 • Check the instrument's counting efficiency using a standard source of the same
5 radionuclide as the source being tested or one with similar energy characteristics. The
6 calibration source should be in the same configuration as the sample. Accuracy of
7 standards should be within plus or minus 5 percent of the stated value and traceable to
8 primary radiation standards such as those maintained by the National Institute of
9 Standards and Technology.
- 10 • Calculate the counting efficiency of the detector.

$$\text{Efficiency in cpm/Bq} = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}}$$

11 where cpm = counts per minute
12 std = standard
13 bkg = background
14 Bq = becquerel

- 15 • Count each wipe sample; determine net count rate.
- 16 • For each sample, calculate and record estimated activity in becquerels (or microcuries).
17 The activity of the sample in becquerels may be calculated using the following formula:

$$\text{Activity of sample [Bq]} = \frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}}$$

- 18 • Sign and date the list of sources, data, and calculations. Retain records for 3 years
19 [under Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2103(a)].
 - 20 • If the wipe test activity is 185 becquerels [0.005 microcuries] or greater, notify the
21 radiation safety officer so that the source can be withdrawn from use and disposed of
22 properly. Also, notify the U.S. Nuclear Regulatory Commission.
- 23 **Reference:** See NUREG–1556, Volume 18, “Consolidated Guidance About Materials Licenses:
24 Program-Specific Guidance About Service Provider Licenses,” if the applicant wants to provide
25 leak testing and sample analysis as a commercial service provider.

1

APPENDIX Q

2

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

3

Information Needed to Support Applicant's Request to Perform Nonroutine Maintenance

Applicants should review the section in this document on "Maintenance," which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Routine maintenance is maintenance that the manufacturer and/or distributor allows their customers to perform and provides instructions in the user manual. Nonroutine maintenance is maintenance that requires specialized training and experience. Nonroutine maintenance includes repairs, removal, replacement, or alterations involving

- electrical and mechanical systems and components that control source or shielding movement
- a self-shielded irradiator's shielding or sealed source(s)
- safety interlocks
- any other component that might affect safe operation of the device
- any other activities during which individuals could receive radiation doses exceeding NRC limits

Follow the manufacturer's and/or distributor's procedures in the instruction manual describing the maintenance activity. It is preferable to use the original equipment manufacturer or distributor (OEM) supplied components or parts. Any non-OEM replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor will need to be evaluated to ensure that they do not degrade the results of the engineering safety analysis performed and accepted as part of the device's SSD registration. If the non-OEM part is integral to the safe operation of the device, the licensee should verify that the part will have the same form, fit, and function as the original component. In addition, the licensee should provide the part's technical information (as specified in Section 8.10.8, "Maintenance") to the U.S. Nuclear Regulatory Commission (NRC) for a safety review. The use of replacement parts may result in the device being a custom device, in accordance with NUREG-1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration." The licensee should not install this part until the NRC has approved the request. Licensees also need to ensure that, after maintenance or repair is completed, the sealed source/device is tested and functions as designed, before the unit is returned to routine use.

For guidance on the use of sources that have not been supplied by the manufacturer and/or distributor, see Regulatory Issue Summary 2013-01, "Use of Aftermarket Sealed Sources Registered Under 10 CFR 32.210," dated March 12, 2013 (ML12313A147).

If nonroutine operations are not performed properly with attention to good radiation safety principles, the sealed source/device may not operate as designed, and personnel performing these tasks could receive radiation doses exceeding NRC limits.

Nonroutine maintenance should be performed only by qualified and specifically authorized individuals. Self-shielded irradiator licensees should conduct these operations only after their procedures have been evaluated and specifically approved by license condition. Accordingly,

1 applicants wishing to perform nonroutine maintenance must provide the following information,
2 as appropriate:

- 3 • Describe the types of nonroutine maintenance to be performed. The principal reason for
4 obtaining this information is to assist in the evaluation of the qualifications of individuals
5 who will conduct the work and the radiation safety procedures they will follow.
- 6 • Identify who will perform nonroutine maintenance and describe their training and
7 experience. Acceptable training and experience includes the following:
 - 8 — previous experience in nonroutine maintenance and radiation safety training
 - 9 — vendor maintenance certification (e.g., manufacturer's or distributor's courses for
10 nonroutine operations or the equivalent)
 - 11 — training or previous experience as technician(s) using preplanned procedures
12 with direct radiation-protection supervision
- 13 • Submit operating and emergency procedures for nonroutine maintenance. These
14 procedures should ensure the following:
 - 15 — verification that the specific maintenance activity and the person who will be
16 conducting this activity are authorized on the license before proceeding
 - 17 — doses to personnel and members of the public are within regulatory limits and as
18 low as is reasonably achievable (e.g., use of shielded containers or shielding)
 - 19 — source is secured against unauthorized removal or access or under
20 constant surveillance
 - 21 — appropriate labels and signs are used
 - 22 — manufacturer's or distributor's instructions and recommendations are followed
 - 23 — any non-OEM replacement components or parts or the use of materials
24 (e.g., lubricants) other than those specified or recommended by the manufacturer
25 or distributor are evaluated to ensure that they do not degrade the engineering
26 safety analysis performed and accepted as part of the device registration
 - 27 — before being returned to routine use, the sealed source/device is tested to verify
28 that it functions as designed and that the source integrity is not compromised
- 29 • Emergency procedures should be developed and reviewed for all potential
30 accident scenarios.
- 31 • Confirm that individuals performing nonroutine operations will wear both whole body and
32 extremity-monitoring devices or perform a prospective evaluation demonstrating that
33 unmonitored individuals performing nonroutine operations are not likely to receive, in a
34 year, a radiation dose in excess of 10 percent of the allowable limits.

- 1 • Verify possession of at least one survey instrument that meets the criteria in Appendix K
2 of this NUREG, "General Guidelines for Radiation-Monitoring Instrument Specifications
3 and Model Survey-Instrument Calibration Program."
- 4 • Describe steps to be taken to ensure that radiation levels in areas where nonroutine
5 operations will take place do not exceed 10 CFR 20.1301 limits. For example,
6 applicants can do the following:
 - 7 — Commit to performing surveys with a survey instrument (as described above).
 - 8 — Specify where and when surveys will be conducted during nonroutine operations.
 - 9 — Commit to maintaining, for 3 years from the date of the survey, records of the
10 survey (e.g., who performed the survey, the date of the survey, the instrument
11 used, and the measured radiation levels corresponding to the location of those
12 measurements), as required by 10 CFR 20.2103, "Records of surveys."
 - 13 — Commit to maintaining documentation describing the work that was completed,
14 especially replacement parts and/or sources.

1

APPENDIX R

2

TRANSPORTATION

TRANSPORTATION

Note: The following list of U.S. Department of Transportation (DOT) regulations is provided to inform licensees about typical requirements that apply to the transportation of licensed material including the preparation of shipments of licensed material. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, transportation requirements change; therefore, licensees should consult the regulations for definitive information about current requirements. Additional information on transportation requirements may be found at the DOT Web site: <http://www.dot.gov/>.

- Table of Hazardous Materials and Special Provisions—49 CFR 172, Subpart B
 - 49 CFR 172.101—Purpose and use of hazardous materials table [proper shipping name, hazard class, identification number]
 - Table 2 to Appendix A of 49 CFR 172.101 - List of Hazardous Substances and Reportable Quantities [for radionuclides]
- Shipping Papers—49 CFR Part 172, Subpart C
 - 49 CFR 172.201—Preparation and retention of shipping papers
 - 49 CFR 172.202—Description of hazardous material on shipping papers
 - 49 CFR 172.203—Additional description requirements
 - 49 CFR 172.204—Shipper's certification [if applicable]
- Markings—49 CFR Part 172, Subpart D
 - 49 CFR 172.301—General marking requirements for non-bulk packagings
 - 49 CFR 172.304—Marking requirements
 - 49 CFR 172.310—Class 7 (radioactive) materials
 - 49 CFR 172.324—Hazardous substances in nonbulk packagings
- Labeling—49 CFR Part 172, Subpart E
 - 49 CFR 172.400—General labeling requirements
 - 49 CFR 172.401—Prohibited labeling
 - 49 CFR 172.403—Class 7 (radioactive) material
 - 49 CFR 172.406—Placement of labels
 - 49 CFR 172.407—Label specifications
 - 49 CFR 172.440—RADIOACTIVE YELLOW-III label
- Placarding—49 CFR Part 172, Subpart F
 - 49 CFR 172.504—General placarding requirements
 - 49 CFR 172.516—Visibility and display of placards
 - 49 CFR 172.556—RADIOACTIVE placard
- Emergency Response Information—49 CFR Part 172, Subpart G
 - 49 CFR 172.600—Applicability and general requirements
 - 49 CFR 172.602—Emergency response information

- 1 — 49 CFR 172.604—Emergency response telephone number
- 2
- 3 • Training—49 CFR Part 172, Subpart H
- 4 — 49 CFR 172.702—Applicability and responsibility for training and testing
- 5 — 49 CFR 172.704—Training requirements
- 6 • Safety and Security Plans—49 CFR Part 172, Subpart I
- 7 — 49 CFR 172.800—Applicability and purpose
- 8 — 49 CFR 172.802—Components of a security plan
- 9 • Preparation for Hazardous Materials for Transportation—49 CFR Part 173, Subpart B
- 10 — 49 CFR 173.25—authorized packaging and overpacks
- 11 • Class 7 (Radioactive) Materials—49 CFR Part 173, Subpart I
- 12 — 49 CFR 173.403—Definitions
- 13 — 49 CFR 173.413—Additional design requirements for Type B packages
- 14 — 49 CFR 173.416—Authorized Type B packages
- 15 — 49 CFR 173.441—Radiation limitations and exclusive use provisions
- 16 — 49 CFR 173.442—Thermal limitations
- 17 — 49 CFR 173.443—Contamination control
- 18 — 49 CFR 173.447—Storage incident to transportation – general requirements
- 19 — 49 CFR 173.448—General transportation requirements
- 20 — 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission
- 21 approved packages
- 22 — 49 CFR 173.474—Quality control for construction of packaging
- 23 — 49 CFR 173.475—Quality control requirements prior to each shipment of Class
- 24 7 (radioactive) materials
- 25 — 49 CFR 173.476—Approval of special form Class 7 (radioactive) materials
- 26 • General Information and Regulations—49 CFR Part 177, Subpart A
- 27 — 49 CFR 177.817—Shipping papers
- 28 • Loading and Unloading—49 CFR Part 177, Subpart B
- 29 — 49 CFR 177.842—Class 7 (radioactive) material

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 A₁ or A₂.
[5] The external dose rate from LSA material or SCO in a single package may not exceed 10 mSv/h (1 rem/h) at 3 m from the unshielded material or objects (see §173.427(a)(1)).
[6] LSA material and SCOs that are or contain fissile material in quantities that are not fissile excepted must be packaged in appropriate Type AF or Type BF packages. For alternate domestic transport provisions, see §173.427(b)(4). For comprehensive guidance on packaging and transportation of LSA material and SCO, see NUREG-1608.
[7] For LSA material and SCO, transport of combustible solids, all liquids and all gases classified as LSA-II and LSA-III material, and transport of all SCO-I and SCO-II is limited to a maximum activity of 100 A₂ in a conveyance (see §173.427(a)(2)).
[8] Unless excepted by §§173.427(c) or (d), the material or object(s) shall be appropriately packaged in a Type IP, DOT-7A Type A or Type B package.
[9] Certain LSA-I and SCO-I may be transported unpackaged under the conditions specified in §173.427(c).

2. Radiation Level, TI and CSI Limits for Transportation by Road, Rail and Air ^[1] (49 CFR 172 - 177, and 10 CFR 71)				
Type of Transport	Non-exclusive use	Exclusive use		
Mode of Transport	Road, Rail, Vessel and Air	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] 0.1 mSv/h (10 mrem/h): at any point two (2) m (6.6 ft) from sides of the vehicle ^[5]	N/A	N/A
Occupied position	N/A	0.02 mSv/h (2 mrem/h): at any normally occupied area ^[6]	Requirement of §176.708 applies	N/A
Transport Index (TI) Limits ^[4]				
Package ^[1,7]	3: passenger aircraft 10: road, rail, vessels and cargo aircraft	No limit		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 ^[4]				
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 §71.50.
[8] For details on TI and CSI limits for transport by vessel, see §176.708.

3. Contamination Limits and Quality Control for Class 7 (Radioactive) Materials: (49 CFR 173.443 and 173.475, and 10 CFR 71)

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

Maximum Permissible Limits for Non-fixed Radioactive Contamination on Packages When Offered for Transport

The level of non-fixed (removable) radioactive contamination on external surfaces of packages offered for transport must be kept as low as reasonable achievable, and shall not exceed the values shown in the following table:

Contaminant	Maximum permissible limits (§173.443(a), Table 9)		
	Bq/cm ²	µCi/cm ²	dpm/cm ²
Beta, gamma and low toxicity alpha emitters	4	10 ⁻⁴	220
All other alpha emitting radionuclides	0.4	10 ⁻⁵	22

The non-fixed contamination shall be determined by:

- (a) wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;
- (b) ensuring each wipe area is 300 cm² in size;
- (c) measuring the activity on each single wiping material and dividing that value by the surface area wiped and the efficiency of the wipe procedure, where an actual wipe efficiency may be used, or it may be assumed to be 0.10.

Alternatively, the contamination level may be determined using alternative methods of equal or greater efficiency.

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

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

- must be kept as low as reasonable achievable; and
- may not exceed the limits set forth in §173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Excepted and Empty Radioactive Material Packages

- The non-fixed radioactive surface contamination on the external surface of excepted and empty packages shall not exceed the limits specified in §173.443(a), Table 9 (as shown above).
- The internal contamination of an empty package must not exceed 100 times the limits in §173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Packages and in Rail and Road Vehicles used for Exclusive Use Shipments of Radioactive Material

- The levels of non-fixed radioactive contamination on the packages (a) at the beginning of transport, may not exceed the levels prescribed in the above table, and (b) at any time during transport, may not exceed ten times the levels prescribed in §173.443(a), Table 9 (as shown above).
- Each transport vehicle used for transporting the radioactive material packages must be surveyed with appropriate radiation detection instruments after each use. If contamination values exceed acceptable levels, the transport vehicle may not be returned to service until the radiation dose rate at each accessible surface is demonstrated to be 0.005 mSv/h (0.5 mrem/h) or less, and that there is no significant non-fixed radioactive surface contamination specified in §173.443(a), Table 9 (as shown above).

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

- The contamination levels must not exceed 10 times the levels prescribed in §173.443(a), Table 9 (as shown above).
- Each vehicle shall be stenciled with the words "For Radioactive Materials Use Only" in letters at least 76 mm (3 in) high in a conspicuous place on both sides of the exterior of the vehicle.
- A survey of the interior surfaces of the empty closed vehicle must show that the radiation dose rate at any point does not exceed 0.1 mSv/h (10 mrem/h) at the surface or 0.02 mSv/h (2 mrem/h) at 1 m (3.3 feet) from the surfaces.
- Each vehicle shall be kept closed except for loading or unloading.

Provisions for Quality Control Prior to Each Shipment of Radioactive Material (§173.475)

- Before each shipment of any radioactive materials package, the offeror must ensure, by examination or appropriate tests, that:
 - (a) the packaging is proper for the contents to be shipped;
 - (b) the packaging is in unimpaired physical condition, except for superficial marks;
 - (c) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;
 - (d) for fissile material, each moderator and neutron absorber, if required, is present and in proper condition;
 - (e) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed;
 - (f) each closure, valve, or other opening of the containment system is properly closed and sealed;
 - (g) each packaging containing liquid in excess of an A₂ quantity and intended for air shipment has been tested to show that it will not leak under an ambient atmospheric pressure of not more than 25 kPa, absolute (3.6 psia), where the test must be conducted on the entire containment system, or on any receptacle or vessel within the containment system, to determine compliance with this requirement;
 - (h) the internal pressure of the containment system will not exceed the design pressure during transportation; and
 - (i) the external radiation and contamination levels are within the allowable limits specified in §173.441 and 443.

4. Hazard Communications for Class 7 (Radioactive) Materials: Shipping Papers (49 CFR 172, Subpart C)

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

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

Shipping Paper Entries		
Always Required	Sometimes Required	Optional Entries
<p><u>Basic description (in sequence):</u></p> <ul style="list-style-type: none"> • UN Identification number • Proper Shipping Name • Hazard Class (7) • Total activity contained in each package in SI units (e.g. Bq, TBq, etc.), or in both SI and customary units (e.g. Ci, mCi, etc.) with customary units in parentheses following the SI units • Number and type of packages <p><u>Additional description:</u></p> <ul style="list-style-type: none"> • Name of each radionuclide^[1] • Description of physical and chemical form (unless special form) • Category of label used • Transport index (TI) of each package bearing a Yellow-II or Yellow-III label <p><u>Additional entry requirements:</u></p> <ul style="list-style-type: none"> • 24 hour emergency telephone number • Shipper's Certification shall be provided by each person offering radioactive material for transportation^[2] • Proper page numbering (e.g. Page 1 of 4) 	<p><u>Materials-based Requirements:</u></p> <ul style="list-style-type: none"> • The criticality safety index (CSI) or "Fissile Excepted" for fissile material • The words "Highway route controlled quantity" or the term "HRCQ" entered in the basic description for highway route controlled quantities • The letters "RQ" entered on the shipping paper either before or after the basic description for each hazardous substance (see §171.8) • Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required • A hazardous waste manifest and the word "Waste" preceding the proper shipping name is required for radioactive material that is hazardous waste <p><u>Package-based Requirements:</u></p> <ul style="list-style-type: none"> • The applicable DOE or NRC package approval identification marking for certified Type AF and Type B packages • The International Atomic Energy Agency (IAEA) Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package <p><u>Shipment- and Administrative-based Requirements:</u></p> <ul style="list-style-type: none"> • Specify "exclusive use shipment" as required • Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use • Specify the notation "DOT-SP" followed by the special permit number^[3] for a special permit shipment 	<ul style="list-style-type: none"> • The weight in grams or kilograms of radionuclides may be inserted instead of activity units for fissile radionuclides, except for Pu-239 and Pu-241 • The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units • The words "RESIDUE: Last Contained * * *" may be included in association with the basic description of the hazardous material last contained in the packaging • Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information
Special Considerations/Exceptions for Shipping Papers		
<ul style="list-style-type: none"> • For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, <u>or</u> be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, <u>or</u> be designated by an "X" (or "RQ" if appropriate). • Emergency response information consistent with §§172.600-606 shall be readily available on the transport vehicle. • Shipments of limited quantities of radioactive material in excepted packages, under UN2908, 2909, 2910 and 2911, are excepted from shipping paper requirements if (a) the package does not contain fissile material unless excepted by §173.453, and (b) the limited quantity of radioactive material is not a hazardous substance or hazardous waste. • For road transport, the shipping papers shall be (a) readily available to authorities in the event of accident or inspection, (b) stored within the driver's immediate reach while he is restrained by the lap belt, (c) readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle, and (d) either in a holder mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat. 		



[1] For mixtures of radionuclides, the radionuclides to be shown must be determined in accordance with §173.433(g), which is commonly known as the 95% rule; abbreviations (symbols) are authorized.

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

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

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

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Markings on Packages		
Markings Always Required Unless Excepted ^[1]	Additional Markings Sometimes Required	Optional Markings
<p>Markings for Non-bulk Packagings:</p> <ul style="list-style-type: none"> • Proper shipping name • Identification number (preceded by "UN" or "NA," as appropriate) • Name and address of consignor or consignee, unless the package is: <ul style="list-style-type: none"> ▪ highway only and no motor carrier transfers; or ▪ part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee <p>Markings for Bulk Packages:</p> <ul style="list-style-type: none"> • Identification number on orange rectangular panel: <ul style="list-style-type: none"> ▪ on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more, or ▪ on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons), or ▪ on each side and end of motor vehicle carrying cylinders permanently installed on a tube trailer 	<p>Package-based marking requirements:</p> <ul style="list-style-type: none"> • Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 lb) • Package type as appropriate, i.e., "TYPE IP-1," "TYPE IP-2," "TYPE IP-3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"^[1] • Marked with international vehicle registration code of country of origin for IP-1, IP-2, IP-3 or Type A package design^[2] • Radiation (trefoil) symbol^[3] on outside of outermost receptacle of each Type B(U) or Type B(M) packaging design  • For NRC or DOE packaging, model number, serial number, gross weight, and package identification number for each certified package (Type AF, Type B(U), Type B(M), Type B(U)F, and Type B(M)F) • For Specification 7A packaging, mark on the outside with "USA DOT 7A Type A", and the name and address or symbol of the manufacturer satisfying §178.3 and §178.350. <p>Materials-based requirements:</p> <ul style="list-style-type: none"> • For non-bulk IP-1 package containing a liquid, use underlined double arrow symbol indicating upright orientation^[4], where the symbol is placed on two opposite sides of the packaging  • If a hazardous substance in non-bulk package, mark outside of each package with the letters "RQ" in association with the proper shipping name <p>Administrative-based requirements:</p> <ul style="list-style-type: none"> • For each Type B(U), Type B(M) or fissile material package destined for export shipment, mark "USA" in conjunction with specification marking, or certificate identification; and package identification indicated in U.S. Competent Authority Certificate • Mark "DOT-SP" followed by the special permit number assigned for each package authorized by special permit • Competent authority identification marking and revalidation for foreign made Type B(U), Type B(M), Type C, Type CF, Type H(U), Type H(M), or fissile material package for which a Competent Authority Certificate is required 	<ul style="list-style-type: none"> • Both the name and address of consignor and consignee is recommended. • Other markings on packages such as advertising are permitted, but must be located away from required markings and labeling.
Special Considerations for Marking Requirements		
<ul style="list-style-type: none"> • All markings are to be (a) on the outside of each packaging, (b) durable and legible, (c) in English, (d) printed on or affixed to the surface of a package or on a label, tag, or sign, (e) displayed on a background of sharply contrasting color, and (f) unobscured by labels or attachments. 		

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

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

[3] The radiation symbol shall be resistant to the effects of fire and water, plainly marked by embossing, stamping or other means resistant to the effects of fire and water that conform to the requirements of Appendix B to Part 172.

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

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

Labeling of Packages (49 CFR 172.400-450)




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

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

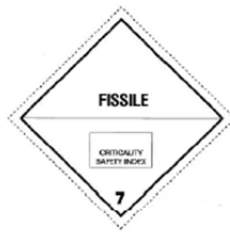

Requirements for Labels^[1]

- Label each package except for (a) excepted packages containing a limited quantity of radioactive material; and (b) Low Specific Activity (LSA) material and Surface Contaminated Objects (SCO), packaged or unpackaged, when transported domestically and when material or object contains less than an A₂ quantity.
- Labeling is required to be (a) printed or affixed to a surface other than the bottom of the package, (b) placed near the proper shipping name marking, (c) printed or affixed to a background of contrasting color or have a dotted or solid line outer border, (d) clearly visible, (e) un-obscured by markings or other attachments, and (f) representative of hazardous material content.
- Display duplicate labels on at least two opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material except as noted above for excepted packages, and packaged or unpackaged LSA material and SCO.

Radioactive Category Labels^[3]

		
White-I	Yellow-II	Yellow-III

Other Labels^[2]

	
Fissile	Empty

Radiation Surface Level (RSL):

mSv/h:	$RSL \leq 0.005$	$0.005 < RSL \leq 0.5$	$0.5 < RSL \leq 2^{[4]}$
mrem/h:	$RSL \leq 0.5$	$0.5 < RSL \leq 50$	$50 < RSL \leq 200^{[4]}$

Transport Index (TI):^[4]

$TI = 0^{[4]}$	$0^{[4]} < TI \leq 1$	$1 < TI \leq 10^{[4, 5]}$
----------------	-----------------------	---------------------------

Fissile labels required for each package containing fissile material, other than fissile-excepted material; and labels must be affixed adjacent to radioactive category labels.

Empty labels required for shipments of empty Class 7 (radioactive) packages satisfying §173.428; and any previously-used labels cannot be visible

Contents on Labels

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

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

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

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

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

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

7. Hazard Communications for Class 7 (Radioactive) Materials: Placarding (49 CFR 172, Subpart F)

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

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

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

- On bulk packages, road transport vehicles, rail cars, and freight containers, and on aircraft unit load devices having a capacity of 640 cubic feet or more^[1], on each side and each end when they contain either a package with a Radioactive Yellow-III label, or low specific activity (LSA) material or surface contaminated objects (SCO) being transported under exclusive use.
- On a square background on any motor vehicle used to transport a package containing Highway Route Controlled Quantity (HRCQ) Class 7 (radioactive) materials^[2].

Visibility and Display of Radioactive Placards [§172.516]

- Placards are required to:
 - be clearly visible, on a motor vehicle and rail car, from the direction they face, except from the direction of another transport vehicle or rail car to which the motor vehicle or rail car is coupled^[3];
 - be securely attached or affixed thereto or placed in a holder thereon;
 - be located clear of appurtenances and devices such as ladders, pipes, doors, and tarpaulins;
 - be located, so far as practical, so dirt or water is not directed to it from transport vehicle wheels;
 - be located at least 3 inches (76.0 mm) away from any marking (e.g. advertising) that could reduce its effectiveness;
 - have authorized words or identification number printed on it displayed horizontally, reading from left to right;
 - be maintained by the carrier so format, legibility, color, and visibility of the placard will not be substantially reduced due to damage, deterioration, or obscurement by dirt or other matter;
 - be affixed to background of contrasting color, or dotted or solid line outer border which contrasts with the background color.

Radioactive Placards

PLACARD (FOR OTHER THAN HRCQ)



White triangular background color in the lower portion with yellow triangle in the upper portion; trefoil symbol, text, class number and inner and outer borders in black.
[see §172.556 for detailed requirements]

PLACARD FOR HRCQ



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

Special Considerations/Exceptions for Placarding

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

[1] See §172.512 for exceptions and variations to the placarding requirements for freight containers and aircraft unit load devices.

[2] See §173.403 for definition of Highway Route Controlled Quantity (HRCQ). A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels; see §172.507(a).

[3] Required placarding of the front of a motor vehicle may be on the front of a truck tractor instead of or in addition to the placarding on the front of the cargo body to which a truck tractor is attached; §172.516(b).

8. Requirements/Guidance for Registration, Emergency Response and Action for Class 7 (Radioactive) Materials: (49 CFR 107, Subpart G, 49 CFR 171.15 and 49 CFR 172, Subparts G and H)

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

Provisions for Persons Who Offer or Transport Class 7 (Radioactive) Materials (49 CFR 107, Subpart G)

- Any person, other than those excepted by §107.606, who offers for transportation, or transports, in foreign, interstate or intrastate commerce any of the following Class 7 (radioactive) materials must satisfy registration and fee requirements of Part 107, Subpart G:
 - a highway route-controlled quantity of radioactive material;
 - a shipment in a bulk packaging with a capacity $\geq 13,248$ L (3,500 gallons) for liquids or gases, or > 13.24 cubic meters (468 cubic feet) for solids; or
 - any quantity of radioactive material that requires placarding, under provisions of Part 172, Subpart F.
- Any person required to register must submit a complete and accurate registration statement on DOT Form F 5800.2 by June 30th for each registration year, or in time to have on file a current Certificate of Registration in accordance with §107.620.
- Each registrant or designee must maintain for a period of 3 years from the date of issuance a copy of the registration statement and Certificate of Registration issued by PHMSA and must furnish its Certificate of Registration (or a copy thereof) and related records to an authorized representative or special agent of DOT upon request.
- Each motor carrier subject to registration requirements of this subpart must carry a copy of its current Certificate of Registration or another document bearing the registration number on board each truck and truck tractor, and the Certificate of Registration or document must be made available, upon request, to enforcement personnel.
- The amount of fees to be paid and procedures to be followed are found at §§107.612 and 616.

Provisions for Providing and Maintaining Emergency Response Information (49 CFR 172, Subpart G)

- When shipping papers for the transportation of radioactive materials are required (see Part 172, Subpart C), emergency response information shall
 - be provided and maintained during transportation and at facilities where materials are loaded for transportation, stored incidental to transportation, or otherwise handled during any phase of transportation;
 - be provided by persons who offer for transportation, accept for transportation, transfer or otherwise handle hazardous materials during transportation;
 - be immediately available for use at all times the hazardous material is present; and
 - include and make available the emergency response telephone number (see §172.604) to any person, representing a Federal, State or local government agency, who responds to an incident involving the material or is conducting an investigation which involves the material
- Emergency response information is information that can be used in mitigating an incident involving radioactive materials. It must contain at least the information specified in §§172.602 and 604; and includes an emergency response telephone number that is monitored at all times the material is in transportation by (a) knowledgeable person, or (b) a person who has immediate access to a knowledgeable person, or (c) an organization capable of accepting responsibility for providing the necessary detailed information concerning the material.
- Each carrier who transports or accepts for transportation radioactive material for which a shipping paper is required shall instruct, according to the requirements of §172.606, the operator of a conveyance to contact the carrier in the event of an incident involving the material.

Actions to be Taken in the Event of Spillage, Breakage, or Suspected Contamination by Radioactive Material

- Except for a road vehicle used solely for transporting Class 7 (radioactive) material, if radioactive material has been released in a road, rail, or air transport conveyance, the conveyance must be taken out of and remain out of service until the radiation dose rate at every accessible surface is less than 0.005 mSv/h (0.5 mrem/h) and the non-fixed radioactive surface contamination levels are below the values the limits in §173.443(a), Table 9 [see Chart 3].
- Each aircraft used routinely, and each motor vehicle used, for transporting radioactive materials under exclusive use, must be (a) periodically checked for radioactive contamination, (b) taken out of service if contamination levels are above acceptable limits, and (c) remain out of service until the radiation dose rates at accessible surfaces are less than 0.005 mSv/h (0.5 mrem/h) and non-fixed radioactive surface contamination levels are below the limits in §173.443(a), Table 9 [see Chart 3].
- Following any breakage, spillage, release or suspected radioactive contamination incident, any rail or air carrier shall notify, as soon as possible, the offeror (i.e. the consignor); special provisions apply for buildings, areas, and equipment that might become contaminated during rail transport. Alternative provisions may apply for motor vehicles transporting radioactive materials under exclusive use. [see §§174.750(a) and 750(e), and §177.843(b)]

Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (§§171.15 and 16)

- Each person in physical possession of radioactive material must provide notice in the event of a reportable incident (see §171.15(b)) as soon as practical, but no later than 12 hours after the occurrence of the reportable incident, to the National Response Center (NRC) by telephone at 800-424-8802 (toll free) or 202-267-2675 (toll call) or online at <http://www.nrc.uscg.mil>.
 - Each notice must include the information specified in §171.15(a)(1) – (a)(7).
- A detailed incident report must also be submitted as required by §171.16.

Guidance on Responding to Emergencies (Emergency Response Guidebook)

- The DOT issues guidance to aid first responders in quickly identifying the specific or generic hazards of the dangerous goods involved in an accident or incident, and for protecting themselves and the general public during the initial response to the accident or incident. For each name or UN ID Number, the user is led to a specific guide that provides insight into potential hazards and steps to be taken for public safety and emergency response.
- The current Emergency Response Guidebook is available at the following URL:
<http://www.phmsa.dot.gov/hazmat/library/erg>



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

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

Provisions for Training (49 CFR 172, Subpart H)

- For any person who is employed by an employer or is self-employed, and who directly affects radioactive materials transportation safety, a systematic program shall be established to ensure that the person:
 - has familiarity with the general provisions of [Part 172, Subpart H](#);
 - is able to recognize and identify radioactive materials;
 - has knowledge of specific requirements of [Part 172](#) that are applicable to functions performed by the employee;
 - has knowledge of emergency response information, self protection measures and accident prevention methods and procedures; and
 - does not perform any function related to the requirements of [Part 172](#) unless instructed in the requirements that apply to that function.
- The person shall be trained pursuant to the requirements of [§§172.704\(a\) and \(b\)](#), may be trained by the employer or by other public or private sources, and shall be tested by appropriate means. The training must include the following:
 - (a) general awareness training providing familiarity with applicable regulatory requirements;
 - (b) function-specific training applicable to functions the employee performs;
 - (c) safety training concerning emergency response information, measures to protect the employee from hazards, and methods and procedures for avoiding accidents;
 - (d) security awareness training providing awareness of security risks and methods designed to enhance transportation security; and
 - (e) in-depth security training if a security plan is required for the shipment(s) involved.
- Initial and recurrent training shall comply with the requirements of [§172.704\(c\)](#)
- Records of training shall be created and retained in compliance with the requirements of [§172.704\(d\)](#).

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

- A security plan for hazardous materials that conforms to the requirements of [Part 172, Subpart I](#) must be developed and adhered to by each person who offers for transportation in commerce or transports in commerce in a motor vehicle, rail car, or freight container any of the following radioactive materials:
 - (a) IAEA Code of Conduct Category 1 and 2 materials (see [§172.800\(b\)\(15\)](#));
 - (b) a highway route controlled quantity (HRCQ) of radioactive material as defined in [§173.403](#) (see [§172.800\(b\)\(15\)](#));
 - (c) known radionuclides in forms listed as radioactive material quantities of concern (RAM-QC) by the NRC (see [§172.800\(b\)\(15\)](#)); or
 - (d) a quantity of uranium hexafluoride requiring placarding under [§172.505\(b\)](#) (see [§172.800\(b\)\(14\)](#)).
- The security plan must include an assessment of possible transportation security risks and appropriate measures to address the assessed risks.
- Specific measures put into place by the plan may vary commensurate with the level of threat at a particular time.
- At a minimum, a security plan must address personnel security, unauthorized access, and en route security.
- The security plan must be
 - (a) in writing;
 - (b) retained for as long as it remains in effect;
 - (c) available as copies or portions thereof to the employees who are responsible for implementing it, consistent with personnel security clearance or background investigation restrictions and a demonstrated need to know;
 - (d) revised and updated as necessary to reflect changing circumstances; and
 - (e) maintained (all copies) as of the date of the most recent revision, when it is updated or revised.
- Security plans that conform to regulations, standards, protocols, or guidelines issued by other Federal agencies, international organizations, or industry organizations may be used to satisfy the requirements in [Part 172](#), provided such security plans address the requirements specified in [Part 172, Subpart I](#).
- Additional security planning requirements may apply for rail transport of a highway route controlled quantity of radioactive material (see [§§172.820 and 173.403](#)).

1

APPENDIX S

2

RADIATION SOURCE USE AND REPLACEMENT STUDY

3

Radiation Source Use and Replacement Study

This appendix reprints the contents of an information sheet originally released in 2008 available at <http://www.nrc.gov/security/nas-facts-sheet.pdf>.

For more information on this topic, the National Academies Press published "Radiation Source Use and Replacement" in 2008 and this book is available at their Web site http://www.nap.edu/catalog.php?record_id=11976

Information Sheet: Radiation Source Use and Replacement Study

Background

Radiation sources are used extensively in the U.S. for industrial applications, research, and medical diagnosis and treatment. The Energy Policy Act of 2005 (EPAc) has several provisions for the Federal Government to evaluate alternative technologies for replacing radiation sources that may pose a national security risk. One of these provisions, EPAc Section 651(d), directs the U.S. Nuclear Regulatory Commission (NRC) to work with the National Academies (NA) to review current industrial, research, and commercial uses of radiation sources and identify technically and economically feasible replacements for these sources. Concerns about the safety and security of radioactive sources that could be used in a radiological dispersal device (RDD) and radiological exposure device (RED) prompted Congress to direct this study.

Overview

The security of radiation sources is a top priority for the NRC. The NRC's efforts have been effective, keeping incidents involving radiation sources and radioactive materials to a minimum and the probability of their consequences low. Most lost or stolen sources are quickly recovered, resulting in minimal or no radiation exposures or contamination. The NRC works with domestic and international organizations on a variety of initiatives to make risk-significant radiation sources more secure and less vulnerable to terrorists.

The regulatory programs of NRC and the Agreement States have served the Nation well, with little need for any major changes before September 11, 2001. In response to the increased terrorist threat since the attacks on that date, the NRC (in concert with the Agreement States) has strengthened the safety and security program for radiation sources to reduce the potential threat from an RDD or radiological exposure device. The NRC conducted security assessments to identify additional safety measures that can practically be implemented to further enhance the safety and security of radiation sources. These safety measures have been implemented for risk-significant sources.

Approach

Alternative technologies to radiation sources may include the replacement of a radiation source with an equivalent (or improved) process that does not require the use of radionuclides. Another approach is to replace a radiation source with a different radiation source that poses a lower risk to public health and safety if it were involved in an accident or used in a terrorist attack.

1 The NA is evaluating these options for risk-significant sources defined as Category 1 and 2
2 sources by the International Atomic Energy Agency's *Code of Conduct on the Safety and*
3 *Security of Radiation Sources* ([http://www-pub.iaea.org/MTCD/publications/PDF/Code-](http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004_web.pdf)
4 [2004_web.pdf](http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004_web.pdf)). The majority of these sources use cobalt-60, cesium-137, or iridium-192 in
5 medical applications, such as gamma knives and blood irradiators, and in industrial and
6 research applications, such as radiography cameras, well logging, and industrial and research
7 irradiators. In the U.S., about 2000 licensees regulated by the NRC and the Agreement States
8 possess Category 1 and 2 sources.



Radiography camera



Blood irradiator

9 The NRC will provide Congress with the recommendations of the NA on alternative technologies
10 to radiation sources. The agency will consider the NA recommendations within its jurisdiction,
11 as well as recommendations of the Department of Energy and the Radiation Source Protection
12 and Security Task Force, which are also evaluating alternative technologies to radiation sources
13 in accordance with the EPAct.

14 The NRC welcomes recommendations to enhance the safety and security of radiation sources
15 and lower the potential risk of terrorist use of radiation sources. Alternative technologies to
16 radiation sources may be one approach to accomplishing this goal. However, the NRC bases
17 its licensing decisions on whether its requirements have been met, without evaluating whether
18 other technologies could have been used. Traditionally, market forces have driven demand for
19 the use of radiation sources and their alternatives in devices.

20 The NA began this study in July 2006, and the study committee has provided an open forum for
21 discussion of alternative technologies with a wide range of stakeholders. The NA issued the
22 committee's report in February 2008.

23 Visit the NA Web site at <http://www8.nationalacademies.org/cp>.

- 24 ➤ **NRC has strengthened its security program for risk-significant radiation**
25 **sources to reduce the potential threat from a radiological dispersal device**
26 **or radiological exposure device since 9/11.**
- 27 ➤ **The NRC works closely with its domestic and international partners to**
28 **make risk-significant radiation sources more secure and less vulnerable to**
29 **terrorists.**

1 ***The National Academies evaluated the uses of risk-significant sources that could be***
2 ***replaced with an equivalent process or that would pose a lower risk if an accident or***
3 ***attack occurs.***

- 4 • The Energy Policy Act of 2005 section 651(d) mandated this study.
- 5 • The study began in July 2006 and the report will be released in February 2008.
- 6 • The National Academies' recommends considering the feasibility of replacing
7 risk-significant radiation sources with alternative technologies that could increase public
8 health and safety and security.

9 ***NRC welcomes this study and others on alternative technologies or source security and***
10 ***will consider all recommendations as it evaluates how to further improve security and***
11 ***while meeting its Strategic Goals.***

- 12 • The Energy Policy Act of 2005 provisions include studies by the Radiation Source
13 Protection and Security Task Force (August 2006) and the Department of Energy (DOE)
14 (August 2006). The Environmental Protection Agency (EPA), DOE, and the Department
15 of Homeland Security (DHS) are also studying alternative technologies to certain
16 radiation sources (ongoing).
- 17 • The Radiation Source Protection and Security Task Force subgroups on Cesium
18 Chloride and Alternative Technologies are expected to issue reports within the next year.
- 19 • The Independent External Review Panel examining licensing practices and security is
20 expected to issue their report in April 2008.
- 21 • The Defense Sciences Board is expected to release a report with recommendations
22 related to Cesium Chloride in 2008.

23 ***NRC will use the Radiation Source Protection and Security Task Force to coordinate its***
24 ***responses with other Federal and State Agencies.***

- 25 • The Radiation Source Protection and Security Task Force was established by the
26 Energy Policy Act of 2005 to provide continuing input to the President and Congress. Its
27 next report is due in 2010.
- 28 • The National Academies' report recommends replacing sources with caution to ensure
29 that essential functions performed by the sources are preserved.
- 30 • NRC is working to develop a quantitative analysis and review of economic and
31 environmental impacts in order to support a technical basis for regulatory decision-
32 making.
- 33 • Accomplishment of some of the recommendations will require the assistance of other
34 Federal agencies, the Agreement States, and possibly Congress.

Security of radiation sources is a top priority for the NRC
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NATIONAL ACADEMY OF SCIENCES REPORT
“RADIATION SOURCE USE AND REPLACEMENT STUDY”

The National Academies study significantly advanced the NRC’s knowledge of alternative technologies to radiation sources and addressed the Congressional mandate in Section 651(d) of the Energy Policy Act of 2005 (EPAct). This report, in combination with two other studies mandated by EPAct, provides technical information and independent insights that are useful to the NRC and its Federal and State partners that are working to further enhance security of radiation sources and prevent misuse of those sources by terrorists. Specifically, the NA report reviewed the current industrial, research, commercial, and medical uses of radiation sources and identified approaches for replacing such sources with lower risk alternatives. It provides an overview of the technical and economic feasibility and risks to workers from such replacements and recommends options for implementing the identified replacements.

The U.S. Environmental Protection Agency, the U.S. Department of Energy, and the Radiation Source Protection and Security Task Force (Task Force) have active programs on alternative technologies to radiation sources that will benefit from this report. Federal and State representatives plan to review this report and identify areas that require further analysis to support their alternative technology programs. For example, the Task Force plans to systematically advance the information contained in the NA report for decision making and identification of long-term solutions, with the goal of submitting a report to Congress in 2010. To meet this goal, the Task Force plans to supplement information in the NA report regarding worker risks, economic costs, implementation methods and schedules, and viable research and development programs on alternative technologies. As part of this effort, the Task Force may consider the following topics described in the NA report:

- International collaboration for enhancing security of radiation sources,
- Disposition options for existing radiation sources,
- Incentives for replacement technologies,
- Federal definition of a “radiological dispersal device,”
- Hazard and risk assessments for replacement technologies,
- Regulatory changes and effects, and
- Role of vendor upgrades to enhance security of and radiation sources and devices.

As these actions demonstrate, the NRC is dedicated to ensuring the security of these radiation sources. The NRC welcomes recommendations from all collaborative efforts on alternative technologies to enhance security while meeting its Strategic Goals.

The NRC’s Advisory Committee on the Medical Uses of Isotopes, or the ACMUI, provided comments on the NA report to the NRC staff. The ACMUI was established in 1958 under the authority of the Federal Advisory Committee Act. The ACMUI membership includes professionals from various disciplines serving in a part-time capacity. The ACMUI charter defines its purpose as providing advice on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The advice provided by the ACMUI helps the staff create medical regulations that are useful, realistic, practical, not overly

1 burdensome, and not inappropriately intrusive in the practice of medicine. A copy of their
2 comments is attached.
3

1 February 20, 2008

2 Robert J. Lewis, Director Division of Material Safety and State Agreements
3 Office of Federal and State Materials
4 and Environmental Management Programs
5 U.S. Nuclear Regulatory Commission
6 Two White Flint North
7 11545 Rockville Drive
8 Rockville, Maryland 20852-2738

9 Dear Mr. Lewis

10 The Advisory Committee on the Medical Use of Isotopes (ACMUI) appreciates the
11 opportunity to comment on the report entitled "Radiation Source Use and Replacement"
12 prepared by National Academy of Science (NAS). The report represents the results of a
13 study, conducted by NAS under Section 651 of the Energy Policy Act of 2005, of the
14 industrial, research, and commercial (including medical) uses of Category 1 and 2 radioactive
15 sources to identify technically and economically feasible replacements for sources that pose
16 a high risk to public health and safety in an accident or terrorist attack. The purpose of the
17 ACMUI is to provide advice to NRC on policy and technical issues that arise in regulating the
18 medical use of byproduct materials for diagnosis and therapy, and, in that capacity, our
19 review of the NAS report was focused on the impact of its recommendations on the practice
20 of medicine.

21 The ACMUI recognizes and appreciates the efforts put forth by NAS in preparing this this
22 report. The ACMUI, however, has several concerns and comments regarding the report and
23 its recommendations:

24 1. The report has suggested alternative replacements for CsCl, e.g., x-ray blood
25 irradiators. However, the report does not address the efficacy of these alternative
26 replacements for CsCl. Further study will need to be carried out on the alternatives to
27 assure that these alternative replacements have the capacity for producing the desired
28 result or effect and to identify any impacts. For example, a linac could be used to irradiate
29 blood in the evening (when it is not being used to treat patients), but the hematologists need
30 the blood irradiated immediately before use, which is generally in the daytime, not in the
31 evenings.

32 2. The report does not address increased or enhanced security methods as an
33 alternative. Enhanced security features would provide a more cost effective means of
34 providing security.

35 3. Terrorist threats exist worldwide. Elimination of CsCl needs to have a global
36 solution, otherwise, the refurbished CsCl irradiator equipment will be sent to underdeveloped
37 countries where the environment is potentially less secure, thus increasing the overall threat
38 risk.

39 4. The report does not acknowledge the fact that the cost of replacement,
40 decommissioning, and disposal of current CsCl technology, as well as the increased operating
41 cost of the X-ray alternatives, will likely be passed on to patients, thereby increasing the already
42 high cost of medical care. One estimate suggests that implementation of the x-ray alternative
43 could increase costs by 177% in comparison to Cs while being less reliable.

1 5. The report does not address the fact that the tax incentives to replace CsCl technology
2 would not work for most hospitals, which are generally not-for-profit.

3 6. The report does not adequately distinguish between Cs-131 and Cs-137. Cs-131 is a
4 new and useful isotope which does not have the dispersal potential of Cs-137. However, both
5 isotopes may be viewed as having the same threat risk by the public due to the word "Cesium".
6 By not distinguishing between these two isotopes of Cesium, any action on CsCl based on this
7 report could potentially deny the useful medical treatment of Cs-131 to the public.

8 7. The NAS report appears to have a bias against Gamma Knife Radiosurgery. The
9 Gamma Knife has proven medical benefit. This technology provides very rapid, focused
10 treatment versus the non-radioactive alternatives. However, the NAS report places the Gamma
11 Knife in a negative light compared to the Linac x-ray alternatives. The successful Gamma Knife
12 treatment method should not be eliminated as it would deny needed medical treatment to patients.

13 8. ACMUI agrees with the NRC staff observation that there are significant environmental
14 and worker risk of using Ethylene Oxide technology. These risks were the reason that Ethylene
15 Oxide technology was eliminated and hence returning to the Ethylene Oxide technology would
16 be a step backward. Further, Ethylene Oxide is used for sterilizing equipment and not for
17 sterilizing blood.

18 ACMUI would be happy to elaborate on the above concerns, and any additional observations,
19 resulting from our review with you, NAS, or Congress, at your convenience.

20 Sincerely

21 Dr. Subir Nag
22 ACMUI
23 <http://www.nrc.gov/security/nas-facts-sheet.pdf>

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 5,
Revision 1 -- Draft Report for
Comment

2. TITLE AND SUBTITLE

Consolidated Guidance About Materials Licenses -- Program-Specific Guidance About Self-Shielded Irradiators (NUREG 1556, Volume 5, Revision 1) -- Draft Report for Comment

3. DATE REPORT PUBLISHED

MONTH	YEAR
January	2017

4. FIN OR GRANT NUMBER

5. AUTHOR(S)

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6. TYPE OF REPORT

Technical

7. PERIOD COVERED (Inclusive Dates)

October 1998 to January 2017

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)

Division of Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
11545 Rockville Pike
Rockville, MD 20852

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above", if contractor, provide NRC Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address.)

Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

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

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

NUREG-1556
Volume 5
Self-Shielded
Irradiator
License
Calibration
Self-Contained

13. AVAILABILITY STATEMENT

unlimited

14. SECURITY CLASSIFICATION

(This Page)

unclassified

(This Report)

unclassified

15. NUMBER OF PAGES

16. PRICE



Federal Recycling Program



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, DC 20555-0001

OFFICIAL BUSINESS



**NUREG-1556, Vol. 5
Revision 1, Draft**

**Consolidated Guidance About Materials Licenses: Program-Specific
Guidance About Self-Shielded Irradiator Licenses**

January 2017