

Consolidated Guidance about Materials Licenses

Program-Specific Guidance about
Service Provider Licenses

Draft Report for Comment

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Consolidated Guidance about Materials Licenses

Program-Specific Guidance about
Service Provider Licenses

Draft Report for Comment

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Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for documents filed under Docket ID **NRC-2014-0124**. Address questions about NRC dockets to Carol Gallagher at 301-287-3422 or by e-mail at Carol.Gallagher@nrc.gov.

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ABSTRACT

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

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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:

<i>Volume No.</i>	<i>Volume Title</i>
1	Program-Specific Guidance about Portable Gauge Licenses
2	Program-Specific Guidance about Industrial Radiography Licenses
3	Applications for Sealed Source and Device Evaluation and Registration
4	Program-Specific Guidance about Fixed Gauge Licenses
5	Program-Specific Guidance about Self-Shielded Irradiator Licenses
6	Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses
7	Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope
8	Program-Specific Guidance about Exempt Distribution Licenses
9	Program-Specific Guidance about Medical Use Licenses
10	Program-Specific Guidance about Master Materials Licenses
11	Program-Specific Guidance about Licenses of Broad Scope
12	Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution
13	Program-Specific Guidance about Commercial Radiopharmacy Licenses
14	Program-Specific Guidance about Well Logging, Tracer, and Field Flood Study Licenses
15	Guidance about Changes of Control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
16	Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees

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

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The current document, NUREG-1556, Volume 18, Revision 1, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider 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 18, issued November 2000.

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

NUREG-1556, Volume 18, Revision 1, is not a substitute for NRC regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable if they include a basis for the staff to make the determinations needed to issue or continue a license.

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ABBREVIATIONS

2	AEA	Atomic Energy Act
3	ALARA	as low as is reasonably achievable
4	ALI	annual limit of intake
5	ANSI	American National Standards Institute
6	AU	authorized user
7	Bq	becquerel
8	CEDE	committed effective dose equivalent
9	CFR	<i>Code of Federal Regulations</i>
10	Ci	curie
11	cpm	counts per minute
12	DFP	decommissioning funding plan
13	DIS	decay-in-storage
14	DOT	U.S. Department of Transportation
15	dpm	disintegrations per minute
16	EA	environmental assessment
17	EPA	U.S. Environmental Protection Agency
18	FA	certification of financial assurance
19	GBq	gigabecquerel
20	G-M	Geiger-Mueller
21	GPO	U.S. Government Printing Office
22	HDR	high dose rate
23	HEPA	high efficiency particulate air
24	hr	hour
25	IN	information notice
26	LLW	low-level radioactive waste
27	MARSAME	Multi-Agency Radiation Survey and Assessment of Materials and
28		Equipment Manual
29	MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
30	MBq	megabecquerel
31	MCi	millicuries
32	MOU	memorandum of understanding
33	mrem	millirem
34	mSv	millisievert
35	NCRP	National Council on Radiation Protection and Measurements
36	NIST	National Institute of Standards and Technology
37	NMSS	Office of Nuclear Material Safety and Safeguards
38	NRC	U.S. Nuclear Regulatory Commission
39	NSTS	National Source Tracking System
40	NVLAP	National Voluntary Laboratory Accreditation Program
41	OEM	Original Equipment Manufacturer
42	OMB	Office of Management and Budget
43	OSL	optically stimulated luminescence
44	PIC	Pocket Ionization Chamber
45	QA	quality assurance
46	R	roentgen
47	rad	radiation absorbed dose
48	rem	roentgen equivalent man

1	RG	regulatory guide
2	RIS	regulatory issue summary
3	RQ	reportable quantities
4	RSO	radiation safety officer
5	RSRM	Risk Significant Radioactive Material
6	SI	International System of Units (abbreviated SI from the French Le Systeme
7		Internationale d'Unites)
8	SNM	special nuclear material
9	SOC	statements of consideration
10	SSD	sealed source and device
11	std	standard
12	STP	Office of State and Tribal Programs
13	Sv	sievert
14	TEDE	total effective dose equivalent
15	TLD	thermoluminescent dosimeters

1. PURPOSE OF REPORT

This report provides guidance to an applicant in preparing a service provider license application based on the risk significance of the proposed activity, as well as providing the U.S. Nuclear Regulatory Commission (NRC) with the appropriate criteria for evaluating such applications.

Service providers offer a variety of commercial services to both specific and general licensees, ranging from low- to high-risk activities, and in some instances, recover both licensed and unlicensed material from the public domain. Customers who possess such radioactive material may require commercial services to manage materials at concentrations and activities they are not authorized to handle. In these unique situations, a service provider licensee is authorized to possess these radioactive materials under its license incident to performing specific services required by its customers. Optionally, customers may elect to transfer licensed material such as radioactive waste and contaminated materials to service providers (e.g., radioactive waste brokers, decontamination and decommissioning service providers or nuclear laundry operators).

Service providers who, in the course of doing business, receive physical samples and possess equipment containing licensed materials related to the performance of commercial service activities—such as leak test and environmental sample analyses and survey instrument and dosimetry calibration services—are also included in this category.

Service providers addressed in this NUREG are limited to licensed entities providing the following types of commercial services based on low or high-risk activities.

LOW RISK—Possession or use incidental to performing the following commercial services:

- analysis of leak test samples (no collection of leak test samples)
- analysis of environmental samples (no collection of environmental samples)
- training/instruction to individuals on radiation safety related topics
- packaging for shipment of radioactive materials in less than U.S. Department of Transportation (DOT) Type A quantities
- service or repair of gas chromatographs and X-ray fluorescent analyzers
- calibration of nuclear medicine/cardiology instruments using low activity sources
- calibration of survey instruments and personnel dosimetry equipment using check or reference sources
- other low risk services not identified above, where radioactive material is used for commercial service activities

HIGH RISK—Possession or use incidental to performing the following commercial services utilizing unsealed or uncontained radioactive material, and high-activity radioactive sealed sources: Installation, radiation surveys, routine and preventive maintenance, adjustment or repair of high dose rate (HDR) remote afterloaders, teletherapy, or gamma stereotactic radiosurgery units that require access to the sealed source(s), driving units, or other electronic

- 1 components that could expose the sealed source, reduce the shielding, or compromise the
2 radiation safety of the device or safety systems.
- 3 • service or repair of portable nuclear gauges (including removal of source rod)
 - 4 • service or repair of fixed gauges
 - 5 • service or repair of fixed gauges mounted on a mobile object like a truck or railcar
 - 6 • storage of radioactive material for other entities
 - 7 • use of unsealed material in tracer studies (example: use inside pipes in a refinery)
 - 8 • use of remote activated robotics in radioactive contaminated areas
 - 9 • calibration of survey instruments and personnel dosimetry equipment as a service for others
 - 10 • installation; radiation surveys; routine and preventive maintenance; adjustment or repair of
11 high dose rate (HDR) remote afterloaders, teletherapy, or gamma stereotactic radiosurgery
12 units that require access to the sealed source(s), driving units, or other electronic
13 components that could expose the sealed source, reduce the shielding, or compromise the
14 radiation safety of the device or safety systems
 - 15 • installation, relocation, removal from service, disposal, radiation surveys, routine or
16 preventive maintenance, adjustment, training or repair of:
 - 17 – self-shielded irradiators (ANSI Category I irradiators)
 - 18 – Title 10 of the *Code of Federal Regulations* (10 CFR) Part 36, “License and Radiation
19 Safety Requirements for Irradiators,” (ANSI Categories II, III and IV irradiators)
 - 20 • nuclear laundry services
 - 21 • retrieval of industrial radiography sealed sources
 - 22 • decontamination and decommissioning services (NUREG-1757, Volume 1)
 - 23 • packaging for shipment of radioactive materials, including the use of DOT Type B Packages
 - 24 • waste management services including: packaging and repackaging of radioactive waste for
25 transportation, commercial incineration, compaction, super compaction, solidification or
26 vitrification
 - 27 • other high risk services not identified above, excluding activities involving critical mass
28 quantities of special nuclear material
- 29 For ANSI Irradiator Categories, see <http://www.dosimetryresources.com/N43-10.htm>
- 30 Chapter 8, “Contents of an Application,” of this report identifies the information needed to
31 complete NRC Form 313, “Application for Materials License” (see Appendix A). The Office of
32 Management and Budget (OMB) has approved the information collection requirements in

1 Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection against
2 Radiation,” and 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of
3 Byproduct Material,” and NRC Form 313 have been approved under OMB Clearance Nos.
4 3150-0014, 3150-0017, and 3150-0120, respectively.

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

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

12
13 Notes and references are self-explanatory and may not be necessary for each item on NRC
14 Form 313.

15 NRC Form 313 does not provide sufficient space for applicants to include full responses to
16 Items 5 through 11, as indicated on the form. Applicants should address those items on
17 separate sheets of paper and submit these sheets, along with the completed NRC Form 313.
18 For the convenience of applicants and for streamlined handling of applications for service
19 provider licenses, Appendix A, “Suggested Format for Providing Information Requested in
20 Items 5 through 11 of NRC Form 313,” may be used to provide supporting information.

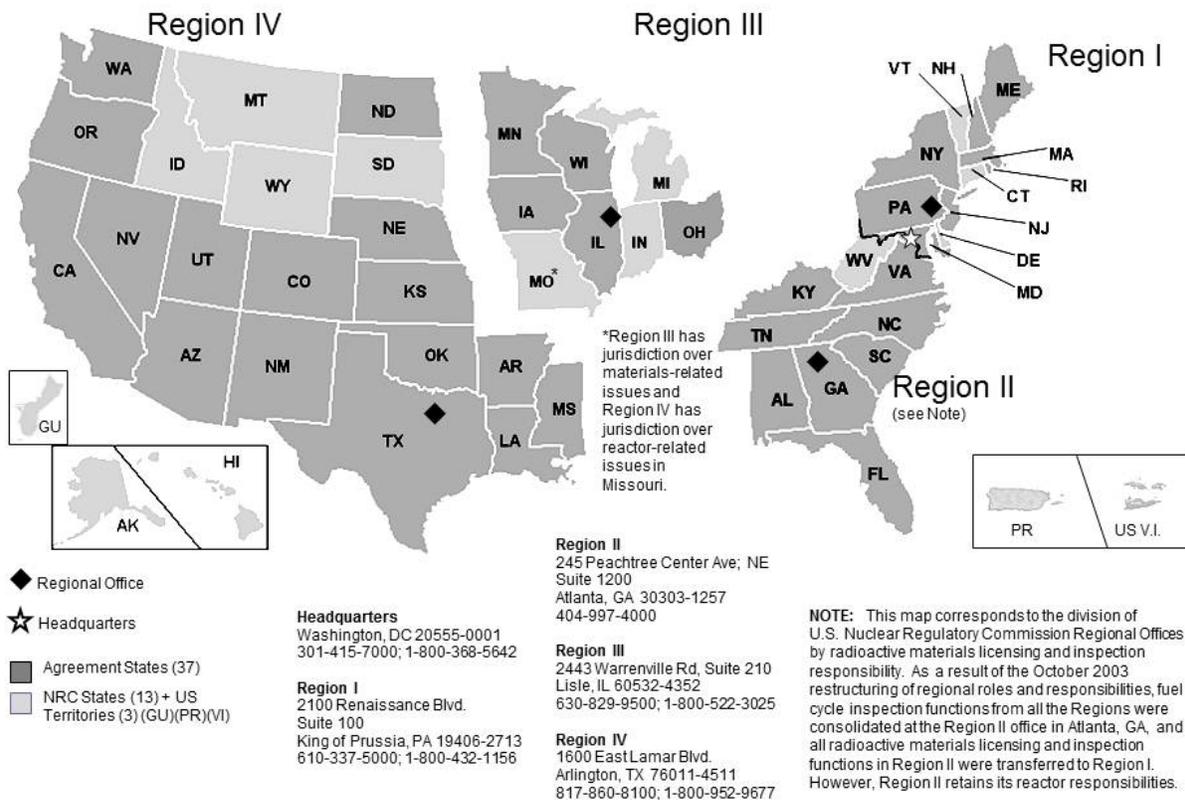
21 In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose
22 equivalent, committed dose equivalent, committed effective dose equivalent, or total effective
23 dose equivalent, as defined in 10 CFR Part 20. Roentgen equivalent man (rem) and its
24 International System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

2. AGREEMENT STATES

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

Locations of NRC Offices and Agreement States



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

In the special situation of work at Federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the land to determine whether the NRC or the Agreement State has regulatory authority. These areas can also include tribal lands of Federally recognized Indian Tribes¹.

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

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

14
 15 Table 2.1 provides a quick way to check on whether the NRC or an Agreement State has
 16 regulatory authority.

17
 18 **Table 2.1 Who Regulates the Activity?**

19

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

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

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

1
2 **Reference:** A current list of Agreement States (including names, addresses, and telephone
3 numbers of responsible officials) is available at the Office of Federal and State Materials and
4 Environmental Management Programs' public Web site, <http://nrc-stp.ornl.gov>. As an
5 alternative, a request for the list can be made to an NRC regional office.

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

3. MANAGEMENT RESPONSIBILITY

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

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

3.1 Commitments and Responsibilities

Pursuant to 10 CFR 30.32(c), 10 CFR 40.31(b), and 10 CFR 70.22(d), each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the behalf of the applicant or licensee. If it is not clear whether the application was signed by someone duly authorized to act for and on the behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual that signed the application is duly authorized to act for and on the behalf of the applicant or licensee. The signature on an application acknowledges the licensee’s commitments and responsibilities for the following:

- Radiation safety, security, and control of radioactive materials and compliance with regulations;
- Completeness and accuracy of the radiation safety records and all information provided to the NRC (10 CFR 30.9, 10 CFR 40.9 and 10 CFR 70.9, “Completeness and accuracy of information”);
- Knowledge about the contents of the license and application;
- Compliance with current NRC and U.S. Department of Transportation regulations and the licensee’s operating and emergency procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and compliance with regulations is maintained;
- Selection and assignment of a qualified individual to serve as the radiation safety officer (RSO) for licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities;
- Commitment to ensure that radiation workers have adequate training;
- Prevention of discrimination of employees engaged in protected activities (10 CFR 30.7, 10 CFR 40.7, and 10 CFR 70.7, “Employee protection”);
- Commitment to provide information to employees about the employee protection and deliberate misconduct provisions in 10 CFR 30.7, 10 CFR 40.7, 10 CFR 30.10, 10 CFR 40.10, and 10 CFR 70.10, “Deliberate misconduct,” respectively;

- 1 • Commitment to obtain the NRC’s prior written consent before transferring control of the
2 license (see Section 9.1, “Timely Notification of Transfer of Control,” of this report); and
- 3 • Notification of the appropriate NRC regional administrator in writing, immediately following
4 the filing of a petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h), 10 CFR
5 40.41 (f), and 10 CFR 70.32(a)(9)), as discussed further in Section 8.2.1, “Notification of
6 Bankruptcy Proceedings,” of this report.

7
8 For information on NRC inspection, investigation, enforcement, and other compliance programs,
9 see the current version of the NRC’s Enforcement Policy and Inspection Procedures available in
10 the NRC’s online library at <http://www.nrc.gov/reading-rm.html>.

11 12 **3.2 Safety Culture**

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

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

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

39 The NRC, as the regulatory agency with an independent oversight role, reviews the
40 performance of individuals and organizations to determine compliance with requirements and
41 commitments through its existing inspection and assessment processes. However, the NRC’s
42 safety culture policy statement and traits are not incorporated into the regulations. Safety
43 culture traits may be inherent to an organization’s existing radiation safety practices and
44 programs. For instance, service providers following operating and emergency procedures to

1 ensure that activities are conducted safely may be taking actions that correspond with the safety
 2 culture trait specified in Table 3.1 as “Work Processes” (the process of planning and controlling
 3 work activities to ensure that safety is maintained). These procedures allow the service provider
 4 to focus on the high risk processes while performing the maintenance activities to maintain
 5 safety. However, licensees should be aware that this is just an example, and should consider
 6 reviewing their radiation safety programs in order to develop and implement a safety culture
 7 commensurate with the nature and complexity of their organizations and functions.

8 Refer to Appendix O for the NRC’s safety culture policy statement. More information on NRC
 9 activities relating to safety culture can be found at: [http://www.nrc.gov/about-nrc/safety-](http://www.nrc.gov/about-nrc/safety-culture.html)
 10 [culture.html](http://www.nrc.gov/about-nrc/safety-culture.html).

11 **Table 3.1 Traits of a Positive Safety Culture**

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

4. APPLICABLE REGULATIONS

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

The current versions of these parts can be found under the "Basic References" link at the NRC's online library at <http://www.nrc.gov/reading-rm.html>; if viewing in a browser, the following list includes direct links to the rules:

- [10 CFR Part 2](#), "Agency Rules of Practice and Procedure"
- [10 CFR Part 19](#), "Notices, Instructions and Reports to Workers: Inspection and Investigations"
- [10 CFR Part 20](#), "Standards for Protection Against Radiation"
- [10 CFR Part 21](#), "Reporting of Defects and Noncompliance"
- [10 CFR Part 30](#), "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- [10 CFR Part 31](#), "General Domestic Licenses for Byproduct Material"
- [10 CFR Part 32](#), "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- [10 CFR Part 33](#), "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- [10 CFR Part 37](#), "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- [10 CFR Part 40](#), "Domestic Licensing of Source Material"
- [10 CFR Part 51](#), "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"
- [10 CFR Part 61](#), "Licensing Requirements for Land Disposal of Radioactive Waste"
- [10 CFR Part 70](#), "Domestic Licensing of Special Nuclear Material"
- [10 CFR Part 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"

- 1 • [10 CFR Part 170](#), “Fees for Facilities, Materials, Import and Export Licenses, and Other
2 Regulatory Services Under the Atomic Energy Act of 1954, as Amended”
- 3 • [10 CFR Part 171](#), “Annual Fees for Reactor Licenses and Fuel Cycle Licenses and
4 Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and
5 Quality Assurance Program Approvals and Government Agencies Licensed by the NRC”
- 6 Copies of the above documents may be obtained by calling the Government Printing Office
7 order desk toll-free at (866) 512-8600, in Washington, DC, at (202) 512-1800, or online at
8 <http://bookstore.gpo.gov>.
- 9 In addition, 10 CFR Parts 1 through 199 can be found on the NRC’s Web site at
10 <http://www.nrc.gov/reading-rm/doc-collections/> under “Regulations (10 CFR).”
- 11 NRC regulations and amendments can also be accessed from the “NRC Library” link on the
12 NRC’s public Web site at <http://www.nrc.gov>. The NRC and all other Federal agencies publish
13 amendments to their regulations in the *Federal Register*.

5. HOW TO FILE

5.1 Paper Application

Applicants for a materials license should do the following:

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

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

5.2 Where to File

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

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State and not with the NRC. However, if work will be

1 conducted at Federally controlled sites, or Federally recognized Indian Tribal lands, in
2 Agreement States, applicants must first determine the jurisdictional status of the land in order to
3 determine whether the NRC or the Agreement State has regulatory authority. See Chapter 2,
4 “Agreement States,” for additional information.

5 **5.3 Transfer to Electronic Format**

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

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

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

6. IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

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

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

- **Proprietary Information and Trade Secrets:** If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application.
- **Personally Identifiable Information:** Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, which can be found on the NRC's Generic Communications webpage under "Regulatory Issue Summaries": <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.
- **Security-Related Information:** Following the events of September 11, 2001, the NRC changed its procedures to avoid release of information that terrorists could use to plan or execute an attack against facilities or citizens in the United States. As a result, certain types of information are no longer routinely released and are treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information and the top of every page of a document that contains such information should be clearly marked: "Security-Related Information—Withhold under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g. an editorial note box) adjacent to that material. For further information, see RIS 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 22, 2005 which can be found on the NRC's Generic Communications webpage under "Regulatory Issue Summaries": <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>. Additional information on procedures and any updates is available at <http://www.nrc.gov/reading-rm/sensitive-info.html>.

7. APPLICATION AND LICENSE FEES

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

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

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

8. CONTENTS OF AN APPLICATION

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

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

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

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

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

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

Refer to Appendix N for guidance regarding the definition of construction and the consideration of activities that can be performed by materials license applicants and potential applicants, and licensees before the NRC has concluded its environmental review of the proposed licensing action. The majority of materials licensing actions will meet the criteria in 10 CFR 51.22(c)(14)(x) for a categorical exclusion. This means that the licensing action will not require an environmental assessment or environmental impact statement in accordance with 10 CFR 51.22(b), since the NRC has already determined that this type of licensing action does not have a significant impact on the environment. It is the applicant's responsibility to review the guidance in Appendix N to determine whether the categorical exclusion applies to the licensing action.

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

1 **8.1 Item 1: License Action Type**

2 Item 1 of NRC Form 313 states the following:

3
4 This is an application for (check appropriate item):

5

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

6
7 Check Box A for a new license request. Note that a pre-licensing visit may be required prior to
8 issuance of the license. Also note that an initial security inspection may be conducted in
9 accordance with NRC Inspection Manual Chapter 2800, "Materials Inspection Program," before
10 issuance of the license.

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

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

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

14 Service provider applicants seeking broad scope authorization should submit the following
15 statement:

16 "We request authorization to make program changes and changes to procedures specifically
17 identified in the application that have been approved by the Commission and were incorporated
18 into the license without prior Commission approval as long as:

- 19 • The proposed revision is documented, reviewed, and approved by the licensee's Radiation
20 Safety Committee in accordance with established procedures prior to implementation;
- 21 • The revised program is in accordance with regulatory requirements, will not change the
22 license conditions, and will not decrease the effectiveness of the Radiation Safety Program;
- 23 • The licensee's staff is trained in the revised procedures prior to implementation; and
- 24 • The licensee's audit program evaluates the effectiveness of the change and its
25 implementation."

26 **8.2 Item 2: Applicant's Name and Mailing Address**

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

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

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

5 **8.2.1 Notification of Bankruptcy Proceedings**

6 **Regulation:** 10 CFR 30.34(h), 10 CFR 40.41(f)

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

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

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

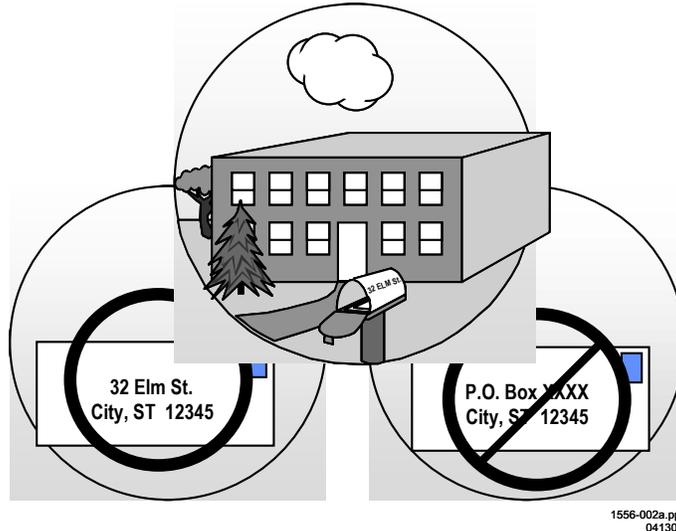
21 **Reference:** See NUREG-1556, Volume 15, “Consolidated Guidance about Materials Licenses:
22 Guidance about Changes of Control and about Bankruptcy Involving Byproduct, Source, or
23 Special Nuclear Materials Licenses.”

24 **8.3 Item 3: Address(es) Where Licensed Material Will Be Used or Possessed**

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

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

32 Service providers who perform work activities at temporary job sites should ensure that they are
33 authorized to perform work at each location. See Table 2.1 to determine the appropriate
34 regulatory jurisdiction.



1
2 **Figure 8.1 Location of Use.** *An acceptable location of use specifies street address, city, state,*
3 *and zip code and does not include a post office box number.*
4

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

5
6 If an applicant submits documents that give the exact location of use and storage for materials,
7 the applicant should mark these documents as “Security-Related Information—Withhold under
8 10 CFR 2.390.” See Chapter 6, “Identifying and Protecting Sensitive Information,” for more
9 details.

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

18
19 **8.4 Item 4: Person to Be Contacted about this Application**

20 Identify the individual who can answer questions about the application and include a telephone
21 number where the individual may be contacted. Also include business cell phone numbers and
22 e-mail addresses. This individual, usually the RSO, will serve as the point of contact during the
23 review of the application. If this individual is not a full-time employee of the licensed entity, his
24 or her position and relationship to the licensee should be specified. The NRC should be notified
25 if the person assigned to this function changes or if his or her telephone number, cell phone
26 number, or e-mail address changes. Notification of a contact change is only in order to provide
27 information and would not be considered an application for license amendment, unless the
28 notification involves a change in the contact person who is also the RSO.
29

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

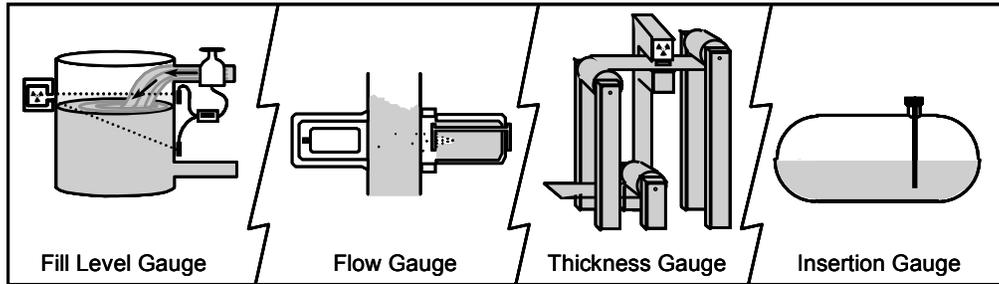
5 6 **8.5 Item 5: Radioactive Material**

7 **8.5.1 Sealed Sources**

8 **Regulations:** 10 CFR 30.3, 10 CFR 30.32(g), 10 CFR 31.5, 10 CFR 31.12, 10 CFR 32.210.

9 **Criteria:** Applicants must provide the manufacturer's name, model number, radionuclide,
10 quantity, and nominal activity for each requested sealed source and manufacturer and model
11 number for each device that they will possess, use, and service in accordance with 10 CFR
12 30.32(g). Service provider licensees will be authorized to possess and use only those sealed
13 sources and devices specifically approved or registered by NRC or an Agreement State.

14 **Discussion:** The NRC or an Agreement State performs safety evaluations of sealed sources
15 and devices before authorizing manufacturers to distribute to licensees. This safety evaluation
16 is documented in a Sealed Source and Device (SSD) registration certificate. Licensees should
17 not make any changes to the sealed source, device, or source/device combination that would
18 alter the description or specifications from those indicated in the respective registration
19 certificates obtaining the NRC's prior permission in a license amendment. Such changes may
20 necessitate a custom registration review, increasing the time needed to process a licensing
21 action. SSD registration certificates contain sections on "Conditions of Normal Use" and
22 "Limitation and Other Considerations of Use." These sections may include limitations derived
23 from conditions imposed by the manufacturer or distributor, by particular conditions of use that
24 would reduce the radiation safety of the device, or by circumstances unique to the sealed
25 source or device. For example, the working life of the device, the appropriate temperature, and
26 other environmental conditions may be specified. Except as specifically approved by the NRC,
27 licensees are required to use sealed sources and devices according to their respective SSD
28 registration certificates. Accordingly, applicants should obtain a copy of the certificate. Service
29 providers, when possessing, using, or servicing sealed sources or devices, should consult with
30 the manufacturer or distributor to ensure that requested sources and devices are compatible
31 and conform to the SSD designations registered with NRC or an Agreement State. Licensees,
32 unless approved by the NRC or an Agreement State, may not make any changes to the sealed
33 source, device, or source/device combination that would alter the description or specifications
34 from those indicated in the respective registration certificates, without obtaining NRC's prior
35 permission in a license amendment.



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1
2 **Figure 8.2 Examples of Sealed Sources or Devices Possessed, Used, or Serviced.**
3

Service providers who remove for disposal/transfer or dispose of *fixed gauges* at customer facilities may wish to perform this service for device models and sealed sources not specifically identified on their license. Specific authorization to provide these limited services for *fixed gauges* that are similar in design and activity to those listed on their license from other manufacturers will be included in the license.

4
5 **Response from Applicant:**

- 6
- 7 • Identify each radionuclide that will be possessed in each sealed source and device and
 - 8 specify the maximum activity per source. Also, specify the maximum number of sources or the total activity for each radionuclide.
 - 9
 - 10 • Identify the manufacturer or distributor and model number of each type of sealed source and device requested or provide SSD Registration Certificate Number.
 - 11
 - 12 • Identify any depleted uranium that is used as shielding material, if applicable.
 - 13
 - 14 • Confirm that each sealed source, device, and source/device combination is registered as
 - 15 an approved sealed source or device by the NRC or an Agreement State.
 - 16
 - 17 • Confirm that the activity per source and maximum activity per device will not exceed the
 - 18 maximum activity listed on the approved certificate of registration issued by the NRC or by an Agreement State.
 - 19
 - 20 • Identify the special circumstances under which sealed sources and devices that are not registered by the NRC or an Agreement State may be possessed, used, or serviced.
 - 21
 - 22 • If the applicant will not take possession of the sealed sources and devices, the applicant should make this statement in its application request.

21 **Note** Generally, licensees who are authorized to possess small quantities of material below
22 the Category 2 quantities described in Appendix A to 10 CFR Part 37, "Physical
23 Protection of Category 1 and Category 2 Quantities of Radioactive Material," are not
24 subject to security requirements. If licensees acquire a Category 2 quantity, applicants
25 and licensees should visit the NRC's public Web site (www.nrc.gov) for additional
26 information regarding security of Category 2 licensed material. Please contact the

appropriate regional office for questions regarding the security of licensed material. If you are subject to these additional security measures, mark the section related to possession of sealed sources and devices with manufacturers, model numbers, and possession limits as follows: “Security-Related Information—Withhold under 10 CFR 2.390.”

Reference: For more information about the SSD registration process, see the current version of NUREG-1556, Volume 3, “Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration.”

8.5.2 Unsealed Radioactive Material

Regulations: 10 CFR 30.32(i), 10 CFR 30.33, 10 CFR 40.31, 10 CFR 70.22.

Criteria: The applicant must provide the name of the radionuclide(s), chemical form, and maximum possession limit that the applicant will possess, use, and service.

Discussion: The applicant should list each requested radionuclide by its element name and its mass number (e.g., carbon-14(C-14)) in item 5. In certain situations, the applicant may request authorization to possess and use any form of byproduct material with atomic numbers from 1 through 83. The name of the specific chemical compound that contains the radionuclide is not required. For volatile radioactive material, applicants should specify whether the requested radionuclides will be acquired in free (volatile) or bound (non-volatile) form, because additional safety precautions may be necessary when handling and using free form volatile material. For example, when requesting authorization to use tritium (H-3) or iodine-125 (I-125), the applicant should specify whether the material will be acquired in free form or bound form. If a radionuclide will be acquired in both free and bound forms, then separate possession limits for each form should be specified.

Applicants requesting an authorization to use volatile radioactive material must provide appropriate facilities, engineering controls, and radiation safety procedures for handling of such material.

Note: Additional safety equipment and precautions may be necessary when handling and using unsealed free-form volatile radioactive materials. Volatile means that a liquid, and in rare cases a solid, becomes a gas at a relatively low temperature when exposed to the environment.

Table 8.1 Types of Radioactive Materials.

Type of Material	Covered by this Report	Examples
Byproduct	Yes	H-3, C-14, Na-22, I-131, I-125, S-35, P-32, P-33, Ca-45, Ni-63, Cd-109, Cs-137, Co-57, Na-22, Cd-109, Tl-201, Ga-67
Source material	Yes	U, Th
Special nuclear material	Yes	Pu-238, Pu-239, U-233, U-235
Naturally occurring radioisotopes	Yes	Ra-226 (Discrete Sources)

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Note: Authorization to possess byproduct materials with atomic numbers 84 through 96 does not include authorization to possess uranium, thorium, or plutonium. Even though these elements have atomic numbers within the range of 84 through 96, they are designated source or special nuclear material (SNM), not byproduct material, and should be requested individually. Quantities of SNM addressed in this guide are limited to small activities that cannot under any circumstances achieve critical mass configuration.

The anticipated possession limit in millicuries (mCi) or curies (Ci) for each radionuclide must also be specified. Possession limits must cover the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radionuclide with a half-life greater than 120 days. These requirements are discussed in the section on Financial Assurance and Decommissioning.

Response from Applicant: For each radionuclide, provide the element name with mass number, the chemical and physical form, and the maximum requested possession limit.

- For potentially volatile materials (e.g., I-125, I-131, H-3, Kr-85), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form.
- For source material, specify the number of kilograms and the activity of natural uranium, depleted uranium and thorium requested.
- For special nuclear material (SNM), specify the number of grams of material and the activity requested for each isotope. Please ensure that the requested amount is less than critical mass.
- If the applicant will not take possession of the unsealed radioactive material, the applicant should make this statement in its application request.

8.5.3 Recordkeeping for Decommissioning

Regulations: 10 CFR 30.34, 10 CFR 30.35, 10 CFR 30.36, 10 CFR 30.51, 10 CFR 40.36(f), 10 CFR 40.61, 10 CFR 70.25(g), 10 CFR 70.51

Criteria: In accordance with 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g) all licensees must maintain records of structures and equipment where licensed materials are used or stored at locations specifically listed in the license. Also pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.51(b) licensees must transfer records important to decommissioning to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and 10 CFR 70.51(a) prior to license termination, each licensee shall forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g) to the appropriate NRC regional office.

1 **Discussion:** Decommissioning requirements are intended to ensure that decommissioning will
2 be carried out minimizing the impact on the public, maximizing occupational health and safety,
3 and maximizing protection of the environment.

4 In accordance with 10 CFR 30.35(g), 10 CFR 40.36(f) and 10 CFR 70.25(g), all licensees must
5 maintain records of structures and equipment where licensed materials are used or stored at
6 locations specifically listed in the license. As built drawings (not blueprints) with modifications of
7 structures and equipment shown, as appropriate, fulfill this requirement. If drawings are not
8 available, licensees may substitute appropriate records concerning the areas and locations
9 where licensed materials are used. In addition, if licensees have experienced unusual
10 occurrences (e.g., leaking sources or other incidents that involve the spread of contamination),
11 they must maintain records about contamination that remains after cleanup or that may have
12 spread to inaccessible areas. Under NRC regulations when terminating the license, licensees
13 must transfer records important to decommissioning to either of the following:

- 14 • the new licensee before licensed activities are transferred or assigned (10 CFR 30.51(e) 10
15 CFR 40.61(e) and 10 CFR 70.51(b)
- 16 • the appropriate NRC Regional Office before the license is terminated (10 CFR 30.51(f), 10
17 CFR 40.61(f), and 10 CFR 70.51(a))

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Decommissioning records described above are not required for temporary job site locations.
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19
20 In accordance with 10 CFR 30.36(d)(3), licensees must begin decommissioning if no principal
21 activities under the license have been conducted for 24 months. Service provider licensees
22 who store or possess radioactive material must comply with the “decommissioning timeliness
23 rule” in 10 CFR 30.36(d). . The intent of 10 CFR 30.36(d) is to prevent delays in
24 decommissioning and site cleanup. Service provider licensees should request an exemption
25 from 10 CFR 30.36(d)(3) if no principal activities under the license have been conducted for 24
26 months). This exemption request will be evaluated on a case-by-case basis to determine the
27 activities that have been conducted at the facility and the extent of decommissioning activities
28 needed, if any. As an alternative, licensees may request an alternate schedule for
29 decommissioning. Refer to Sections 2.2 and 2.6 of NUREG-1757, Volume 3, Consolidated
30 Decommissioning Guidance—Financial Assurance, Recordkeeping and Timeliness,” for
31 guidance on what needs to be provided and the criteria the NRC will use to review a licensee’s
32 request for an alternate schedule.

33
34 **Response from Applicants:**

35 State the following: “Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g),
36 we shall maintain drawings and records important to decommissioning and to transfer these
37 records to an NRC or Agreement State licensee before licensed activities are transferred.
38 Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and 10 CFR 70.51(a) prior to
39 license termination, we shall forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f),
40 and 10 CFR 70.25(g) to the appropriate NRC regional office or to assign the records to the
41 appropriate NRC regional office before the license is terminated.”

1 **8.5.4 Financial Assurance**

2 **Regulations:** 10 CFR 30.34(b), 10 CFR 30.35, 10 CFR 40.36, 10 CFR 70.25.

3 **Criteria:** Financial assurance is not required for many service providers. A service provider
4 who will be authorized to possess licensed material in excess of the limits specified in 10 CFR
5 30.35, 10 CFR 40.36, and 10 CFR 70.25, “Financial assurance and recordkeeping for
6 decommissioning,” must provide evidence of financial assurance for decommissioning.

7 **Discussion:** The NRC’s regulations are intended to ensure that decommissioning will be
8 carried out so as to minimize the impact on the public, maximize occupational health and safety,
9 and maximize protection of the environment. The requirements for financial assurance are
10 specific to the types and quantities of byproduct material authorized on a license.

11 NRC regulations requiring a certification of financial assurance (FA) or a decommissioning
12 funding plan (DFP) are designed to provide reasonable assurance that the technical and
13 environmental components of decommissioning are carried out and unrestricted use of the
14 facilities is possible at the conclusion or termination of licensed activities. These requirements,
15 if applicable, specify that a licensee must either set aside funds for decommissioning activities
16 or provide a guarantee through a third party that funds will be available. Applicants are required
17 to submit a certification of FA or a DFP, or both, when the possession of radioactive material
18 with a half-life ($T_{1/2}$) greater than 120 days exceeds certain limits. Criteria for determining if an
19 applicant is required to submit a DFP and a certification of FA are provided in 10 CFR 30.35,
20 10 CFR 40.36, and 10 CFR 70.24, all entitled, “Financial assurance and record keeping for
21 decommissioning.” A DFP contains a site-specific cost estimate and a certification of FA. An
22 FA certification includes a certification that the licensee has provided the required FA and an
23 acceptable FA instrument.

24
25 NUREG-1757, Volume 3, “Consolidated Decommissioning Guidance—Financial Assurance,
26 Recordkeeping, and Timeliness,” provides guidance acceptable to the NRC staff on the
27 information to be provided for establishing FA for decommissioning and a standard format for
28 presenting the information. Note that FA is required for four types of licensed materials:
29 unsealed byproduct material (10 CFR 30.35); sealed byproduct material (10 CFR 30.35);
30 dispersible source material (10 CFR 40.36); and unsealed special nuclear material (10 CFR
31 70.25). The total amount of FA required is the sum of the FA required for each of these types of
32 materials.

33
34 For radwaste broker service providers, 10 CFR 30.35(c)(5) requires that waste collectors and
35 waste processors, as defined in 10 CFR Part 20, Appendix G, must provide financial
36 assurance in an amount based on a decommissioning funding plan. The decommissioning
37 funding plan must include the cost of disposal of the maximum amount (curies) of radioactive
38 material permitted by license, and the cost of disposal of the maximum quantity, by volume, of
39 radioactive material which could be present at the licensee's facility at any time, in addition to
40 the cost to remediate the licensee's site to meet the license termination criteria of 10 CFR Part
41 20.

1 **Response from Applicants:**

2 Financial assurance is not required for most service provider applicants. If the applicant is
3 going to possess radioactive material but wants to keep the possession limits below the
4 requirements for financial assurance, commit to the following statement:
5

6 “We shall restrict the possession of licensed material to quantities below the minimum limit
7 specified in 10 CFR 30.35(d), 40.36(b) and/or 70.25(c) for establishing decommissioning
8 financial assurance.”
9

10 **OR**
11

12 If financial assurance is required, submit evidence of financial assurance following the guidance
13 in NUREG-1757, Volume 3, Rev. 1.

14 **References:** NUREG-1757, Volume 3, Rev. 1, “Consolidated Decommissioning Guidance—
15 Financial Assurance, Recordkeeping and Timeliness.” The NRC published the new financial
16 assurance rules in the Federal Register on dated June 17, 2011 (76 FR 35512)Agencywide
17 Documents Access and Management System (ADAMS) Accession No. ML121350224]. The
18 regulations became effective on December 17, 2012. The regulations no longer allow escrow
19 accounts or lines of credit. The regulations also require that any licensee that does not use the
20 prepayment option as its financial assurance instrument must have a standby trust fund to
21 receive any funds from the licensee for decommissioning because the NRC cannot receive
22 funds directly.
23

24 **8.5.5 Emergency Plan**

25 **Regulations:** 10 CFR 30.32(i), 10 CFR 30.72

26 **Criteria:** Applicants who will be authorized to possess radioactive material in excess of the
27 quantities listed in 10 CFR 30.72, “Schedule C—Quantities of radioactive materials requiring
28 consideration of the need for an emergency plan for responding to a release,” must prepare for
29 the potential release of radioactive material.

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

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

36 (2) an emergency response plan for responding to the release of radioactive materials in
37 accordance with the criteria listed in 10 CFR 30.32(i)(3).
38

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

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

1 (2) an emergency response plan for responding to the release that contains the information
2 specified in 10 CFR 30.32(i)(3).

3 **References:**

- 4 • Regulatory Guide 3.67, Revision 1, "Standard Format and Content for Emergency Plans for
5 Fuel Cycle and Materials Facilities." (ADAMS Accession No. ML103360487)

7 **8.6 Item 6: Purpose(s) for which Licensed Material Will Be Used**

8 **Regulations:** 10 CFR 30.32 (d); 10 CFR 30.33(a)(1), 10 CFR 40.31(d), 10 CFR 51.21, 10 CFR
9 70.22(a)(2); 10 CFR 70.23(a)(1).

10 **Criteria:** Applicants must provide a basis for confidence that radioactive materials will be used
11 as specified on a license. The variety of uses is described in Section 1, "Purpose of Report,"
12 are delineated into low or high risk activities. Sealed sources and devices must be used in
13 accordance with their respective Sealed Source and Device Registry. Use of sealed sources
14 and devices other than those listed in the SSD Registration Certificate require review and
15 approval by the NRC or an Agreement State.

16 **Discussion:** In the interest of national security and the protection of the public health and
17 safety, and in order to provide a basis for confidence that new applicants will use licensed
18 material as specified in a license, the NRC has changed its policy for processing applications for
19 new licenses. All new applicants for NRC licenses may now be subject to a pre-licensing site
20 visit. The purpose of the visit is to verify the content of the application and that licensed material
21 will be used as specified on the license.

22 **Use of licensed materials in tracer studies:** If the material will be used in tracer/field studies
23 where licensed material is deliberately released into the environment, an environmental
24 assessment (EA) may be needed according to 10 CFR 51.21, "Criteria for and identification of
25 licensing and regulatory actions requiring environmental assessments." NUREG-1748,
26 "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs,"
27 addresses procedures that staff should use in conducting environmental reviews, and is
28 available on NRC's Web site under "Document Collections." Further guidance is provided in
29 memoranda dated March 19, 2004 (Agencywide Documents Access and Management System
30 (ADAMS) Accession No. ML040790751) and October 20, 2009 (ADAMS Accession No.
31 ML092321078). Both of these memoranda are publicly available and can be accessed through
32 ADAMS, which is accessible from the NRC's Web site at [http://www.nrc.gov/reading-
34 rm/adams.html](http://www.nrc.gov/reading-
33 rm/adams.html) .

35 **Use of licensed materials in tracer studies:** If the material will be used in tracer and field
36 studies in which licensed material is deliberately released into the environment, an
37 environmental assessment (EA) may be needed according to 10 CFR 51.21, "Criteria for and
38 Identification of Licensing and Regulatory Actions Requiring Environmental Assessments."
39 NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS
40 Programs," addresses procedures that staff should use in conducting environmental reviews,
41 and is available on the NRC Web site under "Document Collections." Memoranda dated
42 March 19, 2004 (ADAMS Accession No. ML040790751) and October 20, 2009 (ADAMS
43 Accession No. ML092321078), provide further guidance. Both these memoranda are publicly

1 available and can be accessed through the NRC’s Agencywide Documents Access and
2 Management System (ADAMS), which is accessible from the NRC Web site at
3 <http://www.nrc.gov/reading-rm/adams.html>. Applicants for tracer or field studies must provide
4 the NRC with a description of the study for review and approval before performing such studies.

5
6 If you want to perform field studies in which licensed material is deliberately released to the
7 environment, please provide the following information:

- 8 • a complete application describing the type and amount of material to be used, the location of
9 use, and training and experience of the individual using the material
- 10 • a copy of your operating and emergency procedures
- 11 • a description of the amount of radioactive material to be released in the field,
12 decontamination procedures at the conclusion of the experiment, if appropriate, and
13 procedures for minimizing releases
- 14 • a description of the expected radiation dose to humans
- 15 • a sample agreement letter between you and your customer acknowledging the use of
16 radioactive materials at the customer’s site
- 17 • a letter from the appropriate State health authorities indicating that they have reviewed your
18 application and concur with your request

19

Applicants should note that authorization from the NRC to use licensed material in tracer studies does not relieve them of their responsibilities to comply with any other applicable Federal, State or local regulatory requirements.

20

21 If the licensed material will remain at the customer’s facility (and the customer does not maintain
22 an NRC license) and the material is an exempt concentration in accordance with 10 CFR 30.70,
23 “Schedule A—Exempt concentration,” the applicant should apply for a second license; an
24 Exempt-Distribution license. Follow the guidance in NUREG-1556, Volume 8, “Consolidated
25 Guidance about Materials Licenses: Program-Specific Guidance about Exempt Distribution
26 Licenses.”

27

28 **Response from Applicant:** In accordance with 10 CFR 30.32(d), 40.31(d) and 70.22(a)(2), the
29 service provider must specify the purpose for which each radioisotope or sealed source listed in
30 Item 5 is to be used or possessed incident to providing a specific service. The service provider
31 must also specify the specific services that will be provided. Refer to the Section 1, “Purpose of
32 the Report.”

33 **8.7 Item 7: Individual(s) Responsible for Radiation Safety Program**

34 **8.7.1 Radiation Safety Officer (RSO)**

35 **Regulations:** 10 CFR 30.33(a)(3), 10 CFR 40.32(b), 10 CFR 70.22(a)(6).

1 **Criteria:** Radiation Safety Officers (RSOs) must be qualified by training and experience in
2 radiation protection, and be available for advice and assistance on radiological safety matters.
3 The RSO's training and experience must be commensurate with the requested licensed material
4 to be identified on the license. The RSO is typically the first responder for all radiological
5 emergencies.

6 **Discussion:** The person responsible for the radiation safety program is the RSO. The RSO
7 must also be responsible for compliance with the regulations for the use of radioactive material,
8 which may include byproduct, source, and special nuclear material. The RSO must ensure that
9 radiation safety activities are being performed safely according to approved policies and
10 procedures, and that all regulatory requirements are met. The RSO should have full access to
11 all activities involving the use of licensed material and the authority to terminate any activity in
12 which health and safety appear to be compromised without consulting with executive
13 management.

14 The RSO's duties and responsibilities include ensuring radiological safety and compliance with
15 NRC and U.S. Department of Transportation (DOT) regulations and the conditions of the license
16 (see Appendix C).

17 The responsibilities of the RSO may not be transferred to other individuals. Many tasks and
18 duties associated with managing the program may be assigned or delegated to other qualified
19 individuals; however, the responsibility for these tasks and duties remains with the RSO. The
20 NRC recognizes that a qualified individual will on occasion fill in for the RSO when the RSO is
21 away for short periods of time (e.g., professional conferences, vacation, illness). Absences that
22 have a major impact on licensed activities should not occur for extended or indefinite periods of
23 time. Consideration should be given to how individuals temporarily delegated the duties and
24 tasks of the absent RSO could contact the RSO in the event of an emergency.

25 When management selects an RSO, they should keep in mind the duties and responsibilities of
26 the position, and select an individual who is qualified to serve as the RSO. The RSO will need a
27 basic technical knowledge sufficient to understand, in general, the majority of the work being
28 done with licensed materials under his or her responsibility. The individual selected as RSO
29 should have sufficient training and experience to perform the duties required by his or her
30 position. Executive management should ensure that the RSO has sufficient time allocated to
31 carry out the responsibilities of the position.

32 **Response from Applicant:** Provide the following:

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

35 **AND**

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

39 **AND**

- 40 • Confirm that the RSO will be available for emergencies and can be on-site within 24-48
41 hours, if applicable.

42

1 **AND EITHER**

- 2 • Provide the specific training and experience of the RSO, and include the specific dates of
3 training in radiation safety.

4 **OR**

- 5 • Alternative information demonstrating that the proposed RSO is qualified by training and
6 experience (e.g., Board Certification by the American Board of Health Physicists, completion
7 of a bachelor's and/or master's degree in the sciences with at least one year of experience
8 in the conduct of a radiation safety program of comparable size and scope).

9 **Note:** It is important to notify the NRC, as soon as possible, typically within 30 days, of changes
10 in the designation of the RSO. The name and qualifications of the replacement RSO must be
11 submitted to the NRC as part of an amendment request.

12 **8.7.2 Authorized Users and Radiation Workers**

13 **Regulations:** 10 CFR 19.11, 10 CFR 19.12, 10 CFR 19.13, 10 CFR 30.33(a)(3),
14 10 CFR 30.34(e), 10 CFR 40.32, 10 CFR 70.22.

15 **Criteria:** Individuals must receive instruction commensurate with their duties and
16 responsibilities, as required by 10 CFR 19.12, "Instruction to workers," for individuals whose
17 assigned duties involve exposure to radiation or radioactive material, and individuals who in the
18 course of their employment are likely to receive in a year an occupational dose of radiation
19 greater than 1 millisievert (mSv) = (100 millirem (mrem)).

20 **Discussion:** Authorized users (AUs) and radiation workers must have adequate training and
21 experience to use, possess, or provide services involving licensed materials. A person named
22 as an AU on an NRC license is responsible for ensuring that radioactive materials are handled
23 and used safely and in accordance with NRC regulations and the terms and conditions of the
24 NRC license.

25 Duration of training and experience should be commensurate with the expected hazards service
26 provider personnel may encounter during routine and emergency conditions. Successful
27 completion of training as described in Appendix D is evidence of adequate training and
28 experience. Experience requirements could consist of on-the-job training done under the
29 supervision of a qualified individual (AU, RSO, or manufacturer's representative that is
30 authorized by the NRC or an Agreement State for the purpose(s) or activities that will be
31 authorized in the license, when issued.).

32 An AU is a person whose training and experience meet NRC criteria specified in Appendix D,
33 who is named either explicitly or implicitly on the license, and who uses or directly supervises
34 the use of licensed materials. An AU must ensure the proper use of licensed materials
35 possessed under the license. AUs must have training to provide reasonable assurance that
36 they will use, possess, or provide services involving licensed materials in a safe manner,
37 maintain security, prevent unauthorized access, and respond appropriately to emergencies.
38 AUs are responsible for the use of material by radiation workers. Applicants who want to
39 provide radiation safety training involving the use of licensed material as a service to their
40 customers should provide to the NRC for review a description of the training program that
41 corresponds to the appropriate NUREG-1556 volume, to include radiation safety topics,
42 frequency and duration of training, testing methodology, and qualification of course instructors.

1 The NRC will review such requests to determine that the radiation safety aspect of the use of
2 licensed material during hands-on training is adequate to protect occupational workers and
3 members of the public.

4 Service providers should not assume that safety instruction has been adequately covered by
5 previous radiation safety training. Particular attention should be given to individuals performing
6 work or in the immediate vicinity of work being performed with radioactive materials that may
7 require special procedures, e.g., sealed source exchange, service operations that create high
8 radiation areas. Training may be in the form of lecture, demonstrations, videotape, or self-
9 study, and should emphasize practical subjects important to the safe use of licensed material.
10 Emergency drills should be conducted on the likely scenarios a service provider may encounter.
11 The guidance in Appendix D may be used to develop a training program. The program should
12 consider both the topics pertinent for each group of workers and the method and frequency of
13 training.

14 **Response from Applicant:** Provide either of the following:

- 15 • The statement: "Before using licensed material, authorized users will receive the training
16 described in Appendix D in NUREG-1556, Volume 18, Revision 1, 'Consolidated Guidance
17 About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.'"

18 **OR**

- 19 • A description of the training and experience for proposed AUs.

20 **AND/OR**

- 21 • A description of the radiation safety training involving the use of licensed material that will be
22 provided as a service to customers.

23 **Note:** Alternative response will be evaluated using the criteria listed above.

24 **8.8 Item 8: Individuals Working in or Frequenting Restricted Areas**

25 **Regulations:** 10 CFR 19.11, 10 CFR 19.12, 10 CFR 19.13, 10 CFR 20.1801,
26 10 CFR 20.1802, 10 CFR 30.7, 10 CFR 30.9, 10 CFR 30.10, 10 CFR 30.33(a)(3),
27 10 CFR 30.34(e), 10 CFR 40.32(b), 10 CFR 40.41(e), 10 CFR 70.23(a)(2), 10 CFR 70.32(b)

28 **Criteria:** Ancillary personnel may include clerical, housekeeping, security, any customers'
29 personnel or licensee staff members working under the supervision and direction of the service
30 provider's RSO or AU at the time licensed materials are possessed (incident to providing
31 services) under the service provider's license, and other similar types of personnel whose duties
32 may require them to work in the vicinity of radioactive material, whether they are escorted or not
33 by AUs. These individuals should be informed about radiation hazards and the appropriate
34 precautions they should take when working in the vicinity of licensed material. The licensee
35 should assess each individual's involvement with licensed material and provide appropriate
36 training.

1 **Discussion:** Ancillary personnel shall receive radiation safety training commensurate with their
2 duties. Each individual should also receive periodic refresher training.

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

5 **Response from Applicant:** Provide either of the following:

6 • The statement: "Before using licensed materials, personnel will have successfully
7 completed training commensurate with assigned duties."

8 **AND**

9 • A description of the radiation safety training program, including topics covered, groups of
10 workers, assessment of training, qualifications of instructors, and the method and frequency
11 of training.

12 **8.9 Item 9: Facilities and Equipment**

13 **Regulations:** 10 CFR 20.1101(b), 10 CFR 20.1406, 10 CFR 30.33, 10 CFR 30.33(a)(2 and 5),
14 10 CFR 30.35(g), 10 CFR 40.32(c and e), 10 CFR 51.20, 10 CFR 51.21, 10 CFR 70.23(a)(3
15 and 7)

16 **Criteria:** Facilities and equipment must be adequate to protect health, minimize danger to life
17 or property, minimize the possibility of contamination, and keep exposure to occupationally
18 exposed workers and the public ALARA.

19 **Discussion:** Applicants who will never take possession of licensed material, but require a
20 license to perform work with the licensed material at their client's facilities, will not need to
21 provide detailed information regarding their facilities, but should confirm that they will not take
22 possession of radioactive materials.

23 Applicants who will possess licensed material at their facilities must demonstrate that proposed
24 facilities and equipment provide adequate storage capabilities, appropriate shielding, maintain
25 radiation exposures ALARA, and minimize the possibility of contamination or release of licensed
26 materials as a result of normal and emergency conditions including fire, floods, earthquakes,
27 and wind damage. Licensed materials located in an unrestricted area and not in storage must
28 be under the constant surveillance and immediate control of the licensee. Licensed materials
29 should be accessible only by authorized persons and secured or locked when an authorized
30 person is not physically present. If accessible by unescorted, unauthorized persons, use or
31 storage areas cannot be considered restricted areas for purposes of radiation safety.

32 Applicants may elect to delay completing permanent facilities that will be specifically listed on its
33 license and acquiring equipment described in the application until the technical review of the
34 application is completed by the licensing staff. Delaying the acquisition of certain equipment or
35 modifications to the permanent facility allows for changes identified as a result of the technical
36 review of the application.

37

In all cases, the applicant cannot possess or use licensed material until after the facilities are approved, equipment is procured, and the license is issued.

1
2
3 **Construction of a Facility**
4

5 If a licensing action initiated pursuant to 10 CFR Parts 30, 40, or 70 meets any of the criteria in
6 10 CFR 51.20 or 51.21, then commencement of construction of a facility before the NRC staff
7 has completed its environmental review process shall be grounds for denial of the license
8 application, in accordance with 10 CFR 30.33(a)(5), 40.32(e), and 70.23(a)(7). Additional
9 guidance on construction can be found in Appendix N.

10
11 **Response from Applicant:**

12 Service providers listed in the **low-risk group** (e.g., leak test, environmental sample analysis,) only need to provide the location where these services will be performed. Indicate if services will be performed at temporary job sites. No facility description is required. These applicants do not need to provide the information listed below.

16 For those services listed in the **high-risk group** who will have permanent facilities specifically identified on the license, provide the following information as applicable to the service you intend to perform:

20 Submit a drawing or sketch of the proposed permanent facility:

- 21
- 22 1. Identify area(s) assigned for the receipt, storage, security, preparation, handling, waste
- 23 storage and measurement of radioactive materials including sealed sources and devices.
- 24
- 25 2. Show the relationship and distance between restricted areas and adjacent unrestricted
- 26 areas.
- 27
- 28 3. Indicate the scale, or include dimensions on each drawing or sketch. The same scale
- 29 should be used for all sketches and drawings. The recommended scale is 1/4 inch = 1
- 30 foot. Drawings to this scale that do not fit on 8-1/2 x 11-inch paper may be provided as
- 31 sectional drawings.
- 32
- 33 4. Specify shielding materials (e.g., concrete, lead) and means for securing radioactive
- 34 materials from unauthorized removal.
- 35
- 36 5. Illustrate area(s) where explosive, flammable, or other hazardous materials may be
- 37 stored.
- 38
- 39 6. Identify area(s) where radioactive materials may become airborne. The diagram should
- 40 contain descriptions of the ventilation systems, with pertinent airflow rates, filtration
- 41 equipment, sample collection points, and monitoring systems.
- 42
- 43 7. Identify specialized handling tools, facility safety interlocks designed to prevent operation
- 44 of radiological safety systems in the event that operation of a system could result in

1 accidental exposure or release of material (e.g., high efficiency particulate air (HEPA)
2 filters, ventilation system, safety door interlocks, etc.)) or equipment.

- 3
4 8. Identify radioactive waste handling equipment that includes incinerators, compactors,
5 solidification equipment, hold-up tanks, sample collection points, etc.
6

7 In addition, describe:

- 8 1. engineered safety systems (e.g., area monitors, interlocks, alarms)
9
10 2. protective clothing (such as latex or rubber gloves, lab coats or coveralls, respirators,
11 booties, and face shields), auxiliary shielding, absorbent materials, secondary containers
12 for waste water storage for decontamination purposes, plastic bags for storing
13 contaminated items, etc., that will be available for use when handling unsealed or
14 uncontained radioactive materials
15
16 3. the general location of each proposed permanent facility (e.g., located in an industrial
17 park, an office complex) and its current use. If any proposed permanent facility is a
18 private residence, provide diagrams of the installation that include the building, the
19 proposed restricted area or areas, and adjacent areas, including above and below the
20 restricted areas; provide commitments that restricted areas do not include residential
21 quarters, and explain how radiation levels in unrestricted areas will be maintained at less
22 than 1 mSv (100 mrem) per year.
23
24 4. the proposed nuclear laundry facilities, if applicable, used for contaminated protective
25 equipment and clothing. Specify how the contaminated waste water from the laundry
26 machines or sinks is disposed. Operating and emergency procedures should address
27 decontamination of the laundry area and equipment.
28

29 **Note:** Mark drawings and diagrams that provide exact location of materials or depict specific
30 locations of safety or security equipment as "Security-Related Information—Withhold under
31 10 CFR 2.390."
32

33 **For temporary job sites:**

- 34 • No facility description is required. (NOTE: equipment used at temporary job sites will be
35 discussed in the Operating and Emergency procedures section)

36 **8.10 Item 10: Radiation Safety Program**

37 A radiation safety program must be established and submitted to the NRC as part of the
38 application. The program must be commensurate with the scope and extent of activities for the
39 use of licensed materials in service operations. Each applicant must develop, document, and
40 implement a radiation protection program-specific to its types of operations. Radiation safety
41 programs should address the following elements:

- 42 • development, implementation, and maintenance of written operating and emergency
43 procedures to address all likely situations
44 • development and implementation of an ALARA program

- 1 • description of equipment and facilities adequate to protect personnel, the public, and the
2 environment
- 3 • confirmation that licensed activities are conducted only by individuals qualified by training
4 and experience
- 5 • description of organization structure and individuals responsible for ensuring day-to-day
6 oversight of radiation safety program
- 7 • establishment and management of a radiation safety and decommissioning records system
- 8 • implementation of an audit program to ensure that, at least annually, the radiation safety
9 program is reviewed
- 10 • development of a sample agreement letter between you and your customer acknowledging
11 the use of radioactive materials at the customer's site
- 12 • development and implementation of a program to ensure the security and control of licensed
13 material

14

15 **8.10.1 Operating and Emergency Procedures**

16 **Regulations:** 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10
17 CFR 20.1902-1905, 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 30.32(i), 10 CFR 30.34(e),
18 10 CFR 30.50, 10 CFR 30.72

19 **Criteria:** As part of the application package, the licensee must develop, implement, and
20 maintain operating and emergency procedures. Operating procedures for high-risk licensed
21 activities (described in Section 1, "Purpose of the Report") should be submitted with the
22 application. Low-risk licensed activities do not require the submission of operating procedures.
23 Emergency procedures should be submitted and should address the important radiation safety
24 aspects for the proposed activities and address all likely scenarios that may be encountered.

25 **Discussion:** The purpose of operating and emergency procedures is to provide personnel
26 specific guidance for all operations they will perform. The operating and emergency procedures
27 should include each topic important to safe operation considered applicable to the materials and
28 uses proposed in the application.

29 Each licensee must develop, implement, and maintain operating and emergency procedures for
30 all likely scenarios that might be encountered. Emergency scenarios may include: high dose
31 rate alarm, leaking source; stuck source; radioactive spill; natural phenomena such as fire,
32 earthquake and tornados; medical emergency; contaminated or injured individual; inhalation or
33 ingestion due to aerosolized contamination; radiation overexposure; unshielded source; device
34 malfunction; device toppled over or damaged; activation of a safety or security alarm; lost or
35 missing radioactive material, and transportation accident involving the transport of licensed
36 material. The operating and emergency procedures should include the items outlined below:

- 37 • Procedure for obtaining an agreement with customers outlining the responsibilities of both the
38 customer and service provider, when performing service operations at a customer's facility.
39 The written agreement should include:

- 40 1. description of roles and responsibilities of the service provider and the customer

41

- 1 2. notification of the customer if the service provider will bring radioactive material into
2 the customer's facility
- 3
- 4 3. discussion on who will maintain security of the radioactive material (example: during
5 co-mingling of multiple sources from multiple customers)
- 6
- 7 4. discussion on who will take the lead for any emergency situations that might arise
8 from this service call (e.g., spill; injured worker; overexposure; stuck source; leaking
9 source; decontamination activities)
- 10
- 11 5. indication if any aftermarket sources or parts will be used BEFORE servicing.
- 12
- 13 6. description of using customer's calibrated survey meter if the need arises
- 14
- 15 • instructions for handling and using licensed materials
- 16 • instructions for maintaining security during storage and transportation
- 17 • instructions to keep licensed material under control and immediate surveillance during use
- 18 • instructions for posting areas and labeling containers
- 19 • steps to take to keep radiation exposures ALARA
- 20 • steps to maintain accountability during use
- 21 • steps to control access to work sites
- 22 • steps to take and whom to contact when an emergency occurs
- 23 • instructions for using remote handling tools when handling sealed sources, except low-
24 activity calibration sources
- 25 • methods and occasions for conducting radiation surveys, including surveys for detecting
26 contamination
- 27 • procedures to minimize personnel exposure during routine use and in the event of an
28 incident, including exposures from inhalation and ingestion of licensed unsealed materials
- 29 • methods and occasions for locking and securing stored licensed materials
- 30 • procedures for personnel monitoring, including bioassays, and the use of personnel
31 monitoring equipment
- 32 • procedures for transporting licensed materials to temporary job sites, packaging of licensed
33 materials for transport in vehicles (private or common carrier), placarding of vehicles when
34 needed, and physically securing licensed materials in transport vehicles during
35 transportation to prevent accidental loss, tampering, or unauthorized removal
- 36 • procedures for picking up, receiving, and opening packages containing licensed materials, in
37 accordance with 10 CFR 20.1906, "Procedures for receiving and opening packages"
- 38 • instructions for maintaining records in accordance with the regulations and the license
39 conditions
- 40 • procedures for identifying and reporting to the NRC defects and noncompliance as required
41 by 10 CFR 21.21(a) of this chapter

- 1 • procedures and actions to be taken in an emergency situation that will cover all likely
- 2 scenarios, including actions to prevent the spread of contamination and minimize inhalation
- 3 and ingestion of licensed materials and actions to obtain suitable radiation survey
- 4 instruments
- 5 • instructions for the proper storage and disposal of radioactive waste
- 6 • procedures to be followed in the event of uncontrolled release of radioactive unsealed
- 7 licensed material to the environment, including notification of the RSO, the NRC, and other
- 8 Federal and State agencies
- 9 • procedures for identifying and reporting to the NRC incident notifications (see Table 8.2 for a
- 10 description of the typical incident notifications required by NRC regulations)
- 11 • procedures for the implementation and adherence to good health physics practices while
- 12 performing service operations:
 - 13 1. minimization of distance to areas, to the extent practicable, where licensed materials are
 - 14 used and stored
 - 15 2. maximization of survey frequency, within reason, to enhance detection of contamination
 - 16 3. segregation of radioactive material in waste storage areas
 - 17 4. segregation of sealed sources and tracer materials to prevent cross-contamination
 - 18 5. separation of radioactive material from explosives
 - 19 6. separation of potentially contaminated areas from clean areas by barriers or other
 - 20 controls
- 21 • method for reviewing the entire radiation safety program at least annually

22
23 Written documentation of the above should be retained for review during inspection.

24
25 **Table 8.2 Typical NRC Incident Notifications Required for Service Provider Licensees**
26 **(this list is not all-inclusive)**

Event Telephone Notification and Written Report Regulatory Requirement			
	Telephone report	Written report	
Theft or loss of material	immediate	Within 30 days	10 CFR 20.2201(a) & (b)
Whole body dose greater than 0.25 Sv (25 rems) per event	immediate	Within 30 days	10 CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Sv (250 rems) per event	immediate	Within 30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	Within 24 hours	Within 30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)

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

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

3 **Response from Applicant:**

4 Applicants who perform low-risk licensed activities are not required to submit operating
5 procedures, but should provide emergency procedures for all likely scenarios.

6 Applicants who perform high-risk licensed activities should submit their operating and
7 emergency procedures for radiological conditions that might be encountered as part of their
8 license application.

9 **Note:** Service providers who perform specific operations involving sealed sources such as
10 inspection and maintenance of devices, removal and replacement of sealed sources (source
11 exchange), and operations that involve access to the sealed source(s) and safety systems,
12 should include appropriate procedures and instructions for these operations in the
13 applicant's operating and emergency procedures.

14 **OR**

15 Service providers should include operating and emergency procedures that are in
16 accordance with the manufacturer's and distributor's procedures as well as the
17 corresponding sealed source and device registration certificate for the devices that are being
18 serviced or maintained.

16 **8.10.2 Material Receipt and Accountability**

17 **Regulations:** 10 CFR 20.1501(a), 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906,
18 10 CFR 20.2001, 10 CFR 20.2108, 10 CFR 20.2201, 10 CFR 20.2207, 10 CFR 30.34(e),
19 10 CFR 30.35(g), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 31.11, 10 CFR 40.36(f), 10 CFR
20 40.51, 10 CFR 40.61, 10 CFR 40.64, 10 CFR 70.25(g), 10 CFR 70.42, 10 CFR
21 70.51(b), 10 CFR 71.5, 10 CFR 71.47, 10 CFR 71.87

22 **Criteria:** Service provider licensees who will obtain and possess licensed material must do the
23 following:

- 24 • establish maintain, and retain written procedures for safely opening packages (10 CFR
25 20.1906)
- 26 • secure and maintain accountability of licensed material (10 CFR 20.1801; 10 CFR 20.1802;
27 10 CFR Part 37)
- 28 • maintain records of receipt, transfer, and disposal of licensed material (10 CFR 20.2108; 10
29 CFR 30.51(a); 10 CFR 40.61(a); 10 CFR 70.51)
- 30 • Complete a National Source Tracking Transaction Report if they manufacture, transfer,
31 receive, disassemble, or disposes of a nationally tracked source.(10 CFR 20.2207)

32
33 **Discussion:** Licensed radioactive material should only be ordered if it is authorized on the
34 license. The radionuclide and chemical form should be commensurate with that listed on the
35 license and the activity should be within the prescribed license possession limit.

1 Service Provider licensees who will obtain and possess licensed material are required to
2 develop, implement, and maintain written procedures for safely opening packages in
3 accordance with 10 CFR 20.1906, "Procedure for receiving and opening packages." Some
4 packages containing licensed material may require special opening procedures based on the
5 types, quantities, or half-lives of the nuclide being delivered. Arrangements should be made to
6 receive radioactive packages expeditiously when they are delivered to your permanent facility or
7 at temporary job sites at a customer's facility that will receive packages. Alternatively,
8 arrangements may be made for you to be notified when radioactive packages arrive at the
9 carrier's terminal. Control procedures should also be established for the procurement of
10 licensed materials that may be obtained outside the normal channels; e.g., through the loan or
11 other transfer of materials without purchase or through surplus. A model procedure for safely
12 opening packages containing licensed materials is included in Appendix E.

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

22 Licensees should make arrangements to receive radioactive packages when they are delivered
23 or to be notified when radioactive packages arrive at the carrier's terminal so that the licensee
24 can pick up the package expeditiously. Licensees are required to develop, implement, and
25 maintain written procedures for safely opening packages in accordance with 10 CFR 20.1906.
26 Some packages may require special procedures that take into consideration the type, quantity,
27 or half-life of the nuclide being delivered.

28 Individuals that will receive packages containing licensed material should be trained to do the
29 following:

- 30 • identify the package as radioactive by labeling and shipping papers
- 31 • segregate the package from other incoming items in a secured area until released by the
32 RSO
- 33 • notify the RSO

34 When notified that a package of licensed material has arrived, the RSO or his/her staff should
35 retrieve the package and follow the safe opening procedures. If the radioactive material is
36 needed at a customer's location and the package will be transported over public roads by the
37 licensee, it must be repackaged and transported in accordance with DOT regulations.
38

39 NRC regulations in 10 CFR 20.1906(b) and (c) state the requirements for monitoring packages
40 containing licensed material. These requirements are described in Table 8.3, below.

1
2

Table 8.3 Package Monitoring Requirements

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

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

6
7 Regulations in 10 CFR 20.1906(d) require that the licensee immediately notify the final delivery
8 carrier and the NRC Operations Center (310-816-5100), by telephone, when external radiation
9 levels exceed the limits of 10 CFR 71.47, "External radiation standards for all packages." The
10 limits that are applicable to most packages that service provider licensees receive are: (1)
11 radiation levels shall not exceed 200 mrem/hour, and (2) removable radioactive surface
12 contamination for beta/gamma emitters and low toxicity alpha emitters shall not exceed, 220
13 disintegrations per minute per centimeter squared (dpm per cm²); or for all other alpha emitters
14 22 dpm/cm².

15
16 As illustrated in Figure 8.3, licensed materials must be tracked from "receipt to disposal" to
17 ensure accountability; identify when sources/devices may be lost, stolen, or misplaced; and
18 ensure that the possession limit stated on the license is not exceeded.



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Figure 8.3 Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal of licensed material.

Regulations in 10 CFR 20.1801, “Security of stored material,” and 10 CFR 20.1802, “Control of material not in storage,” require licensees 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 not in storage. Applicants should establish policies and procedures to ensure compliance with these security requirements. It is recognized that loss, theft, or misplacement of licensed material can occur; however, licensees should have in place an accountability and control system for promptly detecting losses of licensed material.

Licensed material possessed at customer’s facilities may be received by the customer in advance of the service provider licensee performing services. In most circumstances, this material is received and possessed by the customer under the auspices of the customer’s license. Service provider licensees must have in place an accountability and control system for promptly detecting missing licensed material at permanent facilities, customer’s facilities, temporary job sites, or any other locations where loss, theft, or misplacement of licensed material can occur. Operating and emergency procedures should address how you will maintain control and accountability of licensed material possessed incident to performing commercial services at customers’ facilities.

Licensees who possess Radioactive Material Subject to National Source Tracking System Requirements

Regulations in 10 CFR 20.2207, “Reports of transactions involving nationally tracked sources,” require that each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete a National Source Tracking Report in order to track high-risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay enough to no longer be of concern. Additional information on this subject is provided in Section 8.10.11, Security Program for Category 1 and Category 2 Materials.”

Licensees who also possess Radioactive Materials under a General License or an Exemption

In addition to radionuclides that are specifically listed on their licenses, licensees frequently possess radioactive material that is generally licensed or distributed to them as an exempt

1 quantity or item. Regulations in 10 CFR Part 31, "General Domestic Licenses for Byproduct
2 Material," provide requirements for generally licensed devices. Any person who acquires,
3 receives, possesses, uses, or transfers a generally licensed device must do so in accordance
4 with the provisions of the general license. Generally licensed material possessed by a specific
5 licensee may continue to be possessed under a general license. A specific license does not
6 automatically remove general licensee status nor automatically "move" generally licensed
7 material to the specific license. The NRC recognizes that multiple authorizations can create
8 some confusion and, therefore, a specific licensee always has the option of receiving and
9 possessing radioactive materials that "qualify" for a general license by adding these to its
10 specific license as described in 10 CFR 31.5(c)(8)(iii).

11
12 Similarly, radioactive material received by a specific licensee, which is distributed to it under an
13 exemption from the requirements for a license, is not subject to the terms and conditions of the
14 specific license. With certain restrictions specified in the regulations, any person may receive
15 byproduct material that is exempt from the requirements of a license pursuant to the regulations
16 in 10 CFR 30.11 through 10 CFR 30.21, "Maintenance of records." Such materials may include
17 "exempt quantities" of byproduct materials that do not exceed the applicable quantity listed in 10
18 CFR 30.71, "Schedule B," as well as items such as smoke detectors and self-luminous watches
19 that are distributed in accordance with other NRC regulations. As stated above, the specific
20 licensee always has the option of adding these materials to its license, and controlling them
21 under the conditions of the specific license.

22 **Inventory and Accountability of Radioactive Materials**

23 Licensees who use or possess sealed sources are required by license condition to perform
24 inventories of sealed sources every 6 months. Some sealed sources may not be in use or are
25 rarely used and are placed in storage. In these cases, licensees should confirm that these
26 sealed sources have not been removed from storage at least every 6 months. Licensees are
27 also required by license condition to conduct leak tests of sealed sources at 6-month intervals
28 (or at longer intervals as specified in the SSD Registration Certificate). Since the leak tests
29 require an individual to locate and work with the sealed source, records of leak tests may be
30 used as part of an inventory and accountability program.

31 With regard to unsealed licensed material, licensees may use various methods (e.g., computer
32 programs, manual ledgers, log books) to account for the inventory of unsealed materials from
33 the time of receipt, through the use and storage of the unsealed materials, to removal from
34 inventory through, transfer, disposal, and radioactive decay. These methods help to ensure that
35 possession limits are not exceeded. Licensees should be able to account for all materials in
36 their possession, whether the material is solid, liquid or gas form; whether it is possessed in a
37 stock vial or dispersed in samples, or whether it is placed into waste containers in the
38 laboratory. The licensee should be able to account for the location of all materials possessed,
39 whether the material is located in a secured laboratory cabinet, a locked sample container in a
40 refrigerator or freezer, or in appropriate waste containers awaiting disposal. The RSO should
41 perform periodic update of the total inventory of all unsealed materials possessed under the
42 license. Depending on the how often unsealed materials are received and used, the periodic
43 update may be weekly, monthly, quarterly or at less frequent intervals.

44 NRC regulations applicable to transfers are provided in 10 CFR 30.41, "Transfer of byproduct
45 material." Sample policy transfer statements are included in Appendix E. Transfer of licensed
46 materials within the facility may require special procedures to ensure proper control. In many

1 facilities, pieces of laboratory equipment or components including refrigerators and freezers will
2 become contaminated. Removal of these items for maintenance, repair, or disposal should also
3 be carefully controlled.

4 Licensees must maintain records of receipt, transfer, and disposal (as waste) of all licensed
5 material in accordance with 10 CFR 30.51(a); 10 CFR 40.61(a); 10 CFR 70.51. Table 8.4 below
6 lists each type of record and how long the record must be maintained. Records for the transfer
7 of licensed material should include verification that the receiver is authorized to possess the
8 licensed material being transferred in accordance with 10 CFR 30.41(c). Receipt records
9 should also document cases where excessive radiation levels or radioactive contamination were
10 found on packages or containers of material received and describe the action taken.

11 **Lost Source Policy** is the NRC's policy that a civil penalty may be issued for violations
12 resulting in regulated material being out of the control of the licensee regardless of the use,
13 license type, quantity, or type of regulated material (e.g., loss, abandonment, improper
14 transfer, or improper disposal of regulated material).

15 **Table 8.4 Record Maintenance**

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until the NRC terminates the license
Important to decommissioning	Until the site is released for unrestricted use

16 Receipt, transfer, and disposal records typically contain the following information:

- 17 • radionuclide and activity (in units of becquerels or curies), and date of measurement of
18 byproduct material
- 19 • for each sealed source, manufacturer, model number, location, and, if needed for
20 identification, serial number and as appropriate, manufacturer and model number of device
21 containing the sealed source
- 22 • date of the transfer and name and license number of the recipient, and description of the
23 affected radioactive material (e.g., radionuclide, activity, manufacturer's name and model
24 number, serial number)
- 25 • for licensed materials disposed of as waste, include the radionuclide, activity, date of
26 disposal, and method of disposal (e.g., decay, sewer

27 See the section on "Waste Disposal" for additional information.
28
29

Licensed material possessed incident to performing services at customers' facilities is not normally transferred to the service provider during the time service is being performed. One notable exception is when the service provider is preparing the shipment to be shipped and is designated as the shipper of record (i.e., signing the shipper's certification on the shipping paper).

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Response from Applicant:

Provide the following:

- “Physical inventories will be conducted at intervals not to exceed 6 months, to account for specifically licensed material and devices received and possessed under the license. Records of inventory shall be maintained for a period of 5 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer’s name and/or model numbers, and the date of the inventory.”

OR

- A description of the procedures for ensuring that no specifically licensed material and devices have been lost, stolen, or misplaced.

AND

- “We will comply with the NSTS reporting requirements as described in 10 CFR 22.2207.”
- Alternative responses will be evaluated using the criteria listed above.

Note: No response is needed from applicants for package opening procedures. Package opening procedures will be reviewed during NRC inspections.

References:

- NUREG-1516, “Management of Radioactive Material Safety Programs at Medical Facilities” (1997)
- National Council on Radiation Protection (NCRP) Report No. 114, “Maintaining Radiation Protection Records,” (1992)⁴.
- NCRP Report No. 105, “Radiation Protection For Medical and Allied Health Personnel,” (1989)

⁴ Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814-3095 or ordered electronically at <<http://www.nrpc.com>>.

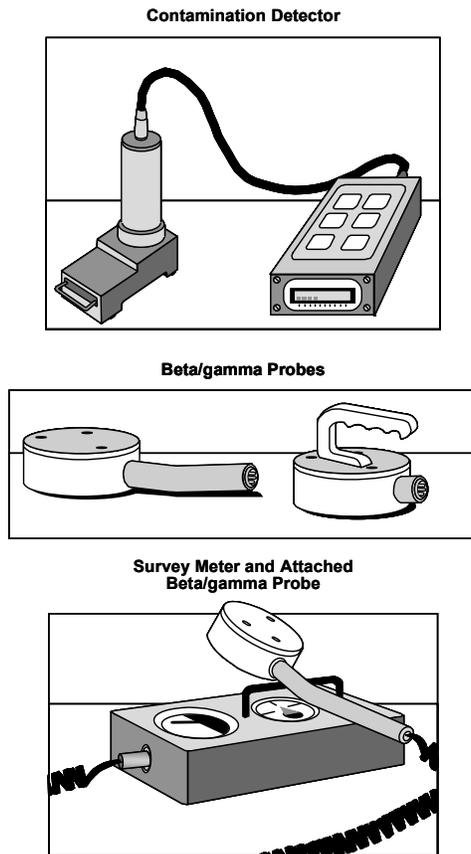
- NCRP Report No. 127, "Operational Radiation Safety Program," (1998)
- NCRP Report No. 157, "Radiation Protection in Educational Institutions," (2007)

8.10.3 Radiation Monitoring Instruments

Regulations: 10 CFR 20.1501; 10 CFR 20.2103(a); 10 CFR 30.33(a)(2).

Criteria: Licensees must possess and periodically calibrate 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: Licensees must ensure that an adequate number of calibrated radiation detection and measurement instruments are available to make radiation measurements. Licensees should ensure that when performing work at temporary job sites, a backup calibrated instrument is readily available if the primary instrument becomes inoperable. Instruments should be calibrated periodically for the types of radiation being measured. In this document, survey instruments are defined as any device used to measure radiological conditions. Figure 8.4 illustrates some common survey instruments used for making contamination surveys and for taking direct radiation measurements.



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Figure 8.4 Examples of Portable Instruments

1 Service provider applications should include:

- 2 • criteria used in determining what radiation detection and monitoring equipment will be
3 required for the type of measurement to be taken (e.g., count rate, dose rate.)
- 4 • type of use
- 5 • number and availability of a sufficient quantity of these calibrated radiation detection and
6 measurement instruments:
 - 7 — ion-chambers
 - 8 — Geiger-Muellers (G-Ms)
 - 9 — liquid scintillation counters
 - 10 — pocket ion chambers (PIC)
 - 11 — alarming ratemeters
 - 12 — area monitors
 - 13 — air samplers

14 The NRC requires that radiation monitoring devices used to determine compliance with
15 regulatory requirements be calibrated periodically by the licensee. Radiation monitoring devices
16 and personnel dosimetry devices (e.g., PIC, alarming ratemeters should be calibrated at least
17 annually (every 12 months) unless otherwise specified by regulation or license condition.
18 Licensees seeking authorization to perform radiation monitoring instrument calibrations should
19 submit procedures for review or commit to implementing the procedure in Appendix F. The
20 licensee may wish to review available industry standards for calibration of instruments such as
21 American National Standards Institute (ANSI) N323A-1997, "Radiation Protection
22 Instrumentation Test and Calibration, Portable Survey Instruments."

23 **Response from Applicant:** Provide one of the following:

- 24 • A description of the instrumentation (as described above) that will be used to perform
25 required radiological surveys and a statement that: "We will use instruments that meet the
26 radiation monitoring instrument specifications published in Appendix F of NUREG-1556,
27 Volume 18, Revision 1, 'Consolidated Guidance about Materials Licenses: Program-
28 Specific Guidance about Service Provider Licenses.' We reserve the right to upgrade our
29 survey instruments as necessary."

30 **OR**

- 31 • A description of the instrumentation (as described above) that will be used to perform
32 required radiological surveys and a statement that: "We will use instruments that meet the
33 radiation monitoring instrument specifications published in Appendix F of NUREG-1556,
34 Volume 18, Revision 1, , 'Consolidated Guidance about Materials Licenses: Program-
35 Specific Guidance about Service Provider Licenses.' Additionally, we will implement the
36 model survey meter calibration program published in Appendix F of NUREG-1556, Volume
37 18, Revision 1, 'Consolidated Guidance about Materials Licenses: Program-Specific
38 Guidance about Service Provider Licenses.' We reserve the right to upgrade our survey
39 instruments as necessary."

40 **OR**

- A description of alternative equipment or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. Include the statement: “We reserve the right to upgrade our survey instruments as necessary.”

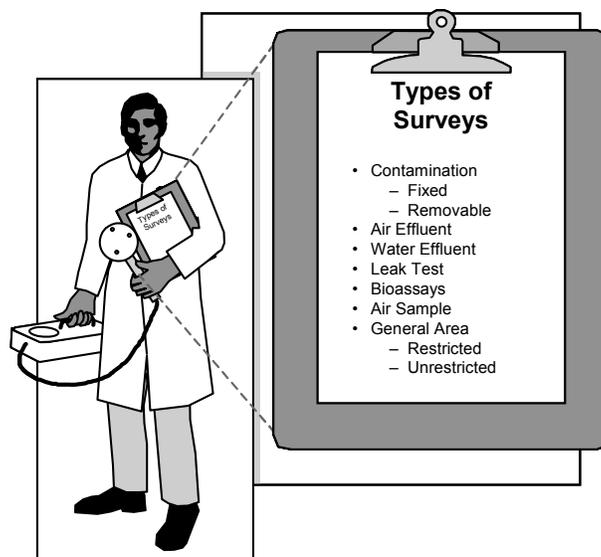
Note: Alternative responses will be reviewed using the criteria listed above.

8.10.4 Surveys

Regulations: 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1406, 10 CFR 20.1501, 10 CFR 20.2103, 10 CFR 20.2203, 10 CFR 30.53

Criteria: Licensees are required by 10 CFR 20.1501, “General,” to make surveys of potential radiological hazards in their workplace. When designing facilities and developing procedures for their safe use, licensees should consider how to minimize radioactive contamination, during operation, decontamination and decommissioning efforts, and radioactive waste generation. Procedures should address contamination of subsurface soil, drains/piping, and other potentially contaminated, inaccessible areas. Records of surveys and leak tests results must be maintained.

Discussion: Surveys are evaluations of radiological conditions and potential hazards (See Figure 8.5). These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. In order to meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, gamma) and compared to the appropriate regulatory limits.



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Figure 8.5 Types of Surveys

1 8.10.4.1 Types of Surveys

2 Radiation surveys are used to detect and evaluate contamination of:

- 3 • facilities
- 4 • equipment
- 5 • personnel (during use, transfer, or disposal of licensed material) (See Figure 8.6)
- 6 • restricted and unrestricted areas

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

9 Regulations in 10 CFR 20.1501 state that surveys are required when it is reasonable under the
10 circumstances to evaluate a radiological hazard and when necessary for the licensee to comply
11 with the regulations. Many different types of surveys may need to be performed due to the
12 particular use of licensed materials. The most important are as follows:

- 13 • surveys for radioactive contamination that could be present on surfaces of floors, walls,
14 laboratory furniture, and equipment
- 15 • measurements of radioactive material concentrations in air for areas where radioactive
16 materials are handled or processed in unsealed form and where operations could expose
17 workers to the inhalation or ingestion of radioactive material or where licensed material is or
18 could be released to unrestricted areas
- 19 • measurements of radioactive material concentrations in water that is allowed by regulation to
20 be released to the environment or to the sanitary sewer
- 21 • bioassays to determine the kinds, quantities or concentration, and in some cases, the
22 location of radioactive material in the human body. A bioassay can be made by direct
23 measurement (*in vivo* counting) or by analysis and evaluation of material excreted or
24 removed from the human body
- 25 • surveys of external radiation exposure levels in both restricted and unrestricted areas

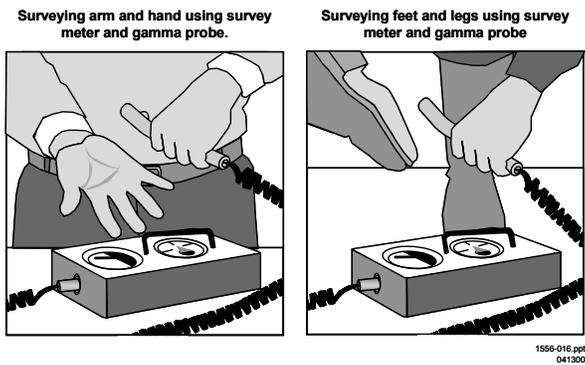
26 Not all instruments can measure a given type of radiation. The presence of other radiation may
27 interfere with a detector's ability to measure the radiation of interest. Correct use of radiation
28 detection and measurements is an important aspect of any radiation safety program. Refer to
29 Appendix F for a listing of the types of radiation survey instruments available.

30 Ambient survey and routine contamination survey frequencies depend on the quantity and use
31 of radioactive materials, as well as the specific protective facilities, equipment, and procedures
32 that are designed to protect the worker and members of the public from external exposure to
33 radiation. NRC regulations do not provide specific limits for surface contamination in restricted
34 areas, only that ALARA considerations must prevail. Each applicant should propose and justify
35 fixed and removable surface contamination limits allowable in a work area before
36 decontamination is required.

37 8.10.4.2 Contamination Survey Frequency

38 Personnel working with, in, or around unsealed forms of radioactive material should survey for
39 contamination. Contamination surveys should be conducted at a frequency appropriate to the

1 types and quantities of radioactive materials in use. If the activity used is greater than or equal
 2 to the smallest annual limit of intake (ALI) (for either inhalation or ingestion) as identified in
 3 10 CFR Part 20, Appendix B, then documented surveys should be performed at least daily and
 4 records retained in accordance with 10 CFR 20.2103, "Records of surveys."



5
 6 **Figure 8.6 Personnel Surveys**
 7

8 *Users of unsealed licensed material should check themselves for contamination (frisk) before*
 9 *leaving the laboratory or any area with potential contamination.*

10
 11 Table 8.5 contains suggested contamination survey frequencies based on ALIs. The suggested
 12 frequency of surveys is based upon the amount of licensed material "in use" at any one time at
 13 any particular location. If licensed material has not been used for a period of time greater than
 14 the required survey frequency, then it is considered to be "not in use."

15 **Table 8.5 Suggested Contamination Survey Frequency**
 16

	< 0.1 ALI	0.1 ALI to < 1.0 ALI	> 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months	Every 6 Months	Every 6 Months

17
 18 8.10.4.3 Contamination in Unrestricted Areas

19 Contamination found in unrestricted areas should be immediately decontaminated to
 20 background levels. When it is not possible to get to background levels, the licensee must
 21 ensure that the amounts do not exceed the contamination levels. When equipment or facilities
 22 that are potentially contaminated are to be released for unrestricted use, surveys should be
 23 completed to ensure that the dose rates are in compliance with current decommissioning
 24 guidance. Surface contamination surveys should be conducted for both removable and fixed
 25 contamination before equipment and facilities are released from restricted to unrestricted use in
 26 order to ensure that they meet current decommissioning limits.

1 The following NRC documents provide guidance on unrestricted use release criteria:

2
3 NUREG-1757, "Consolidated Decommissioning Guidance," has three volumes that address the
4 following topics:

5
6 Volume 1: "Decommissioning Process for Materials Licensees" (ADAMS Accession No.
7 ML063000243)

8 Volume 2: "Characterization, Survey, and Determination of Radiological Criteria" (ADAMS
9 Accession No. ML06300252)

10
11 Volume 3: "Financial Assurance, Recordkeeping, and Timeliness." (ADAMS Accession
12 No. ML12048A683)

13
14 Volume 2 of the NUREG-1757 provides guidance on compliance with the radiological criteria for
15 license termination in 10 CFR Part 20, Subpart E, using a screening approach dose analysis.
16 Volume 2 contains acceptable license termination screening values of common radionuclides
17 for building-surface contamination as well as screening values for soil contaminated with
18 radionuclides. These NUREG-1757 volumes can be found in ADAMS under their respective
19 accession numbers.

20
21 NUREG-1575, Revision 1, "Multi-Agency Radiation Survey and Site Investigation Manual
22 (MARSSIM)," provides detailed guidance for planning, implementing, and evaluating
23 environmental and facility radiological surveys conducted to demonstrate compliance with a
24 dose- or risk-based regulation. The MARSSIM guidance focuses on the demonstration of
25 compliance during the final status survey following scoping, characterization, and any necessary
26 remedial actions. NUREG 1575, Revision 1, can be found under ADAMS Accession No.
27 ML082470583.

28
29 NUREG-1575, Supplement 1, "Multi-Agency Radiation Survey and Assessment of Materials and
30 Equipment Manual (MARSAME)," is a supplement to MARSSIM. MARSAME provides technical
31 information on approaches for planning, implementing, assessing, and documenting surveys to
32 determine proper disposition of materials and equipment. NUREG 1575, Supplement 1, can be
33 found under ADAMS Accession No. ML090260577.

34 8.10.4.4 Survey Record Requirements

35 Each survey record should include the following:

- 36 • a diagram of the area surveyed
- 37 • a list of items and equipment surveyed
- 38 • specific locations on the survey diagram where wipe test was taken
- 39 • ambient radiation levels with appropriate units
- 40 • contamination levels with appropriate units
- 41 • make and model number of instruments used, including calibration dates
- 42 • background levels
- 43 • name of the person making the evaluation and recording the results and date

44 Licensees should record contamination levels observed and procedures followed for incidents
45 involving contamination of individuals. The record should include names of individuals involved,
46 description of work activities, calculated dose, probable causes (including root causes), steps

1 taken to reduce future incidents of contamination, times and dates, and the surveyor's
2 signature.

3 8.10.4.5 Air Monitoring in the Workplace

4 Air sampling can be used to do the following:

- 5 • Determine whether the confinement of radioactive materials is effective.
- 6 • Measure airborne radioactive material concentrations in the workplace.
- 7 • Estimate worker intakes of radioactive material.
- 8 • Determine posting requirements.
- 9 • Determine what protective equipment and measures are appropriate.
- 10 • Warn of significantly elevated levels of airborne radioactive materials.

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

11
12 Refer to Regulatory Guide (RG) 8.25, Revision 1, "Air Sampling in the Workplace," dated June
13 1992 (reviewed October 2011) (ADAMS Accession No. ML003739616) for further guidance on
14 the air sampling.

15 8.10.4.6 Airborne Effluent Release Monitoring

16 Applicants must use procedures and engineering controls to achieve occupational doses and
17 doses to members of the public that are ALARA. To implement ALARA in accordance with 10

18 CFR 20.1101(d), the applicant must establish a constraint on air emissions of radioactive
19 material, excluding Radon-222 and its daughters, such that the individual member of the public
20 likely to receive the highest dose will not be expected to receive a total effective dose equivalent
21 in excess of 10 millirem per year (0.1 millisievert per year) from these emissions. If this dose
22 constraint is exceeded, the applicant must report the exceedance in accordance with 10 CFR
23 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material
24 exceeding the constraints or limits," and promptly take appropriate corrective action to ensure
25 against recurrence.

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

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

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

1 For release points for which monitoring is not practicable, the licensee should estimate the
2 magnitude of the unmonitored effluents. These unmonitored releases will occur anytime
3 unsealed material is handled outside a fume hood or other device that will control the releases.
4 The licensee should include these estimates when demonstrating compliance with dose limits
5 and ALARA goals. Unmonitored releases may be estimated based on the quantity of material
6 used in these areas or the number of procedures performed or other appropriate methods. The
7 unmonitored effluents should not exceed 30 percent of the total estimated effluent releases or
8 10 percent of the permissible air effluent concentrations found on column 1 of Table 2 in
9 10 CFR Part 20, Appendix B, whichever is greater.

10 Effluent monitoring systems should be designed in accordance with ISO 2889 (2010), "Sampling
11 Airborne Radioactive Materials from Stacks and Ducts of Nuclear Facilities," and
12 ANSI N42.18 (2004), "Specification and Performance of On-site Instrumentation for
13 Continuously Monitoring Radioactivity in Effluents."

14 ISO 2889 (2010) sets forth performance-based criteria and recommendations for the design and
15 use of systems for sampling of airborne radioactive materials in the effluent air from the ducts
16 and stacks of nuclear facilities.

17 ANSI N42.18 (2004) provides recommendations for the selection of instrumentation specific to
18 the continuous monitoring and quantification of radioactivity in effluents released to the
19 environment. The effluent streams considered may contain radioactive gases, liquids,
20 particulates, or dissolved solids singly or in combination. This standard specifies detection
21 capabilities, physical and operating limits, reliability, and calibration requirements and sets forth
22 minimum performance requirements for effluent monitoring instrumentation.

23 8.10.4.7 Liquid Effluent Release Monitoring

24 The licensee should evaluate the concentrations of radioactive material in water that is released
25 to the environment and to the sanitary sewer. The licensee must show that these releases meet
26 the limits in 10 CFR 20.1301, "Dose limits for individual members of the public," and
27 10 CFR 20.2003, "Disposal by release into sanitary sewerage," respectively.

28 The topic of sanitary sewerage releases is more fully discussed in Appendix M.

29 **Response from Applicant:** Choose one of the following:

- 30 • State: "We will conduct surveys and maintain contamination levels in accordance with the
31 survey frequencies and contamination levels published in NUREG-1556, Volume 18,
32 Revision 1, Section 8.10.7 "Program-Specific Guidance about Service Provider Licenses."

33 **OR**

- 34
35 • Submit description of alternative survey method and frequency for demonstrating how to
36 evaluate a radiological hazard.

37
38 **Note:** Alternative responses will be reviewed using the criteria listed above.

1 **Additional references:**

- 2 • Regulatory Guide 8.20, Revision 1 “Applications of Bioassay for I-125 and I-131,”
3 September 1979 (ADAMS Accession No. ML080140011);
- 4 • Draft Regulatory Guide DG-8050, Revision 2, , “Applications of Bioassay for Radioiodine,”
5 September 30, 2011 (ADAMS Accession No. ML102800439)
- 6 • Regulatory Guide 8.21, Revision 1, “Health Physics Surveys for Byproduct Material at NRC-
7 Licensed Processing and Manufacturing Plants,” October 1979; (ADAMS Accession No.
8 ML003739577)Regulatory Guide 8.32, “Criteria for Establishing a Tritium Bioassay Program”
9 dated July 1988 (reviewed October 2011). (ADAMS Accession No. ML003739479)
- 10 • *Federal Register* (76 FR 35564) dated December 17, 2012, a final rule amending Section
11 E, “Radiological Criteria for License Termination,” and Section F, “Surveys and Monitoring,”
12 Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection
13 against Radiation.”

14 **8.10.5 Leak Tests**

15 **Regulations:** 10 CFR 35.67, 10 CFR 35.2067(a), 10 CFR 39.35

16
17 **Criteria:** NRC requires testing of sealed sources containing greater than 3.7 MBq (100
18 microcuries) of beta/gamma or 0.37 MBq (10 microcuries) of alpha radioactive material in order
19 to determine whether there is any radioactive leakage from sealed sources. Requirements for
20 leak tests are based on the type of radiation escaping from the inner capsule. Records of test
21 results must be maintained.

22 **Discussion:** Sealed sources and devices that are approved by NRC or an Agreement State
23 and used according to the respective SSD Registration Certificate usually pose little risk of
24 contamination. Leak tests performed at the frequency specified in the SSD Registration
25 Certificate should identify leaking sources. Leaking sources must be immediately withdrawn
26 from use and decontaminated, repaired, or disposed of according to NRC requirements. NRC
27 licenses will require the performance of leak tests on sealed sources at intervals approved by
28 NRC or an Agreement State and specified in the SSD Registration Sheet. The measurement of
29 the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the
30 sample be capable of detecting 185 Becquerel (0.005 microcurie) of radioactivity.

31 Manufacturers, consultants, and other organizations may be authorized by NRC or an
32 Agreement State to either perform the entire leak test sequence for other licensees or provide
33 leak test kits to licensees. In the latter case, the licensee should take the leak test sample
34 according to the kit supplier’s instructions and return it to the kit supplier for evaluation and
35 reporting results. Licensees may also be authorized to conduct the entire leak test sequence
36 themselves. A model leak test procedure can be found in Appendix G.

37 If you will be providing leak tests as a service to others, you may wish to distribute commercial
38 leak test kits.

39

1 Leak test kits should contain:

- 2 • swabs, wipes, absorbent-tipped sticks that are to be used to make the wipes on the
3 specified sources or devices
- 4 • envelopes, vials, where wipe sample will be placed after sample has been taken
- 5 • step-by-step instructions for safe use of the particular kit (these instructions will be
6 specific to the types of devices/sealed sources that the kit is designed)
- 7 • procedures for returning the wipes to you for analysis
- 8 • label for the customer to fill out that identifies:
 - 9 — customer's name
 - 10 — license number
 - 11 — source or device (by manufacturer, model number, nuclide and activity) wiped
 - 12 — the name of the individual who made the wipes

13 **Response from Applicant:** Choose one of the following:

- 14
- 15 • "Leak tests sample collection and analysis will be performed by an organization authorized
16 by NRC or an Agreement State to provide leak testing services to other licensees; or by
17 using a leak test sample collection kit supplied by an organization licensed by NRC or an
18 Agreement State to provide leak test kits and/or sample analysis services to other licensees
19 and according to the instructions provided in the leak test sample collection kit."

20 **OR**

- 21 • "Leak testing and analysis will be done by the applicant." Provide the information in
22 Appendix H supporting a request to perform leak testing and sample analysis and either
23 state that you will follow the model procedures in Appendix G or submit alternative
24 procedures.

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

28 **8.10.6 Occupational Dose**

29 **Regulations:** 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR
30 20.1207, 10 CFR 20.1208, 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1703, 10 CFR
31 20.2106, 10 CFR 20 Appendix B

32 **Criteria:** Each licensee must evaluate the potential exposures of all workers and monitor
33 occupational exposure to radiation when required, and control the occupational dose to
34 individual adults to comply with the dose limits set forth in 10 CFR 20.1201, Occupational dose
35 limits for adults." If monitoring of occupational doses is required in accordance with 10 CFR
36 20.1502, then the licensee must maintain records of the monitoring regardless of the actual
37 dose received in accordance with 10 CFR 20.2106.

38 **Discussion:** "Occupational Dose" is defined in 10 CFR 20.1003, "Definitions," as "the dose
39 received by an individual in the course of employment in which the individual's assigned duties
40 involve exposure to radiation or to radioactive material from licensed and unlicensed sources of

1 radiation, whether in the possession of the licensee or other person. Occupational dose does
2 not include doses received from background radiation, from any medical administration the
3 individual has received, from exposure to individuals administered radioactive material and
4 released under 10 CFR 35.75, "Release of individuals containing unsealed byproduct material
5 or implants containing byproduct material," from voluntary participation in medical research
6 programs, or as a member of the public.

7 The licensee should perform an evaluation of the dose the occupationally exposed individual is
8 likely to receive prior to allowing the individual to receive the dose (prospective evaluation).
9 When performing the prospective evaluation, only a dose that could be received at the facilities
10 of the applicant or licensee performing the evaluation needs to be considered. These estimates
11 can be based on any combination of work location radiation monitoring, survey results,
12 monitoring results of individuals in similar work situations, or other estimates to produce a "best
13 estimate" of the actual dose received. This evaluation need not be made for every individual;
14 evaluations can be made for employees with similar job functions or work areas. If the
15 prospective evaluation shows that an individual's dose is not likely to exceed 10 percent of any
16 applicable regulatory limit, the individual is not required to be monitored for radiation exposure
17 and there are no recordkeeping or reporting requirements for doses received by that individual.
18 If the prospective dose evaluation shows that the individual is likely to exceed 10 percent of an
19 applicable limit appropriate for the individual (i.e., adult, minor, declared pregnant woman),
20 monitoring is required pursuant to 10 CFR 20.1502. See Appendix I for additional information
21 on providing a prospective dose evaluation.

22 Licensees must monitor worker exposures for individuals:

- 23 • adults who are likely to receive in 1 year dose in excess of any of the following:
 - 24 — 5 mSv (0.5 rem) deep-dose equivalent;
 - 25 — 15 mSv (1.5 rems) lens dose equivalent, and
 - 26 — 50 mSv (5 rems) shallow-dose equivalent to the skin of the whole body or skin of any
27 extremity.
- 28 • minors (individuals less than 18 years of age) have annual occupational dose limits that are
29 10 percent of the annual dose limits specified for adults. Licensees must monitor minors who
30 are likely to receive an annual dose in excess of any of the following:
 - 31 — 0.5 mSv (0.05 rem) deep-dose equivalent;
 - 32 — 1.5 mSv (0.15 rem) lens dose equivalent, and
 - 33 — 5 mSv (0.5 rem) shallow-dose equivalent to the skin of the whole body or skin of any
34 extremity.

35 Applicants should verify that the processor is National Voluntary Laboratory
36 Accreditation Program (NVLAP) accredited and may consult with the processor for
37 its recommendations for exchange frequency and proper use.

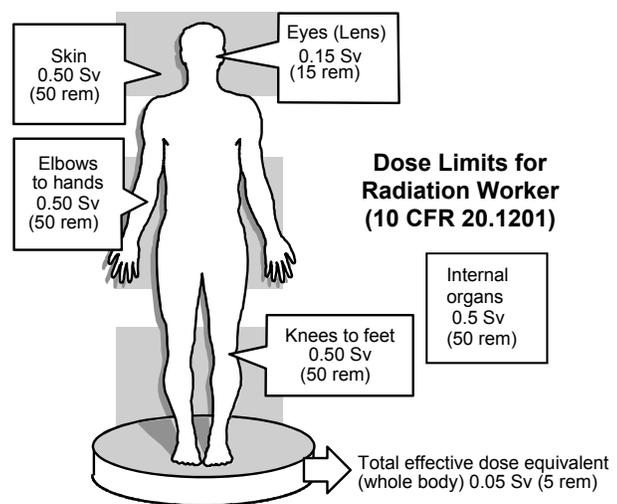
38 As defined in 10 CFR 20.1003, a declared pregnant woman is a woman who has voluntarily
39 informed the licensee, in writing, of her pregnancy and the estimated date of conception. The
40 licensee must ensure that the dose to the embryo/fetus of a declared pregnant woman, during
41 the entire pregnancy, does not exceed 5 mSv (0.5 rem). Licensees are required to monitor
42 declared pregnant women who are likely to receive during the entire pregnancy, from radiation

1 sources external to the body, a deep-dose equivalent in excess of 1.0 mSv (0.1 rem). All of the
2 occupational dose limits continue to be applicable to the declared pregnant woman as long as
3 the dose to the embryo/fetus is not exceeded.

4 Internal exposure monitoring is required for:

- 5 • adults likely to receive in 1 year an intake in excess of 10 percent of the applicable Annual
6 Limits on Intakes (ALI) for ingestion and inhalation;
- 7 • minors likely to receive in 1 year a committed effective dose equivalent (CEDE) in excess of
8 1.0 mSv (0.1 rem), and
- 9 • declared pregnant women likely to receive, during the entire pregnancy, a CEDE in excess of
10 1.0 mSv (0.1 rem)

11
12



13
14
15
16

$$\text{TOTAL EFFECTIVE DOSE EQUIVALENT (TEDE)} = \text{DEEP DOSE FROM EXTERNAL EXPOSURE} + \text{DOSE FROM INTERNALLY DEPOSITED RADIONUCLIDES}$$

17
18
19

Figure 8.7 Annual Dose Limits for Occupationally Exposed Individuals

20 To assess and determine external radiation dose, most licensees use either thermoluminescent
21 dosimeters (TLDs) or optically-stimulated luminescence (OSL) dosimeters. In accordance with
22 10 CFR 20.1501(d)(1), these dosimeters must be processed and evaluated by a laboratory that
23 holds current accreditation from the NVLAP and is approved to process and evaluate the type(s)
24 of radiation being monitored. The exchange frequency for whole-body and extremity dosimeters
25 is generally monthly or quarterly depending on the scope and extent of services.

26
27

Note: Personnel should be familiar with the survey instruments operation and capabilities before using the instrument at a job site.

28

1 **Internal Radiation Dose:**

2 Bioassays are required when individuals work with airborne radioactive material in the
3 quantities, chemical and physical forms, and activities that make it likely that the radionuclide
4 will be ingested, inhaled, or absorbed resulting in an intake in excess of 10percent of the ALIs in
5 Table 1, Columns 1 and 2, of Appendix B to 10 CFR Part 20. One ALI results in a CEDE.

For guidance on developing bioassay programs and determining internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program," dated July 1993, and Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Doses," July 1992.

6
7 **Response from Applicant:** Provide the following:

- 8 • A statement that: "We have done a prospective evaluation and determined that unmonitored
9 individuals are not likely to receive, in 1 year, a radiation dose in excess of 10 percent of the
10 allowable limits in 10 CFR Part 20,"

11 **OR**

- 12 • A statement that: "We will provide dosimetry processed and evaluated by an NVLAP-
13 approved processor that is exchanged at a frequency recommended by the processor in
14 accordance with the criteria in the section entitled 'Occupational Dose' in t NUREG-1556,
15 Volume 18, Revision 1, 'Consolidated Guidance about Materials Licenses: Program-
16 Specific Guidance about Service Provider Licenses,'."

17 **AND**

- 18 • Provide a bioassay program when seeking approval for the use of unsealed radioactive
19 materials. Bioassay programs must include what the applicant considers an acceptable
20 interval or schedule for conducting bioassays, identify action levels or guidelines, and
21 describe specific actions to be taken when action levels are exceeded. Because of the
22 complex nature of bioassay and corresponding data analysis, it is acceptable for applicants
23 to make reference to the procedures in NRC guidance documents. If an applicant elects to
24 provide a bioassay program that is less conservative than recommended in Regulatory
25 Guide 8.20, its rationale should be stated. The applicant may also choose to contract with
26 an outside group for bioassay services. Provide a commitment that each vendor is licensed
27 or otherwise authorized by NRC or Agreement State to provide required bioassay services.

28 **References:**

- 29 • National Voluntary Laboratory Accreditation Program Directory of Accredited Laboratories
30 <http://ts.nist.gov/standards/scopes/dosim.htm>
- 31 • Regulatory Guide 8.7, Revision 2, "Instructions for Recording and Reporting Occupational
32 Radiation Dose Data," November 2005 (ADAMS Accession No. ML052970092);
- 33 • Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations and
34 Assumptions for a Bioassay Program," July 1993 (ADAMS Accession No. ML13064A086)

- 1 • Regulatory Guide 8.20, Revision 1 “Applications of Bioassay for I-125 and I-131,”
2 September 1979 (ADAMS Accession No. ML080140011);
- 3 • Draft Regulatory Guide DG-8050, Revision 2, , “Applications of Bioassay for Radioiodine,”
4 September 30, 2011 (ADAMS Accession No. ML102800439) Regulatory Guide 8.34,
5 Revision 1, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses,”
6 July 1992 (ADAMS Accession No. ML12166A178);
- 7 • Regulatory Guide 8.13, Revision 3, “Instruction Concerning Prenatal Radiation Exposure,”
8 June 1999 (ADAMS Accession No. ML003739505);
- 9 • IN 2003-12, “Problems Involved in Monitoring Dose to the Hands Resulting from the
10 Handling of Radiopharmaceuticals,” August 22, 2003 (ADAMS Accession No.
11 ML032320470);
- 12 • IN 2000-10, “Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits,”
13 July 18, 2000 (ADAMS Accession No. ML003732340);
- 14 • IN 2000-16, “Potential Hazards due to the Volatilization of Radionuclides,” October 5, 2000
15 (ADAMS Accession No. ML003753003).

16 **8.10.7 Public Dose**

17 **Regulations:** 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR
18 20.2107.

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

- 21 • Ensure that licensed material will be used, transported, stored, and disposed of in such a way
22 that members of the public will not receive more than 1 mSv (100 mrem) in one year, and the
23 dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from
24 licensed operations.
- 25 • Control/maintain constant surveillance of licensed material when in use and not in storage.
- 26 • Secure stored licensed material from unauthorized access or removal.

27
28 **Discussion:** “Public dose” is defined in 10 CFR 20.1003as “the dose received by a member of
29 the public from exposure to radiation and/or radioactive material released by a licensee, or to
30 any other source of radiation under the control of a licensee.” Public dose excludes doses
31 received from background radiation and from medical procedures. Whether the dose to an
32 individual is an occupational dose or a public dose depends on the individual’s assigned duties
33 and not on the area (restricted, controlled, or unrestricted) the individual is in when the dose is
34 received.

35 For guidance about accepted methodologies for determining dose to members of public, please
36 refer to Appendix I.

37 Members of the public include persons who work in or may occupy locations where licensed
38 material is used or stored. Employees whose assigned duties do not include the use of licensed

1 material and work in the vicinity where it is used or stored are also included as members of the
2 public. Public dose is controlled, in part, by ensuring that licensed material is secured (e.g.,
3 located in a locked area) to prevent unauthorized access or use. Sealed and unsealed
4 materials are usually restricted by controlling access to the keys needed to gain access to
5 storage locations, including storage bunkers. Only the RSO or authorized user should have
6 access to keys.

7 Public dose is also affected by the choice of storage and use locations at temporary job sites.
8 Licensed material must be located so that the resulting public dose in an unrestricted area (e.g.,
9 an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year
10 or 0.02 mSv (2 mrem) in any one hour. Applicants should use the concepts of controlling time,
11 distance, and shielding when choosing storage and use locations. Decreasing the time that an
12 individual is exposed, increasing the distance from the radioactive material, and adding
13 shielding that is appropriate for the specific type of radiation (e.g., brick, concrete, lead,
14 hydrogenous materials) will reduce the radiation exposure.

15 Information provided on anticipated radiation levels of sealed sources and unsealed materials
16 both inside their respective transport containers and outside the transport container at given
17 distances is the type of information needed to make public dose calculations. Licensees may
18 assess radiation levels located in adjacent areas to radioactive material either by making
19 calculations or by using a combination of direct measurements and calculations. After obtaining
20 anticipated radiation levels or by making direct radiation measurements using an appropriate
21 survey instrument, an applicant can use the “inverse square” law to evaluate the effect on the
22 public, and use this information to determine operating and emergency procedures for using
23 radioactive materials. See Appendix I for an example demonstrating that individual members of
24 the public will not receive doses exceeding the allowable public limits.

25 Figure 8.8 shows the steps to calculate the annual dose to an individual member of the public.

26 There are many possible internal dose pathways that contribute to the total effective dose
27 equivalent (TEDE). The TEDE can, however, be broken down into three major dose pathway
28 groups:

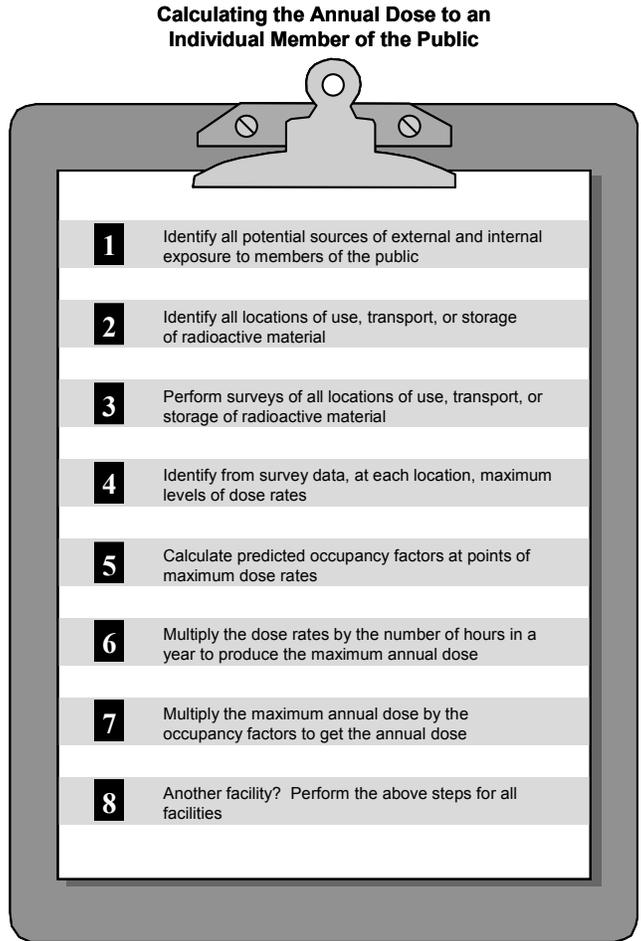
- 29 (1) airborne radioactive material
- 30 (2) waterborne radioactive material
- 31 (3) external radioactive exposure

32 The licensee should review these major pathways and decide which are applicable to its
33 operations.

34 If, after making an initial public dose evaluation, a licensee changes the conditions used for the
35 evaluation (e.g., relocates radioactive material within a designated storage area, increases the
36 amount of radioactive materials in storage, changes the frequency radioactive material is in use,
37 or changes the occupancy of adjacent areas) the licensee must perform a new evaluation to
38 ensure that the public dose limits are not exceeded and take corrective action, if required.

39 Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1302(b).
40 The extent and frequency of monitoring will depend upon each licensee’s specific needs.

1 Regulations in 10 CFR 20.2107, "Records of dose to individual members of the public," require
2 that licensees maintain records sufficient to demonstrate compliance with the dose limits for
3 members of the public until the Commission terminates the license. Refer to Appendix I for
4 additional guidance regarding compliance with the recordkeeping requirements.



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5
6 **Figure 8.8 Calculating Public Dose.** *Steps to calculate the annual dose to an individual*
7 *member of the public (see Appendix I for more information about occupancy factors).*
8

9 **Response from Applicant:** No response is required from the applicant in a license application,
10 but compliance will be evaluated during inspection.

11 During NRC inspections, licensees must be able to provide documentation demonstrating,
12 either by measurement, calculation, or a combination of both, that the total effective dose
13 equivalent to any individual member of the public that is likely to receive the highest dose from
14 licensed operations is less than 1 mSv (100 mrem) in one year, and any unrestricted area does
15 not exceed 0.02 mSv (2 mrem) in any one hour. See Appendix I for examples of methods to
16 demonstrate compliance.

1 **8.10.8 Transportation**

2 **Regulations:** 10 CFR 20.1101; 10 CFR 30.41; 10 CFR 30.51; 10 CFR 71.5; 10 CFR 71.13;
3 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38; 10 CFR 71.47; Subpart H of 10 CFR Part 71;
4 10 CFR Part 110;

5 **Criteria:** Applicants that will be packaging and transporting licensed material must develop,
6 implement, and maintain safety programs for transport of radioactive material to ensure
7 compliance with NRC and DOT regulations.

8 **Discussion:** In 10 CFR 71.5, “Transportation of licensed material,” the NRC requires all
9 licensees who transport radioactive materials outside the site of usage or where transport is on
10 public highways to comply with DOT regulations. Licensees should consider the safety of all
11 individuals who may handle or may come into contact with the transport containers or packages
12 containing licensed material. The primary consideration in packaging licensed material should
13 be to ensure that the package integrity is not compromised during transport, and that the
14 radiation levels or removable contamination levels at the package surfaces meet the regulatory
15 requirements of 10 CFR 71.47, “External radiation standards for all packages.” In all cases,
16 ALARA concerns are addressed prior to, during, and after transporting any radioactive material.

17 Service provider personnel are authorized to prepare packages for shipment at customer
18 facilities. The person signing the Shipper’s Certification on the shipping papers is responsible
19 for proper package preparation. If licensed material is transferred from the customer to the
20 service provider’s license at the customer’s facility the service provider licensee becomes
21 responsible for subsequent shipment of that material. HAZMAT training (49 CFR Part 172,
22 Subpart H-Training) is required for employees that prepare radioactive material packages for
23 shipment.

24 Transporting licensed materials originating at certain facilities (e.g., irradiators) may involve
25 quantities of radioactive material that require a Type B package that involves special
26 requirements. In many cases, this material will be transferred to the service provider’s license
27 and the service provider will then be responsible for its shipment. In these cases, the service
28 provider must ensure that you:

- 29
- 30 • are authorized to possess the licensed material at temporary job sites (i.e., at the facility in question)
 - 31 • take possession of the licensed material that is transferred to you
 - 32 • use an approved Type B package authorized for the material to be transported
 - 33 • are registered with NRC as a user of the Type B package
 - 34 • have an NRC-approved quality assurance (QA) plan

35 The general license requirements of 10 CFR 71.101, “Quality assurance requirements,” apply to
36 all NRC licensees that transport, or deliver to a carrier for transport, licensed material in an
37 NRC-approved transport package. For information about QA plans, see Revision 2 of
38 Regulatory Guide 7.10, “Establishing Quality Assurance Programs for Packaging Used in the
39 Transport of Radioactive Material,” dated March 2005. NRC licensees using NRC-approved
40 transport packages are responsible for ensuring that all of these requirements have been met
41 and that they are using currently authorized packages (see list of approved packages in
42 NUREG-0383, “Directory of Certificates of Compliance for Radioactive Materials Packages”).

1 Renewal of these certificates of compliance must be submitted in accordance with 10 CFR
2 71.38, "Renewal of a certificate of compliance or quality assurance program approval."
3

4 **Note:** Licensees shipping radioactive waste for disposal must prepare the shipment and its
5 shipping manifest as required by 10 CFR Part 20, Appendix F. Service providers that would like
6 to use one transport package for multiple customers with multiple sources during one
7 transportation trip should discuss this process with the appropriate NRC Region or Agreement
8 State staff.

9 During an inspection, the NRC uses the provisions of 10 CFR 71.5 and a "Memorandum of
10 Understanding with DOT on the Transportation of Radioactive Material" (signed June 6, 1979)
11 to examine and enforce various DOT requirements. See Appendix J for a list of DOT
12 regulations that may be applicable to service provider licensees.

13 Service providers who may transport licensed material by air mode outside of the United States
14 may need to comply with the International Air Transport Association (IATA) regulations
15 (www.iata.org). Service providers may also need to obtain an additional license from the NRC
16 for import and export of licensed material in accordance with 10 CFR Part 110, "Export and
17 Import of Nuclear Equipment and Material." Service providers should be aware of countries that
18 are listed as embargoed destinations in 10 CFR 110.28, "Embargoed destinations."

19

Note: Service providers must comply with import and export requirements as specified in 20 10 CFR Part 110 and obtain the necessary authorizations.
--

21 **Response from Applicant:** No response is needed from applicants during the licensing phase.
22 However, before making shipments of licensed materials in Type B packages, a licensee must
23 have registered with the NRC as a user of the package and obtained NRC's approval of its QA
24 program. Transportation issues will be reviewed during inspection.

25 **References:** "Radioactive Materials Regulations Review" can be obtained by calling DOT's
26 Office of Hazardous Material Initiatives and Training at 202-366-2301. See the Notice of
27 Availability (on the inside front cover of this report) to obtain a copy of the "Memorandum of
28 Understanding with DOT on the Transportation of Radioactive Material," the current version of
29 Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the
30 Transport of Radioactive Material," (ADAMS Accession No. ML050540330) and NUREG-
31 1660/RAMREG-002, "U.S.-Specific Schedules of Requirements for Transport of Specified
32 Types of Radioactive Material Consignments."

33 **8.10.9 Maintenance**

34 **Regulations:** 10 CFR 20.1101; 10 CFR 30.34(e).
35

36 **Criteria:** Service providers who perform maintenance as a commercial service to other
37 licensees must maintain devices (e.g., survey instrument calibrators and self-shielded
38 irradiators) according to the manufacturer's written recommendations and instructions and SSD
39 registry, if applicable.

40 "Routine maintenance" of the device includes, but is not limited to, cleaning, lubrication,
41 changing batteries, relays or fuses. "Non-routine maintenance" is the repair, removal,
42 replacement, or alteration involving activities during which personnel could receive radiation

1 doses exceeding NRC limits. These activities could include maintenance on electrical and
2 mechanical systems that directly control source or shielding movement, the device's shielding or
3 sealed source (e.g. removal), safety interlocks, any component that may affect safe operation of
4 the device, or any other non-routine maintenance that must be performed by the device
5 manufacturer (or distributor) or a person specifically licensed by the NRC or an Agreement
6 State.

7
8 **Note:** Only a person specifically licensed by the NRC or an Agreement State (see
9 comment below) shall install, maintain, adjust, or repair a device that involves work on
10 the sealed source(s) shielding, the source(s) driving unit, 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 the source(s).

11
12 **Discussion:** Before any maintenance or repair work is done on licensed devices, the service
13 provider licensee should ensure that:

- 14 • the service to be performed is authorized on the service provider's license;
15 • the manufacturer's and distributor's procedures will be used and followed; otherwise provide
16 an equivalent procedure that will be used to perform this particular service activity;
17 • only trained and qualified individuals will perform the activity;
18 • only approved parts and components will be used;
19 • all necessary specialized equipment will be available to perform these activities; and
20 • the device will be tested for full operation before it is returned to routine use.

21
22 The license will require that non-routine maintenance be performed by the manufacturer (or
23 distributor) or other persons specifically licensed by the NRC or an Agreement State to perform
24 such services. Applicants seeking authorization to perform non-routine maintenance should
25 develop and submit specific procedures for review if they do not have access to the
26 manufacturer's or distributor's procedures. See Appendix K for more information.

27
28 Use of replacement parts (non-safety related):

29
30 If an identical original equipment manufacturer (OEM) replacement part cannot be obtained and
31 the maintenance activity does NOT involve work:

- 32 • on the sealed source(s) shielding,
33 • on the source(s) driving unit,
34 • on other electrical or mechanical component that could expose the source, or:
35 • would reduce the shielding around the source(s),
36 • could compromise the radiation safety of the device or the source(s),

37 the service provider may substitute a non-OEM part provided that it has the same form, fit, and
38 function and this new part does not invalidate the Sealed Source and Device Registration
39 Certificate.

40
41 **EXAMPLE:** Replacement Parts NOT critical to the safe operation.

1 A light bulb on the device is not working. The service provider should replace the bulb but does
2 not obtain an OEM bulb. Instead, the service provider obtains a bulb from a local vendor retail
3 store. The bulb is the same wattage and similar in size. The bulb can fit into the socket. When
4 installed, the bulb is operational. The service provider ensures that the bulb met the form, fit
5 and function test. If the bulb was needed to illuminate red as an indicator warning light on the
6 device, the service provider should make sure that the bulb met that function, since the
7 instruction user manual may have pictures or diagrams indicating what to do if a red light is
8 illuminated. Again, the service provider should perform a form, fit and function test to ensure that
9 the device functioned accordingly.

10
11 Use of replacement parts (safety related):

12
13 If an identical OEM replacement part cannot be obtained and the maintenance does involve
14 work:

- 15 • on the sealed source(s) shielding,
- 16 • on the source(s) driving unit,
- 17 • on other electrical or mechanical component that could expose the source, or
- 18 • would reduce the shielding around the source(s), or
- 19 • could compromise the radiation safety of the device or the source(s),

20 the service provider may obtain a part from another vendor or fabricate the part. The service
21 provider should verify that the replacement part will have the commensurate form, fit, and
22 function as the original component; and provide this technical information to its customer. The
23 service provider should instruct its customer to provide the technical information to the NRC or
24 Agreement State for a safety review of the information submitted by the customer, before
25 maintenance activities occur. The service provider must have its customer obtain NRC or
26 Agreement State approval in accordance with 10 CFR 32.210 to ensure compliance with
27 radiation safety measures of the original equipment BEFORE beginning this service activity.

28
29 The NRC approval for the use of non-OEM parts that could affect the safety of the device may
30 be granted through one of two pathways: (1) approval of the use of the replacement parts as a
31 license amendment in accordance with 10 CFR 30.32(g)(1)(ii), or (2) issuance of a custom
32 sealed source and device registration to the customer of the service provider in accordance with
33 10 CFR 30.32(g)(1)(i). The safety review for the license amendment is limited in scope,
34 depending on the replacement parts involved, and is conducted by the technical staff based on
35 the existing sealed source and device registration certificate. The custom registration process
36 involves a submission, by the customer, of information similar to that submitted for a new
37 device registration, a full safety evaluation by the sealed source and device registration staff,
38 and the payment of an application fee and annual fees by the customer.

39
40 **EXAMPLE: Replacement Parts CRITICAL to safe operation**

41
42 A service provider is replacing a manually operated self-shielded irradiator with a pneumatic
43 tower assembly. The tower was fabricated by another service provider (here referred to as the
44 sub-contractor). The sub-contractor fabricates and sells a pneumatic tower to the service
45 provider. The service provider should ensure that the sub-contractor also provides essential
46 technical specifications, drawings, and other relevant information to the service provider. All of
47 the technical information including a form, fit and function assessment should be provided to the
48 customer by the service provider. The service provider should instruct the customer to send this
49 information to the regulator for a safety review. Once the safety review is complete and the

1 customer receives authorization to change the tower from manual to pneumatic operation, the
2 service provider may proceed with the replacement.

3
4 Equipment Defects

5
6 Equipment defects that could create a substantial safety hazard or equipment failures involving
7 NRC-regulated activities must be reported to the NRC in accordance with 10 CFR 21.21 and 10
8 CFR 30.50. For example, a safety interlock failure for an irradiator/calibrator and a failure of a
9 source retraction mechanism in a high dose rate (HDR) afterloader are defects that must be
10 reported to the NRC. IN 91-39, "Compliance with 10 CFR Part 21, Reporting of Defects and
11 Noncompliance," dated June 17, 1991, provides additional guidance on determining whether a
12 safety hazard exists and sample procedures for identifying and reporting defects. The
13 information notice can be found on the NRC's Generic Communications Web page under
14 Information Notices: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.

15
16 **Response from Applicant:**

17 For performance of routine maintenance, submit either of the following:

- 18 • The statement: "We will implement and maintain procedures for routine maintenance of
19 our device according to each manufacturer's (or distributor's) written recommendations
20 and instructions."

21 **OR**

- 22
23 • Alternative procedures for the NRC's review.

24
25 For performance of non-routine maintenance, submit either of the following:

- 26
27 • The statement: "We will have the device manufacturer (or distributor) or other person
28 authorized by NRC or an Agreement State perform non-routine maintenance."

29
30 **OR**

- 31
32 • Alternative procedures for the NRC's review addressing the information listed in
33 Appendix K.

34 **AND**

- 35 • If OEM replacement parts cannot be used, for sealed source shielding, the source
36 driving unit, or other electrical or mechanical component that could expose the source,
37 reduce the shielding around the source, or compromise the radiation safety of the device
38 or the source, the service must not begin until the customer has obtained NRC approval.

39
40 **Note:** Alternative procedures submitted by the applicant for performing routine maintenance will
41 be reviewed using the criteria in Appendix L. Information requested in Appendix L will be
42 reviewed on a case-by-case basis; if approved, the license will contain a specific condition
43 authorizing the licensee to perform non-routine maintenance.

1 **References:** IN 91-39, "Compliance with 10 CFR Part 21, Reporting of Defects and
2 Noncompliance," dated June 17, 1991, can be found on the NRC's Generic Communications
3 Web page under Information Notices: [http://www.nrc.gov/reading-rm/doc-collections/gen-
5 comm/](http://www.nrc.gov/reading-rm/doc-collections/gen-
4 comm/).

5 Regulatory Issue Summary 2013-01 "Use of Aftermarket Sealed Sources Registered under
6 10 CFR 32.210," issued March 12, 2013 (ADAMS Accession No. ML12313A147)

7 **8.10.10 Audit Program**

8 **Regulations:** 10 CFR 20.1101; 10 CFR 20.2102 – 20.2110; 10 CFR 21.21(a); 10 CFR 37.55;
9 and 10 CFR 71.5.

10 **Criteria:** Licensees must review the content and implementation of their radiation protection
11 programs at least annually to ensure that the program:

- 12 • is commensurate with the scope and extent of licensed activities
- 13 • is compliant with NRC and DOT regulations (as applicable)
- 14 • is compliant with the terms and conditions of the license
- 15 • maintains occupational doses and doses to members of the public ALARA
- 16 • is documented and appropriate records are maintained for the required duration

17 **Discussion:** Appendix L contains a suggested audit checklist that is specific to Service
18 Provider licensees who perform activities within the scope of this document. All areas indicated
19 in Appendix L may not be applicable to every licensee and may not need to be addressed
20 during each audit. For example, licensees do not need to address areas that do not apply to
21 their activities, and activities that have not occurred since the last audit. Generally, audits are
22 conducted at least once every 12 months.

23 The NRC encourages licensee management to conduct performance-based reviews by
24 observing work in progress, interviewing staff, and spot-checking required records. As a part of
25 the audit program, applicants should consider performing unannounced audits to determine if,
26 for example, Safe Use and Emergency Procedures are available and are being followed.

27 It is essential that, once identified, problems are corrected comprehensively and in a timely
28 manner. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and
29 Implementation of Corrective Action," provides guidance on this subject. The NRC routinely
30 reviews licensee's records to verify if appropriate corrective actions were implemented in a
31 timely manner to address recurrence. It is in the best interest of the licensee to identify potential
32 violations of regulatory requirements and take necessary steps to correct them. The NRC can
33 opt to exercise discretion and may elect not to cite the licensee for these violations if prompt and
34 effective corrective actions are implemented. For information on the NRC's use of discretion in
35 issuing a notice of violation, refer to the most recent version of NRC's enforcement documents
36 at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/>. The NRC's Enforcement Policy
37 may be found online at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>
38 and the Enforcement Manual may be found online at [http://www.nrc.gov/about-
40 nrc/regulatory/enforcement/guidance.html](http://www.nrc.gov/about-
39 nrc/regulatory/enforcement/guidance.html)

41 Licensees must maintain records of audits and other reviews of program content and
42 implementation for 3 years from the date of the record, in accordance with 10 CFR 20.2102.

1 The NRC has found audit records that contain the following information acceptable:

- 2
- 3 • date of audit
- 4 • name of person or persons who conducted the audit
- 5 • names of persons contacted by the auditor or auditors
- 6 • areas audited
- 7 • audit findings and corrective actions
- 8 • follow-up
- 9

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

12 **References:**

- 13 • Inspection Procedure 87126, "Industrial/Academic/Research Inspection Field Notes,"
14 September 2005 (ADAMS Accession No. ML052730315)
- 15 • IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective
16 Action," dated May 1, 1996, (ADAMS Accession No. 9604290193).
- 17 • Enforcement guidance and policy, available online at [http://www.nrc.gov/reading-rm/doc-](http://www.nrc.gov/reading-rm/doc-collections/enforcement/)
18 [collections/enforcement/](http://www.nrc.gov/reading-rm/doc-collections/enforcement/)

19

20 **8.10.11 Security Program for Category 1 and Category 2 Materials**

21

22 **Regulations:** 10 CFR 20.2207, 10 CFR Part 37

23

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

25

26 **Note:** The requirements in 10 CFR 20.2207 are only applicable to those licensees that
27 manufacture, transfer, receive, disassemble, or dispose of Category 1 and Category 2 sources.,
28 as specified in Appendix E to 10 CFR Part 20 . The regulations in 10 CFR Part 37, "Physical
29 Protection of Category 1 and Category 2 Quantities of Radioactive Material," apply to licensees
30 that possess an aggregate amount of category 1 or category 2 quantity of radioactive material.,
31 as specified in Appendix A to 10 CFR Part 37.

32

33 **Discussion:** The regulations in 10 CFR 20.2207 require that each licensee that manufactures,
34 transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and
35 submit an NSTS report. The NSTS is a major security initiative of the NRC. The NSTS is a
36 secure, accessible, and easy-to-use computer system that tracks high-risk radioactive sources
37 from the time they are manufactured or imported through the time of their disposal or export, or
38 until they decay enough to no longer be of concern.

39

40 In accordance with 10 CFR Part 37, "Physical Protection of Category 1 and Category 2
41 Quantities of Radioactive Material," licensees authorized to possess Category 1 or Category 2
42 quantities of radioactive material must establish, implement, and maintain a security program to
43 ensure physical protection of the radioactive material. For additional guidance implementing
44 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for
45 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive
46 Material."

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

5
6 If licensees possess, ship, or receive quantities of material exceeding Category 1, then they
7 must also comply with requirements specific to Category 1 quantities. Refer to 10 CFR Part 37
8 for these additional requirements.

9
10 Per 10 CFR Part 37, Subpart B, licensees must establish an access authorization program to
11 ensure that individuals who have unescorted access to Category 1 and 2 quantities of
12 radioactive material and reviewing officials are trustworthy and reliable.

13
14 Per 10 CFR Part 37, Subpart C, licensees must establish a physical protection program to
15 monitor and, without delay, detect, assess, and respond to any actual or attempted
16 unauthorized access to Category 1 or Category 2 quantities of radioactive material in use or
17 storage.

18
19 Per 10 CFR Part 37, Subpart D, licensees must provide for physical protection of Category 1 or
20 Category 2 quantity of radioactive materials in transit. These requirements apply to a person
21 delivering material to a carrier for transport, as well as cases in which the person transports
22 material.

23
24 **Note:** Refer to 10 CFR Part 37 and associated guidance in NUREG-2155 for additional details
25 on security guidance.

26
27 **Response from Applicant:** No response is required from an applicant or licensee that would
28 become newly subject to 10 CFR Part 37.

29 30 **8.11 Item 11: Waste Management**

31 **Regulations:** 10 CFR 20.1904, 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003,
32 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2008;
33 10 CFR 20.2108, 10 CFR 30.51, 10 CFR Part 20 Appendix G, 10 CFR Part 61.

34
35 **Criteria:** Radioactive waste must be managed and disposed of in accordance with regulatory
36 requirements and license conditions. Appropriate records of waste disposal must be
37 maintained.

38 **Discussion:** This section applies to service providers who generate radioactive waste as a
39 result of services operations, or provide waste management services to customers. Waste
40 management service may include, but is not limited to, commercial incineration, compaction,
41 solidification/vitrification, and packaging, repackaging, and transportation of radioactive waste.
42 Service providers who perform these activities as a service to other licensees should also refer
43 to Section 8.10.1, "Operating and Emergency Procedures."

44 Radioactive waste generated or handled when conducting licensed activities may include
45 contaminated samples, sealed sources, and unusable items contaminated with radioactive
46 material (e.g., absorbent paper, gloves, filters, tools). You may also be called upon to package
47 radioactive waste at customer facilities for disposal.

1 Service providers may not receive radioactive waste from other licensees for processing,
2 storage, or disposal, unless specifically authorized to do so by the NRC. If customers wish to
3 dispose of radioactive waste including sealed sources, service provider licensees may assist
4 them only by transferring licensed material to any person authorized to possess these materials.
5 Individuals authorized to possess materials include:

- 6 • the original manufacturer
- 7 • the distributor
- 8 • commercial firms licensed by the NRC or an Agreement State to accept radioactive
9 waste from other persons, or another specific licensee authorized to possess the
10 licensed material

11 All radioactive waste must be stored in appropriately labeled containers until it is disposed.
12 During the period between storage and disposal, container integrity must be assured. All
13 radioactive waste must be secured against access or removal by unauthorized personnel.
14 Licensees may implement procedures to reduce the volume of radioactive waste for final
15 disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures
16 include volume reduction by segregating, consolidating, compacting, or allowing certain waste
17 to decay-in-storage (DIS). Waste compaction or other treatments can reduce the volume of
18 radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne
19 radioactivity) to workers and members of the public. The program should include adequate
20 safety procedures to protect workers, members of the public, and the environment.

21
22 In accordance with 10 CFR 20.2001, all licensees must dispose of radioactive waste through
23 one of the following methods:

- 24 • DIS
- 25 • release into sanitary sewerage
- 26 • transfer to an authorized recipient
- 27 • extended interim storage
- 28 • disposal of waste as if it were not radioactive (specific wastes)
- 29 • release in effluents to unrestricted areas, other than into sanitary sewerage
- 30 • obtaining prior approval from the NRC of an alternate method

31 With service provider licensees, the NRC's experience is that most dispose of radioactive waste
32 by transfer to an authorized recipient(s). Applicants requesting authorization to dispose of
33 radioactive waste by incineration should refer to Policy and Guidance Directive PG 8-10,
34 "Disposal of Incinerator Ash as Ordinary Waste," dated January 1997.
35

Note: Compliance with NRC regulations does not relieve a licensee for the responsibility of complying with any other applicable Federal, State, or local regulations. Furthermore, some radioactive waste called "mixed waste" may include additional hazards (e.g., biohazard or chemical hazard). The storage and disposal of "mixed waste" must also comply with all other applicable Federal, State, and local regulatory requirements.

36
37 Applicants should describe their radioactive waste management program. This program should
38 include procedures for handling and storing, characterization and minimization, and disposal of
39 radioactive waste. Appropriate training should be provided to waste handlers. In accordance
40 with 10 CFR 20.2108, licensees must maintain all appropriate records of radioactive waste
41 disposal. The U.S. Environmental Protection Agency (EPA) issued guidance for development of

1 a comprehensive program to reduce hazardous waste, including radioactive waste. The NRC
2 transmitted these guidelines to licensees in IN 94-23, "Guidance to Hazardous, Radioactive,
3 and Mixed Waste Minimization Program," dated March 25, 1994.

4 **Disposal by Decay-in-storage**

5 Materials with half-lives of less than or equal to 120 days may be disposed of by DIS. The
6 minimum holding period of the waste should be based on the longest lived half-life in the waste.
7 Such waste may be disposed of as ordinary trash if radiation surveys (performed in a low
8 background area and without any interposed shielding) of the waste at the end of the holding
9 period indicate that radiation levels are indistinguishable from background. All radiation labels
10 must be defaced or removed from containers and packages prior to disposal as ordinary trash,
11 in accordance with 10 CFR 20.1904(b). If the decayed waste is compacted, all labels that are
12 visible in the compacted mass must also be defaced or removed.

13 Procedures for management of waste being held for DIS should include methods of segregation
14 according to half-life, surveys prior to disposal, and maintenance of records of disposal.
15 Records should include the date when the waste was put in storage for decay, date of disposal,
16 and results of final survey before disposal as ordinary trash. Appendix M provides a model
17 procedure for disposal of radioactive waste by DIS that incorporates the above guidelines.

18 **Release into Sanitary Sewerage**

19 Regulations in 10 CFR 20.2003, "Disposal by release into sanitary sewerage, "authorize
20 disposal of radioactive waste by release into a public sanitary sewerage system if each of the
21 following conditions is met:

- 22 • Material is readily soluble (or is easily dispersible biological material) in water.
- 23 • Quantity of licensed material that the licensee releases into the sewer each month averaged
24 over the monthly volume of water released into the sewer does not exceed the concentration
25 specified in 10 CFR Part 20, Appendix B, Table 3.
- 26 • If more than one radioisotope is released, the sum of the ratios of the average monthly
27 discharge of a radioisotope to the corresponding limit in 10 CFR Part 20, Appendix B,
28 Table 3, cannot exceed unity.
- 29 • Total quantity of licensed material released into the sanitary sewerage system in a year does
30 not exceed 185 gigabecquerel (GBq) (5 Ci) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci)
31 of all other radioisotopes combined.

32 Licensees are responsible to demonstrate that licensed materials discharged into the public
33 sewerage system are indeed readily soluble in water. NRC IN 94-07, "Solubility Criteria for
34 Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR 20," dated
35 January 1994, provides acceptable criteria for evaluating solubility of liquid waste. Liquid
36 scintillation media and ash are examples of material that may or may not be "readily
37 dispersible." Careful consideration should be given to the possibility of reconcentration of
38 radioisotopes that are released into the sewer. The NRC alerted licensees to the potentially
39 significant problem of reconcentration of radionuclides released to sanitary sewerage systems in
40 IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage
41 Systems Permitted under 10 CFR 20.303 (now 10 CFR 20.2003)," dated December 1984.

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

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

13 **Incineration**

14 Applicants that wish to treat or dispose of licensed material by incineration must comply with the
15 requirements of 10 CFR 20.2004, "Treatment or disposal by incineration." You do not need
16 specific NRC approval in order to incinerate certain categories of radioactive waste. For
17 example, 10 CFR 20.2005, "Disposal of specific wastes," provides that tritium and carbon-14 in
18 low-level concentrations in liquid scintillation media and animal tissue may be disposed of
19 without regard to radioactivity. Policy and Guidance Directive PG 8-10, "Disposal of Incinerator
20 Ash as Ordinary Waste," dated January 1997, provides guidance on the disposal of ash.

21
22 Applicants that are considering disposal of radioactive material by incineration should review
23 Regulatory Guide (RG) 8.37, "ALARA Levels for Effluents from Materials Facilities," dated
24 July 1993. RG 8.37 deals with the application of ALARA in controlling gaseous and liquid
25 effluents and references documents containing acceptable methods of effluent monitoring.

26
27 After you review your program and confirm that you have waste that requires specific NRC
28 approval for incineration, a description of the procedures used to incinerate waste should be
29 provided. A model program for disposal of radioactive waste by incineration is described in
30 Appendix M.

31
Note: Incinerators must also be authorized by other Federal, State, and local authorities to
operate.

32 33 **Compaction**

34 Licensees may implement procedures to reduce the volume of radioactive waste for final
35 disposal in an authorized LLW disposal facility. These procedures include volume reduction by
36 segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste
37 compaction or other treatments can reduce the volume of radioactive waste, but such processes
38 may pose additional radiological hazards (e.g., airborne radioactivity or increased radiation
39 levels) to workers, members of the public, and the environment. Safety procedures to address
40 these concerns should be implemented. A model program for disposal of radioactive waste by
41 compaction is described in Appendix M.

42

1 **Transfer to an Authorized Recipient**

2 When transferring radioactive waste, it is the licensee's responsibility to verify that the intended
3 recipient is authorized to receive the radioactive waste prior to making any shipment. The
4 radioactive waste must be packaged in approved containers for shipment, and each container
5 must identify the radioisotopes and the amounts contained in the waste. Additionally, packages
6 must comply with the requirements of the particular burial site's license and state requirements.
7 Each shipment must comply with all applicable NRC and DOT requirements. In some cases,
8 the waste handling contractor may provide guidance to the licensee for packaging and
9 transportation requirements; however, the licensee is ultimately responsible for ensuring
10 compliance with all applicable regulatory requirements.

11 The shipper must provide all information required in the NRC's Uniform Low-Level Radioactive
12 Waste Manifest, and transfer this recorded manifest information to the intended recipient in
13 accordance with 10 CFR Part 20, Appendix G, "Requirements for Transfers of Low-Level
14 Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests."
15 Each shipment manifest must include a certification by the waste generator, as specified in
16 Section II of the appendix. Each person involved in the transfer for disposal and disposal of
17 waste, including waste generator, waste collector, waste processor, and disposal facility
18 operator, must comply with requirements specified in Section III, "Control and Tracking," of
19 Appendix G.

20 Licensees should implement procedures to reduce the volume of radioactive waste for final
21 disposal in an authorized LLW disposal facility. These procedures include volume reduction by
22 segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste
23 compaction or other treatments can reduce the volume of radioactive waste, but such processes
24 may pose additional radiological hazards (e.g., airborne radioactivity) to workers and members
25 of the public. The program should include adequate safety procedures to protect workers,
26 members of the public, and the environment.

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

27
28 **Disposal of Specific Waste as if It Were Not Radioactive**

29 In accordance with 10 CFR 20.2005, the following radioactive wastes may be disposed of as
30 non-radioactive waste:

- 31 • liquid scintillation media (including vials and other items contaminated with liquid scintillation
32 media) containing no more than 1.85 kBq (0.05 mCi) of H-3 or C-14 per gram of the medium
33 • animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 mCi) of H-3 or
34 C-14 per gram averaged over the weight of the entire animal

35 Applicants must have procedures that will ensure that the above limits are not exceeded and
36 that the disposal of animal tissue or carcasses containing licensed material is in a manner that
37 will not permit their use either as food for humans or animals. Applicants must maintain
38 accurate records of these disposals, in accordance with 10 CFR 20.2108.

1 **Extended Interim Storage**

2 Some licensees do not have an LLW disposal facility available to them and therefore must use
3 onsite interim storage until such time that a facility becomes available. Licensees should
4 exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site
5 extended interim storage of radioactive waste only as a last resort. The protection of workers
6 and the public is enhanced by disposal rather than storage of waste. Licensees may also find it
7 more economical to dispose of radioactive waste than to store it on-site because as the
8 available capacity decreases, the cost of disposal of radioactive waste may continue to
9 increase. Other than DIS, LLW should be stored only when disposal capacity is unavailable and
10 for no longer than is necessary. NRC IN 90-09, "Extended Interim Storage of Low-Level
11 Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 5, 1990, provides
12 guidance to licensees for requesting an amendment to authorize extended interim storage of
13 LLW.

14 **Alternate Methods**

15 Applicants may also request alternate methods for the disposal of radioactive waste generated
16 at their facilities. Such requests must describe the waste containing licensed material, including
17 the physical and chemical properties that may be important to assess risks associated with the
18 waste, and the proposed manner and conditions of waste disposal, in accordance with 10 CFR
19 20.2002. Additionally, the applicant must submit its analysis and evaluation of pertinent
20 information on the nature of the environment, nature and location of other affected facilities, and
21 operating and emergency procedures to ensure that radiation doses are maintained ALARA and
22 within regulatory limits.

23 **Response from Applicant:**

- 24 • A statement that: "We will use the model waste procedures published in Appendix M of
25 NUREG-1556, Volume 18, Revision 1 'Consolidated Guidance about Materials Licenses:
26 Program-Specific Guidance About Service Provider Licenses,'"
27

28 **OR**

- 29
30 • If the applicant wishes to use only selected model procedures, provide a statement that:
31 "We will use the model waste procedures that are published in Appendix M of NUREG-
32 1556, Volume 18, Revision 1 'Consolidated Guidance About Materials Licenses: Program-
33 Specific Guidance About Service Provider Licenses.'" (Specify either (1) DIS, (2) disposal of
34 liquids into sanitary sewerage, (3) incineration, or (4) compaction.)
35

36 **OR**

- 37
38 • Provide procedures for waste management by any of the methods described in this section.
39 Applicants should contact appropriate regional office of the NRC for guidance to obtain
40 approval of any method(s) of waste disposal other than those discussed in this section.
41

42 **OR**

- 1 • If access to a radioactive waste burial site is unavailable, the applicant should request
2 authorization for extended interim storage of waste. Applicant should refer to NRC
3 IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and
4 Materials Licensees," dated February 1990, for guidance when requesting extended
5 storage.

6
7 Alternative responses will be reviewed using the criteria listed above.

8
9 **References:** See the notice of availability on the inside front cover of this report to obtain
10 copies of:

- 11 • Policy and Guidance Directive (P&GD) 94-05, "Updated Guidance on Decay-in-Storage,"
12 dated February 1995 (ML060320644).
- 13 • Information Notice (IN) 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste
14 Minimization Program," dated March 1994 (ML9403160172).
- 15 • IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the
16 Revised 10 CFR 20," dated January 1994 (ML9401240059).
- 17 • IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage
18 Systems Permitted under 10 CFR 20.303 (now 10 CFR 20.2003)," dated December 1984.
- 19 • IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and
20 Materials Licensees," dated February 1990.
- 21 • All Agreement State Letter SP-97-056, dated August 1997, "Technical, Solubility Criteria."
22 INs are available on NRC's Web site at <http://www.nrc.gov>.

23
24

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

25 26 **8.12 Item 12: Fees**

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

29
30 Direct all questions about NRC fees or completion of Item 12 on NRC Form 313 to the Office of
31 the Chief Financial Officer at NRC headquarters in Rockville, MD, (301) 415-7554. Information
32 about fees may also be obtained by calling the NRC's toll-free number, (800) 368-5642,
33 extension 415-7554. The e-mail address is Fees.Resource@nrc.gov.

34
35 **Note:** Applicants who wish to perform service operations (e.g., licensees that will repackage
36 radioactive wastes) that require an environmental assessment should review 10 CFR Part 51
37 (particularly 10 CFR 51.30, 51.60, and 51.66) for further information concerning the
38 environmental information needed by NRC to prepare an environmental assessment.
39 Environmental assessments are full-cost recovery items under 10 CFR Part 170. Full cost will
40 be determined based on the professional staff time and appropriate staff time expended as
41 described in footnote e.3. to 10 CFR 170.31.

Note: 10 CFR 51.22(c)(14)(xii) grants a categorical exclusion for the acceptance of packaged radioactive wastes from others for transfer to licensed land burial facilities provided the interim storage period for any package does not exceed 180 days and the total possession limit for all packages held in interim storage at the same time does not exceed 50 curies.

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8.13 Item 13: Certification

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

Notes:

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

9. AMENDMENTS AND RENEWALS TO A LICENSE

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109(a), 10 CFR 30.36(a), 10 CFR 40.42(a), 10 CFR 70.38(a)).

Applicants for license amendment or renewal should do the following:

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

9.1 Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b)

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

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

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses or Agreement State licenses.
- Materials are properly handled and secured.
- Persons using these materials are competent and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material.
- Public health and safety are not compromised by the use of such materials.

- 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, for more information
- 3 about transfer of ownership.

10. APPLICATIONS FOR EXEMPTIONS

Regulations: 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 30.11, 10 CFR 40.14, 10 CFR 70.17

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

Discussion: Various sections of the NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, "Application for exemptions"; 10 CFR 20.2301, "Applications for exemptions"; 10 CFR 30.11, "Specific exemptions"; 10 CFR 40.14, "Specific exemptions"; 10 CFR 70.17, "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. Exemption requests must be accompanied by descriptions of the following:

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

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

11. TERMINATION OF ACTIVITIES

Regulations: 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36(d), 10 CFR 30.36(j)(1), 10 CFR 30.51(f), 10 CFR 40.36(f), 10 CFR 40.42, 10 CFR 40.61(d), 10 CFR 70.25(g), 10 CFR 70.38, 10 CFR 70.51(b), 10 CFR 70.78.

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 licensed activities at the entire site.
 - For licensees subject to 10 CFR 30.36, a decision to permanently cease licensed activities in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements.
 - For licensees subject to 10 CFR 40.42 or 10 CFR 70.38, a decision to permanently cease licensed activities in any separate building or outdoor area.
 - No principal activities under the license have been conducted for a period of 24 months.
 - No principal activities having 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 to the appropriate NRC regional office a completed NRC Form 314, "Certificate of Disposition of Materials" (or equivalent information), and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final leak tests, final status survey, if applicable).
- Before a license is terminated, send the records important to decommissioning to the appropriate NRC regional office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), 10 CFR 40.61(d) and/or 10 CFR 70.51(b), transfer records important to decommissioning to the new licensee in accordance with 10 CFR 30.35(g), 10 CFR 40.36(f), 10 CFR 70.25(g).

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

1 For guidance on the disposition of licensed material, see Section 8.11, "Waste Management."
2 For guidance on decommissioning records, see Section 8.5.3, "Recordkeeping for
3 Decommissioning."
4

5 **Response from Applicant:** The applicant is not required to submit a response to the NRC
6 during the initial application. The licensee's obligations in this matter begin when the license
7 expires or at the time the licensee ceases operations, whichever is earlier. These obligations
8 are to undertake the necessary decommissioning activities, to submit NRC Form 314 or
9 equivalent information, and to perform any other actions summarized in "Criteria" above.
10

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

APPENDIX A

U.S. NUCLEAR REGULATORY COMMISSION FORM 313

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Appendix A 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>(03-2014) 10 CFR 30, 32, 33, 34 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 internet 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: 05/31/2015		
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.		
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001 ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713	IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352 ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511	
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.		
1. THIS IS AN APPLICATION FOR <i>(Check appropriate item)</i> <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____	2. NAME AND MAILING ADDRESS OF APPLICANT <i>(Include ZIP code)</i> _____ _____ _____	
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED _____ _____ _____	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION _____ BUSINESS TELEPHONE NUMBER _____ BUSINESS CELLULAR TELEPHONE NUMBER _____ BUSINESS EMAIL ADDRESS _____	
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.		
5. RADIOACTIVE MATERIAL a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. _____ _____	
8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.	7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE. _____ _____	
10. RADIATION SAFETY PROGRAM.	9. FACILITIES AND EQUIPMENT. _____ _____	
12. LICENSE FEES <i>(Fees required only for new applications, with few exceptions*)</i> <small>(See 10 CFR 170 and Section 170.31)</small>	11. WASTE MANAGEMENT. _____ _____	
FEE CATEGORY <input type="text"/> AMOUNT ENCLOSED \$ <input type="text"/>		
13. CERTIFICATION. <i>(Must be completed by applicant)</i> THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.		
CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE _____ _____	SIGNATURE _____ _____	DATE _____
FOR NRC USE ONLY		
TYPE OF FEE APPROVED BY _____	FEE LOG _____	FEE CATEGORY _____
AMOUNT RECEIVED \$ _____	CHECK NUMBER _____	COMMENTS _____ _____
DATE _____		

6

APPENDIX B

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

1 **Appendix B Suggested Format for Providing Information Requested in**
2 **Items 5 through 11 of NRC Form 313**

3
4 Appendix B is designed to be used for all types of applicants requesting a service provider
5 license. This appendix is divided into three categories of applications based on the risk
6 significance of the proposed activity. Refer to Section 1, "Purpose of the Report," for examples
7 of activities that are categorized as low or high risk significance. Using this appendix
8 successfully requires the applicant to do an initial review of the NUREG and the license
9 application, and then determine the level of risk of the proposed activity. Once the level of risk
10 is determined, the applicant should use the corresponding application checklist for the highest
11 risk of the proposed activities (low or high risk). The next step is to select the individual
12 elements in the selected application checklist that apply to the types of service(s) requested.
13 Highlight or circle Item Nos., or in some other way identify the areas that require specific
14 information. Provide the information on the specific elements that you identified as requiring
15 input for obtaining authorization for the requested services.

16
17 After selecting the applicable items that need to be addressed, refer to the corresponding
18 sections in the NUREG. It is necessary for applicants to provide the level of detail required for
19 the individual types of service(s) requested in the application. Note that providing information
20 for very limited licenses (e.g., leak test service provider) requires less information than would be
21 required for a commercial nuclear laundry or a waste management license. Applicants for
22 service provider licenses requiring authorization for types and quantities of material specific for
23 broad scope licenses should refer to NUREG-1556, Vol. 11, "Consolidated Guidance about
24 Material Licenses: Program-Specific Guidance about Licenses of Broad Scope." Applicants for
25 service provider licenses requiring authorization for research and development should refer to
26 NUREG-1556, Vol. 7, "Consolidated Guidance about Material Licenses: Program-Specific
27 Guidance about Academic, Research and Development, and Other Licenses of Limited Scope."
28

29 **Possession or Use Incidental to Performing All Activities as a Commercial Service**
30 **Provider**

31
32 **All applicants should complete Tables B.1 through B.3. In addition, applicants that will**
33 **only be performing the activities listed under the low risk uses should also complete**
34 **Table B.4. If an applicant will be performing any of the uses listed as high risk, then**
35 **Table B.5 should be completed.**

1 **Table B.1 Items 5 & 6: Unsealed Radioactive Materials To Be Possessed and Proposed**
 2 **Uses**

Unsealed Radionuclide	Chemical or Physical Form				Total Activity Requested	Use Code*
	<input type="checkbox"/> Gas	<input type="checkbox"/> Liquid	<input type="checkbox"/> Solid	<input type="checkbox"/> Other: Specify		
	<input type="checkbox"/> Gas	<input type="checkbox"/> Liquid	<input type="checkbox"/> Solid	<input type="checkbox"/> Other: Specify		
	<input type="checkbox"/> Gas	<input type="checkbox"/> Liquid	<input type="checkbox"/> Solid	<input type="checkbox"/> Other: Specify		
	<input type="checkbox"/> Gas	<input type="checkbox"/> Liquid	<input type="checkbox"/> Solid	<input type="checkbox"/> Other: Specify		
	<input type="checkbox"/> Gas	<input type="checkbox"/> Liquid	<input type="checkbox"/> Solid	<input type="checkbox"/> Other: Specify		

3
 4 Is the applicant going to possess, or take possession from its clients of, unsealed radionuclides?
 5 Provide a response and explain.
 6 Yes No Explain:

7
 8 **Table B.2 Items 5 & 6: Sealed Radioactive Materials To Be Possessed and Proposed Uses**

Radionuclide (Sealed Source)	Device Manufacturer and Model No.	Sealed Source Device Registration No.	Maximum Activity per Source	Total Source Activity	Use Code

9
 10 Is the applicant going to possess, or take possession from its clients of, sealed radionuclides
 11 and/or devices? Provide a response and explain.
 12 Yes No Explain:

13 **Table B.3 Items 5 & 6: Source and Special Nuclear Materials To Be Possessed and**
 14 **Proposed Uses**

Source Material				
	Material	Mass	Activity	Use Code*
<input type="checkbox"/>	Depleted Uranium	Kilograms	mCi	
<input type="checkbox"/>	Uranium-238	Grams	mCi	
<input type="checkbox"/>	Thorium-232	Grams	mCi	
<input type="checkbox"/>	Other: Specify	Grams	mCi	
Special Nuclear Material				
<input type="checkbox"/>	Uranium-234	Grams	mCi	
Special Nuclear Material				

	Material	Mass	Activity	Use Code*
<input type="checkbox"/>	Uranium-235	Grams	mCi	
<input type="checkbox"/>	Plutonium-238	Grams	mCi	
<input type="checkbox"/>	Plutonium-239	Grams	mCi	

1 * **PURPOSE/USE CODE FOR WHICH LICENSED MATERIAL WILL BE POSSESSED OR**
2 **USED**

3
4 **Low Risk Activities (Complete Table B.4):**

- 5 A. Analysis of Leak Test Samples (no collection)
6 B. Analysis of Environmental Samples (no collection)
7 C. Sample Collection and Analysis of Leak Tests
8 D. Sample Collection and Analysis of Environmental Samples
9 E. Calibration of instrument/dosimeter using low activity sources
10 F. Service/repair of gas chromatographs, X-ray fluorescence analyzers, and/or similar
11 devices
12 G. Training/instruction to individuals on radiation safety related topics
13 H. other low risk services not identified above, where radioactive material is used for
14 commercial service activities

15
16 **High Risk Activities (Complete Table B.5):**

- 17 I. Service and/or repair of portable nuclear gauges (including removal of source rod)
18 J. Service and/or repair of fixed gauges
19 K. Service and/or repair of fixed gauges mounted on a mobile object like a truck or railcar
20 L. Storage of radioactive material for other entities
21 M. Use of unsealed material in tracer studies (example: use inside pipes in a refinery)
22 N. Use of remote activated robotics in radioactive contaminated areas
23 O. Calibration of survey instruments and personnel dosimetry equipment as a service for
24 others.
25 P. Installation, radiation surveys, routine and preventive maintenance, adjustment or repair
26 of high dose rate (HDR) remote afterloaders, teletherapy, or gamma stereotactic
27 radiosurgery units that require access to the sealed source(s), driving units, or other
28 electronic components that could expose the sealed source, reduce the shielding, or
29 compromise the radiation safety of the device or safety systems.
30 Q. Installation, relocation, removal from service, disposal, radiation surveys, routine or
31 preventive maintenance, adjustment, training or repair of:
32 (1) self shielded irradiators (ANSI Category I irradiators).
33 (2) 10 CFR Part 36 irradiators (ANSI Categories II, III and IV irradiators)
34 R. Nuclear laundry services
35 S. Retrieval of industrial radiography sealed sources
36 T. Decontamination and decommissioning services (NUREG-1757, Volume 1)
37 U. Waste management services including: packaging and repackaging of radioactive
38 waste for transportation, commercial incineration, compaction, super compaction,
39 solidification or vitrification
40 V. Other high risk services not identified above, excluding activities involving critical mass
41 quantities of special nuclear material.

1 If you desire to perform tracer/field studies in which licensed material is deliberately released to
 2 the environment, please provide the following information:

- 3 • A complete application describing the type and amount of material to be used, the
 4 location of use, and training and experience of the individual using the material.
- 5 • A copy of your operating and emergency procedures.
- 6 • A description of the amount of radioactive material to be released in the field,
 7 decontamination procedures at the conclusion of the experiment, if appropriate, and
 8 procedures for minimizing releases.
- 9 • A description of the expected radiation dose to humans.
- 10 • A sample agreement letter between you and your customer acknowledging the use of
 11 radioactive materials at the customer's site.
- 12 • A letter from the appropriate state health authorities indicating that they have reviewed
 13 your application and concur with your request.

14 **Possession and/or Use Incidental to Performing Low Risk Activities as a Commercial**
 15 **Service Provider**

16
 17 **Table B.4 Items 5.3 through 11: Training and Experience, Facilities and Equipment,**
 18 **Radiation Safety Program, and Waste Disposal for Low Risk Activities**

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
RADIOACTIVE MATERIAL					
5.3	Recordkeeping For Decommissioning "Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g), we shall maintain drawings and records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred, or assign the records to the appropriate NRC regional office before the license is terminated."	<input type="checkbox"/>			
5.4	Financial Assurance Financial assurance is not required for most service provider applicants. If the applicant is going to possess radioactive material but wants to keep the possession limits below the requirements for financial assurance, commit to the following statement by checking "Yes." If the applicant is				

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
5.4	<p>Financial Assurance (Cont.)</p> <p>not going to possess licensed material, check "N/A."</p> <p>"We shall restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b) and/or 70.25(c) for establishing decommissioning financial assurance."</p> <p>If financial assurance is required, submit evidence of financial assurance following the guidance in NUREG-1757, Volume 3, Rev. 1.</p>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
5.5	<p>Emergency Plans</p> <p>The applicant is not required to submit a response to emergency plans during the licensing process.</p>	No response is necessary for this section.			
7	<p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE</p>				

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
7.1	<p>Radiation Safety Officer Name of the proposed radiation safety officer (RSO) who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.</p> <p style="text-align: center;">AND</p> <p>Demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position, demonstrating day-to-day oversight of the radiation safety activities.</p> <p style="text-align: center;">AND</p> <p>Confirm that the RSO will be available for emergencies and can be on-site within 24-48 hours, if applicable.</p> <p style="text-align: center;">AND EITHER</p> <p>Provide the specific training and experience of the RSO, and include the specific dates of training in radiation safety.</p> <p style="text-align: center;">OR</p> <p>Provide alternative information demonstrating that the proposed RSO is qualified by training and experience (e.g., Board Certification by the American Board of Health Physicists, completion of a bachelor's and/or master's degree in the sciences with at least one year of experience in the conduct of a radiation safety program of comparable size and scope).</p>				<p style="text-align: right;"><input type="checkbox"/></p>

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
10 10.1	<p>Radiation Safety Program</p> <p>Operating and Emergency Procedures</p> <p>Low-risk licensed activities do not require the submission of operating procedures.</p> <p>Submit emergency procedures for all likely scenarios that might be encountered specific to the scope and size of your radiation safety program.</p>				<input type="checkbox"/>
10.2	<p>Material Receipt and Accountability</p> <p>“Physical inventories will be conducted at intervals not to exceed 6 months, to account for specifically licensed material and devices received and possessed under the license. Records of inventory shall be maintained for a period of 5 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer’s name and/or model numbers, and the date of the inventory.”</p> <p style="text-align: center;">OR</p> <p>A description of the procedures for ensuring that no specifically licensed material and devices have been lost, stolen, or misplaced.</p>	<input type="checkbox"/>			

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
10.2	<p>Material Receipt and Accountability (Cont.)</p> <p>AND</p> <p>“We will comply with the NSTS reporting requirements as described in 10 CFR 22.2207.”</p> <p>No response is needed from applicants for package opening procedures. Package opening procedures will be reviewed during NRC inspections.</p>				
10.3	<p>Radiation Monitoring Instruments</p> <p>Describe the instrumentation that will be used to perform the required radiological surveys and state that: “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F of NUREG-1556, Volume 18, Revision 1 ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.’ We reserve the right to upgrade our survey instruments as necessary.”</p>	<input type="checkbox"/>		<input type="checkbox"/>	

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
10.3	<p>Radiation Monitoring Instruments (Cont.)</p> <p style="text-align: center;">OR</p> <p>Describe the instrumentation that will be used to perform the required radiological surveys and state that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix F of NUREG-1556, Volume 18, Revision 1 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.' Additionally, we will implement the model survey meter calibration program published in Appendix F of NUREG-1556, Volume 18, Revision 1 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.' We reserve the right to upgrade our survey instruments as necessary."</p>	<input type="checkbox"/>		<input type="checkbox"/>	

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
10.3	<p>Radiation Monitoring Instruments (Cont.)</p> <p style="text-align: center;">OR</p> <p>A description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. Include the statement: "We reserve the right to upgrade our survey instruments as necessary" in your response.</p>	<input type="checkbox"/>		<input type="checkbox"/>	
10.4	<p>Surveys</p> <p>"We will conduct surveys and maintain contamination levels in accordance with the survey frequencies and contamination levels in accordance with the criteria in the section entitled "Surveys" in NUREG-1556, Volume 18, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."</p> <p style="text-align: center;">OR</p> <p>Submit description of alternative survey method and frequency for demonstrating how to evaluate a radiological hazard.</p>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
10.11	<p>Security Program for Category 1 and Category 2 Materials</p> <p>Licensees must ensure the security and control of licensed material.</p> <p>The regulations in 10 CFR 20.1801 and 10 CFR 20.1802 require licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage. In addition, 10 CFR Part 37 describes increased security measures for certain types and amounts of radioactive material.</p>	<p>No response is required from an applicant or licensee conducting low risk activities that would not be subject to 10 CFR Part 37.</p>			
11	<p>Waste Management</p> <p>“We will use the model waste procedures published in Appendix M of NUREG-1556, Volume 18, Revision 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.’”</p> <p style="text-align: center;">OR</p>	<input type="checkbox"/>		<input type="checkbox"/>	

1 **Possession and/or Use Incidental to Performing High Risk Activities**
 2 **as a Commercial Service Provider**

3
 4 **Table B.5 Items 5.3 through 11: Training and Experience, Facilities and Equipment,**
 5 **Radiation Safety Program, and Waste Disposal for High Risk Activities**

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
RADIOACTIVE MATERIAL					
5.3	Recordkeeping For Decommissioning “Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g), we shall maintain drawings and records important to decommissioning and to transfer these records to an NRC or Agreement State licensee before licensed activities are transferred, or to assign the records to the appropriate NRC regional office before the license is terminated.”	<input type="checkbox"/>			
5.4	Financial Assurance Financial assurance is not required for most service provider applicants. If the applicant is going to possess radioactive material but wants to keep the possession limits below the requirements for financial assurance, commit to the following statement: “We shall restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d), 40.36(b) and/or 70.25(c) for establishing decommissioning financial assurance.” <p style="text-align: center;">OR</p> If financial assurance is required, submit evidence of financial assurance following the guidance in NUREG-1757, Volume 3, Rev. 1.	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
5.5	<p>Emergency Plans</p> <p>If an emergency plan is required as described in 10 CFR 30.72, provide either:</p> <p>An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or</p> <p>An emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3).</p>			<input type="checkbox"/>	<input type="checkbox"/>
7	<p>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE</p>				
7.1	<p>Radiation Safety Officer</p> <p>Name of the proposed RSO who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.</p> <p style="text-align: center;">AND</p>				<input type="checkbox"/>

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
9	<p data-bbox="358 338 711 369">Facilities And Equipment</p> <p data-bbox="358 405 948 604">For service providers performing the high-risk activities that will not take possession of radioactive material, provide the location where these services will be performed. Also indicate if services will be performed at temporary job sites.</p> <p data-bbox="639 621 683 653" style="text-align: center;">OR</p> <p data-bbox="358 669 932 835">For those services listed in the high-risk group who will have permanent facilities specifically identified on the license, provide the following information as applicable to the service you intend to perform:</p> <ol data-bbox="370 905 954 1675" style="list-style-type: none"> 1. Drawing or sketch of the proposed permanent facility. Indicate the scale, or include dimensions on each drawing or sketch. The same scale should be used for all sketches and drawings. The recommended scale is 1/4 inch = 1 foot. Drawings to this scale that do not fit on 8-1/2 x 11-inch paper may be provided as sectional drawings; 2. Identify area(s) assigned for the receipt, storage, security, preparation, handling, waste storage and measurement of radioactive materials including sealed sources and devices; 3. Show distance between restricted areas and adjacent unrestricted areas; 4. Specify shielding materials (e.g., concrete, lead,) and means for securing radioactive materials from unauthorized removal; 				<p data-bbox="1308 405 1333 436" style="text-align: center;"><input type="checkbox"/></p> <p data-bbox="1308 636 1333 667" style="text-align: center;"><input type="checkbox"/></p>

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
9	<p>Facilities And Equipment (Cont.)</p> <p>5. Illustrate area(s) where explosive, flammable, or other hazardous materials may be stored;</p> <p>6. Identify area(s) where radioactive materials may become airborne. The diagram should contain descriptions of the ventilation systems, with pertinent airflow rates, filtration equipment, sample collection points, and monitoring systems;</p> <p>7. Identify specialized handling tools, facility safety interlocks designed to prevent operation of radiological safety systems in the event that operation of a system could result in accidental exposure or release of material (e.g., high efficiency particulate air (HEPA) filters, ventilation system, safety door interlocks) or equipment;</p> <p>8. Identify radioactive waste handling equipment that includes, e.g., incinerators, compactors, solidification equipment, hold-up tanks, sample collection points, ;</p> <p>In addition, describe:</p> <p>1. Engineered safety systems (e.g., area monitors, interlocks, alarms);</p> <p>2. Protective clothing (such as latex or rubber gloves, lab coats or coveralls, respirators, booties, and face shields), auxiliary shielding, absorbent materials, secondary containers for wastewater storage for decontamination purposes, plastic bags for storing such items as contaminated items, that will be available for use when handling unsealed or uncontained radioactive materials;</p>				

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
9	<p>Facilities And Equipment (Cont.)</p> <p>3. The general location of each proposed permanent facility (e.g., located in an industrial park, an office complex) and its current use. If any proposed permanent facility is a private residence, provide diagrams of the installation that include the building, the proposed restricted area or areas, and adjacent areas, including above and below the restricted areas; provide commitments that restricted areas do not include residential quarters, and explain how radiation levels in unrestricted areas will be maintained at less than 1 mSv (100 mrem) per year.</p> <p>4. The proposed nuclear laundry facilities, if applicable, used for contaminated protective equipment and clothing. Specify how the contaminated waste water from the laundry machines or sinks is disposed. Operating and emergency procedures should address decontamination of the laundry area and equipment.</p>				
10 10.1	<p>Radiation Safety Program</p> <p>Operating and Emergency Procedures</p> <p>Submit operating and emergency procedures for radiological conditions that might be encountered specific to the scope and size of your radiation safety program. Refer to Section 8.10.1 for additional details.</p>				<input type="checkbox"/>

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
10.4	<p>Surveys</p> <p>“We will conduct surveys and maintain contamination levels in accordance with the survey frequencies and contamination levels in accordance with the criteria in the section entitled “Surveys” in NUREG-1556, Volume 18, Revision 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses.”</p> <p style="text-align: center;">OR</p> <p>Submit description of alternative survey method and frequency for demonstrating how to evaluate a radiological hazard.</p>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
10.5	<p>Leak Tests</p> <p>“Leak tests sample collection and analysis will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees, or by using a leak test sample collection kit supplied by an organization licensed by NRC or an Agreement State to provide leak test kits and/or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit.”</p> <p style="text-align: center;">OR</p> <p>“Leak testing and analysis will be done by the applicant.” Provide the information in Appendix G supporting a request to perform leak testing and sample analysis and either (1) state that you will follow the model procedures in Appendix G or (2) submit alternative procedures.”</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
10.7	<p>Public Dose</p> <p>The applicant is not required to submit a response to the public dose section during the licensing phase. However, during NRC inspections, licensees must demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from licensed operations does not exceed the annual limit for individual members of the public.</p>	No response is needed from applicants during the licensing phase. Public dose will be reviewed during inspection.			
10.8	<p>Transportation</p> <p>In accordance with 10 CFR 71.17, before the first use of a Type B package, a licensee, in this case the service provider licensee, must submit in writing the licensee's name, license number, and package identification number specified in the package approval to the NRC as a user of the package. The licensee must also have obtained the NRC's approval of its Quality Assurance program.</p>	No response is needed from applicants during the licensing phase. Transportation issues will be reviewed during inspection.			
10.9	<p>Routine Maintenance</p> <p>"We will implement and maintain procedures for conducting routine maintenance of devices according to each manufacturer's (or distributor's) written recommendations and instructions."</p> <p style="text-align: center;">OR</p> <p>Provide alternative routine maintenance procedures for NRC's review.</p>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

Item Nos.	Title and Criteria	Yes	No	N/A	Description Attached
11	<p>Waste Management (Cont.)</p> <p style="text-align: center;">OR</p> <p>Provide procedures for waste management by any of the methods described in Section 8.11, "Waste Management" of this volume. Applicants should contact the appropriate regional office of the NRC for guidance as to how to obtain approval of any method(s) of waste disposal other than those discussed in this section.</p> <p style="text-align: center;">OR</p> <p>If access to a radioactive waste burial site is unavailable, the applicant should request authorization for extended interim storage of waste. Applicants should refer to NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990, for guidance when requesting extended storage.</p>	<input type="checkbox"/>			

APPENDIX C

TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

Appendix C Typical duties and responsibilities of RSOs

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Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the radiation safety officer (RSO) considers unsafe are stopped;
- Radiation exposures are as low as is reasonably achievable (ALARA);
- Development, distribution, implementation, and maintenance of up-to-date operating and emergency procedures to cover all likely scenarios;
- Investigating any incidents and responding to any emergencies;
- Serving as a point of contact for the U.S. Nuclear Regulatory Commission's (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/devices, loss of licensed material, fire, theft, etc.
- Unusual occurrences are investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken to prevent recurrence;
- Licensed materials are properly secured;
- Possession, installation, relocation, use, storage, repair and maintenance of sealed sources, devices and radioactive wastes are consistent with the limitations in the license, individual Sealed Source and Device Registration Certificate(s), and the manufacturer's specific recommendations and instructions;
- 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;
- 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;
- Implementing personnel monitoring program, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits;
- Licensed material is transported in accordance with all applicable U.S. Department of Transportation (DOT) requirements;
- Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner;
- Ordering, receipt, surveys, and delivery of licensed material;
- Monitoring and surveys of all areas in which radioactive material is used;
- Performing/overseeing the inventory and leak testing of sealed sources;
- Packaging, labeling, and surveys of all shipments of byproduct material leaving the facility;
- Training personnel;
- Effluent monitoring;
- Licensed material is disposed of properly;

- 1 • Administering waste disposal program;
- 2 • Performing/overseeing the inventory and leak testing of sealed sources;
- 3 • Overseeing decontamination activities;
- 4 • Maintaining required records that are necessary to support the license and satisfy NRC or
- 5 Agreement States regulations.

6

7 **Model Delegation of Authority**

8

9 Memo To: Radiation Safety Officer

10 From: Chief Executive Officer

11 Subject: Delegation of Authority

12

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

24

25

26 _____
Signature of Management Representative

27 I accept the above responsibilities,

28

29

30 _____
Signature of Radiation Safety Officer

31

32

33 **cc: Affected department heads**

34

35

Date

Date

APPENDIX D

CRITERIA FOR ACCEPTABLE TRAINING AND EXPERIENCE FOR AUTHORIZED USERS

1 **Appendix D Criteria for Acceptable Training and Experience for Authorized Users**

2 **Classroom Training**

3 Classroom training may be in the form of lecture, videotape, or self-study that emphasizes
4 practical subject matter important to the safe handling of licensed materials. Duration and
5 technical level of training should be commensurate with the expected hazards encountered
6 during routine and emergency conditions. Training records should be kept in accordance with
7 Title 10 of the *Code of Federal Regulations* (10 CFR) 30.51(b) and be available for inspection.

8 **Frequency of Training**

- 9 • Before assuming duties with, or in the vicinity of, radioactive materials;
- 10 • Whenever there is a significant change in duties, regulations, or the terms and conditions of
11 the license;
- 12 • Annually for refresher training.

13 **Suggested Radiation Safety Topics**

- 15 • Fundamentals of Radiation Safety:
 - 16 — Characteristics of radiation;
 - 17 — Units of radiation dose and quantity of radioactivity;
 - 18 — Hazards of exposure to radiation;
 - 19 — Levels of radiation from licensed material;
 - 20 — Methods of controlling radiation dose (time, distance, and shielding);
 - 21 — As low as is reasonably achievable (ALARA) concept.
- 22 • Radiation Detection Instruments:
 - 23 — Operation;
 - 24 — Calibration;
 - 25 — Limitations of radiation survey instruments;
 - 26 — Radiation survey techniques for measuring radiation field;
 - 27 — Radiation survey techniques for measuring removable/fixed contamination;
 - 28 — Handling and proper use of personnel monitoring equipment.
- 29 • Radiation Protection Equipment and Use:
 - 30 — Proper use of protective equipment;
 - 31 — Decontamination of contaminated protection equipment.
- 32 • U.S. Nuclear Regulatory Commission (NRC) regulations (10 CFR Parts 19 and 20).
- 33 • NRC regulations (10 CFR Parts 21, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, and 71) as
34 applicable.
- 35 • Licensee's operating and emergency procedures.
- 36 • Case histories relevant to operations.

- 1 • Course Examination (Didactic):
 - 2 — Successful completion of closed-book written/oral examination depending on the
 - 3 complexity and hazards of authorized activities
 - 4 — Review of incorrect answers with student.
- 5 • On-the Job Training and Examination (Practical):
 - 6 — On-the-job training done under the supervision of a qualified individual (authorized user
 - 7 (AU), radiation safety officer (RSO), or manufacturer's representative authorized by the
 - 8 NRC or an Agreement State) that includes supervised hands-on experience performing
 - 9 the task authorized on the license that are commensurate with the expected hazards
 - 10 during routine and emergency conditions;
 - 11 — Practical examination consisting of an assessment by the RSO to ensure that each
 - 12 proposed AU is qualified to work independently and that each individual is knowledgeable
 - 13 of the radiation safety aspects of licensed activities. This may be demonstrated by
 - 14 observing the proposed AU perform licensed activities.
- 15 • Discussion and/or drill on all applicable emergency procedures annually.
- 16 • Retraining on areas found to be deficient in both the practical and didactic areas.

17

18 **Classroom Course Instructor Qualifications**

19 The person conducting the training should be a qualified individual (e.g., a person who meets
20 the qualifications for RSO or AU on the license and is familiar with the licensee's program).
21 Instructors who provide classroom training to individuals in the principles of radiation and
22 radiation safety should have knowledge and understanding of these principles beyond those
23 obtainable in a course similar to the one given to prospective authorized users. Individuals who
24 provide instruction in the hands-on use of licensed materials should have training and
25 experience that would qualify them to be authorized users, or should possess a thorough
26 understanding of the licensee operations.

27

APPENDIX E

MATERIAL ORDERING AND PACKAGE RECEIPT AND OPENING

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Appendix E Material Receipt and Accountability

The radiation safety officer (RSO) should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded. The RSO should be aware of how much licensed material is actually possessed as opposed to the licensed possession limits. The licensed inventory includes all radioactive materials in use, in storage, and in waste. The regulations in 10 CFR 30.51, "Records," require the licensee to maintain records of receipt, transfer, and disposal of all licensed materials.

Sample Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.
- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the Radiation Safety Office (or designated receiving area).
- If radioactive material will be held at an alternate location (for example, a carrier's holding facility) or shipped directly to the service provider's customer's location, the RSO should ensure that the package is received properly.
- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, or other Management Representative

Subject: Procedures for Receipt of Packages Containing Radioactive Material

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

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

1 RSO:

2 Office phone:

3 Business cell phone:

4 **Sample Instructions to Personnel Involved in Material Receipt**

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

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

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

20 Name:

21 Phone:

22

For additional information on worker training, see Section 8.8, "Training for Individuals Working In or Frequenting Restricted Areas."
--

23

24 **Sample Model Procedure for Safely Opening Packages Containing Licensed Materials**

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

- 27 • Wear gloves to prevent hand contamination.
- 28 • Visually inspect the package for any sign of damage (e.g., crushed, punctured). If
29 damage is noted, stop and notify the RSO.
- 30 • Monitor the external surfaces of a labeled package according to specifications in
31 Table 8.3, Section 8.10.1.
- 32 • Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, to
33 ensure that the shipment does not exceed license possession limits.
- 34 • Open the outer package (following supplier's directions if provided). Open inner
35 package to verify contents (compare requisition, packing slip and label on the bottle or
36 other container). Check integrity of the final source container (e.g., inspecting for

1 breakage of seals or vials, loss of liquid, discoloration of packaging material, high count
2 rate on smear). Again check that the shipment does not exceed license possession
3 limits. If you find anything other than expected, stop and notify the RSO.

- 4 • Survey the packing material and packages for contamination before discarding. If
5 contamination is found, treat as radioactive waste. If no contamination is found,
6 obliterate the radiation labels prior to discarding in the regular trash.
- 7 • Maintain records of receipt, package survey, and wipe test results.
- 8 • Notify the final carrier and by telephone, telegram, mailgram, or facsimile, the
9 Administrator of the appropriate NRC Regional Office listed in 10 CFR 20, Appendix D,
10 when removable radioactive surface contamination exceeds the limits of
11 10 CFR 71.87(i); or external radiation levels exceed the limits of 10 CFR 71.47, "External
12 radiation standards for all packages."

13 14 **Sample Transfer Policy Statement**

15 Licensed material shall not be transferred or shipped from one licensee to another without the
16 approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance
17 with DOT, the NRC, or U.S. Postal Service Regulations, whichever is applicable. If licensed
18 material is possessed at a customer's facility incident to performing services, this material will
19 not be transferred to the service provider unless the service provider will be preparing it to be
20 shipped AND will be the shipper of record (i.e., signing the Shipper's Certification on the
21 shipping paper.)
22

23 Prior to any transfer of radioactive materials, the RSO shall verify that the recipient is authorized
24 to receive the licensed material (e.g., nuclide, source/device model number, activity), as
25 required by 10 CFR 30.41, "Transfer of byproduct material."

APPENDIX F

RADIATION MONITORING INSTRUMENT SPECIFICATIONS AND MODEL SURVEY INSTRUMENT CALIBRATION PROGRAM

Appendix F Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

The specifications in Table F.1⁵ will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facilities or job sites.

Table F.1 Typical Survey Instruments⁶

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

⁵ Table from The Health Physics and Radiological Health Handbook, Revised Edition, edited by Bernard Shleien, 1992 (except for * items).

⁶ Instruments used to measure radiological conditions at licensed facilities or job sites.

Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
	Gamma	All energies	< 1 percent

1

2 In addition to selecting an instrument that is appropriate for the radiation(s) of interest, it is
 3 important to know if the instrument is sufficiently sensitive to make measurements at the
 4 required level. This is particularly important for measurements such as leak test samples and
 5 bioassay measurement, and for decommissioning of facilities or equipment. The “minimum
 6 detectable activity” (MDA) for your instrument should be a small fraction (10 to 50 percent) of
 7 the criteria you must meet.

8

9 Example 1: A sealed source is considered to be leaking if a removable contamination exceeds
 10 185 becquerels (0.005 microcurie, or 11,100 disintegrations per minute (dpm)). The instrument
 11 used to measure wipe test samples should have an MDA of 10 percent of that limit, or
 12 1,100 dpm for the radionuclide being tested; this is usually easy for cobalt-60 or cesium-137, but
 13 more difficult to detect for nickel-63, depending on the instrument used to analyze the sample.

14

15 Example 2: You are closing a laboratory where uranyl acetate (generally licensed pursuant to
 16 10 CFR 40.22, “Small quantities of source material”) was used. The total residual
 17 contamination screening value for uranium-238 is 101 dpm/100 cm². The MDA for direct
 18 measurements of uranium-238 should be made at 10 to 50 percent of the screening value for
 19 uranium-238, or 10 to 50 dpm/100 cm².

20

21 When the sample count time and the background count time are the same, a simplified
 22 calculation can be used to determine the MDA for a static measurement. This simplified
 23 calculation assumes that the type I error (false positive) and Type II error (false negative) are
 24 both selected to be equal in probability and at the 95 percent confidence error.

25

26 **Note 1:** This calculation can be modified for more complex situations as described in
 27 NUREG-1575, Chapter 6, “Field Measurements Methods and Instrumentation.”

28

29 **Note 2:** This equation applies only to instruments used in scalar mode, accumulating counts of
 30 radiation detected over a defined period of time. It is NOT applicable to survey instruments
 31 used in rate meter mode.

32

33 This simplified equation is:

34

$$35 \quad \text{MDA} = \frac{(3 + 4.65\sqrt{B})}{\epsilon t}$$

36

37 Where B = number of background counts

38 t = minutes of background count = minutes of sample count

39 ϵ = efficiency of instrument, determined using a calibration standard

$$40 \quad \epsilon = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in dpm}}$$

41

42

1 where: cpm = counts per minute
2 std = standard
3 bkg = background
4

5 Example:

6
7 A gas-flow proportional counter is used in scalar mode to make 1-minute counts of samples.

8 sample count time = 1 minute = t

9 background count time = 1 minute = t

10 background counts = 300 counts

11 efficiency = 0.15 counts/disintegrations (c/d) = €

12
13 Then $MDA = \frac{(3 + 4.65\sqrt{B})}{\epsilon t} = \frac{(3 + 4.65\sqrt{300 \text{ counts}})}{(0.15 \text{ c/d})(1 \text{ minute})}$

14
15
16 = 557 dpm
17

18 According to this calculation, you would be confident that 95 percent of the time, the instrument
19 can reliably detect measurements as low as 557 dpm. This is the minimum activity that the
20 instrument can detect; results below this number are not reliable at the 95 percent confidence
21 interval. However, all numerical results should be reported.
22

23 From the basic MDA, you can determine the minimum detectable concentration (MDC) for your
24 actual measurement conditions.
25

26 For example, suppose the above measurement was made with a survey meter probe with a
27 surface area of 15 square centimeters (cm²), then the MDC would be calculated as follows:
28

29 MDC = 557 dpm/15 cm² = 37 dpm/ cm² or 3700 dpm/100 cm²
30

31 Determining the MDA or MDC for instruments used in rate meter mode and for scanning
32 surveys is more complicated. If you will be performing surveys for decommissioning, which
33 require direct measurement surveys, scanning measurement surveys, and surveys for
34 removable contamination, review NUREG-1757, "Consolidated Decommissioning Guidance."
35 Additional information related to determining the MDA and MDC for direct measurements and
36 scanning measurements may be found in Chapter 6 and Appendix H of NUREG-1575.
37

38 **Model Instrument Calibration Program**

39 **Training**

40 Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that
41 he or she has sufficient training and experience to perform independent survey instrument
42 calibrations. Training records should be retained.

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

- 45 • Principles and practices of radiation protection;
- 46 • Radioactivity measurements, monitoring techniques, and using instruments;

- 1 • Mathematics and calculations for using and measuring radioactivity;
- 2 • Biological effects of radiation.

3

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

- 5 • Observing authorized personnel performing survey instrument calibration;
- 6 • Conducting survey meter calibrations under the supervision and in the physical presence
- 7 of an individual authorized to perform calibrations.

8

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

- 10 • Individuals conducting calibrations will wear assigned dosimetry.
- 11 • Individuals conducting calibrations will use a calibrated and operable survey instrument to
- 12 ensure that unexpected changes in exposure rates are identified and corrected.
 - 13 — To reduce doses received by individuals not calibrating instruments, calibrations will be
 - 14 conducted in an isolated area of the facility or at times when no one else is present.
 - 15 — The calibration source should be well collimated, and the calibration area should be
 - 16 designed to minimize scatter of radiation, which could affect the calibration process.
 - 17 — The calibration area should be appropriately controlled so that persons entering the area
 - 18 will be aware if a radiation source is in use. Posting as a radiation area also may be
 - 19 required.
 - 20 — Depending on the type of calibrator or irradiator source used for calibration, the device
 - 21 and facilities may fall under the regulations on 10 CFR Part 36, “Licenses and Radiation
 - 22 Safety Requirements for Irradiators,” and require interlocks and alarms. Review
 - 23 NUREG-1556, Vol. 5, “Program-Specific Guidance about Self-Shielded Irradiator
 - 24 Licenses” and Vol. 6, “Program-Specific Guidance about 10 CFR Part 36 Irradiator
 - 25 Licenses,” for additional guidance.

26

27 **Model Procedure for Calibrating Survey Instruments**

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

- 29 • Approximate a point source.
- 30 • Have its apparent source activity or the exposure rate at a given distance traceable by
- 31 documented measurements to a standard certified to be within ± 5 percent accuracy by
- 32 National Institute of Standards and Technology (NIST).
- 33 • Approximate the same energy and type of radiation as the environment in which the
- 34 calibrated device will be employed or develop energy curves to compensate for differing
- 35 energies.
- 36 • For dose rate and exposure rate instruments, the source should be strong enough to
- 37 give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hour (30 mR/hr) at
- 38 100 cm [e.g., 3.1 GBqs (85 mCi) of cesium-137 or 7.8×10^2 MBqs (21 mCi) of cobalt-
- 39 60].

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

- 3 • Linear readout instruments with a single calibration control for all scales should be
4 adjusted at the point recommended by the manufacturer or at a point within the normal
5 range of use. Instruments with calibration controls for each scale should be adjusted on
6 each scale. After adjustment, the response of the instrument should be checked at
7 approximately 20 percent and 80 percent of full scale. The instrument's readings should
8 be within ± 15 percent of the conventionally true values for the lower point and \pm
9 10 percent for the upper point.
- 10 • Logarithmic readout instruments, which commonly have a single readout scale spanning
11 several decades, normally have two or more adjustments. The instrument should be
12 adjusted for each scale according to site specifications or the manufacturer's
13 specifications. After adjustment, calibration should be checked at a minimum of one
14 point on each decade. Instrument readings should have a maximum deviation from the
15 conventionally true value of no more than 10 percent of the full decade value.
- 16 • Meters with a digital display device shall be calibrated the same as meters with a linear
17 scale.
- 18 • Readings above 2.58×10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but
19 such scales should be checked for operation and response to radiation.
- 20 • The inverse square and radioactive decay laws should be used to correct changes in
21 exposure rate due to changes in distance or source decay.

22

23 **Surface Contamination Measurement Instruments**⁷

- 24 • A survey meter's efficiency must be determined by using radiation sources with similar
25 energies and types of radiation that the survey instrument will be used to measure.
- 26 • If each scale has a calibration potentiometer, the reading should be adjusted to read the
27 conventionally true value at approximately 80 percent of full scale, and the reading at
28 approximately 20 percent of full scale should be observed. If only one calibration
29 potentiometer is available, the reading should be adjusted at mid-scale on one of the
30 scales, and readings on the other scales should be observed. Readings should be
31 within 20 percent of the conventionally true value.

32

33 **Model Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas** 34 **Flow Proportional Counters, and Multichannel Analyzers**

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

- 36 • Approximate the geometry of the samples to be analyzed;
- 37 • Have its apparent source activity traceable by documented measurements to a standard
38 certified to be within ± 5 percent accuracy by NIST;

⁷ ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration."

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

3
4 **Calibration**

- 5 • Calibration of survey instruments used in assessing dose or exposure rates must be
6 conducted at 6 to 12 month intervals or after instrument servicing.
- 7 • Calibration should produce readings within ± 20 percent of the actual values over the
8 range of the instrument.
- 9 • Calibration of liquid scintillation counters will include quench correction.

10
11 **Calibration Records**

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

- 14 • The owner or user of the instrument;
- 15 • A description of the instrument, including the manufacturer's name, model number, serial
16 number, and type of detector;
- 17 • A description of the calibration source, including the exposure rate at a specified
18 distance or activity on a specified date;
- 19 • For each calibration point, the calculated exposure rate or count rate, the indicated
20 exposure rate or count rate, the deduced correction factor (the calculated exposure rate
21 or count rate divided by the indicated exposure rate or count rate), and the scale
22 selected on the instrument;
- 23 • For instruments with external detectors, the angle between the radiation flux field and
24 the detector (i.e., parallel or perpendicular);
- 25 • For instruments with internal detectors, the angle between radiation flux field and a
26 specified surface of the instrument;
- 27 • For detectors with removable shielding, an indication as to whether the shielding was in
28 place or removed during the calibration procedure;
- 29 • The exposure rate or count rate from a check source, if used;
- 30 • The name of the person who performed the calibration and the date it was performed.

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

- 32 • For exposure rate meters, the source isotope used to calibrate the instrument (with
33 correction factors) for each scale;
- 34 • The efficiency of the instrument for each of the isotopes that the instrument will be used
35 to measure radiological conditions (if efficiency is not calculated before each use);
- 36 • For each scale or decade not calibrated, an indication that the scale or decade was
37 checked only for function but not calibrated;

- 1 • The date of calibration and the next calibration due date;
- 2 • The apparent exposure rate or count rate from the check source, if used.

3
4 Service providers who will perform calibrations as a commercial service should also include
5 their company name and radioactive materials license number on the calibration certificate.

6
7 **References:**

- 8 1. "The Health Physics & Radiological Health Handbook, Revised Edition," edited by Bernard
9 Shleien, dated 1992.
- 10 2. ANSI N323B-2003, "Radiation Protection Instrumentation Test and Calibration-Portable
11 Survey Instrument for Near Background Operation." Copies may be obtained from the
12 American National Standards Institute at the following address: www.ansi.org .

APPENDIX G

MODEL LEAK TEST PROGRAM

1
2 **Appendix G Model Leak Test Program**
3

4 **Training**
5

6 Before allowing an individual to perform leak testing, the licensee must ensure that he or she
7 has sufficient classroom and on-the-job training to show competency in performing leak tests
8 independently, in accordance with 10 CFR 30.33(a)(3).
9

10 Classroom training may be in the form of lecture, online, video, or self-study, and should cover
11 the following subject areas:
12

- 13 • principles and practices of radiation protection
- 14 • radioactivity measurements, monitoring techniques, and using instruments
- 15 • mathematics and calculations used for measuring radioactivity
- 16 • biological effects of radiation
17

18 Appropriate on-the-job-training consists of the following:
19

- 20 • observing authorized personnel collecting and analyzing leak test samples
- 21
- 22 • collecting and analyzing leak test samples under the supervision and in the physical
23 presence of an individual authorized to perform leak tests
24

25 **Facilities and Equipment**
26

- 27 • To ensure achieving the required sensitivity of measurements, analyze leak tests in a
28 low-background area.
29
- 30 • Use a calibrated and operable survey instrument to check leak test samples for gross
31 contamination before they are analyzed.
32
- 33 • Analyze the leak test sample using an instrument that is appropriate for the type of
34 radiation to be measured (e.g., NaI (TI) well-counter system for gamma-emitters, liquid
35 scintillation for beta-emitters, gas-flow proportional counters for alpha-emitters).
36
- 37 • If the sensitivity of the counting system is unknown, the minimum detectable activity
38 (MDA) should be determined. The MDA may be determined using the following formula:
39

40
$$MDA = \frac{2.71 + 4.65 \sqrt{(bkg \times t)}}{t \times E}$$

41
42

43 where: *MDA* = minimum detectable activity in disintegrations per minute (dpm)

44 *bkg* = background count rate in counts per minute (cpm)

45 *t* = background counting time in minutes

46 *E* = detector efficiency in counts per disintegration
47

For example,

48 where: *bkg* = 200 counts per minute (cpm)

1 $E = 0.1$ counts per disintegration (10 percent efficient)

2 $t = 2$ minutes

3
4 $MDA = \frac{2.71 + 4.65 \sqrt{(200 \text{ cpm} \times 2 \text{ minutes})}}{2 \times 0.1} = \frac{2.71 + 4.65 \sqrt{(400)}}{0.2}$

5
6
7 $= \frac{2.71 + 4.65 (20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2}$

8
9
10 $= \frac{478.55 \text{ disintegrations}}{\text{minute}}$

11
12
13 becquerels (Bq) = $\frac{1 \text{ disintegration}}{\text{second}}$

14
15
16 $\text{Bq} = \frac{478.55 \text{ disintegration}}{\text{minutes}} \times \frac{\text{minute}}{60 \text{ seconds}} = 7.976 \text{ Bq}$

17
18
19 **Frequency for Conducting Leak Tests of Sealed Sources**

20
21 Leak tests will be conducted at the frequency specified in the respective Sealed Source and
22 Device Registration Certificate.

23
24 **Leak Testing Kits**

25 Leak test kits should contain:

- 26
- 27 • For example, swabs, wipes, absorbent-tipped sticks, that are to be used to make the
wipes on the specified sources or devices
 - 28 • For example, envelopes, vials,., where the leak test sample will be placed after the
29 sample has been taken
 - 30 • Step-by-step instructions for safe use of the particular kit (these instructions will be
31 specific to the types of devices/sealed sources that the kit is designed)
 - 32 • Procedures for shipping the sample for analysis
 - 33 • A label that contains the following information:
 - 34 — Customer's (or Company) name
 - 35 — License number
 - 36 — Date leak test was taken
 - 37 — Source or device (by manufacturer, model number, nuclide and activity)
 - 38 — The name of the individual who performed the leak test
- 39

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

- 41
- 42 • Either use a leak test kit or, for each source to be tested, list identifying information such
43 as the manufacturer's name, model number, serial number, radionuclide, and activity of
44 the sealed source.
- 45

- 1 • If one is available, use a survey meter to monitor exposure.
- 2
- 3 • Prepare a separate sample (e.g., cotton swab or filter paper) for each source.
- 4
- 5 • Number each wipe to correlate with identifying information for each source.
- 6
- 7 • Wipe the most accessible area where contamination would accumulate if the sealed
- 8 source were leaking (see manufacturer's instructions).
- 9
- 10 • Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcuries) of the
- 11 radionuclide.
- 12
- 13 • Using the selected instrument, count and record background count rate.
- 14
- 15 • Check the instrument's counting efficiency using a standard source of the same
- 16 radionuclide as the source being tested or one with similar energy characteristics.
- 17 Accuracy of standards should be within plus or minus 5 percent of the stated value and
- 18 traceable to primary radiation standards such as those maintained by the National
- 19 Institute of Standards and Technology.
- 20
- 21 • Calculate efficiency.

22
23 For example: $\frac{[(\text{cpm from } \textit{std}) - (\text{cpm from } \textit{bkg})]}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$

24
25
26 where: cpm = counts per minute
27 *std* = standard
28 *bkg* = background
29 Bq = becquerel
30

- 31 • Count each wipe sample; determine net count rate.
- 32
- 33 • For each sample, calculate and record estimated activity in Bq (or millicuries).
- 34
- 35 For example: $\frac{[(\text{cpm from wipe sample}) - (\text{cpm from } \textit{bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$
- 36
- 37
- 38 • Sign and date the list of sources, data, and calculations. Retain records for 3 years
- 39 (under 10 CFR 20.2103(a)). If the wipe test activity is 185 Bq (0.005 microcurie) or
- 40 greater, notify the radiation safety officer (RSO) so that the source can be withdrawn
- 41 from use and disposed of properly. Also notify the U.S. Nuclear Regulatory Commission
- 42 (NRC) in accordance with the conditions of the license.
- 43

44 **Example Notification for a Leaking Source:**

45 Name and mailing address of customer

46
47 NRC Regional Office address

48
49 Re.: Notice of Leak Test Exceeding 0.005 microcuries (185 becquerels)

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Dear Sir or Madam,

Per the requirements of our NRC materials license <insert license number>, I am notifying your office of a sealed source that has exhibited a wipe in excess of 0.005 microcuries. The wipe was detected during a scheduled 6 month wipe of our sealed sources used in the laboratories/room at the address below. The instrument housing the sealed source was removed from service.

Following is information provided in accordance with the requirements outlined in 10 CFR 30.50 (c)(2).

A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned.

The high wipe was determined during a routine 6 month wipe of sealed sources. The initial wipe result was <insert activity> microcuries on the <insert location wipe tested>. The high wipe was reported to the RSO by our service provider.

Possible cause of the high wipe is attributed to _____.

Manufacturer:<insert manufacturer>
Model Number: <insert model number>

The exact location of the event:

- Lab/Room <insert bldg., lab or room number>

The isotopes, quantities, and chemical and physical form of the licensed material involved:

- Isotope: <insert isotope>
- Quantity: <insert activity of source>
- Chemical and physical form: <insert sealed or plated, form>

Date and time of the event:

Date and Time: <insert date and time of event>

Corrective actions taken or planned and the results of any evaluations or assessments <insert actions here>

The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

No exposure expected. The sealed source was housed in an enclosed instrument. Please contact me if you have any questions.

Sincerely,
RSO

APPENDIX H

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

1 **Appendix H Guidance for Demonstrating That Unmonitored Individuals Are Not Likely to**
2 **Exceed 10 Percent of the Allowable Limits**

3 Dosimetry is required for individuals likely to receive, in 1 year from sources external to the
4 body, a dose in excess of 10 percent of the applicable regulatory limits in 10 CFR 20.1201,
5 “Occupational dose limits for adults.” Therefore, a licensee should evaluate the doses its
6 workers receive in performing these tasks to assess whether dosimetry is required.
7

8 **Example:**

9 A radiation measurement of the work area indicates a dose rate of 0.015 mSv/hr (1.5 mrem/hr).
10 Service provider personnel are not expected to spend more than a total of 6 hours per week at
11 the location of the measurement. Based on this measured dose rate, the annual dose is
12 expected to be less than 4.68 mSv (468 mrem). Specifically, $6 \text{ hr/wk} \times 1.5 \text{ mrem/hr} \times 52 \text{ wk/yr} =$
13 468 mrem . Based on the above, if any service personnel work in the area less than 6 hours per
14 week, no dosimetry is required. If the service personnel work in the area for greater than 6
15 hours per week, then dosimetry is required. The threshold for monitoring is 10 percent (500
16 millirems) of the applicable limit (for personnel with an annual dose limit of 5,000 millirems).

17 **Guidance to Licensees**

18
19 Licensees who wish to demonstrate that they are *not* required to provide dosimetry to their
20 workers must prepare a record of the results of surveys used in assessing individual dose
21 equivalents in accordance with 10 CFR 20.2103(b)(1). The written evaluation should be similar
22 to that shown in the example above. The expected dose rates, times, and distances used in the
23 above example may *not* be appropriate to individual licensee situations. In their evaluations,
24 licensees should use information appropriate to the type of work being conducted.
25

26 Table H.1 is an example of the documentation to show that unmonitored individuals will not
27 exceed 10 percent of the allowable dose limits.
28

29 Licensees should review evaluations periodically and revise them as needed. They should
30 check assumptions used in their evaluations to ensure that the assumptions are up-to-date and
31 accurate, especially when there is an increase in the possession of radioactive material.

1

Table H.1 Dosimetry Evaluation

Dosimetry Evaluation for _____			
A.	Time needed to perform the entire work activity	_____ minutes	_____ hour (divide # of minutes by 60)
B.	Expected whole-body dose rate that the individual will encounter, determined using measured or manufacturer-provided data	_____ millirem/hour	
C.	Time the <i>extremities</i> were exposed to the unshielded source (if applicable)	_____ minutes	_____ hour
D.	Expected extremity dose rate that the individual will encounter, determined using measured or manufacturer-provided data for the unshielded source at the typical distance from the hands to the unshielded source	_____ millirem/hour	
Estimated Whole Body Dose Equivalent*			
Formula: (_____ hours in Row A) x (_____ millirem/hour in Row B) = (_____ estimated millirem) x (_____ # times conducted each year) = _____ millirem			
Estimated Extremity Dose Equivalent**			
Formula: (_____ hours in Row C) x (_____ millirem/hour in Row D) = (_____ estimated millirem) x (_____ # of times conducted each year) = _____ millirem			

2

* An expected Whole Body Dose Equivalent *less than* 500 millirem requires no dosimetry.

3

** An expected Extremity Dose Equivalent *less than* 5,000 millirem requires no dosimetry.

4

APPENDIX I

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

Appendix I Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

This appendix describes methods for determining radiation dose to members of the public.

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in one calendar year resulting from the licensee’s possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

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

Table I.1 Doses to Members of the Public

Doses to Members of the Public	
<p>INCLUDES doses from:</p> <ul style="list-style-type: none"> • Radiation and/or radioactive material released by a licensee • Sources of radiation under the control of a licensee • Air effluents from sources of licensed radioactive materials 	<p>DOES NOT INCLUDE doses from:</p> <ul style="list-style-type: none"> • Sanitary sewerage discharges from licensees • Natural background radiation • Medical administration of radioactive material • Voluntary participation in medical research

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

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

- Demonstrating by measurement or calculation that the total effective dose equivalent (TEDE) to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem).
- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed

1 the values specified in Table 2 of Appendix B to Title 10 of the *Code of Federal*
2 *Regulations* (10 CFR) Part 20; and if an individual were continuously present in an
3 unrestricted area the dose from external sources would not exceed 0.02 mSv (2 mrem)
4 in an hour and 0.5 mSv (0.05 rem) in a year.

- 5 • Demonstrating that air emissions of radioactive materials do not result in doses greater
6 than the constraint limit of 0.1 mSv (10 mrem) TEDE.
- 7 • Demonstrating by measurement or calculation that the TEDE to an individual will not
8 exceed 0.02 mSv (2 mrem) in any one hour at an established boundary for temporary
9 job sites.

10 In order to perform a dose assessment, licensees should identify all potential sources of
11 external and internal radiation exposure to members of the public and all locations of use,
12 transport, and storage of radioactive material at their facilities. Licensees must then take
13 radiation measurements or perform calculations to demonstrate compliance.

14 **Measurements**

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

- 19 • dose rate surveys for radiation exposures from external radiation sources
- 20 • measurements of radionuclides in air and water effluent

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

25 Radioactivity releases may be determined by effluent monitoring or by effluent sampling and
26 analysis. Airborne effluents may be discharged when volatile materials are used, such as
27 during waste compactions or incinerations, but the discharge itself is usually not continuous
28 since volatile materials are often used periodically rather than continuously. Liquid effluents
29 may be discharged continuously or may be stored and subsequently discharged on a batch
30 basis. For each type of source and for each route of potential exposure, consider the location of
31 measurement points, whether continuous or periodic monitoring is required, the frequency of
32 sampling and measurement, and any additional information. For discharges of airborne
33 radionuclides, for example, it may be necessary to obtain information on the efficiency of filters
34 and the air flow rate of the discharge system, as well as meteorological data and the distance to
35 the nearest individual member of the public.

36 **Calculation Method**

37 Using a calculation method, the licensee must determine the highest dose an individual is likely
38 to receive at the boundary of the unrestricted area. The licensee must take into account the
39 individual's exposure from external sources and the concentration of radionuclides in gaseous
40 and liquid releases. In practice, the licensee may wish to make conservative assumptions to
41 simplify the dose calculation.

1 The public dose limit applies to the individual who is likely to receive the highest dose from
2 licensed operations. Therefore, the dose calculations must consider the location with the
3 potential for the highest internal and external exposures. A conservative calculation should
4 assume that the individual was continuously present 24 hours a day, 365 days a year, or an
5 occupancy factor of 1 (see Table I.2). If the result of the calculation using an occupancy factor
6 of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further
7 evaluation.

8 If the calculation demonstrates that the public dose limit is exceeded with an occupancy factor
9 of 1, then more realistic assumptions of the individual's occupancy at the points of highest
10 internal and external exposures may be made. The licensee may use the occupancy factors in
11 Table I.1 or may calculate a specific occupancy factor by determining the likely fraction of time
12 that the individual is present.

13 **Table I.2 Standard Occupancy Factors**

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

14

15 **Records**

16 The licensee must maintain records to demonstrate compliance with the dose limit for individual
17 members of the public until the Commission terminates the license. In general, survey and
18 monitoring records of ambient radiation and effluent radioactivity should be adequate.

19 Records demonstrating the dose to an individual member of the public should identify the
20 instruments used in the survey, the name of the surveyor, the date of the survey, the location of
21 the survey(s) including a description or drawing of the area surveyed, survey results, and if
22 applicable, the occupancy factors used and justification for their use. In addition, records
23 demonstrating the dose to an individual member of the public that involve effluent sampling
24 analysis should include information on concentrations of specific radionuclides, minimum
25 detectable activity of the system, and the estimated uncertainty of measurements.

26 Service provider licensees who perform tracer flow studies at temporary job sites must maintain
27 records in accordance with 10 CFR 32.12, "Same: Records and material transfer reports," and
28 10 CFR 32.52, "Same: Material transfer reports and records."

29 The following is a simple example to demonstrate the above concepts for calculating, direct
30 measurement with sensitive instrumentation, and combination of calculating and measurement.

31

1 **Recordkeeping**

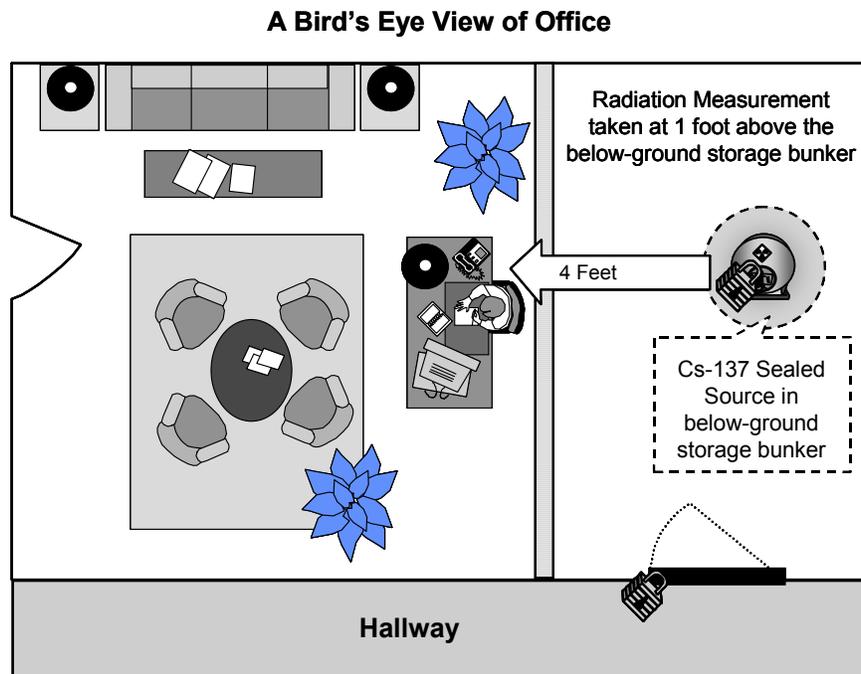
2 Regulations in 10 CFR 20.2107 “Records of dose to individual members of the public,” require
3 licensees to maintain records demonstrating compliance with the dose limits for individual
4 members of the public.

5 **Calculation Method⁸**

6 These measurements must be made with calibrated survey meters sufficiently sensitive to
7 measure background levels of radiation. However, licensees must exercise caution when
8 making these measurements, and they must use currently calibrated radiation survey
9 instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of
10 2080 hours (i.e., a “work year” of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert
11 (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available Geiger-Mueller survey instruments.

12



13
14
15

Figure I.1 Bird's-Eye View of Office with Stored Calibration Source

⁸ For ease of use, the examples in this Appendix use conventional units. The conversions to SI units are as follows: 1 foot (ft) = 0.305 meter; 1 mrem = 0.01 mSv.

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

4 Licensees may also choose to use environmental thermoluminescent dosimeters (TLDs) in
5 unrestricted areas next to the down-hole source storage area for monitoring. This direct
6 measurement method would provide a definitive measurement of actual radiation levels in
7 unrestricted areas without any restrictive assumptions. Records of these measurements can
8 then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100
9 mrem/yr) limit.

TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for environmental monitoring. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF₂ that are used for environmental monitoring.

10

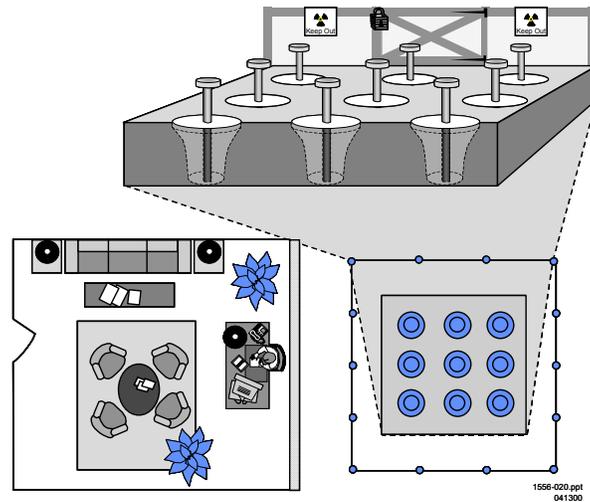
11 The combined measurement-calculation method may be used to estimate the maximum dose to
12 a member of the public. The combined measurement-calculation method takes a tiered
13 approach, going through a two-part process, starting with a worst case situation and moving
14 toward more realistic situations. It makes the following simplifications: (1) each cesium-137
15 source is considered a point source; (2) typical radiation levels are encountered when the
16 source is in the unshielded position; and (3) no credit is taken for any shielding found between
17 the source storage area and the unrestricted areas. The method is only valid for the source
18 activity at the time of measurement and must be repeated if the source strength or shielding is
19 changed.

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

29 **Example**

30 To better understand the combined measurement-calculation method, we will examine DISPOZ,
31 Inc., a waste management broker. Yesterday, the company's president noted that the top shield
32 of the down-hole storage area is close to an area used by workers whose assigned duties do
33 not include the use of licensed materials, and he asked Jenny, the radiation safety officer
34 (RSO), to determine if the company is complying with the NRC's regulations.

1 The area in question is near the floor under the workers' desks, which constitutes the primary
 2 shield of the down-hole storage area. Jenny measures the distance from the shield to the
 3 center of the area in question and, using a calibrated survey instrument, measures the highest
 4 dose rate at one foot from the shield to be 2 mrem per hour.



5
 6 **Figure I.2 Down-Hole Storage Array in Waste Broker Facility.**
 7

8 Table I.3 summarizes the information Jenny has on the down-hole storage area.

9 **Table I.3 Information Known about Dose at the Shield of the Cs-137 Source**

Description of Known Information	Cesium-137 Logging Source
Dose rate encountered at 1 foot from the top of the shield, in mrem/hr	2 mrem/hr
Distance from the face of the shield to the nearest occupied work area, in ft	4 ft

10

11 **Example: Part 1**

12 Jenny's first thought is that the distance between the down-hole storage area shield and the
 13 area in question may be sufficient to show compliance with the regulation in 10 CFR 20.1301,
 14 "Dose limits for individual members of the public." So, taking a worst case approach, she
 15 assumes: (1) the cesium-137 is constantly located in down-hole storage area (i.e., 24 hr/day);
 16 and (2) the workers are constantly in the unrestricted work area (i.e., 24 hr/d). Jenny proceeds
 17 to calculate the dose the workers might receive hourly and yearly from the source, as shown in
 18 Table I.4 below.

1 **Table I.4 Calculation Method, Part 1: Hourly and Annual Doses Received from a**
 2 **Source Stored in Above Ground**

Step No.	Description	Input Data	Results
1	Multiply the measured dose rate measured at 1.0 ft from the face of the shield floor in mrem/hr by the square of the distance (ft) at which the measurement was made (e.g., 1 ft from the face of the shield)	$2 \times (1)^2$	2
2	Square of the distance (ft) from the face of the shield to the nearest unrestricted area, in ft^2	$(4)^2$	16
3	Divide the result of Step 1 by the result of Step 2 to calculate the dose received by an individual in the area near the shield. HOURLY DOSE RECEIVED FROM SOURCE, in mrem in an hour	2/16	0.125
4	Multiply the result of Step 3 by 40 hr/work week x 52 weeks/year = MAXIMUM ANNUAL DOSE RECEIVED FROM Cs-137 Source, in mrem in a year	$0.125 \times 40 \times 52$	260

3
 4 **Note:** The result in Step 3 demonstrates compliance with the 2 mrem in any one hour limit. Re-
 5 evaluate if assumptions change. If the result in Step 4 exceeds 100 mrem/yr, proceed to Part 2
 6 of the calculation method.

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

10 **Example: Part 2**

11 Jenny reviews the assumptions and recognizes that the workers are not in the area all of the
 12 time. A realistic estimate of the number of hours the workers spend in the area is made,
 13 keeping the other assumptions constant (i.e., the source is constantly in the down-hole storage
 14 area (i.e., 24 hr/day). The annual dose received is then recalculated.

1 **Table I.5 Calculation Method, Part 2: Annual Dose Received from a Source Stored**
 2 **Above Ground**

Step No.	Description	Results
7	A. Average number of hours per day an individual spends in area of concern (e.g., a non-radiation worker spends 1.5 hr/day in the area near the shield; the remainder of the day the workers are away from the area assigned to jobs unrelated to radiation (e.g., painting, grounds keeping, desk jobs). B. Average number of days per week in area C. Average number of weeks per year in area (e.g., full-time workers)	1.5 5 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	1.5 x 5 x 52 = 390
9	Multiply the results in Step 3 by the results of Step 8 = ANNUAL DOSE RECEIVED FROM CESIUM-137 LOGGING SOURCE CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN, in mrem in a year	0.125 x 390 = 49

3
 4 Jenny is pleased to note that the calculated annual dose received is significantly lower, and
 5 does not exceed the 100 mrem in a year limit.

6 Jenny is glad to see that the results in Step 9 show compliance with the 100 mrem in a year
 7 limit. Had the result in Step 9 been higher than 100 mrem in a year, then Jenny could have
 8 done one or more of the following:

- 9 • Consider whether the assumptions used to determine occupancy are accurate, revise
 10 the assumptions as needed, and recalculate using the new assumptions.
- 11 • Calculate the effect of any shielding located between the storage area and the floor of
 12 the public area—such calculation is beyond the scope of this Appendix.
- 13 • Take corrective action (e.g., change work patterns to reduce the time spent in the area
 14 near the shield) and perform new calculations to demonstrate compliance.
- 15 • Designate the area inside the use area as a restricted area and the workers as
 16 occupationally exposed individuals. This would require controlling access to the area for
 17 purposes of radiation protection and training the workers as required by 10 CFR 19.12,
 18 “Instruction to workers.”

19

1
2 Note that in the example, Jenny evaluated the unrestricted area outside only one wall of the
3 down-hole storage area. Licensees also need to make similar evaluations for other unrestricted
4 areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose
5 received below regulatory requirements.

In addition, licensees should be alert to changes in situations (e.g., adding sources to the storage area, changing the work habits of the workers, or otherwise changing the estimate of the portion of time spent in the area in question) and should perform additional evaluations, as needed.

6
7 **References:**
8 National Council on Radiation Protection and Measurements (NCRP) Report No. 151,
9 “Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy
10 Facilities (2005).”

APPENDIX J
TRANSPORTATION

Appendix J Transportation

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

10 CFR 71.5 requires compliance with DOT regulations in 49 CFR Parts 107, 171 through 180 and 390 through 397, appropriate to the mode of transport. The following are the major areas in DOT regulations most relevant for transporting radioactive materials as Type A or Type B quantities:

49 CFR Part 172 – Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans

A. Table of Hazardous Materials and Special Provisions—Subpart B

1. 49 CFR 172.101—Purpose and use of hazardous materials table

B. Shipping Papers—Subpart C

1. 49 CFR 172.201—Preparation and retention of shipping papers
2. 49 CFR 172.202—Description of hazardous material on shipping papers
3. 49 CFR 172.203—Additional description requirements
4. 49 CFR 172.204—Shipper's certification [if applicable]

C. Marking—Subpart D

1. 49 CFR 172.301—General marking requirements for non-bulk packagings
2. 49 CFR 172.304—Marking requirements
3. 49 CFR 172.310—Class 7 (radioactive) materials
4. 49 CFR 172.324—Hazardous substances in non-bulk packagings

D. Labeling—Subpart E

1. 49 CFR 172.400—General labeling requirements
2. 49 CFR 172.401—Prohibited labeling
3. 49 CFR 172.403—Class 7 (radioactive) material
4. 49 CFR 172.406—Placement of labels
5. 49 CFR 172.436—RADIOACTIVE WHITE-I label
6. 49 CFR 172.438—RADIOACTIVE YELLOW-II label
7. 49 CFR 172.440—RADIOACTIVE YELLOW-III label

E. Placarding—Subpart F

1. 49 CFR 172.504—General placarding requirements
2. 49 CFR 172.516—Visibility and display of placards
3. 49 CFR 172.556—RADIOACTIVE placard

F. Emergency Response Information—Subpart G

1. 49 CFR 172.600—Applicability and general requirements
2. 49 CFR 172.602—Emergency response information
3. 49 CFR 172.604—Emergency response telephone number

- 1 G. Training—Subpart H
2 1. 49 CFR 172.702—Applicability and responsibility for training and testing
3 2. 49 CFR 172.704—Training requirements
4
5 H. Safety and Security Plans – Subpart I
6 1. 49 CFR 172.800—Purpose and applicability
7 2. 49 CFR 172.802—Components of a security plan
8
9 Shippers—General Requirements for Shipments and Packaging 49 CFR Part 173
10
11 A. Class 7 (Radioactive Materials) – Subpart I.
12
13 1. 49 CFR 173.25—authorized packaging and overpacks
14 2. 49 CFR 173.403—Definitions
15 3. 49 CFR 173.411—Industrial packagings
16 4. 49 CFR 173.412—Additional design requirements for Type A packages
17 5. 49 CFR 173.413—Requirements for Type B packages
18 6. 49 CFR 173.415—Authorized Type A packages
19 7. 49 CFR 173.416—Authorized Type B packages 8. 49 CFR 173.433—Requirements for
20 determining basic radionuclide values, and for the listing of radionuclides on shipping
21 papers and labels
22 9. 49 CFR 173.435—Table of A1 and A2 values for radionuclides
23 10. 49 CFR 173.441—Radiation limitations and exclusive use provisions
24 11. 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission approved
25 packages
26 12. 49 CFR 173.475—Quality control requirements prior to each shipment of Class 7
27 (radioactive) materials
28 13. 49 CFR 173.476—Approval of special form Class 7 (radioactive) materials
29
30
31 Carriage by Public Highway—49 CFR Part 177
32 A. General Information and Regulations-Subpart A
33
34 49 CFR 177.817—Shipping papers
35
36 B. Loading and Unloading – Subpart B
37
38 49 CFR 177.842—Class 7 (radioactive) material
39 Applicants should visit the U.S. DOT Web site for additional information on transportation
40 requirements: <http://www.dot.gov/>.
41

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 ^[2]					
Package ^[1,7]	3: passenger aircraft 10: road, rail, vessels and cargo aircraft		No limit		10
Conveyance ^[4]	50: road, rail and passenger aircraft 50 to No limit: vessels ^[8] 200: cargo aircraft		No limit		200
Overpack	N/A: for road, rail 50 to 200: vessels ^[8] 3: passenger aircraft; 10: cargo aircraft		N/A	No limit ^[8]	N/A
Criticality Safety Index (CSI) Limit for fissile material ^[2]					
Package ^[1,7]	50		100	100	100
Conveyance ^[4]	50: road, rail and air 50: for holds, compartments or defined deck areas of vessels ^[8] 200 to No limit: for a total vessel ^[8]		100	200 to No limit: for a total vessel ^[8]	100
Overpack	50: road, rail, vessels ^[8] and air		N/A		

- [1] The limits in this table do not apply to excepted packages.
 [2] In addition to any applicable radiation level, TI and CSI limits, separation distance requirements apply to packages, conveyances, freight containers and overpacks; to occupied positions; and to materials stored in transit. Separation distances are based on the sum of the TIs and, for fissile materials, also the sum of the CSIs.
 [3] Higher package surface radiation levels may be allowed through an approved special arrangement.
 [4] Conveyance is, for transport by public highway or rail, any transport vehicle or large freight container; and for transport by air, any aircraft.
 [5] The outer surfaces (sides, top and underside) of vehicles are defined for road and rail vehicles in §173.441.
 [6] For rail, normally occupied areas include the transport vehicle and adjacent rail cars. The 0.02 mSv/h (2 mrem/h) limit does not apply to carriers operating under a State or federally regulated radiation protection program where personnel wear radiation dosimetry devices.
 [7] Additional TI and CSI limits apply for individual packages when non-fissile radioactive material packages are mixed with fissile material packages. Also, see CSI limits established by §71.59.
 [8] For details on TI and CSI limits for transport by vessel, see §176.708.

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

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

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

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

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

The non-fixed contamination shall be determined by:

- (a) wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;
- (b) ensuring each wipe area is 300 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, or be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, or be designated by an "X" (or "RQ" if appropriate). Emergency response information consistent with §§172.600-606 shall be readily available on the transport vehicle. Shipments of limited quantities of radioactive material in excepted packages, under UN2908, 2909, 2910 and 2911, are excepted from shipping paper requirements if (a) the package does not contain fissile material unless excepted by §173.453, and (b) the limited quantity of radioactive material is not a hazardous substance or hazardous waste. For road transport, the shipping papers shall be (a) readily available to authorities in the event of accident or inspection, (b) stored within the driver's immediate reach while he is restrained by the lap belt, (c) readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle, and (d) either in a holder mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat. 		

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

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

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

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

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

Markings on Packages

Markings Always Required Unless Excepted ^[1]	Additional Markings Sometimes Required	Optional Markings
<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

- 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)**

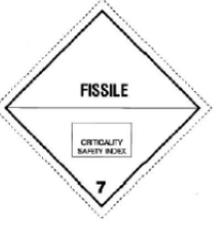
These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

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]

Other Labels ^[2]

				
White-I	Yellow-II	Yellow-III	Fissile	Empty
Radiation Surface Level (RSL):				
mSv/h:	RSL ≤ 0.005	0.005 < RSL ≤ 0.5	0.5 < RSL ≤ 2^[4]	
mrem/h:	RSL ≤ 0.5	0.5 < RSL ≤ 50	50 < RSL ≤ 200^[4]	
Transport Index (TI):^[4]				
	TI = 0^[4]	0^[4] < TI ≤ 1	1 < TI ≤ 10^[4, 5]	
			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 Emergency Response Guidebook 2008 (ERG2008) is available at the following URL:
http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/erg2008_eng.pdf



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

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

Provisions for Training (49 CFR 172, Subpart H)

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

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

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

APPENDIX K

INFORMATION NEEDED TO SUPPORT APPLICANT'S REQUEST TO PERFORM NON-ROUTINE MAINTENANCE CHECKLIST

1 **Appendix K Information Needed to Support Applicant’s Request to Perform Non-Routine**
2 **Maintenance Checklist**

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

5 Routine maintenance is maintenance that the manufacturer or distributor allows their customers
6 to perform in accordance with instructions in the user manual. Non-routine maintenance is
7 maintenance that requires specialized training and experience. Non-routine operations include
8 installation of the sealed source/device, repair or maintenance involving or potentially affecting
9 components, including electronics, related to the radiological safety (e.g., the source, source
10 holder, source drive mechanism, shutter, shutter control, or shielding), relocation, replacement,
11 and disposal of sealed sources, alignment, removal of a sealed source/device from service, and
12 any other activities during which personnel could receive radiation doses exceeding NRC limits.

13 The service provider may obtain replacement parts from the manufacturer/distributor or have its
14 customer order the parts from the manufacturer/distributor. If neither the service provider nor
15 the customer can obtain a replacement part from the manufacturer or distributor, the service
16 provider may purchase a part from another vendor or fabricate the part.
17

18 It is preferable to use the original equipment manufacturer or distributor (OEM) supplied
19 components or parts. Any non-OEM replacement components or parts, or the use of materials
20 (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor
21 will need to be evaluated to ensure that they do not degrade the results of the engineering
22 safety analysis performed and accepted as part of the device SSD registration. If the service
23 provider uses a part integral to the safe operation of the device that has not been provided by
24 the manufacturer, the service provider should verify that the part will have the commensurate
25 form, fit, and function as the original component. In addition, the service provider should
26 provide the information related to the form, fit, and function of a non-OEM part (as specified in
27 Section 8.10.9 “Maintenance”) to the customer and the customer should provide the technical
28 information to the NRC for a safety review. The use of replacement parts may result in the
29 device being a custom device in accordance with NUREG-1556, Volume 3, “Applications for
30 Sealed Source and Device Evaluation and Registration.” The service provider should not install
31 this part until verifying that its customer has retained the appropriate authorization to
32 proceed. Licensees also should ensure that, after maintenance or repair is completed, the
33 sealed source/device is tested and functions as designed, before the unit is returned to routine
34 use.
35

36 For guidance on the use of sources that have not been supplied by the manufacturer and/or
37 distributor, see Regulatory Issue Summary 2013-01, March 12, 2013 (Agencywide Documents
38 Access and Management System (ADAMS) Accession No. ML12313A147).
39

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

43 Thus, applicants wishing to perform non-routine operations must use personnel with special
44 training and follow appropriate procedures consistent with the manufacturer’s or distributor’s
45 instructions and recommendations that address radiation safety concerns (e.g., use of radiation

1 survey meter, shielded container for the source, and personnel dosimetry (if required)).
2 Accordingly, provide the following information.

3 Describe the types of work, maintenance, cleaning, or repair that involve:

- 4 • installation, relocation, or alignment of the sealed source/device
- 5 • components, including electronics, related to the radiological safety of the device (e.g.,
6 the source, source holder, source drive mechanism, shutter, shutter control, or shielding)
- 7 • replacement and disposal of sealed sources
- 8 • removal of a sealed source/device from service
- 9 • a potential for any portion of the body to come into contact with the primary radiation
10 beam
- 11 • any other activity during which personnel could receive radiation doses exceeding NRC
12 limits

13 The principal reason for obtaining this information is to assist in the evaluation of the
14 qualifications of individuals who will conduct the work and the radiation safety procedures they
15 will follow.

- 16 • Identify who will perform non-routine operations and their training and experience.
17 Acceptable training would include manufacturer's or distributor's courses for non-routine
18 operations or equivalent.
- 19 • Verify that the maintenance activities are authorized on the license.
- 20 • Submit operating and emergency procedures for non-routine operations. These
21 procedures should ensure the following:
 - 22 — Doses to personnel and members of the public are within regulatory limits and
23 ALARA (e.g., use of shielded containers or shielding).
 - 24 — The source is secured against unauthorized removal or access or under constant
25 surveillance.
 - 26 — Appropriate labels and signs are used.
 - 27 — Manufacturer's or distributor's instructions and recommendations are followed.
 - 28 — Any non-manufacturer/non-distributor supplied replacement components or parts,
29 or the use of materials (e.g., lubricants) other than those specified or
30 recommended by the manufacturer or distributor are evaluated to ensure that they
31 do not degrade the engineering safety analysis performed and accepted as part of
32 the device registration.
 - 33 — Before being returned to routine use, the sealed source/device is tested to verify
34 that it functions as designed and source integrity is not compromised.
- 35 • Emergency procedures should be developed and reviewed for all potential accident
36 scenarios.
- 37 • Confirm that individuals performing non-routine operations will wear both whole body
38 and extremity monitoring devices or perform a prospective evaluation demonstrating that
39 unmonitored individuals performing non-routine operations are not likely to receive, in 1
40 year, a radiation dose in excess of 10 percent of the allowable limits.

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- Verify possession of at least one survey instrument that meets the criteria in “Radiation Safety Program–Instruments in NUREG-1556, Volume 18, Revision 1, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses,’.”
 - Describe steps to be taken to ensure that radiation levels in areas where non-routine operations will take place do not exceed the limits in 10 CFR 20.1301, “Dose limits for individual members of the public.” For example, applicants can do the following:
 - Commit to performing surveys with a survey instrument (as described above).
 - Specify where and when surveys will be conducted during non-routine operations.
 - Commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by 10 CFR 20.2103.
 - Commit to providing the customer a service report describing the work that was completed, especially replacement parts and/or sources.

APPENDIX L

SUGGESTED [SPECIFIC PROGRAM] AUDIT CHECKLIST

1 assurance is or is not needed based on possession limits on the license and whether financial
2 instruments are still valid or need revision.

3 **Section 7, Leak Tests.** Verify that all sealed/plated foil sources are tested for leakage at the
4 prescribed frequency described in the Sealed Source and Device Registration certificate, and in
5 accordance with licensee commitments. Records of results should be maintained.

6
7 **Section 8, Inventories.** Verify that physical inventories are conducted at least once every 6
8 months to account for all sources; inventory records should be maintained. In addition,
9 licensees in possession of nationally tracked sources must complete an annual reconciliation
10 inventory in accordance with 10 CFR 20.2207, "Reports of transactions involving nationally
11 tracked sources."

12
13 **Section 9, Radiation Surveys.** Verify that the licensee has appropriate, operable, and
14 calibrated survey instruments available, that the instruments are calibrated periodically in
15 accordance with 10 CFR 20.1501, "General," and in accordance with license conditions.
16 Calibration records must be retained for 3 years after the record is made in accordance with
17 10 CFR 20.2103, "Records of surveys." Check that radiation levels in areas adjacent to use are
18 within regulatory limits. Verify compliance with 10 CFR 20.1301, "Dose limits for individual
19 members of the public." Records of surveys must be retained for 3 years after the record is
20 made.

21
22 **Section 10, Receipt and Transfer of Radioactive Material (Includes Waste Disposal).**
23 Verify that packages containing licensed material, received from others, are received, opened,
24 and surveyed in accordance with 10 CFR 20.1906, "Procedures for receiving and opening
25 packages." Ensure that transfers are performed in accordance with 10 CFR 30.41, "Transfer of
26 byproduct material." Records of surveys, receipt, and transfer must be maintained in
27 accordance with 10 CFR 20.2103 and 30.51, "Records."

28 **Section 11, Transportation.** Determine compliance with U.S. Department of Transportation
29 (DOT) requirements. Verify that radioactive packages are prepared, marked, and labeled in
30 accordance with 49 CFR Parts 172 and 173 requirements. Verify that shipping papers are
31 prepared, that they contain all needed information, and that they are readily accessible during
32 transport (49 CFR 172.200, 201, 202, 203, 204 and 177.817(e)). Verify that any import and/or
33 export of licensed material is conducted in accordance with the requirements set forth
34 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material."

35 **Section 12, Personnel Radiation Protection.** Evaluate the licensee's determination that
36 unmonitored personnel are not likely to receive more than 10 percent of the allowable limits (i.e.,
37 500 millirem in a year). Alternately, if personnel dosimetry is provided and required, verify that it
38 complies with 10 CFR 20.1501(c) and licensee commitments. Review personnel monitoring
39 records; compare exposures of individuals doing similar work; determine reasons for significant
40 differences in exposures. If any worker voluntarily declared her pregnancy in writing, evaluate
41 the licensee's compliance with 10 CFR 20.1208, "Dose equivalent to an embryo/fetus." Check
42 whether records are maintained as required by 10 CFR 20.2101, 2102, 2103, 2104 and 2106.

43 **Section 13, Security of Risk Significant Radioactive Material (RSRM)** The auditor should
44 conduct a hands-on and record review of the licensee's physical protection program to verify the
45 licensee's compliance with 10 CFR Part 37, "Physical Protection of Category 1 and Category 2

1 Quantities of Radioactive Material.” NUREG-2155, “Implementation Guidance for 10 CFR Part
2 37, ‘Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material’,”
3 contains useful information. Licensees may propose alternative ways for demonstrating
4 compliance with these requirements.

5 **Section 14, Auditor’s Independent Measurements (If Applicable).** The auditor should make
6 independent survey measurements and compare the results with those made or used by the
7 licensee.

8 **Section 15, Radioactive Effluents, Waste Management and Disposal.** Determine if
9 radioactive effluents and radioactive waste are properly disposed and records maintained.

10 **Section 16, Notification and Reports.** Check to determine the licensee’s compliance with the
11 notification and reporting requirements in 10 CFR Parts 19, 20, 21, 30, 31, 32, 33, 34, 35, 36,
12 37, 39, 40, 70, and 71. Ensure that the licensee is aware of the telephone number for NRC’s
13 Emergency Operations Center; 301–816-5100.

14 **Section 17, Posting and Labeling.** Check for compliance with the posting and labeling
15 requirements of 10 CFR 19.11, 20.1902, 20.1904, and 21.6.

16
17 **Section 18, Recordkeeping for Decommissioning.** Check to determine compliance with
18 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g). The Decommissioning Planning Rule
19 [76 FR 35512 (June 17, 2011,)] requires licensees to minimize contamination released into the
20 site, and to identify the location and amount of significant residual radioactivity throughout the
21 facility and site, including in the subsurface. The results of these surveys must be documented
22 in records important to decommissioning if the identified contamination will require remediation
23 to meet the unrestricted use criteria of 10 CFR 20.1402, “Radiological criteria for unrestricted
24 use.”

25
26 **Section 19, NRC Correspondence.** Check to determine if the licensee is receiving such
27 documents as regulatory issue summaries, bulletins, information notices, and FSME
28 Newsletters, from the NRC. Check whether the licensee took appropriate action in response to
29 NRC mailings.

30 **Section 20, License Conditions or Issues.** Verify compliance with conditions on the service
31 provider’s license. Review last license condition to determine if all documents listed should
32 remain on the license or be revised.

33 **Section 21, Performance-based Review.** Licensee management may conduct performance-
34 based reviews by observing work in progress, interviewing staff, and spot-checking required
35 records. As a part of the audit program, applicants should consider performing unannounced
36 audits to determine if, for example, Safe Use and Emergency Procedures are available and are
37 being followed.

38 **Section 22, Problems or Deficiencies Noted; Recommendations.** Note any deficiencies that
39 were identified and the corrective actions taken (or to be taken), and timeframe for completion.

40 **Section 23, Evaluation of Other Factors.** Evaluate licensee management’s involvement with
41 the radiation safety program, whether the RSO has sufficient time to perform his/her duties, and
42 whether the licensee has sufficient staff to handle the workload and maintain compliance with

1 regulatory requirements. The NRC conducts performance based observations during
2 inspections and encourages licensees to also observe licensed activities in process as part of
3 the audit review.

4 **Note:** All areas indicated in audit notes may not be applicable to every license and may not
5 need to be addressed during each audit.
6

7 **Sample Audit Checklist**

8 Audit Report No. _____ License No. _____

9 Licensee's name and mailing address:
10

11 _____

12 _____

13 _____

14 _____

15 Audit of licensed activities at (Address(es)):
16

17 _____

18 _____

19 _____
20

21 Contact at Audit Location _____ Telephone No. _____

22 Date of this Audit _____

23 Summary of Findings and Action:

24 No deficiencies

25 Deficiencies

26 Indicate if corrective actions taken to prevent recurrence from the previous audit were
27 comprehensive and effective Recommendations:
28

29

30

31 Auditor: _____ Date: _____

32 (Signature)

33

34

35 1. AUDIT HISTORY N/A (N/A means "Not applicable" – Initial Audit)

- 1 a. Last audit of this location conducted on: _____
- 2 b. Problems/deficiencies identified during last two audits or two years,
- 3 whichever is longer Y N
- 4 c. Open problems/deficiencies from the previous audits:
- 5
- 6

Status Requirement	Problem/Deficiency	Corrective Action Taken (Y/N)	Open/Closed

- 13 d. Any previous problem/deficiency not corrected or repeated Y N N/A
- 14 Explain:
- 15

16 **2. ORGANIZATION AND SCOPE OF PROGRAM**

- 17 a. Briefly describe organizational structure
- 18 b. Structure is as described in license documents Y N
- 19 c. Multiple authorized locations of use listed Y N
- 20 Provide address(es) of those locations reviewed as part of this audit:
- 21 d. Briefly describe scope of activities involving licensed material, frequency
- 22 of use, staff size
- 23 e. Radiation Safety Officer:
- 24 Authorized on license Y N
- 25 Fulfills duties as RSO Y N
- 26 f. Use of licensed material only by authorized individuals Y N
- 27 Remarks:
- 28

29 **3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS**

- 30 a. Instructions to workers per [10 CFR 19.12] Y N
- 31 b. Training program implemented as required [L/C] Y N
- 32 c. Training records maintained [L/C] Y N
- 33 d. Evaluation of individuals' understanding of procedures and requirements
- 34 based on interviews, observation of selected workers was performed Y N
- 35 If so:
- 36 Each has an up-to-date copy of the licensee's operating use and emergency
- 37 procedures Y N
- 38 Adequate understanding of:
- 39 Operating procedures Y N
- 40 Emergency procedures Y N
- 41 e. 10 CFR Part 20
- 42 Workers cognizant of requirements for:
- 43 Radiation Protection Program [20.1101] Y N
- 44 Annual dose limits [20.1301, 20.1302] Y N
- 45 NRC Forms 4 and 5 Y N
- 46 10 percent monitoring threshold [20.1502] Y N
- 47 Dose limits to embryo/fetus and declared pregnant women [20.1208] Y N
- 48 Procedures for opening packages [20.1906] Y N

- 1 f. 10 CFR Parts 19, 20, 21, 30, 37, 40, 70 and 71 reviewed as applicable Y N
2 Remarks:
3
- 4 4. INTERNAL AUDITS, REVIEWS OR INSPECTIONS
5 a. Audits are conducted Y N
6 1. Audits conducted by _____
7 2. Frequency _____
8 b. Content and implementation of the radiation protection program reviewed
9 at least annually [20.1101(c)] Y N
10 c. Records maintained [20.2102] Y N
11 Remarks:
12
- 13 5. FACILITIES
14 a. Facilities as described in license documents Y N
15 b. Access to restricted area/licensed material in accordance with 20.1801,
16 20.1802 Y N
17 Remarks:
18
- 19 6. MATERIALS
20 Isotopes, quantities, model numbers, and use as authorized on license Y N
21 Using NUREG-1757 Volume 3: Financial Assurance is current Y N N/A
22 [10 CFR 30.35, 10 CFR 40.36, 10 CFR 70.25]
23 Remarks:
24
- 25 7. LEAK TESTS
26 a. Leak test performed as described in correspondence with NRC
27 (leak test kit; service provider licensee performed and/or analyzed) Y N
28 b. Frequency: every 6 months or other interval, as approved by NRC or
29 Agreement State Y N
30 c. Records with appropriate information maintained Y N
31 Remarks:
32
- 33 8. INVENTORIES
34 a. Conducted at 6-month intervals [L/C] Y N
35 b. Visual verification confirmed or security seal still in place Y N
36 c. Transactions entered into the National Source Tracking System,
37 including annual reconciliation [10 CFR 20.2207] Y N N/A
38 d. Records with appropriate information maintained Y N
39 Remarks:
40
- 41 9. RADIATION SURVEYS
42 a. Instruments and Equipment:
43 Appropriate operable survey instrumentation possessed or readily
44 available [L/C] Y N
45 Calibrated as required [20.1501] Y N
46 Calibration records maintained [20.2103(a)] Y N
47 b. Briefly describe survey requirements [20.1501]:
48 c. Performed as required [20.1501(a)] Y N
49 Radiation levels within regulatory limits Y N
50 Corrective action taken and documented Y N N/A

- 1 d. Records maintained [20.2103] Y N
- 2 e. Protection of members of the public:
- 3 Adequate surveys made to demonstrate either (a) that the TEDE to the
- 4 individual likely to receive the highest dose does not exceed 100 mrem in
- 5 a year, or (b) that if an individual were continuously present in an unrestricted
- 6 area, the external dose would not exceed 2 mrem in any hour and 50 mrem in
- 7 a year [20.1301(a)(1), 20.1302(b)] Y N
- 8 Unrestricted area radiation levels do not exceed 2 mrem in any 1 hour
- 9 [20.1301(a)(2)]..... Y N
- 10 Records maintained [20.2103, 20.2107] Y N

11 Remarks:

12

13 **10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL**

- 14 a. Describe how packages are received and by whom:
- 15
- 16 b. Written package opening procedures established and followed
- 17 [20.1906(e)]..... Y N
- 18 c. If package shows evidence of degradation, monitor
- 19 for contamination and radiation levels..... Y N N/A
- 20 d. Monitoring of degraded packages performed within time
- 21 specified [20.1906(c)]..... Y N N/A
- 22 e. Transfer(s) between licensees performed in compliance with 30.41 Y N N/A
- 23 f. Records of receipt/transfer maintained [30.51] Y N
- 24 g. Transfers within licensee's authorized users or locations performed
- 25 as required [L/C]..... Y N N/A
- 26 h. Package receipt/distribution activities evaluated for compliance with
- 27 20.1301 [20.1302] Y N N/A

28 Remarks:

29

30 **11. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 170-189) N/A**

- 31 a. Licensee shipments are:
- 32 Delivered to common carriers Y N N/A
- 33 Transported in licensee's own private vehicle..... Y N N/A
- 34 No shipments since last audit Y N
- 35 b. Hazmat Training
- 36 1. Applicability and responsibility for training and
- 37 testing [49 CFR (172.702)] Y N N/A
- 38 2. Training requirements [49 CFR (172.704)] Y N N/A
- 39 c. Packages..... N/A
- 40 Authorized packages used [173.415, 416]..... Y N N/A
- 41 Closed and sealed during transport [173.475(f)]..... Y N
- 42 Properly labeled and marked [172.403, 173.441] Y N
- 43 d. Shipping Papers..... N/A
- 44 Prepared and used [172.200(a)] Y N
- 45 Proper {Shipping Name, Hazard Class, UN Number, Quantity, Package
- 46 Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form,
- 47 Activity, Category of Label, TI, Shipper's Name, Certification and Signature,
- 48 Emergency Response Phone Number, "Cargo Aircraft Only" (if applicable)}
- 49 [172.200-204] Y N
- 50 Readily accessible during transport [177.817(e)]..... Y N

- 1 f. Vehicles..... Y N N/A
- 2 Cargo blocked and braced [177.842(d)]..... Y N
- 3 Placarded, if needed [172.504] Y N
- 4 Proper overpacks, if used (shipping name, UN Number, labeled,
- 5 statement indicating that inner package complies with specification
- 6 package) [173.25] Y N N/A
- 7 g. Any incidents reported to DOT [171.15, 171.16]..... Y N
- 8 Remarks:
- 9

10 12. PERSONNEL RADIATION PROTECTION

- 11 a. ALARA considerations are incorporated into the Radiation Protection
- 12 Program [20.1101(b)] Y N
- 13 b. Adequate documentation of determination that unmonitored
- 14 individuals are not likely to receive >10 percent of
- 15 allowable limit [20.1502(a)] Y N N/A
- 16 **OR**
- 17 c. External dosimetry required and used Y N N/A
- 18 Supplier: _____ Frequency: _____
- 19 Supplier is NVLAP-approved [20.1501(d)(1)] Y N
- 20 Dosimeters exchanged at required frequency [L/C]..... Y N
- 21 d. Occupational intake monitored and assessed [20.1502(b)] Y N N/A
- 22 e. Reports:..... Y N N/A
- 23 Reviewed by: _____ Frequency: _____
- 24 Auditor reviewed personnel monitoring records for period _____ to _____
- 25 Prior dose determined for individuals likely to receive doses [20.2104]..... Y N
- 26 Maximum exposures TEDE: _____ Other: _____
- 27 f. NRC Forms or equivalent [20.2104(d), 20.2106(c)]:
- 28 NRC-4 "Cumulative Occupational Exposure History" Complete: Y N
- 29 NRC-5 "Occupational Exposure Record for a Monitoring Period" Complete: Y N
- 30 g. Worker declared her pregnancy in writing during audit period
- 31 (review records) Y N N/A
- 32 If yes, determine compliance with [20.1208] Y N
- 33 and check for records per 20.2106(e) Y N
- 34 h. Records of exposures, surveys, monitoring, and evaluations maintained
- 35 [20.2102, 20.2103, 20.2106, L/C]..... Y N
- 36 i. Pocket dosimeters and/or alarming rate meters [L/C]: Y N
- 37 Possessed and used as required Y N
- 38 Operable and calibrated/checked at required frequency Y N
- 39 Records maintained Y N N/A
- 40 Remarks:
- 41

42 13. SECURITY PROGRAM FOR CATEGORY 1 AND CATEGORY 2 MATERIALS

- 43 [10 CFR Part 37]
- 44 a. Commensurate security program implemented Y N N/A
- 45 b. Trustworthiness and Reliability Determinations Made Y N
- 46 c. Access Control to information and RSRM..... Y N
- 47 d. Monitoring/Detection/Assessment/Response Operational 24/7..... Y N N/A
- 48 e. Valid test of security system to ensure operability Y N N/A
- 49 f. Local Law Enforcement Agency Coordination and Written Plan Y N N/A

- 1 d. Disposal of liquid scintillation (LS) media and/or animal carcasses:..... N/A
 2 Licensee disposes of LS media and carcasses contaminated with only H-3 or
 3 C-14, and at a concentration not exceeding 0.05 µCi/g per 20.2005..... Y N
 4 Records maintained [20.2108] Y N

5 Remarks:

- 6
 7 e. Transfers for disposal at land disposal facilities:..... N/A
 8 Waste transferred to person specifically licensed to receive waste [30.41,
 9 20.2001(b)]..... Y N
 10 Each shipment accompanied by a shipment manifest prepared as specified
 11 in Section I of Appendix G to 10 CFR Part 20 [10 CFR 20.2006(b)
 12 and Section III.A.4 of Appendix G to 10 CFR Part 20] Y N
 13 Shipment manifests certified as specified in Section II of Appendix G to
 14 10 CFR Part 20 [10 CFR 20.2006(c)]..... Y N
 15 Compliance with Section III of Appendix G to 10 CFR Part 20 [10 CFR 20.2006(d)]:
 16 **Note:** The licensee's waste is likely to be Class A waste not packaged for
 17 disposal in cardboard or fiberboard boxes [61.56(a)]
 18 Liquid wastes solidified [61.56(a)] Y N
 19 Volume of solid wastes contain less than 1 percent freestanding liquid
 20 [61.56(a)(3)] Y N
 21 Waste does not generate harmful vapors [61.56(a)]..... Y N
 22 Waste structurally stable, i.e., will maintain its physical dimensions and
 23 form under expected disposal conditions [61.56(b)] Y N
 24 Void spaces within the waste and between the waste and its package
 25 minimized [61.56(b)]..... Y N
 26 Waste packages labeled to identify their proper class [Section III.A.2 of
 27 Appendix G to 10 CFR Part 20] Y N
 28 Licensee conducts a QA program to ensure compliance with 61.55 and
 29 61.56, and which includes management evaluation of audits
 30 [Section III.A.3 of Appendix G to 10 CFR Part 20] Y N
 31 For shipments not acknowledged by recipient within 20 days after
 32 transfer, incident investigated and reported [Section III.A.9 of
 33 Appendix G to 10 CFR Part 20] Y N N/A
 34 Records maintained [20.2108] Y N

35 Remarks:

- 36
 37 f. Special disposal procedures and other effluents (e.g., hood exhausts, special
 38 dilutions):..... N/A
 39 Performed in accordance with L/C Y N
 40 Appropriate surveys conducted [20.1501, L/C] Y N
 41 Operations comply with 20.1201 and 20.1301 Y N
 42 Special disposals per 20.2001 and 20.2002, i.e., no improper/unauthorized
 43 disposals were noted Y N
 44 Use of dose constraint/ALARA [20.1101(d)] Y N
 45 Records maintained [20.2108] Y N

46 Remarks:

- 47
 48 g. Waste compaction operations:..... N/A
 49 Airborne releases evaluated and controlled [20.1501, 20.1701, L/C] Y N
 50 Internal exposures evaluated and controlled [20.1501, 20.1204, 20.1702,

- 1 20.1703, 20.1201] Y N
2 Compliance with 20.1301 evaluated [20.1302] Y N
3 Remarks:
4
5 h. Waste storage areas: N/A
6 Adequate protection from the elements (floods, tornadoes, hurricanes, etc.)
7 and fire [L/C]..... Y N
8 Adequate control of waste in storage [20.1801]..... Y N
9 Containers properly labeled and area properly posted [20.1902, 20.1904] Y N
10 Package integrity adequately maintained [L/C]..... Y N
11 Adequate records of surveys and material accountability are maintained
12 [20.2103, 20.2108] Y N
13
14 16. NOTIFICATION AND REPORTS..... N/A
15 a. Licensee in compliance with 19.13, 30.50 (reports to individuals,
16 public and occupational, monitored to show compliance with Part 20).. Y N N/A
17 b. Licensee in compliance with 20.2201, 30.50 (theft or loss)..... Y N None
18 c. Licensee in compliance with 20.2202, 30.50 (incidents)..... Y N None
19 d. Licensee in compliance with 20.2203, 30.50 (overexposures and
20 high radiation levels) Y N None
21 e. Licensee in compliance with 21.21 (device defect)..... Y N None
22 f. Licensee aware of telephone number for NRC Emergency Operations
23 Center [301-816-5100]..... Y N
24
25 17. POSTING AND LABELING
26 a. NRC Form 3 "Notice to Workers" is posted [19.11]..... Y N
27 b. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures
28 adopted pursuant to Part 21, and license documents are posted, or a notice
29 indicating where documents can be examined is posted [19.11, 21.6]..... Y N
30 c. Other posting and labeling per [20.1902, 1904] and the licensee is not
31 exempted by 20.1903, 1905..... Y N
32 Remarks:
33
34 18. RECORDKEEPING FOR DECOMMISSIONING N/A
35 a. Records of information important to the safe and effective decommissioning
36 of the facility maintained in an independent and identifiable location until
37 license termination Y N
38 b. Records include all information outlined in 30.35(g), 40.36(f), 70.25(g)..... Y N
39 Remarks:
40
41 19. NRC CORRESPONDENCE
42 a. Review of such documents as NRC Regulatory Issue Summaries, Bulletins, Information
43 Notices, FSME Newsletters Y N
44 b. Appropriate action taken in response to NRC correspondence. Y N
45 Remarks:
46

- 1 20. LICENSE CONDITIONS OR ISSUES N/A
2 a. Review license conditions; NRC/Agreement State violations, Orders, Confirmatory
3 Action Letters; site-specific procedures and other safety or security issues, and describe
4 findings:
5
6 b. Problems/deficiencies identified at licensee facilities other than at audit location:
7
8 c. Evaluation of compliance:
9
- 10 21. PERFORMANCE-BASED REVIEW N/A
11 a. Conduct performance-based reviews of radiation workers performing licensed activities:
12 (1) to assess the capability of the radiation workers to maintain exposures ALARA;
13 (2) to assess that radiation workers follow the operating procedures;
14 (3) to assess the effectiveness of the operating procedures and compliance with the
15 regulations, license conditions and the licensee commitments submitted in
16 support of a license (and incorporated by "tie-down" conditions);
17 (4) to ensure the safe and secure use of radioactive material;
18 (5) to verify that radiation workers are cognizant of the emergency procedures and, if
19 necessary, would be able to implement them and maintain exposures ALARA;
20 and
21 (6) to ensure that emergency procedures have been developed for all likely
22 scenarios.
23 b. Take the necessary actions to address programmatic and performance deficiencies with
24 radiation workers and facilitate immediate corrective measures.
25
- 26 **Note:** Performance-based reviews may include observation of licensed activities, review of
27 records, and interviews with key personnel.
28
- 29 22. PROBLEMS OR DEFICIENCIES NOTED AND RECOMMENDATIONS N/A
30 **Note:** Briefly state (1) the requirement and (2) how and when violated. Provide
31 recommendations for improvement.
32
- 33 23. EVALUATION OF OTHER FACTORS
34 a. Senior licensee management is appropriately involved with the radiation
35 safety program and/or radiation safety officer (RSO) oversight Y N
36 b. RSO has sufficient time to perform his/her radiation safety duties and is not
37 too busy with other assignments Y N
38 c. Licensee has sufficient staff Y N
39 d. Performance-based review (observation of licensed activities conducted)..... Y N
40 Remarks:

1 **Note:** All areas indicated in audit notes may not be applicable to every license and may not
2 need to be addressed during each audit. For example, licensees do not need to address areas
3 that do not apply to the licensee's activities, and activities that have not occurred since the last
4 audit need not be reviewed at the next audit.

5
6
7 Date of This Audit _____ Date of Last Audit _____

8 Next Audit Date _____

9 Auditor _____ Date _____

10
11 (Signature) _____

12
13 Management Review _____ Date _____

14
15 (Signature) _____

APPENDIX M

MODEL WASTE DISPOSAL PROGRAM

Appendix M Model Waste Disposal Program

General Guidelines

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary “non-radioactive” waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind workers that nonradioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, inflammability), and costs.
5. Waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
6. Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.
7. Consult with radioactive waste brokers to ensure that any waste that a licensee generates will be accepted at a low level waste disposal facility.
8. A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest in accordance with 10 CFR Part 20, Appendix G, “Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests.”

Model Procedure for Disposal by Decay-in-storage (DIS)

Applicants should assure that adequate space and facilities are available for the storage of waste for DIS. Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.

1. Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
2. Short-lived waste should be segregated from long-lived waste.
3. Waste should be stored in suitable well-marked containers and the containers should provide adequate shielding.
4. Liquid and solid wastes should be stored separately.
5. When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.

- 1 6. The identification label should include the date when the container was sealed, the
2 longest-lived radioisotope in the container, total activity, date when the longest-lived
3 radioisotope cannot be distinguished from the background radiation level, and the name of
4 the individual who sealed the container. The container may be transferred to the DIS
5 area. When large quantities are held for DIS, sufficient quantities may be present after
6 allowing the material to decay; therefore persons performing surveys should be aware of
7 the potential for measurable radiation.
- 8 7. The contents of the container should be allowed to decay based on the longest-lived
9 radioisotope in the container.
- 10 8. Prior to disposal as ordinary trash, each container should be monitored as follows:
 - 11 a. Select a radiation detection survey meter capable of detecting the isotope in question
12 and check the instrument for proper operation.
 - 13 b. Survey the contents of each container in a low background area.
 - 14 c. Remove any shielding from around the container.
 - 15 d. Monitor all surfaces of the container.
 - 16 e. Discard the contents as ordinary trash only if the surveys of the contents indicate no
17 residual radioactivity, i.e., surface readings are indistinguishable from background.
 - 18 f. If the surveys indicate residual radioactivity, return the container to DIS area and
19 contact the RSO for further instructions.
- 20 9. If the surveys indicate no residual radioactivity, record the date when the container was
21 sealed, the disposal date, type of waste (e.g., used or unused material, gloves,), survey
22 instrument used, and the name of the individual performing surveys and disposing of the
23 waste.

24 All radiation labels must be defaced or removed from containers and packages prior to disposal
25 as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need
26 the labels removed provided that the following is done: waste barrels are sealed prior to delivery
27 to the waste disposal firm and delivered directly from the licensee's facility; labels are removed
28 from the waste barrels/containers; and the waste is incinerated, not placed in a landfill, and the
29 waste disposal firm is cautioned not to open the container prior to incineration.

30 **Model Procedure for Disposal of Liquids into Sanitary Sewerage**

- 31 1. Confirm that the sewer system is a public system, not a private sanitary sewer, septic
32 system or leach field.
- 33 2. Confirm that the liquid waste being discharged is soluble (or is biological material that is
34 readily dispersible) in water.
- 35 3. Calculate the amount of each radioisotope that can be discharged by using the information
36 from prior, similar discharges and the information in 10 CFR Part 20, Appendix B.
- 37 4. Make sure that the amount of each radioisotope does not exceed the monthly and annual
38 discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR Part 20, Appendix B,
39 Table 3.
- 40 5. If more than one radioisotope is released, the sum of the ratios of the average monthly
41 discharge of a radioisotope to the corresponding limit in 10 CFR Part Part 20, Appendix B,
42 Table 3 must not exceed unity.

- 1 6. Total quantity of licensed material released into the sanitary sewerage system in a year
2 does not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci)
3 of all other radioisotopes combined.
- 4 7. Record the date, radioisotope(s), estimated activity of each radioisotope, location where
5 the material is discharged, and the name of the individual discharging the waste.
- 6 8. Liquid waste should be discharged only via designated sinks or toilets.
- 7 9. Discharge liquid waste slowly to minimize splashing with water running to be sure that the
8 material moves out of the sink into the sewer system.
- 9 10. Survey the sink and surrounding work surfaces to confirm that no residual material or
10 contamination remained in the sink or on work surfaces. Decontaminate as appropriate.
- 11 11. Decontaminate all areas or surfaces if found to be contaminated.
- 12 12. For all releases to the sanitary sewer from the licensed facility, maintain records identifying
13 each location of release (i.e., the sink that was used for disposal), and each radioisotope
14 and its quantity and concentration that is released into the sewer system, that demonstrate
15 compliance with the regulatory limits for total quantity released and concentrations
16 released by the licensed facility.

17 **Model Procedure for Disposal by Incineration**

- 19 1. Training and experience of the person who will be responsible for the on-site and day-to-
20 day supervision of incinerator operations, if different from the RSO.
- 21 2. Chemical and/or physical form of the waste.
- 22 3. How the waste is segregated, packaged and labeled for transfer from the generation site
23 to the incinerator.
- 24 4. Methods for determining concentration of radioactivity averaged over the weight of the
25 material to be incinerated (microcuries per gram of waste medium) for each isotope to be
26 incinerated; and the total radioactivity of each isotope per burn. Describe procedures for
27 ensuring that environmental release limits specified in 10 CFR Part 20 will not be
28 exceeded and remains as low as is reasonably achievable (ALARA).
- 29 5. Procedures for packaging, handling, securing and monitoring of waste to prevent
30 contamination and unnecessary exposure to personnel or property.
- 31 6. Method for measuring or estimating the concentration of radioactive material remaining in
32 the ash residue.
- 33 7. Procedures for collection, handling, and disposal of the ash residue.
- 34 8. Records that document receipts, incinerations, environmental releases of effluents, and
35 disposals of ash generated in the incineration process that include the units that will be
36 used in these records (e.g., Ci/ml).
- 37 9. Characteristics of the site location and incinerator including: height of the stack, rated air
38 flow (cubic feet per hour or similar units), proximity of the stack or other discharge to
39 occupied areas (e.g., residences, school, hospital), and distance to the nearest air intake
40 ducts of adjacent buildings. Describe any scrubbers, filters, or air cleaning equipment that
41 is present.
- 42 10. Methods for evaluating airborne and liquid concentration of radionuclides released from
43 the stack, scrubbers, condensers, and associated systems.

- 1 11. Radiation safety procedures for monitoring personnel involved in incineration operations,
2 and for monitoring all effluent generated by the incineration process. The procedures must
3 ensure that regulatory limits for environmental releases of radioactivity will not be
4 exceeded. The applicant should describe the disposal method for any ash generated that
5 exceeds regulatory limits.
- 6 12. Written commitment that the applicant has coordinated with appropriate state and local
7 authorities and that such permits and other authorizations as may be necessary have
8 been obtained.
- 9 13. Maintain annual reports related to 40 CFR Part 61, Licensing Requirements for Land
10 Disposal of Radioactive Waste.

11 **Model Procedure for Compaction**

12 The following information should be provided from licensees that propose to compact waste.

- 13
- 14
- 15 1. Describe the compactor to demonstrate that it is adequately designed and manufactured
16 to safely compact the type and quantity of waste generated during licensed operations
17 (e.g., provide manufacturer's specifications, annotated sketches, photographs).
- 18 2. Describe the type, quantities, and concentrations of waste to be compacted.
- 19 3. Provide an analysis of the potential for airborne release of radioactive material during
20 compaction activities.
- 21 4. Provide the location of the compactor(s) within the waste processing area(s), as well as
22 a description of the ventilation and filtering systems used in conjunction with the
23 compactors. Include a description of the procedures for monitoring filter blockage and
24 exchange.
- 25 5. Discuss the methods used to monitor worker breathing zones and/or exhaust systems.
- 26 6. Discuss the types and frequencies of surveys that will be performed for contamination
27 control in the compactor area.
- 28 7. Discuss the instruction provided to compactor operators, including instructions for
29 protective clothing, checks for proper functioning of equipment, method of handling
30 uncompacted waste, and method of examining containers for defects.

31 **Nuclear Laundry**

32 Based on 10 CFR 20.2003, "Disposal by release into sanitary sewerage," a nuclear laundry
33 licensee is authorized to dispose of radioactive waste by release into the sanitary sewer.
34 Generally, a nuclear laundry licensee is not authorized to possess or transfer for disposal
35 radioactive waste except that generated as a result of laundering activities, such as solid
36 residue waste from the water treatment or air exhaust systems. The solid residue resulting from
37 laundry activities must be disposed of in accordance with license requirements and
38
39

1 10 CFR 20.2001, "General requirements," which usually results in transfer to a licensed
2 radioactive waste disposal facility.

3
4 Solid residue waste, such as sludge and lint from the water treatment or air exhaust systems,
5 and process liquids, are considered to be part of the waste generated as a result of the nuclear
6 laundry operation. Rejected laundry items, such as coveralls and rubber shoe covers, that are
7 unusable or contaminated with residual radioactivity exceeding the pre-set radiation limits for
8 reuse, are returned to the customers for treatment and disposal in accordance with the
9 customers' waste management program. In some cases, it might be acceptable to conclude that
10 zippers, in the case of dissolved disposable protective clothing, are more like residue from the
11 laundry process and, therefore, to allow licensed nuclear laundry facilities to send them directly
12 for disposal as radioactive waste. The NRC finds this approach acceptable. NRC would also
13 find acceptable an approach where by where the zippers would be treated like unusable
14 material similar to rejected laundry items, noted above, that are returned to the customers for
15 treatment and disposal. Thus, in either case, the NRC does not consider a nuclear laundry
16 facility, including one engaged in laundering and dissolving of disposable protective clothing, to
17 constitute a waste receipt or processing facility.

APPENDIX N

INTERIM STAFF GUIDANCE ON CONSTRUCTION

1 **Appendix N Interim Staff Guidance on Construction**

2
3 **INTERIM STAFF GUIDANCE TO NUREG-1556 AND NUREG-1520:**
4 **COMMENCEMENT OF CONSTRUCTION AT EXISTING AND PROPOSED SOURCE,**
5 **BYPRODUCT, AND SPECIAL NUCLEAR MATERIAL FACILITIES AND IRRADIATORS WITH**
6 **SIGNIFICANT ENVIRONMENTAL IMPACTS**

7
8 **PURPOSE AND SCOPE**
9

10 This Interim Staff Guidance (ISG) provides guidance to U.S. Nuclear Regulatory Commission
11 (NRC) staff on the new definition of construction and the consideration of activities that can be
12 performed by materials license applicants and potential applicants (hereinafter collectively
13 referred to as “applicants”), and licensees before the NRC staff has concluded its environmental
14 review of the proposed licensing action.
15

16 This ISG applies to the review of licensing actions related to the receipt and possession of
17 licensable source, byproduct, and special nuclear material (SNM) for the conduct of any activity
18 which the NRC determines will significantly affect the quality of the environment. This ISG is
19 intended to provide guidance to NRC staff but may also be instructive to all holders of operating
20 licenses for source, byproduct, and SNM facilities and irradiators, and all persons that have
21 submitted applications to construct source, byproduct, and SNM facilities or irradiators, or have
22 submitted letters of intent to submit such applications under Title 10 of the *Code of Federal*
23 *Regulations* (10 CFR) Parts 30, 36, 40, and 70.
24

25 This ISG applies to all Part 30, 36, 40 and 70 materials facilities other than uranium recovery
26 facilities. Site preparation activities at uranium recovery facilities are addressed in Regulatory
27 Issue Summary 2009-12, Uranium Recovery Policy Regarding Site Preparation Activities at
28 Proposed, Unlicensed Uranium Recovery Facilities, September 23, 2009, ML092090353.
29

30 If a licensing action initiated pursuant to 10 CFR Parts 30, 40, or 70 meets any of the criteria in
31 10 CFR 51.20 or 51.21, then commencement of construction of a facility before the NRC staff
32 has completed its environmental review process is grounds for denial of the license application,
33 in accordance with 10 CFR 30.33(a)(5), 40.32(e), and 70.23(a)(7). However, if the licensing
34 action meets the criteria in 10 CFR 51.22(c) for a categorical exclusion, and the NRC has not
35 determined that an environmental assessment or an environmental impact statement is required
36 in accordance with 10 CFR 51.22(b), then commencement of construction before the NRC staff
37 concludes the environmental process should not be the sole basis for denial of the license
38 application, as the NRC has already determined that this category of actions does not have a
39 significant impact on the environment. In accordance with 10 CFR 36.15, commencement of
40 construction of an irradiator will only be grounds for denial if the licensee or applicant has not
41 submitted both an application and the requisite licensing fee.
42

43 **BACKGROUND**
44

45 The NRC amended its regulations in September 2011, by revising certain provisions applicable
46 to the licensing and approval processes for byproduct, source and SNMs licenses, and
47 irradiators in the final rule, “Licenses, Certifications, and Approvals for Materials Licensees” (76
48 FR 56951; September 15, 2011) (Material Licenses Construction Rule). The revisions
49 contained in the Material Licenses Construction Rule revised the definitions of “construction”

1 and “commencement of construction” with respect to materials licensing actions conducted
2 under the NRC's regulations. The NRC adopted these changes to further improve the
3 effectiveness and efficiency of the licensing and approval processes for future materials license
4 applications, as well as to eliminate certain inconsistencies that existed within the NRC's
5 regulations with respect to the use and definition of the terms “construction” or “commencement
6 of construction” for certain materials licensees for purposes of its environmental reviews.
7

8 The new definitions of “commencement of construction” in 10 CFR 30.4, 36.2, 40.4, and 70.4
9 are identical.

10
11 *Commencement of construction* means taking any action defined as “construction” or any other
12 activity at the site of a facility subject to the regulations in this part that has a reasonable nexus
13 to:

- 14 1. Radiological health and safety; or
- 15 2. Common defense and security.

16
17 In 10 CFR 150.31, *commencement of construction* means taking any action defined as
18 “construction” or any other activity at the site of a facility subject to the regulations in this part
19 that has a reasonable nexus to radiological health and safety. The regulations in 10 CFR
20 150.31 address the requirement for Agreement State regulation of byproduct material. Although
21 Agreement State licensees may find this ISG informative, they should also communicate with
22 the pertinent Agreement State agency for that agency’s applicable requirements and guidance.
23

24 The new definitions of “construction” in 10 CFR 30.4, 36.2, and 70.4 are also identical.

25
26 *Construction* means the installation of foundations, or in-place assembly, erection, fabrication,
27 or testing for any structure, system, or component of a facility or activity subject to the
28 regulations in this part that are related to radiological safety or security. The term “construction”
29 does not include:

- 30 (1) Changes for temporary use of the land for public recreational purposes;
- 31 (2) Site exploration, including necessary borings to determine foundation conditions or
32 other preconstruction monitoring to establish background information related to the
33 suitability of the site, the environmental impacts of construction or operation, or the
34 protection of environmental values;
- 35 (3) Preparation of the site for construction of the facility, including clearing of the site,
36 grading, installation of drainage, erosion and other environmental mitigation
37 measures,
38 and construction of temporary roads and borrow areas;
- 39 (4) Erection of fences and other access control measures that are not related to the safe
40 use of, or security of, radiological materials subject to this part;
- 41 (5) Excavation;
- 42 (6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse
43 and shop facilities, utilities, concrete mixing plants, docking and unloading facilities,
44 and office buildings) for use in connection with the construction of the facility;
- 45 (7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior
46 utility and lighting systems, potable water systems, sanitary sewerage treatment
47 facilities, and transmission lines);
48
49
50

- 1
- 2 (8) Procurement or fabrication of components or portions of the proposed facility occurring
- 3 at other than the final, in-place location at the facility; or
- 4 (9) Taking any other action that has no reasonable nexus to:
- 5 (i) Radiological health and safety, or
- 6 (ii) Common defense and security.
- 7

8 “Construction,” as defined in 10 CFR 40.4, also includes the installation of wells associated with
9 radiological operations (e.g., production, injection, or monitoring well networks associated with
10 in-situ recovery or other facilities).

11
12 The Atomic Energy Act of 1954, as amended, expressly limits the NRC’s regulatory authority to
13 matters concerning the radiological public health and safety or common defense and security
14 and non-radiological hazards to the extent such hazards result from the actual processing of by-
15 product material. The NRC has determined that this authority does not extend to site
16 preparation activities that do not have a nexus to radiological health and safety or common
17 defense and security.

18
19 This guidance provides criteria for NRC staff to use in evaluating whether a particular
20 construction activity has a nexus to radiological health and safety, and thus falls under the
21 jurisdiction of the NRC for licensing purposes. An activity or action has a reasonable nexus to
22 radiological health and safety or the common defense and security if that activity or action has a
23 rational, direct link to ensuring that a materials facility is operating, or will operate, in accordance
24 with the NRC’s regulations and in a manner that protects the public health and safety or the
25 common defense and security from radiological hazards. The revised definition of construction
26 in 10 CFR 30.4, 36.2, 40.4, 70.4, and 150.31 list activities that are not considered “construction.”
27 This guidance provides examples of activities that fall under each of the excepted activities that
28 do not constitute construction. This guidance addresses some important considerations for
29 materials licensees and applicants that were emphasized in the response to comments on the
30 proposed Material Licenses Construction Rule. For example, site preparation activities that are
31 not considered “construction,” while not under NRC jurisdiction may be subject to the regulatory
32 authority of another Federal, State, or local agency which may require National Environmental
33 Policy Act or state environmental review. NRC’s responsibilities under the National Historic
34 Preservation Act of 1966, as amended (NHPA), must also be satisfied before a license is
35 issued. Specifically, as noted in the SOC to the final Material Licenses Construction Rule,
36 under certain circumstances the NRC may be required to deny a license application if the NRC
37 determines that the applicant intentionally significantly adversely affected, or allowed to be
38 affected, a historic property with intent to avoid the requirements of §106 of the NHPA.

39 40 **DISCUSSION OF EXAMPLES**

41
42 In addition to the background discussion provided above, the following examples clarify the
43 delineation of site preparation activities and construction activities. It is important to recognize
44 that the NRC may have regulatory authority over activities that can occur before construction
45 begins, such as procurement of basic components as defined in 10 CFR Part 21, the process
46 of dedicating commercial grade items or basic components, or procurement of items relied on
47
48 for safety (IROFS) as defined in 10 CFR Part 70. It should also be noted that, while site
49 preparation activities may not require prior NRC approval, various local, State, or other Federal
50 permits may be required.

1
2 BYPRODUCT MATERIAL (10 CFR PART 30)
3

4 Prior to the conclusion of the environmental review process, applicants for byproduct material
5 licenses or license amendments should not perform construction activities that have a nexus to
6 radiological health and safety or the common defense and security. An activity or action has a
7 reasonable nexus to radiological health and safety or the common defense and security if that
8 activity or action has a rational, direct link to ensuring that a licensed materials facility is
9 operating, or will operate, in accordance with the NRC's regulations and in a manner that

10
11 protects the public health and safety or the common defense and security from radiological
12 hazards.
13

14 Installation of foundations or in-place assembly, erection, fabrication, or testing for any structure,
15 system, or component of a facility or activity subject to 10 CFR Part 30 that are related to
16 radiological health and safety or common defense and security should not be performed prior to
17 the conclusion of the environmental review of a license application or amendment. Byproduct
18 material license applicants subject to 10 CFR Part 30 may perform those site preparation
19 activities identified in revised 10 CFR 30.4 before the NRC has completed its environmental
20 review of the license application.
21

22 Excavation and other site preparation activities that do not have a reasonable nexus to
23 radiological public health and safety or common defense and security, whether permanent or
24 temporary, are not "construction" activities. For example, piles driven to support the erection of
25 a bridge for a temporary or permanent access road to a new facility would not be considered as
26 construction and may be performed prior to the NRC staff concluding its environmental review
27 of a proposed action.
28

29 The installation of a temporary feature within an excavation for a building in which materials
30 license activities will be conducted and that will be removed during construction is a site
31 preparation activity. Such features include retaining walls, dewatering systems, ramps, and
32 other structures that will have no physical presence following construction.
33

34 Construction includes installation of the foundation, including soil compaction; the installation of
35 permanent drainage systems and geofabric; the placement of backfill, concrete (e.g., mudmats),
36 or other materials that will not be removed before placement of the foundation of a structure; the
37 placement and compaction of a subbase; the installation of reinforcing bars to be incorporated
38 into the foundation of the structure; the erection of concrete forms for the foundations that will
39 remain in place permanently (even if nonstructural); and the placement of concrete or other
40 material constituting the foundation of any safety-related feature.
41

42 The term "permanent" in this context includes anything that will exist in its final, in-place facility
43 location after commencement of operations with licensed material. Construction also includes
44 the "onsite, in-place" fabrication, erection, integration, or testing activities for any in-scope
45

46 safety-related equipment. The terms "onsite, in place, fabrication, erection, integration, or
47 testing" describe the process of constructing a facility in its final, onsite plant location, where
48 components or modules are integrated into the final, in-plant location. The fabrication,
49 assembly, and testing of components and modules in a shop building, warehouse, or laydown

1 area, even if located onsite, is not construction. However, the installation or integration of the
2 safety-related equipment into its final plant location is construction.

3
4 Construction also includes driving piles for safety-related equipment. Hence, an applicant must
5 obtain a license before driving piles for safety-related equipment. However, driving piles that do
6 not ensure the structural stability or integrity of a safety-related structure (e.g., piles driven to
7 support the erection of a bridge for a temporary or permanent access road) is not construction;
8 therefore, those piles may be driven prior to the NRC staff concluding its environmental review
9 of a proposed action.

10 IRRADIATORS (10 CFR PART 36)

11
12
13 An applicant for a new irradiator license under 10 CFR Part 36 may perform the non-
14 construction activities identified in revised 10 CFR 36.2 at any time. However, installation of
15 foundations or in-place assembly, erection, fabrication, or testing for any structure, system, or
16 component of a facility or activity subject to 10 CFR Part 36 that have a reasonable nexus to
17 radiological safety or security should not be performed prior to the submission of an application
18 for a license and the fee required by 10 CFR 170.31. An activity or action has a reasonable
19 nexus to radiological health and safety or the common defense and security if that activity or
20 action has a rational, direct link to ensuring that a licensed materials facility is operating, or will
21 operate, in accordance with the NRC's regulations and in a manner that protects the public
22 health and safety or the common defense and security from radiological hazards. Activities that
23 have a reasonable nexus to radiological health and safety or common defense and security
24 include, but are not limited to, construction of systems subject to 10 CFR Part 36, Subpart C,
25 and the following:

- 26
- 27 • Earthwork
- 28 • Pool excavation
- 29 • Footings and foundation for pool
- 30 • Irradiator foundations and walls
- 31 • Backfill pool
- 32 • Install pool liner
- 33 • Mechanical rough-in
- 34 • Electrical rough-in
- 35 • Shoring for roof
- 36 • Form and place roof
- 37 • Slab on grade
- 38

39 Subpart C of 10 CFR Part 36 currently lists the systems that have a nexus to radiological health
40 and safety and defines the related engineering and safety concerns associated with each
41 system:

- 42
- 43 • Access Control: Adequacy of access control systems using interlocks and radiation
44 monitors to prevent inadvertent entry to areas where radiation sources are unshielded;
45 to provide emergency exits; and to ensure compliance with all the requirements of 10
46 CFR 36.23. For computer-controlled access-control systems, licensing staff should
47 consider expert evaluation of the software/system logic before operational testing.
- 48 • Site: Potential need for protection against flooding and earth slides.

- 1 • Base (soil, rock) for the Pool and Shielding Structures: Strength, settlement,
2 liquefaction, ground water, soil compaction.
- 3 • Footers and Foundations for the Pool and Shielding Structures: Strength and
4 reinforcement, alignment with pool and shielding structures.
- 5 • Pool and Shielding Structures: Strength and reinforcement, proper density of shielding
6 materials, correct dimensions, minimization of voids in concrete or other shielding.
- 7 • Pool Liner: Contact with pool structure, penetrations in the liner, leak-tight welds.
- 8 • Pool Plumbing: Makeup water system; water cleanup system; effect of construction
9 materials on pool-water chemistry; drainage system (potentially contaminated spilled
10 water should flow into the pool); siphon breakers; radiation detection and alarm systems.
- 11 • Penetrations Through Shielding: Any significant effect on structural strength, shielding,
12 or both.
- 13 • Source Rack Protection: If the product to be irradiated moves on a product conveyor
14 system, the source rack and the mechanism that moves the rack must be protected by a
15 barrier or guides to prevent products and product carriers from hitting or touching the
16 rack or mechanism.
- 17 • Source-Rack Mechanical Positioning System: Strength and stiffness of the rack and
18 positioning cables or chains, source shroud will not interfere with source positioning,
19 adequacy of motive power, potential for jamming.
- 20 • Source-Rack Movement and Position-Sensing System: Structural attachments for
21 electrical and mechanical transducers, adequacy of transducers for interacting with the
22 source-rack control system.
- 23 • Source-Rack Electrical Control System: Adequacy of the design of logistical and
24 operational electrical circuitry and electromechanical components, to ensure
25 unambiguous response of the system, which includes programmable controllers or
26 computers and their interaction with operations, interlocks, doors, signals, and alarms.
- 27 • Source-Leak Detection: Adequacy of systems for detecting and isolating leaking
28 sources.
- 29 • Hard Wiring: Adequacy of wire gauge and insulation to safely carry design currents and
30 to withstand radiation and ozone damage if exposed; locating and attaching wiring to
31 prevent fretting, wear, and exposure to potential fire hazards; accessibility to wiring for
32 inspection and repair.
- 33 • Uninterruptable Electrical Power Supply: Adequate and reliable power capability to
34 operate all electrical systems that are important to safety (including backup power
35 sources); compatibility of the power supply with the electrical system.
- 36 • Fire Protection System: Adequacy to detect fire and smoke and to be manually as well
37 as automatically initiated; must ensure that raised sources are immediately lowered into
38 the pool.
- 39 • Emergency Systems for Returning an Up-stuck Source Rack to the Pool: Capability of
40 the electrical control system to sense and signal the occurrence of an up-stuck source-
41 rack; adequacy of mechanical or electrical means for personnel to safely release and
42 lower the rack; need for, and adequacy of, a system to cool the source-rack until it can
43 be released and lowered.
- 44 • Ozone Ventilation System: Capability of the system to be properly initiated and to
45 provide adequate volume flow rate of air to protect personnel and components.
- 46 • System for Transferring Sources from and to Transport Vehicles: Adequately sized
47 openings in the shield-structure roof if sources are roof-loaded; structural adequacy of
48 the roof-shield plug and its supports for its removal and replacement; structural and

1 mechanical adequacy of systems for moving shipping containers into and out of the pool
2 area.

3
4 URANIUM CONVERSION FACILITIES, ENRICHMENT FACILITIES, FUEL FABRICATION
5 FACILITIES, AND URANIUM HEXAFLUORIDE (UF₆) DECONVERSION FACILITIES (10 CFR
6 PART 40 and 10 CFR PART 70)
7

8 If any of the following actions are performed before the NRC staff has completed its
9 environmental review process, then the NRC has grounds for denial of a license application, in
10 accordance with 10 CFR 40.32(e), and 70.23(a)(7):
11

- 12 1. Procurement or construction of engineered items that are items relied on for safety
13 (IROFS) required to meet the performance requirements of 10 CFR 70.61.
- 14 2. Construction of guard stations, fences, vehicle barriers, or other features that are, or will
15 become, components of physical security systems required by regulations or orders.
- 16 3. Construction or installation of equipment whose purpose is the detection of radioactive
17 material accidents or mitigation of the consequences of radioactive material accidents.
- 18 4. Installation of storage tanks that contain chemicals that could affect the safety of
19 licensed material.
- 20 5. Construction of facilities or warehouses that will be used for operations involving
21 licensed material.
- 22 6. Driving of piles; subsurface preparation; placement of backfill, concrete, or permanent
23 retaining walls within an excavation; installation of foundations; or in-place assembly,
24 erection, fabrication, or testing, which are for IROFS and on-site emergency facilities.
- 25 7. Erection of buildings, offices, construction trailers and warehouses that will become part
26 of a Standard Practice Procedures Plan for Protection of Classified Information.
27

28 Construction includes the onsite, in-place fabrication, erection, integration, or testing activities
29 for any safety related item. The terms "onsite, in place, fabrication, erection, integration, or
30 testing" describe the process of constructing a fuel cycle facility in its final, onsite plant location,
31 where components or modules are integrated into the final, in-plant location. Under the
32 definition of "construction" applicants and existing licensees may be able to fabricate, assemble,
33 and test components and modules in a shop building, warehouse, or laydown area, even if
34 these facilities are located onsite. However, the installation or integration of that safety related
35 equipment into its final plant location is a construction activity and should not be performed until
36 after the NRC staff concludes its environmental review of the license application.
37

38 Excavation includes the removal of any soil, rock, gravel, or other material below the final
39 ground elevation to the final parent material, and may be conducted prior to the conclusion of
40 the NRC staff's environmental review. However, placing permanent, nonstructural dewatering
41 materials, mudmats, or engineered backfill in advance of placing the foundation and associated
42 permanent retaining walls for buildings or structures that will contain licensed materials are
43 construction activities and should not be performed prior to the conclusion of the NRC staff's
44 environmental review.
45

46 Construction includes driving piles for buildings or structures that will contain licensed materials.
47 Hence the driving of piles for such buildings or structures should not be performed before the
48 NRC staff concludes its environmental review. Driving piles that do not ensure the structural
49 stability or integrity of buildings or structures within the scope of the definition of "construction"
50 (e.g., piles driven to support the erection of a bridge for a temporary or permanent access road)

1 is not “construction”; therefore, those piles may be driven prior to the conclusion of the NRC
2 staff’s environmental review.

3
4 In addition to 10 CFR 40.4, 51.4, and 70.4 criteria that are used to determine the scope of
5 activities that fall within the definition of construction, construction includes the necessary
6 excavation for safety related items. A necessary excavation is the portion of an excavation that
7 provides sufficient construction access to the structures that are within the definition of
8 construction. Applicants should ensure, and NRC staff will confirm, that these construction
9 activities are separate from, and do not result in, adverse interactions with construction-related
10 safety related item including influence on the stability (static and dynamic) analyses.

11
12 Construction includes any change made to the parent material in which the excavation occurs
13 (e.g., soil compaction, rock grouting); the driving of piles; the installation of foundations; the
14 installation of permanent drainage systems and geofabric; the placement of backfill, concrete
15 (e.g., mudmats) or other materials that will not be removed before placement of the foundation
16 of a structure; the placement and compaction of a subbase; and the installation of reinforcing
17 bars to be incorporated into the foundation of any safety related items that fall within the
18 definition of construction. The foregoing items fall within the definition of construction because
19 they have a rational, direct link to ensuring that a licensed materials facility is operating, or will
20 operate, in accordance with the NRC’s regulations and in a manner that protects the public
21 health and safety from radiological hazards.

22
23 ACTIVITIES WHICH HAVE NO REASONABLE NEXUS TO RADIOLOGICAL SAFETY OR
24 SECURITY

25
26 The NRC has determined that, in general, the following activities at source, byproduct, and SNM
27 facilities and irradiators listed in 10 CFR 30.4, 36.2, 40.4, and 70.4, do not have a reasonable
28 nexus to radiological health and safety and the common defense and security may be
29 performed by a licensee or applicant at any time. Note that in some circumstances, based on
30 the specific licensing proposal, any of these activities could be determined to have a reasonable
31
32 nexus to radiological health and safety or common defense and security and, based on that
33 determination, these activities would be construction:

- 34
35 (1) Changes for temporary use of the land for public recreational purposes;
36 (2) Site exploration, including necessary borings to determine foundation conditions or
37 other preconstruction monitoring to establish background information related to the
38 suitability of the site, the environmental impacts of construction or operation, or the
39 protection of environmental values;
40 (3) Preparation of the site for construction of the facility, including clearing of the site,
41 grading, installation of drainage, erosion and other environmental mitigation
42 measures,
43 and construction of temporary roads and borrow areas;
44 (4) Erection of fences and other access control measures that are not related to the safe
45 use of, or security of, radiological materials subject to 10 CFR Parts 30, 36, 40, or
46 70;
47 (5) Excavation;
48 (6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse
49 and shop facilities, utilities, concrete mixing plants, docking and unloading facilities,
50 and office buildings) for use in connection with the construction of the facility;

- 1 (7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior
2 utility and lighting systems, potable water systems, sanitary sewerage treatment
3 facilities, and transmission lines);
- 4 (8) Procurement or fabrication of components or portions of the proposed facility occurring
5 at other than the final, in-place location at the facility; or
- 6 (9) Taking any other action that has no reasonable nexus to:
 - 7 (i) Radiological health and safety, or
 - 8 (ii) Common defense and security.

9
10 While the above site preparation activities may not require prior NRC approval, other Federal,
11 State, or Local permits may be required.

12 13 **FINAL RESOLUTION**

14
15 This interim staff guidance will be incorporated into the next revisions of NUREG-1556, and
16 NUREG-1520.

17 18 **APPLICABILITY**

19
20 This ISG is applicable to all 10 CFR Parts 30, 36, 40, and 70 license applicants and existing
21 licensees considering site preparation activities or construction activities at a facility that is
22 subject to, or will be subject to, the licensing requirements of these parts.

23 24 **REFERENCES**

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5

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APPENDIX O

SAFETY CULTURE STATEMENT OF POLICY

Appendix O Safety Culture Statement of Policy

The safety culture policy statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011 and can be found at: <http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf>. It is also posted in the U.S. Nuclear Regulatory Commission's (NRC's) Agencywide Documents Access and Management System (ADAMS) Accession No. ML11146A047.

Safety Culture Policy Statement

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

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

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

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

1 The following are traits of a positive safety culture:
2

3 (1) *Leadership Safety Values and Actions*—Leaders demonstrate a commitment to safety in
4 their decisions and behaviors.
5

6 (2) *Problem Identification and Resolution*—Issues potentially impacting safety are promptly
7 identified, fully evaluated, and promptly addressed and corrected commensurate with their
8 significance.
9

10 (3) *Personal Accountability*—All individuals take personal responsibility for safety.
11

12 (4) *Work Processes*—The process of planning and controlling work activities is implemented so
13 that safety is maintained.
14

15 (5) *Continuous Learning*—Opportunities to learn about ways to ensure safety are sought out
16 and implemented.
17

18 (6) *Environment for Raising Concerns*—A safety conscious work environment is maintained
19 where personnel feel free to raise safety concerns without fear of retaliation, intimidation,
20 harassment, or discrimination.
21

22 (7) *Effective Safety Communication*—Communications maintain a focus on safety.
23

24 (8) *Respectful Work Environment*—Trust and respect permeate the organization.
25

26 (9) *Questioning Attitude*—Individuals avoid complacency and continuously challenge existing
27 conditions and activities in order to identify discrepancies that might result in error or
28 inappropriate action.
29

30 There may be traits not included in this Statement of Policy that are also important in a positive
31 safety culture. It should be noted that these traits were not developed to be used for inspection
32 purposes.
33

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

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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 service providers. 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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