

# **Consolidated Guidance About Materials Licenses**

Program-Specific Guidance About  
Licenses Authorizing Distribution to  
General Licensees

Draft Report for Comment

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Draft Report for Comment

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Prepared by:  
U.S. Bhachu  
V. Cox  
F.C. Gaskins  
R.G. Gattone  
C. Mattsen  
M. Shober

Office of Nuclear Material Safety and Safeguards



## COMMENTS ON DRAFT REPORT

- 1
- 2 Any interested party may submit comments on this report for consideration by the NRC staff.  
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5 them by the end of the comment period specified in the *Federal Register* notice announcing the  
6 availability of this report.
- 7 **Addresses:** You may submit comments by any one of the following methods. Please include  
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10 Web site and on the Federal rulemaking Web site <http://www.regulations.gov>.
- 11 **Federal Rulemaking Website:** Go to <http://www.regulations.gov> and search for documents  
12 filed under Docket ID **NRC-2015-0252**. Address questions about NRC dockets to Carol  
13 Gallagher at (301) 415-3463 or by e-mail at [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov).
- 14 **Mail comments to:** Cindy Bladey, Chief; Rules, Announcements, and Directives Branch  
15 (RADB), Division of Administrative Services, Office of Administration; Mail Stop:  
16 OWFN–12–H8, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
- 17 For any questions about the material in this report, please contact: Vanessa Cox, Project  
18 Manager, at (301) 415-8342 or by e-mail at: [Vanessa.Cox@nrc.gov](mailto:Vanessa.Cox@nrc.gov).
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20 record and entered into the Agencywide Documents Access and Management System. Do not  
21 provide information you would not want to be publically available.



## ABSTRACT

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

In addition to providing guidance on the distribution of generally licensed (GL) products containing byproduct material regulated under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 31, "General Domestic Licenses for Byproduct Material," and 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," the agency has revised this document to include guidance on the distribution of GL source material, incorporating the rulemaking on 10 CFR Part 40, "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions," (78 FR 32310; May 29, 2013) and of GL special nuclear materials regulated under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

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## FOREWORD

The U.S. Nuclear Regulatory Commission's (NRC's) NUREG-1556 technical report series provides a comprehensive source of 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, and license reviewers and other NRC personnel. The NUREG-1556 series currently includes the following volumes:

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

The current document, NUREG-1556, Volume 16, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees," is intended for use by applicants, licensees, NRC sealed source and device reviewers, license reviewers, and other NRC personnel. This revision provides a general update to the previous information contained in NUREG-1556, Volume 16, issued December 2000. Appendix A of this NUREG lists documents applicable to licenses authorizing

1 distribution (initial transfer) to general licensees that the NRC staff considered in the  
2 development of this NUREG report.

3 This report takes a risk-informed, performance-based approach to licenses authorizing  
4 distribution (initial transfer) to general licensees. A team composed of staff from NRC  
5 Headquarters, NRC regional offices, and Agreement States prepared this document, drawing on  
6 their collective experience in radiation safety in general and as specifically applied to licenses  
7 authorizing the distribution (initial transfer) to general licensees.

8 NUREG–1556, Volume 16, is not a substitute for NRC or Agreement State regulations. The  
9 approaches and methods described in this report are provided for information only. Methods  
10 and solutions different from those described in this report may be acceptable if they include a  
11 basis for the staff to make the determinations needed to issue or renew a license or complete a  
12 sealed source and device review.

13 \_\_\_\_\_

14 Daniel S. Collins, Director  
15 Division of Material Safety, State, Tribal and Rulemaking Programs  
16 Office of Nuclear Material Safety and Safeguards

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1

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3 the report. All participants provided insights, observations, and recommendations.

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

### 7 **The Participants for this Revision**

8 Bhachu, Ujagar S.  
9 Comfort, Gary C.  
10 Cox, Vanessa  
11 Gaskins, Farrah C.  
12 Gattone, Robert G.  
13 Mattsen, Catherine R.  
14 Shober, Megan



1

## ABBREVIATIONS

2	AEA	Atomic Energy Act
3	Bq	becquerel
4	CFR	Code of Federal Regulations
5	Ci	curie
6	GBq	gigabecquerel
7	GL	generally licensed or general license
8	kBq	kilobecquerel
9	MBq	megabecquerel
10	NMSS	Office of Nuclear Material Safety and Safeguards
11	$\mu$ Ci	microcurie
12	mCi	millicurie
13	NRC	U.S. Nuclear Regulatory Commission
14	OMB	Office of Management and Budget
15	PII	Personally Identifiable Information
16	RIS	Regulatory Issue Summary
17	RSO	radiation safety officer
18	SSD	sealed source and device
19	U.S.C.	U.S. Code



# 1 PURPOSE OF REPORT

This report provides guidance to an applicant in preparing an application to distribute generally licensed (GL) materials, products, or devices and the U.S. Nuclear Regulatory Commission (NRC) criteria for evaluating such applications. It also provides guidance for certain GL devices covered in Title 10 of the *Code of Federal Regulations* (10 CFR) 31.5, “Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere,” on the use, possession, and annual registration requirements.

GL–distribution licenses authorize the distribution (initial transfer) of byproduct material, source material, or special nuclear material to persons generally licensed under the following regulations:

- 10 CFR 31.5 “Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere”
- 10 CFR 31.7 “Luminous safety devices for use in aircraft”
- 10 CFR 31.8 “Americium-241 and radium-226 in the form of calibration or reference sources”
- 10 CFR 31.10 “General license for strontium 90 in ice detection devices”
- 10 CFR 31.11 “General license for use of byproduct material for certain in vitro clinical or laboratory testing”
- 10 CFR 40.22 “Small quantities of source material”
- 10 CFR 40.25 “General license for use of certain industrial products or devices”
- 10 CFR 70.19 “General license for calibration or reference sources”

This report identifies the information needed to complete NRC Form 313, “Application for Material License”, for the manufacture or initial transfer of products or materials containing byproduct material, source material, or special nuclear material to be used under general license. Appendix B of this NUREG provides an example of the NRC Form 313. To acquire a copy, the form can be found at <http://www.nrc.gov/reading-rm/doc-collections/forms>. The Office of Management and Budget (OMB) has approved the information collection requirements in 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” 10 CFR Part 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 40, “Domestic Licensing of Source Material,” 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” NRC Form 313, and NRC Form 483, “Registration Certificate—In vitro Testing with Byproduct Material under General License,” under OMB Clearance Nos. 3150-0017, 3150-0016, 3150-0001, 3150-0020, 3150-0009, 3150-0120, and 3150-0038, respectively. NRC Form 653, “Transfer of Industrial Devices Report (To General Licensees),” is also included under OMB Clearance No. 3150-0001.

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

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

8 Notes and references are self-explanatory and may not be found for each item on  
9 NRC Form 313. Appendix A of this NUREG includes specific NRC references used in the  
10 development of this guidance document.

11 NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5  
12 and 6, as indicated on the form. Applicants should address those items on separate sheets of  
13 paper and submit them along with the completed NRC Form 313.

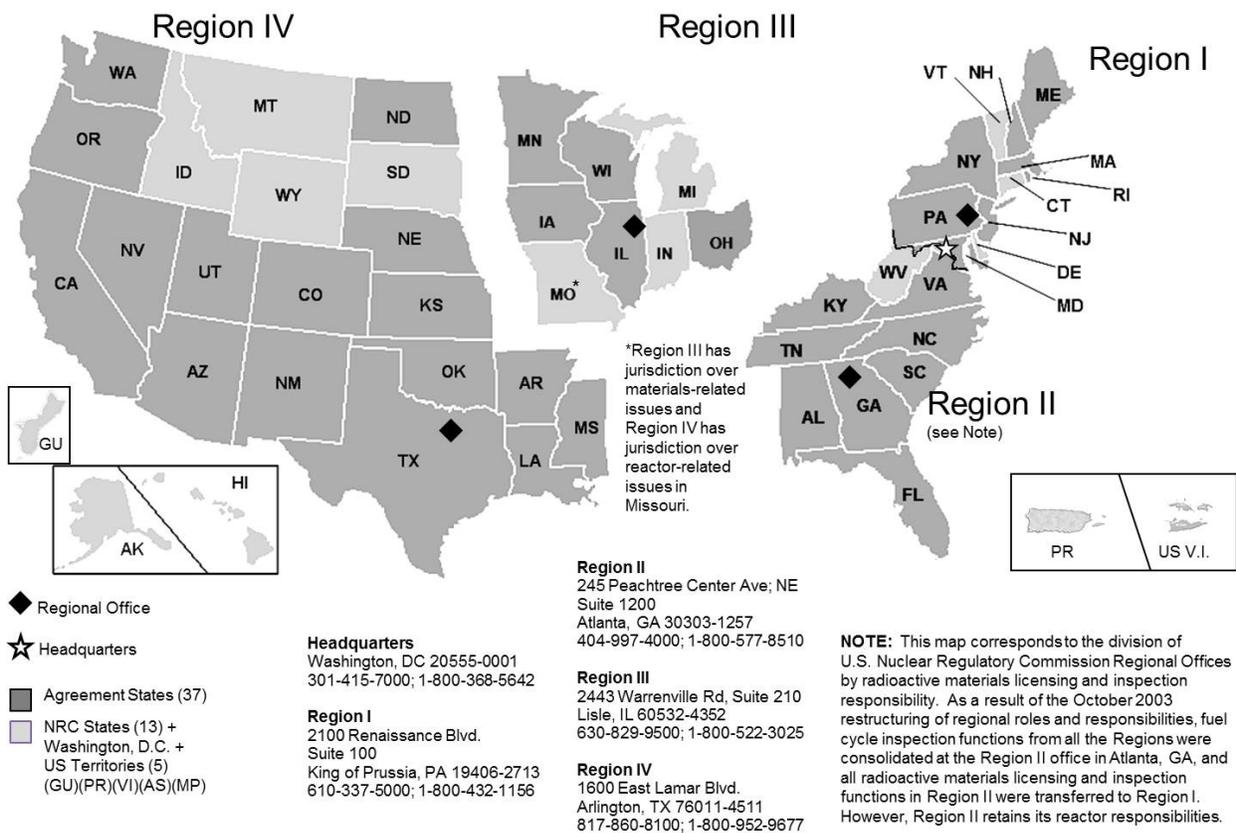
14 In this document, “dose” or “radiation dose” means absorbed dose, dose equivalent, effective  
15 dose equivalent, committed dose equivalent, committed effective dose equivalent, or total  
16 effective dose equivalent (TEDE), as defined in 10 CFR Part 20, “Standards for Protection  
17 Against Radiation.”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

1

## 2 AGREEMENT STATES

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

<sup>1</sup>Locations of NRC Offices and Agreement States



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

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

1 In the special situation of work at federally controlled sites in Agreement States, it is necessary  
 2 to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement  
 3 State has regulatory authority. These areas can also include Tribal lands of federally  
 4 recognized Indian Tribes.<sup>2</sup> Certain States, called Agreement States (see Figure 2-1), have  
 5 entered into agreements with the NRC that give them the authority to license and inspect  
 6 byproduct, source, and special nuclear materials, in quantities not sufficient to form a critical  
 7 mass, that are used or possessed within their borders. Any applicant, other than a Federal  
 8 entity, who wishes to possess or use licensed material in one of these Agreement States should  
 9 contact the responsible officials in that State for guidance on preparing an application. These  
 10 applications should be filed with State officials and not with the NRC. In areas under  
 11 exclusive Federal jurisdiction within an Agreement State, the NRC continues to be the  
 12 regulatory authority.

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

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

<b>Applicant and Proposed Location of Work</b>	<b>Regulatory Agency</b>
Federal agency, regardless of location (except that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with 10 CFR 30.12, “Persons Using Byproduct Material under Certain Department of Energy and Nuclear Regulatory Commission contracts”; also, see 10 CFR 40.11 and/or 10 CFR 70.11, if applicable)	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

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<sup>2</sup>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](http://www.bia.gov).

<b>Table 2-1. Who Regulates the Activity?</b>	
<b>Applicant and Proposed Location of Work</b>	<b>Regulatory Agency</b>
Non-Federal entity on federally recognized Indian Tribal land	NRC <sup>3</sup>
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State	Agreement State
Non-Federal entity in Agreement State	Agreement State <sup>4</sup>
Non-Federal entity in Agreement State at federally controlled site <b>not</b> subject to exclusive Federal jurisdiction	Agreement State <sup>4</sup>
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 <b>not</b> directly connected with Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor	Agreement State <sup>4</sup>
Import and export of material	NRC

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

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

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



### 3 MANAGEMENT RESPONSIBILITY

The U.S. Nuclear Regulatory Commission (NRC) recognizes that effective management of radiation safety programs is vital to achieving safe 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 increases in safety and compliance.

“Management” refers to the processes for conducting and controlling a radiation safety program and to the individuals who are responsible for those processes and who have the *authority to provide necessary resources* to achieve regulatory compliance.

#### 3.1 Commitments and Responsibilities

Pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR 30.32(c), 10 CFR 40.31(b), and 10 CFR 70.22(d)), each application must be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee. The person signing the application should be a duly authorized management representative. A signature by a management representative acknowledges management’s commitments and responsibilities to the following:

- 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, all titled “Completeness and accuracy of information”)
- knowledge about the contents of the license and application
- compliance with current NRC and U.S. Department of Transportation (DOT) regulations and the licensee’s operating, emergency, and security procedures
- commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and compliance with regulations is maintained
- commitment to report defects, noncompliances, or reportable events in accordance with regulations
- selection and assignment of a qualified individual to serve as the radiation safety officer (RSO) for licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities
- commitment to ensure that radiation workers have adequate training
- prevention of discrimination of employees engaged in protected activities (10 CFR 30.7, 10 CFR 40.7, and 10 CFR 70.7, “Employee protection”)

- 1 • commitment to provide information to employees regarding deliberate misconduct  
2 provisions (10 CFR 30.10, 10 CFR 40.10, and 10 CFR 70.10, “Deliberate misconduct”)
- 3 • commitment to obtaining the NRC’s prior written consent before transferring control of  
4 the license (see Section 11.1 of this report)
- 5 • notification of the appropriate NRC Regional Administrator in writing, immediately  
6 following filing of petition for voluntary or involuntary bankruptcy [10 CFR 30.34(h),  
7 10 CFR 40.41(f), and 10 CFR 70.32(a)(9)], as discussed further in Section 11.2,  
8 “Notification of Bankruptcy Proceedings,” of this report

9 For information on NRC inspection, investigation, enforcement, and other compliance programs,  
10 see the current version of the NRC’s Enforcement Policy and inspection procedures available in  
11 the NRC’s online library, under “Document Collections,” at <http://www.nrc.gov/reading-rm.html>.

### 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, NRC’s  
42 safety culture policy statement and traits are not incorporated into the regulations.

1 Safety culture traits may be inherent to an organization’s existing radiation safety practices and  
 2 programs. For instance, each person licensed in the manufacture of the ice detection device  
 3 containing strontium-90 must maintain quality assurance systems that will ensure that the  
 4 safety-related components of the distributed devices are capable of performing their intended  
 5 functions. The need to establish and maintain quality assurance systems may correspond with  
 6 the safety culture traits specified in Table 3-1 as “Work Processes” (the process of planning and  
 7 controlling work activities is implemented so that safety is maintained). However, licensees  
 8 should be aware that this is just an example, and should consider reviewing their radiation  
 9 safety programs in order to develop and implement a safety culture commensurate with the  
 10 nature and complexity of their organizations and functions.

11 Refer to Appendix C of this NUREG for the NRC’s Safety Culture Policy Statement. More  
 12 information on NRC activities relating to safety culture can be found at  
 13 <http://www.nrc.gov/about-nrc/safety-culture.html>.

<b>Table 3-1. Traits of a Positive Safety Culture</b>		
<b>Leadership Safety Values and Actions</b>	<b>Problem Identification and Resolution</b>	<b>Personal Accountability</b>
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.
<b>Work Processes</b>	<b>Continuous Learning</b>	<b>Environment for Raising Concerns</b>
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.
<b>Effective Safety Communications</b>	<b>Respectful Work Environment</b>	<b>Questioning Attitude</b>
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, licensee's, or registrant's responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of Title 10 of the *Code of Federal Regulations* (10 CFR) contain regulations applicable to the licensing of byproduct, source, and special nuclear materials. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

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

- [10 CFR Part 2](#) "Agency Rules of Practice and Procedure"
- [10 CFR Part 19](#) "Notices, Instructions and Reports to Workers: Inspection and Investigations"
- [10 CFR Part 20](#) "Standards for Protection Against Radiation"
- [10 CFR Part 21](#) "Reporting of Defects and Noncompliance"
- [10 CFR Part 30](#) "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- [10 CFR Part 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 40](#) "Domestic Licensing of Source Material"
- [10 CFR Part 51](#) "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"
- [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"
- [10 CFR Part 170](#) "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services under the Atomic Energy Act of 1954, as Amended"

- 1 • [10 CFR Part 171](#) “Annual Fees for Reactor Licenses and Fuel Cycle Licenses and  
2 Materials Licenses, Including Holders of Certificates of Compliance,  
3 Registrations, and Quality Assurance Program Approvals and  
4 Government Agencies Licensed by the NRC”

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

8 In addition, 10 CFR Parts 1 through 199 can be found on the NRC’s Web site at  
9 <http://www.nrc.gov/reading-rm/doc-collections/> under “Regulations (10 CFR).”

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

14 Table 4-1 lists the general licenses, which include the primary regulations for general licensees,  
15 and the corresponding requirements for distributors of GL products, by section and title.  
16 Additional requirements are applicable to general licensees. Appendix D of this NUREG  
17 contains tables of all of the requirements applicable for each general license.

<b>Table 4-1. General Licenses and Associated GL Distribution Requirements</b>	
<b>General License</b>	<b>GL Distribution Requirements</b>
10 CFR 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere	10 CFR 32.51 Byproduct material contained in devices for use under 10 CFR 31.5; requirements for license to manufacture or initially transfer
10 CFR 31.6 General license to install devices generally licensed in 10 CFR 31.5	10 CFR 32.51a Same: Conditions of licenses
	10 CFR 32.52 Same: Material transfer reports and records
	10 CFR 32.210 Registration of product information

<b>Table 4-1. General Licenses and Associated GL Distribution Requirements (Continued)</b>	
<b>General License</b>	<b>GL Distribution Requirements</b>
10 CFR 31.7 Luminous safety devices for use in aircraft	10 CFR 32.53 Luminous safety devices for use in aircraft; requirements for license to manufacture, assemble, repair, or initially transfer
	10 CFR 32.54 Same: Labeling of devices
	10 CFR 32.55 Same: Quality assurance, prohibition of transfer
	10 CFR 32.56 Same: Material transfer reports
	10 CFR 32.210 Registration of product information
10 CFR 31.8 Americium-241 or radium-226 in the form of calibration or reference sources	10 CFR 32.57 Calibration or reference sources containing americium-241 or radium-226; requirements for license to manufacture or initially transfer
	10 CFR 32.58 Same: Labeling of devices
	10 CFR 32.59 Same: Leak testing of each source
10 CFR 31.10 General license for strontium-90 in ice detection devices	10 CFR 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer
	10 CFR 32.62 Same: Quality assurance; prohibition of transfer
	10 CFR 32.210 Registration of product information
10 CFR 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing	10 CFR 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license

<b>Table 4-1. General Licenses and Associated GL Distribution Requirements (Continued)</b>			
<b>General License</b>		<b>GL Distribution Requirements</b>	
10 CFR 40.22	Small quantities of source material	10 CFR 40.54	Requirements for license to initially transfer source material for use under 10 CFR 40.22
		10 CFR 40.55	Conditions of licenses to initially transfer source material for use under the 'small quantities of source material' general license: Quality control, labeling, safety instructions, and records and reports
10 CFR 40.25	General license for use of certain industrial products or devices	10 CFR 40.34	Special requirements for issuance of specific licenses
		10 CFR 40.35	Conditions of specific licenses issued pursuant to 10 CFR 40.34
10 CFR 70.19	General license for calibration or reference sources	10 CFR 70.39	Specific licenses for the manufacture or initial transfer of calibration or reference sources

1 **Note:** 10 CFR 31.6–A GL to install devices generally licensed in 10 CFR 31.5, but for  
2 installation and servicing by specific licensees (10 CFR 32.51 equivalent or service licensees)

3 Part 31 contains another GL that authorizes possession of byproduct material:

4 **10 CFR 31.12 General License for Certain Items and Self-Luminous Products**  
5 **Containing Radium-226**

- 6 • antiquities originally intended for use by the general public
- 7 • intact timepieces containing more than 0.037 MBq [1 µCi] of radium-226, nonintact  
8 timepieces, and timepiece hands and dials no longer installed in timepieces
- 9 • luminous items installed in air, marine, or land vehicles (see Figure 4-1)
- 10 • all other luminous products, provided that no more than 100 items are used or stored at  
11 the same location at any one time
- 12 • small radium sources containing no more than 0.037 MBq [1 µCi] of radium-226



**Figure 4-1. Aircraft Gauge.** *Certain Luminous Items Containing Radium-226 in Aircraft Are Authorized Under 10 CFR 31.12.*

- 1 As no new manufacture or initial distribution of products for use under this general license is
- 2 allowed, these products will not be discussed further in this document. However, for
- 3 completeness, Appendix D of this NUREG includes a table of requirements applicable to
- 4 general licensees under 10 CFR 31.12 (Table D-6).



## 5 DISTRIBUTION TO GENERAL LICENSEES

### 5.1 General

There are two types of licenses: (i) general and (ii) specific. The Commission issues a specific license to a named person who has filed an application for the license. A general license (GL), which is provided by regulation, grants authority to a person for certain activities involving byproduct, source, or special nuclear material and is effective without the need for a user to file an application with the Commission or the issuance of a licensing document to a particular person. However, certain GLs may require registration with the Commission and certain GLs are only applicable to persons otherwise specifically licensed.

Under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 31, the U.S. Nuclear Regulatory Commission (NRC) grants general licenses for the use of certain items containing byproduct material and provides the primary requirements associated with these general licenses. Under 10 CFR Part 40, the NRC provides general licenses for source material, and 10 CFR Part 70 provides general licenses for special nuclear material.

The NRC requires specific licenses for manufacturers and distributors (initial transferors) of products and materials to be used under general licenses. The specific requirements for distribution of byproduct material to general licensees appear in 10 CFR Part 32, Subpart B. The specific requirements for distribution of source material to general licensees appear in 10 CFR 40.34, 10 CFR 40.35, 10 CFR 40.54, and 10 CFR 40.55. The specific requirements for distribution of special nuclear material to general licensees are contained in 10 CFR 70.39.

The regulations in 10 CFR 40.22 authorize certain persons to receive and use source material under a general license if the source material meets requirements pertaining to isotopic concentrations, chemical and physical form, and weight limits. The requirements for a specific license for initial distribution to licensees under 10 CFR 40.22 (and equivalent Agreement State regulations) are relatively new (published May 29, 2013; 78 FR 32310).

The distributor of the GL material, product, or device is required to assure the NRC or an Agreement State that all products are distributed in accordance with the terms, conditions, and representations made in its license application. These specific licenses are issued by the NRC or an Agreement State and are referred to as "GL-distribution" licenses. GL-distribution licenses only authorize the distribution of materials, products, and devices to general licensees and do not authorize possession or use of material; therefore, applicants for GL-distribution licenses need to file a separate application for a specific license authorizing possession or use of the material with the NRC regional office based on the State or territory in which the material will be possessed or used or both. However, applicants should determine where to file the application for the GL-distribution license based on the location from which the applicant wishes to distribute, not necessarily the location where the product is to be manufactured. Chapter 2 of this document (Figure 2-1) identifies Agreement States and NRC regional offices.

A license authorizing distribution to general licensees cannot be issued until the applicant (i) obtains a Sealed Source and Device (SSD) registration certificate from the NRC or an Agreement State (see Section 5.2) for the device (if applicable) and (ii) obtains a possession and use license.

1 NUREG-1556, Volume 12 provides information on applications for manufacturing  
2 and distribution.

### 3 **5.2 Licensing and Sealed Source and Device Registration**

4 Applicants for a GL-distribution license are required to provide specific information about  
5 the sources and products, as outlined in 10 CFR 32.51, 10 CFR 32.53, 10 CFR 32.57,  
6 10 CFR 32.61, 10 CFR 32.71, 10 CFR 40.34, 10 CFR 40.54, or 10 CFR 70.39. In addition,  
7 applicants for a GL-distribution license should provide specific information about the sources  
8 and products as otherwise indicated in the NUREG-1556 series concerning the radionuclides  
9 and activities, containment and construction, labeling, quality control and assurance programs,  
10 and other aspects. The NRC will evaluate the information submitted in the application to ensure  
11 it meets all applicable industry standards and regulations and will contact the applicant, if  
12 necessary, to obtain additional clarification or information.

13 The applicants will perform an SSD safety evaluation on the devices authorized for use under  
14 10 CFR 31.5, 10 CFR 31.7, and 10 CFR 31.10 that the applicant proposes to distribute to  
15 general licensees. The information required by 10 CFR 32.51, 10 CFR 32.53, and  
16 10 CFR 32.61 is in addition to that specifically required by 10 CFR 32.210 and should be  
17 submitted as part of the request for device registration. An SSD registration certificate  
18 summarizes the safety evaluation. The current version of Volume 3, "Applications for Sealed  
19 Source and Device Evaluation and Registration," of NUREG-1556 contains information about  
20 the review and approval process for SSDs. Upon satisfactory completion of the SSD  
21 evaluation, the applicant will receive a registration certificate. The registration certificate must  
22 be complete and available before the licensing reviewer may issue the license.

23 As of the date of this document, 14 Agreement States (Arkansas, Georgia, Iowa, Minnesota,  
24 New Jersey, New Mexico, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island,  
25 Utah, Virginia, and Wisconsin) do not have authority to perform SSD safety evaluations. The  
26 NRC regulates applicants and registration certificate holders located in these States in the same  
27 manner, with respect to Sealed Source and Device registration, as those located in a  
28 non-Agreement State. Applicants from those Agreement States should contact the NRC's  
29 Office of Nuclear Material Safety and Safeguards.

30 An SSD evaluation is *not* required for devices and products authorized under 10 CFR 31.8,  
31 10 CFR 31.11, 10 CFR 40.22, 10 CFR 40.25, or 10 CFR 70.19. In these cases, the safety of  
32 the product is entirely addressed by the license reviewer.

**Notes concerning registration certificates:**

- The licensee can only distribute devices as authorized in the registration certificate.
- Modifications to a device or sealed source require an amendment to the registration certificate.
- Devices that have been modified cannot be distributed until the registration certificate has been amended or issued to the licensee.

1 Licensees must conduct their programs in accordance with the following:

- 2 • statements, representations, and procedures contained in their application and other  
3 subsequent correspondence with the NRC
- 4 • terms and conditions of the license
- 5 • SSD registration, if applicable
- 6 • applicable NRC regulations or orders

7 Under 10 CFR 30.9, 10 CFR 40.9, and 10 CFR 70.9, the information provided in the application  
8 must be complete and accurate in all material respects. Information is considered to be material  
9 if it is likely to change or affect an agency decision to issue a license; therefore, information  
10 should be clear, specific, accurate, and complete. The regulations in 10 CFR 30.10,  
11 10 CFR 40.10, and 10 CFR 70.10 state that those providing information concerning an  
12 applicant's or licensee's activities may not deliberately engage in misconduct or provide  
13 incomplete or inaccurate information to the NRC.

14 It is important that applicants and licensees understand that the information provided in an  
15 application and approved in the license is considered a limitation by the NRC on the licensee to  
16 engage only in those activities and products as described in the application or license.  
17 Applicants and licensees should notify the NRC of any changes or additions to the information  
18 submitted in the application. Although some changes may not result in an amendment to the  
19 license, licensees should not assume that an amendment is not needed or that an amendment  
20 request has been granted until they receive a written confirmation in the form of a letter or  
21 license amendment.

### 22 **5.3 Types of Generally Licensed Products**

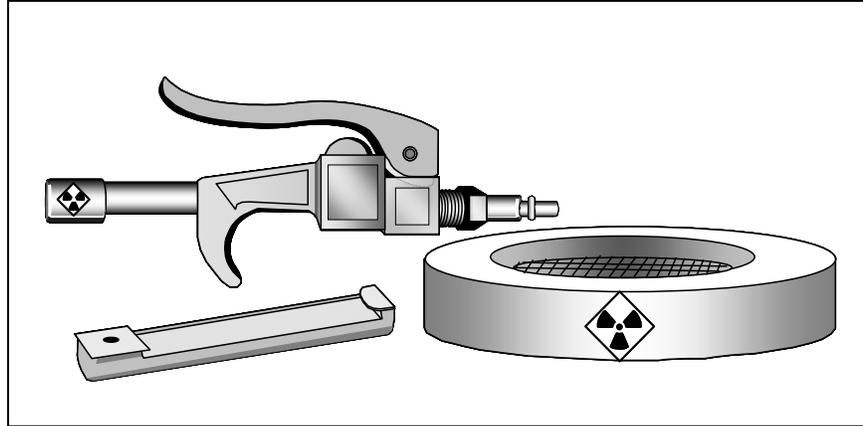
23 This section lists the applicable regulations and some examples under each of materials,  
24 products, or devices that may be distributed under a GL distribution license and possessed by a  
25 general licensee.

#### 26 **10 CFR 31.5 Certain detecting, measuring, gauging, or controlling devices and certain** 27 **devices for producing light or an ionized atmosphere**

28 Byproduct material contained in devices designed and manufactured for the purpose of  
29 detecting, measuring, gauging, or controlling thickness, density, level, interface location,  
30 radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or  
31 an ionized atmosphere (see Figures 5-1 through 5-4).

#### 32 **10 CFR 31.7 Luminous Safety Devices for Use in Aircraft**

- 33 • luminous safety devices containing only hydrogen-3 (tritium) or promethium-147  
34 (see Figure 5-5)
- 35 • tritium devices not to exceed 10 Ci [370 GBq] per device
- 36 • promethium-147 devices not to exceed 300 millicuries (mCi) [11 GBq] per device

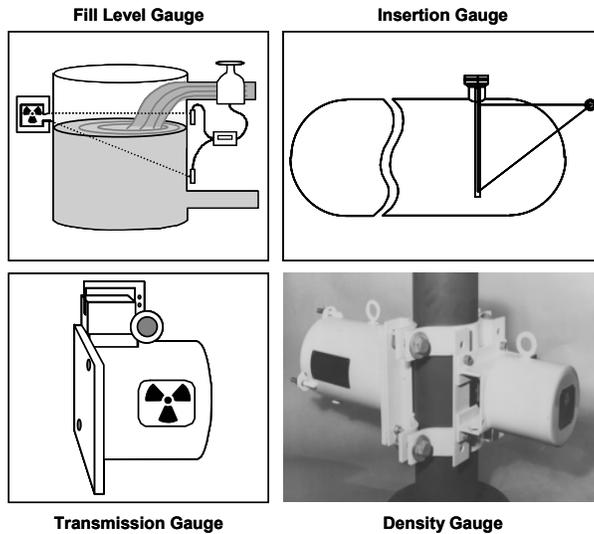


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**Figure 5-1. Static Eliminators.** *Certain static elimination devices can be possessed under 10 CFR 31.5.*



**Figure 5-2. Gas Chromatograph Units.** *Certain gas chromatograph units (detector cells) used for the analysis of chemical composition can be possessed under 10 CFR 31.5.*



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060500

**Figure 5-3. Fixed Gauging Devices.** *Certain nuclear gauges can be possessed under 10 CFR 31.5.*



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092000

**Figure 5-4. Tritium Exit Signs.** *Certain tritium exit signs can be possessed under 10 CFR 31.5 {typical devices contain 935 gigabecquerels (GBq) [25 curies (Ci)] of tritium per sign}.*



**Figure 5-5. Luminous Exit Sign** *Safety devices, such as luminous exit signs, containing tritium or promethium-147 that are used in aircraft may be used under the 10 CFR 31.7 general license.*

1 **10 CFR 31.8 Americium-241 or Radium-226 in the Form of Calibration or**  
2 **Reference Sources**

- 3 • single source not to exceed 0.185 megabecquerels (MBq) [5 microcuries ( $\mu\text{Ci}$ )] at any  
4 one time, at any one location of use or storage (see Figure 5-6)



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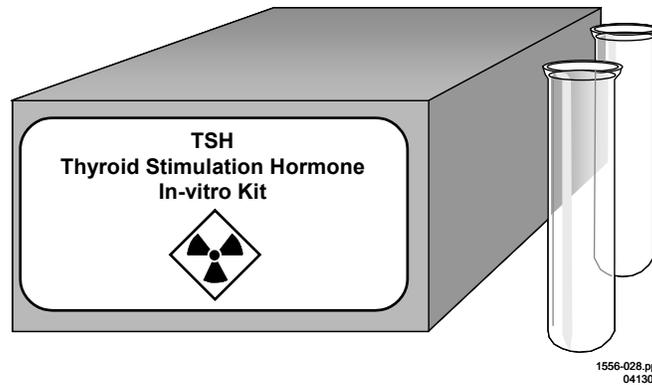
**Figure 5-6. Calibration Standards.** *Certain calibration and reference sources containing americium-241 or radium-226 can be possessed under a general license authorized in 10 CFR 31.8 by those otherwise specifically licensed.*

1 **10 CFR 31.10 General license for strontium-90 in ice detection devices**

- 2 • each device not to exceed 50  $\mu\text{Ci}$  [1.85 MBq]

3 **10 CFR 31.11 General license for use of byproduct material for certain in vitro clinical or**  
4 **laboratory testing (see Figure 5-7)**

- 5 • iodine-125 not to exceed 10  $\mu\text{Ci}$  [370 kBq]
- 6 • iodine-131 not to exceed 10  $\mu\text{Ci}$  [370 kBq]
- 7 • carbon-14 not to exceed 10  $\mu\text{Ci}$  [370 kBq]
- 8 • tritium not to exceed 50  $\mu\text{Ci}$  [1.85 MBq]
- 9 • cobalt-57, not to exceed 10  $\mu\text{Ci}$  [370 kBq]
- 10 • iron-59 not to exceed 20  $\mu\text{Ci}$  [740 kBq]
- 11 • selenium-75 not to exceed 10  $\mu\text{Ci}$  [370 kBq]
- 12 • mock iodine-125 not to exceed 0.05  $\mu\text{Ci}$  [1.85 kBq] of iodine-129 and 0.005  $\mu\text{Ci}$  [185 Bq]
- 13 of americium-241



**Figure 5-7. In Vitro Kit.** *Certain in vitro kits used in medicine, veterinary medicine, hospitals, and clinical laboratories are authorized under 10 CFR 31.11.*

1 **10 CFR 40.22 Small quantities of source material**

- 2 • up to 7 kg [15.4 lb] of uranium and thorium total at any one time, with no more than a  
3 total of 70 kg [154 lb] of uranium and thorium throughput in any one calendar year

4 Example: depleted uranium used as radiation shielding for an accelerator

5 **10 CFR 70.19 General license for calibration or reference sources**

- 6 • at any one time, at any one location of storage or use, no more than 5  $\mu\text{Ci}$  [185 kBq] of  
7 plutonium in the form of calibration or reference sources

8 **5.4 Identifying and Protecting Sensitive Information**

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

12 The applicant or licensee should identify, mark, and protect sensitive information against  
13 unauthorized disclosure to the public. License applications that contain sensitive information  
14 should be marked as indicated below, in accordance with 10 CFR 2.390, "Public Inspections,  
15 Exemptions, Requests for Withholding," before the information is submitted to the NRC. Key  
16 examples are as follows:

- 17 • **Proprietary Information/Trade Secrets:** If it is necessary to submit proprietary  
18 information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow  
19 this procedure could result in disclosure of the proprietary information to the public or  
20 substantial delays in processing the application. Appendix M of this NUREG provides a  
21 checklist for requests for withholding proprietary information from public disclosure.
- 22 • **Personally Identifiable Information:** Personally identifiable information (PII) about  
23 employees or other individuals should not be submitted unless specifically requested by  
24 the NRC. Examples of PII are social security number, home address, home telephone  
25 number, date of birth, and radiation dose information. If PII is submitted, a cover letter  
26 should clearly state that the attached documents contain PII, and the top of every page  
27 of a document that contains PII should be clearly marked as follows: "Privacy Act

1 Information—Withhold under 10 CFR 2.390.” For further information, see Regulatory  
2 Issue Summary (RIS) 2007-04, “Personally Identifiable Information Submitted to the  
3 U.S. Nuclear Regulatory Commission,” dated March 9, 2007, and Information Notice (IN)  
4 2013-22, “Recent Licensing Submittals Containing Personally Identifiable Information,”  
5 dated November 15, 2013, which can be found on the NRC’s Generic Communications  
6 Web page under “Regulatory Issue Summaries” and “Information Notices,” respectively:  
7 <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.

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

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

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

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

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

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

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

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

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

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

## 16 **5.5 Foreign Vendors**

17 Foreign vendors are unique in that the NRC has no jurisdiction over foreign entities. In  
18 accordance with 10 CFR 110.53, "United States address, records, and inspections," foreign  
19 vendors or licensees involved in importing and exporting nuclear material and equipment are  
20 required to have an office in the U.S. where papers may be served, where records can be  
21 maintained, and where the NRC can inspect the applicant's activities and records as necessary  
22 to accomplish its mission. Therefore, the NRC will not issue a GL-distribution license to a  
23 foreign vendor unless the requirements set forth in 10 CFR 110.53 have been satisfied.



## 6 HOW TO FILE

### 6.1 Application Preparation

Applicants wishing to distribute or initially transfer products containing byproduct, source, or special nuclear material to persons generally licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 31, 10 CFR Part 40, or 10 CFR Part 70 may complete the U.S. Nuclear Regulatory Commission (NRC) Form 313 (see Appendix B of this NUREG). An application for a distribution license should contain information about only the distribution of radioactive material (not possession and use).

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete NRC Form 313 (Appendix B of this NUREG), Items 1 through 4, 12, and 13, on the form itself. A link to the form is available at <http://www.nrc.gov/reading-rm/doc-collections/forms/>.
- Complete NRC Form 313 Items 5 and 6, as applicable, and attach the responses to those items separately.
- Omit NRC Form 313 Items 7 through 11, as they are not applicable to distribution licenses; these items are covered by the possession and use license.
- Provide sufficient detail for the NRC to determine that equipment, facilities, 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 pages, as applicable, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Avoid submitting proprietary information and personally identifiable information. If submitted, proprietary, personal privacy, security-related, and other sensitive information should be clearly identified according to 10 CFR 2.390, "Public inspections, exemptions, requests for withholding" (see Section 5.4, "Identifying and Protecting Sensitive Information," of this NUREG).

### 6.2 Where to File

Applicants wishing to distribute or initially transfer products (containing byproduct material to persons generally licensed under 10 CFR Part 31, or containing source material to persons generally licensed under 10 CFR Part 40, or containing special nuclear material to persons generally licensed under 10 CFR Part 70 or equivalent Agreement State regulations) from 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 from which the material will be distributed or initially transferred. 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

1 submitted to Regions I, III, or IV. All applicants for materials licenses located in the Region II  
2 geographical area should send their applications to Region I.

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

9 Requests for safety evaluation and registration of sealed sources and devices are submitted  
10 directly by applicants to the U. S. Nuclear Regulatory Commission, Materials Safety Licensing  
11 Branch, Office of Nuclear Material Safety and Safeguards, Materials Safety Licensing Branch  
12 ATTN: SDDR, Washington, DC 20555-0001.

### 13 **6.3 Paper Applications**

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

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

Applications must be signed by the applicant, licensee, or a person duly authorized as required by 10 CFR 30.32(c), 10 CFR 40.31(b), or 10 CFR 70.22(d) (see Section 8.8, "Certification").
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25 Please note that if it is necessary when filing for a license to reference information contained in  
26 other licensees' file(s) or registration certificate(s), whether current or inactive, the information  
27 should be submitted, in its entirety, as part of the application.

28 All license applications or information submitted to the NRC is made available to the public. If it  
29 is necessary to submit proprietary information, licensees should follow the procedure in  
30 10 CFR 2.390. Failure to follow this procedure could result in the disclosure of the proprietary  
31 information to the public or substantial delays in processing the application. Licensees should  
32 not submit employee personal information (i.e., home address, home telephone number,  
33 Social Security Number, date of birth, and radiation dose information) unless specifically  
34 requested by the NRC. Section 5.4 of this NUREG provides additional guidance.

1 **6.4 Electronic Applications**

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



1

## 7 APPLICATION AND LICENSE FEES

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

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

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



1 **8 CONTENTS OF AN APPLICATION**

2 The following information applies to the indicated items on the U.S. Nuclear Regulatory  
3 Commission (NRC) Form 313 (Appendix B of this NUREG).

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

6 **8.1 Item 1: License Action Type**

7 Item 1 of NRC Form 313 states the following:

8 This is an application for (check appropriate item):

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

9 Check box A for a new license request. Note that a pre-licensing visit may be conducted prior  
10 to 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. See “License  
13 Amendments and Renewals” in Chapter 11 of this report.

14 **Note:** Chapter 13 of this report provides information on how to terminate a license.

15 **8.2 Item 2: Name and Mailing Address of Applicant**

16 List the legal name of the applicant’s corporation or other legal entity with direct control over the  
17 distribution of the radioactive material (product). A division or department within a legal entity  
18 may not be a licensee. An individual may be designated as the applicant only if the individual is  
19 acting in a private capacity and the distribution of radioactive material (product) is not connected  
20 with employment in a corporation or other legal entity. Provide the mailing address where  
21 correspondence should be sent. A post office box number is an acceptable mailing address.

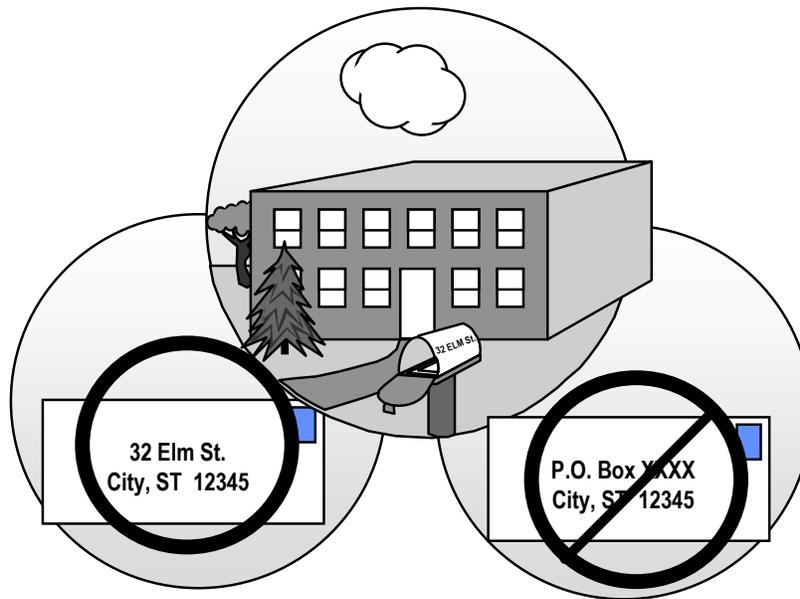
22 Notify the NRC of changes in mailing address. These changes do not require a fee.

23 **Note:** Although an applicant must have a U.S. address in order for the NRC to issue it a  
24 license, the licensee’s mailing address may be based on an address located in the territories of  
25 Puerto Rico, Guam, American Samoa, Northern Mariana Islands, or the U.S. Virgin Islands.

26 **Note:** The NRC must be notified and the transfer approved before control of a specific license  
27 issued by the NRC is transferred, and the licensee must receive written consent from the NRC  
28 before implementing the change of control (see Section 11.1, “Timely Notification of Transfer of  
29 Control”). The NRC must also be notified when bankruptcy proceedings have been initiated  
30 (see Section 11.2, “Notification of Bankruptcy Proceedings”).

1 **8.3 Item 3: Address(es) From Which Licensed Material Will**  
2 **Be Distributed**

3 An applicant must distribute products containing licensed material from an address in the U.S.  
4 Specify the street address, city, and State or other descriptive address (e.g., on Highway 10,  
5 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for every  
6 facility used as a location from which distribution will occur. Sketches or street maps indicating  
7 the nearest intersection and the location of the proposed facility are helpful but not required.  
8 The descriptive address should be sufficient to allow an NRC inspector to find the facility  
9 location. A post office box address is not acceptable (see Figure 8-1). In addition, applicants  
10 are encouraged to provide global positioning system (GPS) coordinates, as appropriate, for  
11 each facility from which material will be transferred to general licensees, including a warehouse  
12 located in a remote area.



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

**Figure 8-1. Location of Distribution**

13 A license amendment is required before distributing licensed material at an address or location  
14 not already listed on the license.

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

15 If an applicant submits documents that give the exact location of use and storage for any  
16 amount of radioactive material, the applicant should mark these documents as  
17 “Security-Related Information—Withhold under 10 CFR 2.390.” See Section 5.4, “Identifying  
18 and Protecting Sensitive Information,” of this NUREG for more details.

1 **8.4 Item 4: Person To Be Contacted About This Application**

2 Identify the individual who can answer questions about the application and include a telephone  
3 number where the individual may be contacted. Also include business cell phone numbers and  
4 e-mail addresses. This individual, usually the radiation safety officer (RSO), will serve as the  
5 point of contact during the review of the application and during the period of the license. If this  
6 individual is not a full-time employee of the licensed entity, his or her position and relationship to  
7 the applicant should be specified. No individual other than the duly authorized applicant may,  
8 for any licensing matter, act on behalf of the applicant or provide information without the  
9 applicant's written authorization. The NRC should be notified if the person assigned to this  
10 function changes or if his or her telephone number, cell phone number, or e-mail address  
11 changes. Notification of a contact change is only provided for informational purposes and would  
12 not be considered an application for license amendment, unless the notification involves a  
13 change in the contact person who is also the RSO.

14 **8.5 Item 5: Radioactive Material**

15 Applicants should determine what devices or products are to be distributed and provide  
16 information about each type of product, a list of the radionuclides (include manufacturer's name  
17 and model number, if applicable), the physical form, and the maximum activity of radioactive  
18 material that will be used in each source for each product type. Activity may be specified either  
19 in terms of becquerels or curies. For some products containing source material, the weight in  
20 grams may be acceptable.

21 **8.6 Item 6: Purpose(s) for Which Licensed Material Will Be Used**

22 Describe in general terms the purpose(s) for which the byproduct, source, or special nuclear  
23 material will be used, for example, a fixed transmission gauge containing cesium-137 for  
24 distribution to persons generally licensed under 10 CFR 31.5. Detailed information required  
25 about the specific products to be distributed is discussed in Chapter 9. In cases where a device  
26 registration will be issued, much of the detailed information about the device will be submitted in  
27 the request for device registration.

28 **8.7 Item 12: License Fees**

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

31 Direct all questions about the NRC's fees or completion of Item 12 of NRC Form 313 to the  
32 Office of the Chief Financial Officer at NRC Headquarters in Rockville, Maryland,  
33 (301) 415-7554. Information about fees may also be obtained by calling NRC's toll free number,  
34 (800) 368-5642, extension 415-7554. The e-mail address for fees questions is  
35 [Fees.Resource@nrc.gov](mailto:Fees.Resource@nrc.gov)

36 **8.8 Item 13: Certification**

37 A representative of the corporation or legal entity filing the application should sign and date  
38 NRC Form 313. The representative signing the application must be authorized to make binding  
39 commitments and to sign official documents on behalf of the applicant. As discussed previously  
40 in Chapter 3, "Management Responsibility," signing the application acknowledges

1 management's commitment to and responsibility for the radiation protection program. The NRC  
2 will return all unsigned applications for proper signature.

3 **Notes:**

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



1 5 rem [0.05 Sv]. Additional limits apply to individual organs and tissues. Thus, for a whole body  
2 external exposure, the criterion for ordinary conditions of handling, storage, and use of devices  
3 under 10 CFR 31.5 is that no person is likely to receive a dose in one year of more than  
4 10 percent of 5 rem [0.05 Sv], which is 500 mrem [5 mSv]. For nonuniform exposure and for  
5 potential intakes under accident conditions, individual organ and tissue limits may also need to  
6 be considered. As such, dose assessments would need to involve some conservatism to cover  
7 uncertainties in the assumptions, generally those working with GL devices should not be  
8 regularly exposed to more than 100 mrem [1 mSv]/year.

9 Column IV of the table in 10 CFR 32.24 contains a number of specific dose limits for various  
10 organs and tissues, with the whole body limit being 15 rem [150 mSv].

11 Under 10 CFR 31.5(c)(2), general licensees are required to test devices at intervals not greater  
12 than 6 months, or at other intervals specified in the label. Any testing intervals longer than  
13 6 months are determined on a case-by-case basis, based on information provided by an  
14 applicant distributor under 10 CFR 32.51(b). If the applicant desires that the device be required  
15 to be tested at intervals longer than 6 months, either for proper operation of the on-off  
16 mechanism and indicator, if any, or for leakage of radioactive material or for both, he must  
17 submit sufficient information to demonstrate that the longer interval is justified by performance  
18 characteristics of the device or similar devices, and by design features that have a significant  
19 bearing on the probability or consequences of leakage of radioactive material from the device or  
20 failure of the on-off mechanism and indicator. The types of factors that will be considered by the  
21 NRC in making these determinations are listed in 10 CFR 32.51(b).

22 Which activities a general licensee is authorized to perform, such as installing, servicing, and  
23 testing, are also determined on a case-by-case basis, based on information submitted by the  
24 applicant distributor under 10 CFR 32.51(c). If the applicant desires that the general licensee  
25 be authorized to install the device, collect the sample to be analyzed by a specific licensee for  
26 leakage of radioactive material, service the device, test the on-off mechanism and indicator, or  
27 remove the device from installation, the applicant should include written instructions to be  
28 followed by the general licensee, estimated calendar quarter doses associated with such activity  
29 or activities, and the bases for these estimates. The submitted information must demonstrate  
30 that performance of this activity or activities by an individual untrained in radiological protection,  
31 in addition to other handling, storage, and use of devices under the general license, is unlikely  
32 to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in  
33 10 CFR 20.1201(a). In other words, the estimated doses from these additional activities  
34 potentially authorized for the general licensee to conduct, when added to the doses estimated  
35 for the purposes of 10 CFR 32.51(a)(ii) will not cause anyone to exceed the same limits.

36 Paragraph (c) of 10 CFR 32.210 also requires certain information to be submitted as a basis for  
37 registering the device. Although the requirements of 10 CFR 32.51 cover similar categories  
38 of information, they are in addition to and not a substitute for meeting the requirements of  
39 10 CFR 32.210(c). Paragraph (d) of 10 CFR 32.210 refers to Subpart B of 10 CFR Part 32 for  
40 additional criteria for certain GL devices. Thus, the criteria in 10 CFR 32.51 discussed here are  
41 also considered in the registration process and should be addressed in the application for  
42 evaluation and registration of the device.

43 The information on labeling submitted under 10 CFR 32.51(a)(2) will supply the basis for  
44 meeting the requirements of 10 CFR 32.51(a)(3) through (5), which specify the labeling  
45 requirements for the devices; that information must be consistent with those requirements.  
46 Those requirements include reference to the radiation symbol described in 10 CFR 20.1901, for

1 the purpose of labeling devices that have separable source housings providing the primary  
2 shielding and for devices that are subject to registration under 10 CFR 31.5(c)(13). The  
3 information provided through the label must include instructions and precautions necessary to  
4 assure safe installation, operation, and servicing of the device; however, documents such as  
5 operating and service manuals may be identified in the label and used to provide this  
6 information. Applicants should submit a sample or drawing of the typical or generic label, as  
7 well as any operating and service manuals that are to be used as part of meeting the labeling  
8 requirements.

9 Conditions for any license issued under 10 CFR 32.51 appear in 10 CFR 32.51a and 32.52.

- 10 • Applicants should provide a copy of the information packet to be sent to customers  
11 before transfers of devices (required by 10 CFR 32.51a). Paragraph (c) of that section  
12 allows for the applicant to propose an alternative approach to informing customers than  
13 that specified in paragraphs (a) and (b). Details concerning information to be provided to  
14 customers can be found in Appendix E of this NUREG.

15 The requirements for records and reporting are specified in 10 CFR 32.52. Information  
16 concerning the recordkeeping and reporting requirements are not required to be included in the  
17 application, because the requirements are fully specified in the regulations. However, these  
18 requirements are a very important part of the regulatory framework for the general license in  
19 10 CFR 31.5, and one needs to be aware of these responsibilities. The details concerning  
20 recordkeeping and quarterly reporting requirements, as well as the NRC Form 653 that can be  
21 used for making the reports, appear in Appendix F of this NUREG.

22 The certificate holder is also subject to 10 CFR 32.210(f), which requires that the device be  
23 manufactured and distributed in accordance with the statements and representations made by  
24 the applicant and the provisions of the registration certificate.

25 **Note:** Section 31.6 provides a general license to install and service devices covered by  
26 10 CFR 31.5 in any non-Agreement State and in offshore waters, as defined in 10 CFR 150.3(f),  
27 to persons who hold a specific license issued by an Agreement State authorizing the holder to  
28 manufacture, install, or service such a device. This general license requires that the device has  
29 been manufactured, labeled, installed, and serviced in accordance with applicable provisions of  
30 the specific license issued to such person by the Agreement State and that such person  
31 assures that any labels required to be affixed to the device under regulations of the Agreement  
32 State that licensed manufacture of the device bear a statement that removal of the label is  
33 prohibited. This means that those authorized by an Agreement State under equivalent  
34 provisions to 10 CFR 32.51 or otherwise specifically authorized by a specific license of an  
35 Agreement State to manufacture, install, or service such a device may install and service  
36 devices covered by 10 CFR 31.5 in any non-Agreement State and in offshore waters without  
37 following the procedures for reciprocity in 10 CFR 150.20.

38 For those licensed under 10 CFR 32.51, some Agreement States have comparable provisions  
39 to 10 CFR 31.6 and some do not. The licensee is responsible for compliance with the  
40 requirements applicable for installation or servicing in each State where the licensee wants to  
41 do so.

1 **Discussion:**

2 Information on the design of the device and its proposed uses [10 CFR 32.51(a)(2)] serves a  
3 number of purposes. The first consideration is whether the device in fact is covered by the  
4 general license in 10 CFR 31.5. The device must be for one of the identified purposes. Note,  
5 byproduct material produces ionizing radiation, and may in any situation produce some ionized  
6 atmosphere. In order for a device to fall under the general license based on the purpose of  
7 producing an ionized atmosphere, this must be the desired end result of the product, such as  
8 that of a static eliminator.

9 Dose evaluations

10 The information on the potential hazards of the device submitted under 10 CFR 32.51(a)(2)  
11 must demonstrate that the device meets certain dose criteria. This involves performing a dose  
12 assessment that is consistent with all of the information about the device submitted under  
13 10 CFR 32.51 and 32.210(c).

14 In order to be able to adequately assess the potential doses that could result from use of a  
15 device under the general license, applicants should anticipate how the product will be used and  
16 the likely conditions of use. This should include routine conditions with the material contained  
17 [10 CFR 32.51(a)(2)(ii)], as well as severe accident conditions such as fire and explosion  
18 [10 CFR 32.51(a)(2)(iii)]. Note the latter regulation uses the words “fire *and* explosion” to  
19 suggest conditions severe enough to cause release of the material. When evaluating potential  
20 dose consequences of severe accidents, assumptions should be conservative. It is important  
21 to be able to make reasonable assumptions about the factors that affect the likely and  
22 possible doses.

23 In developing scenarios for the dose assessment, the applicant should be able to make  
24 reasonable assumptions about the industries that they expect to serve with their device(s) and  
25 how the device(s) will be used. The reviewer will determine if the assumptions presented are  
26 indeed reasonable. This determination becomes particularly important if the projected doses  
27 are approaching an applicable limit.

28 Dose evaluation for additional tasks

29 Typically, general licensees are not permitted to make changes to or replace or leak-test  
30 sources for the devices in their possession. These activities are typically performed by the  
31 device manufacturer or by a service provider who holds a specific license authorizing such  
32 work. If a GL-distribution license applicant desires that general licensees be authorized to  
33 install the device, collect or conduct analysis of leak-test samples, service the device, test the  
34 on/off mechanism and indicator, or remove the device from installation, the applicant must, as  
35 required by 10 CFR 32.51(c), estimate doses, per calendar quarter, associated with these  
36 activities and provide written instructions to be followed by the general licensee.

37 Prototype testing

38 Paragraph (a)(2)(ii) of 10 CFR 32.51 includes the criterion: “Under ordinary conditions of  
39 handling, storage, and use of the device, the byproduct material contained in the device will not  
40 be released or inadvertently removed from the device.” The prototype tests are important in  
41 demonstrating that the device will meet this criterion, and need to represent the conditions that  
42 the product will likely encounter during its life. The applicant should test the devices’

1 performance in temperatures, pressures, impacts, vibrations, and punctures the device is likely  
2 to encounter. Following each of these tests, the applicant should evaluate the device for  
3 leakage and for the source dislodging from the source holder, if applicable.

#### 4 Quality control/quality assurance

5 Quality control should include ensuring that devices all have the required labels. In addition,  
6 applicants should describe how labels will be adhered and how labels will remain legible during  
7 normal conditions of use. Quality control should also address ensuring that required information  
8 is provided to each customer before the transfer of devices, including for transactions conducted  
9 over the Internet.

#### 10 Informing customers

11 As spelled out in Appendix E of this NUREG, there are very specific pieces of information that  
12 must be provided to customers prior to transfer (10 CFR 32.51a). Paragraph (b) of  
13 10 CFR 32.51a allows the alternative of providing customers in Agreement States under general  
14 license provisions equivalent to 10 CFR 31.5 with copies of certain NRC regulations in lieu of  
15 copies of the relevant Agreement State equivalent provisions. Note, however, that Agreement  
16 States are not required to have regulations identical to 10 CFR 31.5. Distributors providing only  
17 NRC regulations to a customer in an Agreement State must also include a note explaining that  
18 use of the device is regulated by the Agreement State. In addition to the information also  
19 required under 10 CFR 32.51a(a), distributors must also provide all such customers with contact  
20 information for the Agreement State regulatory authority from which more information may be  
21 obtained. Thus, distributors must keep abreast of the regulations in each State into which they  
22 plan to distribute devices. As both distributors and their customers need to be aware of all such  
23 Agreement State regulations, it is preferable that distributors send copies of the actual  
24 Agreement State regulations to customers in those States.

25 **Note:** Licensees may also provide Appendices D, G, and/or H of this NUREG to customers.  
26 Appendices G and H of this NUREG contain information about GL devices in question and  
27 answer format. Appendix G of this NUREG may be helpful to a wide range of general  
28 licensees, and Appendix H of this NUREG may be helpful to general licensees that use  
29 self-luminous exit signs. Table D-1 of Appendix D of this NUREG lists all requirements  
30 applicable to general licensees under 10 CFR 31.5. These appendices may be used as  
31 additional ways of informing customers but do not replace the information required by  
32 10 CFR 32.51a and will not satisfy a distributor's obligations under 10 CFR 32.51a.

#### 33 **Response From Applicant:**

34 An applicant should provide sufficient information relating to the design, manufacture, prototype  
35 testing, quality control procedures, labeling or marking, proposed uses, installation, servicing,  
36 leak testing, operating and safety instructions, potential hazards of the devices, and conditions  
37 of handling, storage, and use of device(s) to demonstrate that the product will meet the safety  
38 criteria set forth in the regulations. This includes the following:

- 39 • all of the specific information required about the device(s) one intends to distribute
- 40 • a dose assessment addressing all of the appropriate scenarios to demonstrate that the  
41 device meets the safety criteria in 10 CFR 32.51(a)(2)(ii) and (a)(2)(iii), which references  
42 the table in 10 CFR 32.24

- 1 • information on quality control and information on product labeling (actual example labels  
2 are helpful)
- 3 • information on the safety instructions that will be provided to recipients
- 4 • when seeking longer testing intervals for general licensees, submit sufficient information  
5 to demonstrate that such longer interval is justified by performance characteristics and  
6 by design features that affect the probability or consequences of leakage from the device  
7 or failure of the on-off mechanism and indicator
- 8 • when seeking authorization for general licensees to perform certain service activities, as  
9 described in 10 CFR 32.51(c), submit the written instructions to be followed by the  
10 general licensee, the estimated calendar quarter doses associated with such activities,  
11 and the basis for these estimates

12 To confirm the applicant’s understanding of its responsibilities as a licensee, applicants should  
13 submit the following or substantially similar statements:

- 14 • “We will transfer only devices that are manufactured consistent with all of the statements  
15 in the application, as approved by the NRC and referenced in the registration certificate  
16 and the license.”
- 17 • “We will transfer devices only to persons authorized to use such devices, either by the  
18 general license in 10 CFR 31.5, or by an equivalent general license if the potential  
19 recipient is in an Agreement State.”
- 20 • “We will provide information to customers prior to purchase, in accordance with  
21 10 CFR 32.51a(a) and (b).”
- 22 • “We will provide quarterly transfer reports in accordance with 10 CFR 32.52(a) and (b)  
23 and will maintain records in accordance with 10 CFR 32.52(c).”

24 Additional guidance pertaining to obtaining the registration certificate under 10 CFR 32.210 is  
25 provided in NUREG–1556, Volume 3.

26 **9.2 10 CFR 32.53: Requirements for Distribution of Luminous Safety**  
27 **Devices for Use in Aircraft**

28 **Regulations:** 10 CFR 31.7, 10 CFR 32.53, 10 CFR 32.54, 10 CFR 32.55, 10 CFR 32.56,  
29 10 CFR 32.210

30 **Criteria:** 10 CFR 32.53 provides the requirements for applications for a specific license to  
31 manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or  
32 promethium-147 for use in aircraft, for distribution to persons generally licensed under  
33 10 CFR 31.7.

34 A specific license under 10 CFR 32.53 and a registration certificate under 10 CFR 32.210 are  
35 required for distribution of devices to be used under the general license in 10 CFR 31.7.

1 Paragraph (a) of 10 CFR 32.53 indicates that the applicant must satisfy the general  
2 requirements of 10 CFR 30.33. These requirements are addressed separately in guidance  
3 regarding possession licenses.

4 Paragraph (b) of 10 CFR 32.53 requires the submission of sufficient information regarding each  
5 device pertinent to evaluation of the potential radiation exposure, including:

- 6 • chemical and physical form and maximum quantity of tritium or promethium-147 in  
7 each device
- 8 • details of construction and design
- 9 • details of the method of binding or containing the tritium or promethium-147
- 10 • procedures for and results of prototype testing to demonstrate that the tritium or  
11 promethium-147 will not be released to the environment under the most severe  
12 conditions likely to be encountered in normal use
- 13 • quality assurance procedures to be followed that are sufficient to ensure compliance with  
14 10 CFR 32.55

15 After receiving the application, the NRC may require the submittal of additional information,  
16 including experimental studies and tests, to facilitate a determination of the safety of the device.

17 Paragraph (c) of 10 CFR 32.53 specifies the quantity and radiation level limits for the devices to  
18 be distributed for use under 10 CFR 31.7. The quantity limits are also stated directly in the  
19 general license of 10 CFR 31.7 and so cannot be overwritten by any provision of the distribution  
20 license or registration certificate, or any specific exemption granted to a distributor under  
21 10 CFR 30.11.

22 Paragraph (d) of 10 CFR 32.53 specifies the findings that the NRC must make before issuing  
23 the registration certificate or the license:

- 24 (i) The method of incorporation and binding of the tritium or promethium-147 in the device  
25 is such that the tritium or promethium-147 will not be released under the most severe  
26 conditions, which are likely to be encountered in normal use and handling of the device.
- 27 (ii) The tritium or promethium-147 is incorporated or enclosed so as to preclude direct  
28 physical contact by any person with it.
- 29 (iii) The device is so designed that it cannot easily be disassembled.
- 30 (iv) Prototypes of the device have been subjected to and have satisfactorily passed the  
31 required tests.

32 Paragraph (e) of 10 CFR 32.53 specifies certain aspects of the prototype tests that must be  
33 performed. The information on prototype testing submitted under 10 CFR 32.53(b)(4) must be  
34 consistent with those requirements.

35 Paragraph (c) of 10 CFR 32.210 also requires certain information to be submitted as a basis for  
36 registering the device. Generally, the requirements of 10 CFR 32.53 cover similar categories of

1 information but are in addition to and not a substitute for meeting the requirements of  
2 10 CFR 32.210(c). Paragraph (d) of 10 CFR 32.210 refers to Subpart B of 10 CFR Part 32 for  
3 additional criteria for certain GL devices. Thus, the requirements of 10 CFR 32.53 discussed  
4 here are also considered in the registration process and should be addressed in the application  
5 for evaluation and registration of the device.

6 Conditions for any license issued under 10 CFR 32.53 appear in 10 CFR 32.54, 32.55,  
7 and 32.56.

- 8 • Applicants should submit [in accordance with 10 CFR 32.210(c)] a sample or drawing of  
9 the typical or generic label consistent with the requirements of 10 CFR 32.54(a), or  
10 propose using the alternative approach in 10 CFR 32.54(b), which allows for some of the  
11 information to be included in an accompanying leaflet.
- 12 • The information on quality assurance/quality control submitted under 10 CFR 32.53(b)(5)  
13 must be consistent with the requirements of 10 CFR 32.55, which specify certain  
14 aspects of quality assurance.
- 15 • The requirements for material transfer reporting are specified in 10 CFR 32.56.  
16 Information concerning the reporting requirements is not required to be included in the  
17 application, because the requirements are fully specified in the regulations. Details  
18 concerning recordkeeping and annual reporting requirements appear in Appendix I of  
19 this NUREG.

20 The certificate holder is also subject to 10 CFR 32.210(f), which requires that the device be  
21 manufactured and distributed in accordance with the statements and representations made by  
22 the applicant and the provisions of the registration certificate.

### 23 **Discussion:**

24 An applicant may request to have models listed as a series on the registration certificate. In  
25 order to have the models listed as a series, the design and construction of the models in the  
26 series should have similarities. Applicants should provide detailed engineering drawings of  
27 each basic device that contain overall dimensions, maximum and minimum dimensions,  
28 tolerances, materials of construction, and differences between models in the series.

### 29 Prototype tests

30 An application under 10 CFR 32.53 must include a description of and the results of prototype  
31 tests on at least five prototype devices that have been tested and satisfactorily passed the tests  
32 required by the 10 CFR 32.53(d)(4).

33 The devices must be subjected to tests that adequately take into account the individual,  
34 aggregate, and cumulative effects of environmental conditions expected in service that could  
35 adversely affect the effective containment of tritium or promethium-147, such as temperature,  
36 moisture, absolute pressure, water immersion, vibration, shock, and weathering.

1 Acceptable prototype testing procedures

2 Aircraft safety devices are an example of a product that is expected to be subjected to severe  
3 environmental conditions. In the past, the NRC has found the following step-by-step procedures  
4 acceptable for the testing of prototype luminous safety devices for use in aircraft, with each  
5 device being subjected to all of the tests.

6 (a) Temperature-altitude test. The device is placed in a test chamber as it would be used in  
7 service. A temperature-altitude condition schedule is followed as outlined in the  
8 following steps:

9 Step 1. The internal temperature of the test chamber is reduced to  $-62\text{ }^{\circ}\text{C}$  [ $-80\text{ }^{\circ}\text{F}$ ], and  
10 the device is maintained for at least 1 hour at this temperature at atmospheric pressure.

11 Step 2. The internal temperature of the test chamber is raised to  $-54\text{ }^{\circ}\text{C}$  [ $-65\text{ }^{\circ}\text{F}$ ] and  
12 maintained until the temperature of the device has stabilized at  $-54\text{ }^{\circ}\text{C}$  [ $-65\text{ }^{\circ}\text{F}$ ] at  
13 atmospheric pressure.

14 Step 3. The atmospheric pressure of the chamber is reduced to 83 millimeters of  
15 mercury absolute pressure, while the chamber temperature is maintained at  $-54\text{ }^{\circ}\text{C}$   
16 [ $-65\text{ }^{\circ}\text{F}$ ].

17 Step 4. The internal temperature of the chamber is raised to  $-10\text{ }^{\circ}\text{C}$  [ $+14\text{ }^{\circ}\text{F}$ ] and  
18 maintained until the temperature of the device has stabilized at  $-10\text{ }^{\circ}\text{C}$  [ $+14\text{ }^{\circ}\text{F}$ ], and the  
19 internal pressure of the chamber is then adjusted to atmospheric pressure. The test  
20 chamber door is then opened in order that frost will form on the device, and it remains  
21 open until the frost has melted but not long enough to allow the moisture to evaporate.  
22 The door is then closed.

23 Step 5. The internal temperature of the chamber is raised to  $+85\text{ }^{\circ}\text{C}$  [ $185\text{ }^{\circ}\text{F}$ ] at  
24 atmospheric pressure. The temperature of the device is stabilized at  $+85\text{ }^{\circ}\text{C}$  [ $185\text{ }^{\circ}\text{F}$ ]  
25 and maintained for 2 hours. The device is then visually inspected to determine the  
26 extent of any deterioration.

27 Step 6. The chamber temperature is reduced to  $+71\text{ }^{\circ}\text{C}$  [ $160\text{ }^{\circ}\text{F}$ ] at atmospheric  
28 pressure. The temperature of the device is stabilized at  $+71\text{ }^{\circ}\text{C}$  [ $160\text{ }^{\circ}\text{F}$ ] for a period of  
29 30 minutes.

30 Step 7. The chamber temperature is reduced to  $+55\text{ }^{\circ}\text{C}$  [ $130\text{ }^{\circ}\text{F}$ ] at atmospheric  
31 pressure. The temperature of the device is stabilized at this temperature for a period of  
32 4 hours.

33 Step 8. The internal temperature of the chamber is reduced to  $+30\text{ }^{\circ}\text{C}$  [ $86\text{ }^{\circ}\text{F}$ ] and the  
34 pressure to 138 millimeters of mercury absolute pressure and stabilized. The device is  
35 maintained under these conditions for a period of 4 hours.

36 Step 9. The temperature of the test chamber is raised to  $+35\text{ }^{\circ}\text{C}$  [ $95\text{ }^{\circ}\text{F}$ ], and the  
37 pressure is reduced to 83 millimeters of mercury absolute pressure and stabilized. The  
38 device is maintained under these conditions for a period of 30 minutes.

1 Step 10. The internal pressure of the chamber is maintained at 83 millimeters of  
 2 mercury absolute pressure, and the temperature is reduced to +20 °C [68 °F] and  
 3 stabilized. The device is maintained under these conditions for a period of 4 hours.

4 (b) *Vibration tests.* This procedure applies to items of equipment (including  
 5 vibration-isolating assemblies) intended to be mounted directly on the structure of  
 6 aircraft powered by reciprocating, turbojet, or turbo-propeller engines or to be mounted  
 7 directly on gas-turbine engines. The device is mounted on an apparatus dynamically  
 8 similar to the most severe conditions likely to be encountered in normal use. At the end  
 9 of the test period, the device is inspected thoroughly for possible damage. Vibration  
 10 tests are conducted under both resonant and cycling conditions.

**Table 9-1. Vibration Test Schedule [Times shown refer to one axis of vibration]**

Type	Vibration at room temperature (minutes)	Vibration at 160 °F [71 °C] (minutes)	Vibration at -65 °F [-54 °C] (minutes)
Resonance	60	15	15
Cycling	60	15	15

11 (1) *Determination of resonance frequency.* Individual resonance frequency surveys are  
 12 conducted by applying vibration to each device along each of any set of three mutually  
 13 perpendicular axes and varying the frequency of applied vibration slowly through a  
 14 range of frequencies from 5 cycles per second to 500 cycles per second with the  
 15 double amplitude of the vibration not exceeding that shown in Figure 9-1 for the  
 16 related frequency.

17 (2) *Resonance tests.* The device is vibrated at the determined resonance frequency for  
 18 each axis of vibration for the periods and temperature conditions shown in Table 9-1 and  
 19 with the applied double amplitude specified in Figure 9-1 for that resonance frequency.  
 20 When more than one resonant frequency is encountered with vibration applied along any  
 21 one axis, the test period may be accomplished at the most severe resonance or the  
 22 period may be divided among the resonant frequencies, whichever is considered most  
 23 likely to produce failure. When resonant frequencies are not apparent within the  
 24 specified frequency range, the specimen is vibrated for periods twice as long as those  
 25 shown for resonance in Table 9-1 at a frequency of 55 cycles per second and an applied  
 26 double amplitude of 0.060 inch [0.152 centimeter (cm)].

27 (3) *Cycling.* Devices to be mounted only on vibration isolators are tested by applying  
 28 vibration along each of three mutually perpendicular axes of the device with an applied  
 29 double amplitude of 0.060 inch [0.152 cm] and the frequency cycling between 10 and  
 30 55 cycles per second in 1-minute cycles for the periods and temperature conditions  
 31 shown in Table 9-1. Devices to be installed in aircraft without vibration isolators are  
 32 tested by applying vibration along each of three mutually perpendicular axes of the  
 33 device with an applied double amplitude of 0.036 inch [0.0914 cm] or an applied  
 34 acceleration of 10G, whichever is the limiting value, and the frequency cycling between  
 35 10 and 500 cycles per second in 15-minute cycles for the periods and temperature  
 36 conditions shown in Table 9-1.

37 (c) *Accelerated weathering tests.* The device is subjected to 100 hours of accelerated  
 38 weathering in a suitable weathering machine. Panels of Corex D glass surrounds the  
 39 arc to cut off the ultraviolet radiation below a wave-length of 2,700 angstroms. The light

1 of the carbon arcs should fall directly on the face of the device. The temperature at the  
2 sample is maintained at 50 °C [122 °F] plus or minus 3 °C [37.4 °F]. Temperature  
3 measurements are made with a black-panel thermometer.

4 (d) *Shock test.* The device is dropped upon a concrete or iron surface in a 3-foot  
5 [0.913 meter] free gravitational fall or is subjected to equivalent treatment in a test  
6 device simulating such a free fall. The drop test is repeated 100 times from  
7 random orientations.

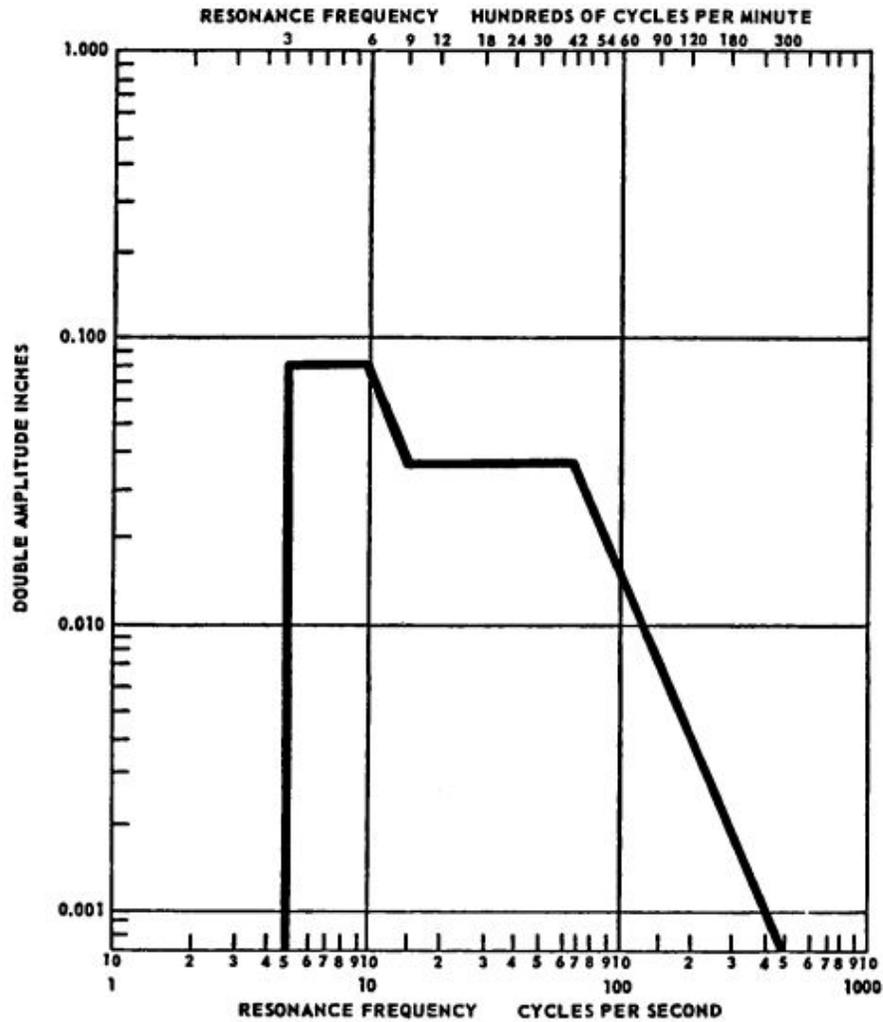


Figure 9-1. Amplitude of Vibration at Resonance Frequency

8 (e) *Hermetic seal and waterproof test.* On completion of all other tests described above, the  
9 device is immersed in 30 inches [76.2 cm] of water for 24 hours and shows no visible  
10 evidence of water entry. Absolute pressure of the air above the water is then reduced to  
11 1 inch [254 millimeter] of mercury. Lowered pressure is maintained for 1 minute or until  
12 air bubbles cease to be given off by the water, whichever is the longer. Pressure is then  
13 increased to normal atmospheric pressure. Any evidence of bubbles emanating from  
14 within the device, or water entering the device, is to be considered leakage.

1 (f) *Observations.* After each of the tests described above, each device is examined for  
2 evidence of physical damage and for loss of tritium or promethium-147. Any evidence of  
3 damage to or failure of any device that could affect containment of the tritium or  
4 promethium-147 is considered cause for rejection of the design if the damage or failure  
5 is attributable to a design defect. Loss of tritium or promethium-147 from each tested  
6 device is measured by wiping with filter paper an area of at least 100 square centimeters  
7 on the outside surface of the device, or by wiping the entire surface area if it is less than  
8 100 square centimeters. The amount of tritium or promethium-147 in the water used in  
9 the hermetic seal and waterproof test described by test paragraph (e) above is also  
10 measured. Measurements are made in an apparatus calibrated to measure tritium or  
11 promethium-147, as appropriate. The detection on the filter paper of more than  
12 2,200 disintegrations per minute of tritium or promethium-147 per 100 square  
13 centimeters of surface wiped or in the water of more than 0.1 percent of the original  
14 amount of tritium or promethium-147 in any device is considered cause for rejection of  
15 the tested device. This is also the case if there is any evidence of physical damage  
16 (such as those seen by the naked eye or vision-enhancing devices).

#### 17 Quality assurance/quality control

18 Licensees under 10 CFR 32.53 are required by 10 CFR 32.55(a) to visually inspect *each* device  
19 and reject any that has an observable physical defect that could adversely affect containment of  
20 the tritium or promethium-147.

21 In sampling of lots, the standard for acceptance is 95 percent confidence that the Lot Tolerance  
22 Percent Defective of 5.0 percent will not be exceeded.

23 As specifically required by 10 CFR 32.55(c), the licensee shall subject each inspection lot to:

- 24 • tests that adequately take into account the individual, aggregate, and cumulative effects  
25 of environmental conditions expected in service that could adversely affect the  
26 effective containment of tritium or promethium-147, such as absolute pressure and  
27 water immersion
- 28 • inspection for evidence of physical damage, containment failure, or for loss of tritium or  
29 promethium-147 after each stage of testing, using methods of inspection adequate for  
30 applying the required criteria for finding a unit defective

#### 31 Acceptable sampling test procedures

32 The NRC has found the following procedures acceptable for testing of luminous safety devices  
33 for use in aircraft, with each unit in the sample being subjected to the following tests:

- 34 (1) Each device is immersed in 30 inches of water for 24 hours and shows no visible  
35 evidence of water entry. Absolute pressure of the air above the water is then reduced to  
36 1 inch of mercury. Lowered pressure is maintained for 1 minute or until air bubbles  
37 cease to be given off by the water, whichever is longer. Pressure is then increased  
38 to normal atmospheric pressure. Any device that leaks, as evidenced by bubbles  
39 emanating from within the device or water entering the device, is considered a  
40 defective unit.

1 (2) The immersion test water from the preceding test is measured for tritium or  
2 promethium-147 content by an apparatus that has been calibrated to measure tritium or  
3 promethium-147, as appropriate. If more than 0.1 percent of the original amount of  
4 tritium or promethium-147 in any device is found to have leaked into the immersion test  
5 water, the leaking device is considered a defective unit.

## 6 Labeling

7 Applicants should submit a sample or drawing of the typical or generic label, and the  
8 accompanying leaflet, if applicable. 10 CFR 32.54 provides very specific requirements  
9 for labeling.

10 In addition to the sample or drawing, applicants should also describe how labels will be adhered  
11 and how labels will remain legible during normal conditions of use. In this case, the normal  
12 conditions of use may cover a significant range of environmental conditions.

## 13 Informing customers

14 There are no regulations beyond the labeling requirements that require distributors to inform  
15 their customers of the requirements of the general license in 10 CFR 31.7. However, Table D-2  
16 of Appendix D of this NUREG presents a listing of all requirements applicable to general  
17 licensees under 10 CFR 31.7 and may be made available to customers for information.

## 18 **Response From Applicant:**

19 An applicant should provide sufficient information regarding each device, pertinent to the  
20 evaluation of the potential radiation exposure, including:

- 21 • all of the specific information required as to the devices one intends to distribute
- 22 • information on prototype testing and quality assurance

23 To confirm your understanding of your responsibilities as a licensee, submit the following or  
24 substantially similar statements:

- 25 • “We will transfer only devices that are manufactured consistent with all of the statements  
26 in the application, as approved by the NRC and referenced in the registration certificate  
27 and the license.”
- 28 • “We will label devices, as outlined in this application and in accordance with  
29 10 CFR 32.54.”
- 30 • “We will conduct quality assurance/quality control, as outlined in this application and in  
31 accordance with 10 CFR 32.55.”
- 32 • “We will maintain records and provide annual material transfer reports, in accordance  
33 with 10 CFR 32.56.”

34 Additional guidance pertaining to obtaining the registration certificate under 10 CFR 32.210 is  
35 provided in NUREG-1556, Volume 3.

1 **9.3 10 CFR 32.57: Requirements for Distribution of Calibration or**  
2 **Reference Sources Containing Americium-241 or Radium-226**

3 **Regulations:** 10 CFR 31.8, 10 CFR 32.57, 10 CFR 32.58, 10 CFR 32.59

4 **Criteria:** 10 CFR 32.57 provides the requirements for applications for a specific license to  
5 manufacture or initially transfer calibration or reference sources containing americium-241 or  
6 radium-226 to persons generally licensed under 10 CFR 31.8.

7 The applicant must obtain a specific license under 10 CFR 32.57 in order to distribute  
8 calibration or reference sources containing americium-241 or radium-226 for use under the  
9 general license in 10 CFR 31.8. Note that an SSD registration certificate is not required for  
10 americium-241 or radium-226 calibration sources to be used under the general license in  
11 10 CFR 31.8 nor is it required for such sources to be used under specific licenses at this  
12 activity level.

13 Paragraph (a) of 10 CFR 32.57 indicates that the applicant must satisfy the general  
14 requirements of 10 CFR 30.33. These requirements are addressed separately in a  
15 possession license.

16 Paragraph (b) of 10 CFR 32.57 requires the submission of sufficient information for the NRC to  
17 evaluate the potential for radiation exposure. This information includes the following:

- 18 (1) chemical and physical form and maximum quantity of americium 241 or radium-226 in  
19 the source
- 20 (2) details of construction and design
- 21 (3) details of the method of incorporation and binding of the americium-241 or radium-226 in  
22 the source
- 23 (4) procedures for and results of prototype testing of sources, which are designed to contain  
24 more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the  
25 americium-241 or radium-226 contained in each source will not be released or be  
26 removed from the source under normal conditions of use
- 27 (5) details of quality control procedures to be followed in manufacture of the source
- 28 (6) description of labeling to be affixed to the source or the storage container for the source

29 After receiving the application, the NRC may require the submittal of additional information,  
30 including experimental studies and tests, to facilitate a determination of the safety of the device.

31 Paragraph (c) of 10 CFR 32.57 specifies a quantity limit for the sources to be distributed for use  
32 under 10 CFR 31.8, which is that each source must contain no more than 5  $\mu\text{Ci}$  [185 kBq] of  
33 americium-241 or radium-226. The byproduct material must be in calibration or reference  
34 sources consisting of americium-241 or radium-226 in order to be eligible for use under  
35 10 CFR 31.8.

36 Paragraph (d) of 10 CFR 32.57 specifies the findings that the NRC must make for any type of  
37 source containing more than 0.005  $\mu\text{Ci}$  [185 Bq] of americium-241 or radium-226 before issuing  
38 the license:

1 (i) the method of incorporation and binding of the americium-241 or radium-226 in the  
2 source is such that the americium-241 will not be released or removed from the source  
3 under normal conditions of use and handling of the source

4 (ii) the source has been subjected to and has satisfactorily passed appropriate  
5 required tests

6 Paragraph (e) of 10 CFR 32.57 specifies certain aspects of the prototype tests that must be  
7 performed, including that at least five prototypes of each source be tested.

8 Conditions for any license issued under 10 CFR 32.57 appear in 10 CFR 32.58 and 32.59.

9 • The information on labeling submitted under 10 CFR 32.57(b)(6) will form the basis  
10 for meeting the requirements of 10 CFR 32.58 and must be consistent with  
11 those requirements.

12 • The information on quality control procedures submitted under 10 CFR 32.57(b)(5)  
13 should include a basis for meeting the leak testing requirements of 10 CFR 32.59.

14 **Discussion:**

15 Acceptable prototype testing procedures for calibration or reference sources containing  
16 americium-241 or radium-226

17 The NRC has previously accepted the following procedures for prototype testing of these  
18 calibration and reference sources, with each source being subjected to all of the tests in the  
19 following order:

20 (i) *Initial measurement.* The quantity of radioactive material deposited on the source is first  
21 measured by direct counting of the source.

22 (ii) *Dry wipe test.* The entire radioactive surface of the source is wiped with filter paper with  
23 the application of moderate finger pressure. Removal of radioactive material from the  
24 source is determined by measuring the radioactivity on the filter paper or by direct  
25 measurement of the radioactivity on the source following the dry wipe.

26 (iii) *Wet wipe test.* The entire radioactive surface of the source is wiped with filter paper  
27 moistened with water with the application of moderate finger pressure. Removal of  
28 radioactive material from the source is determined by measuring the radioactivity on the  
29 filter paper after it has dried or by direct measurement of the radioactivity on the source  
30 following the wet wipe.

31 (iv) *Water soak test.* The source is immersed in water at room temperature for a period of  
32 24 consecutive hours. The source is then removed from the water. Removal of  
33 radioactive material from the source is determined by direct measurement of the  
34 radioactivity on the source after it has dried or by measuring the radioactivity in the  
35 residue obtained by evaporation of the water in which the source was immersed.

36 (v) *Dry wipe test.* On completion of the preceding test, the dry wipe test described in  
37 paragraph (b) is repeated.

1 Labeling

2 Each source or storage container for the source must bear a label that contains sufficient  
3 information on the safe use and storage of the source, as well as specific statements as  
4 required by 10 CFR 32.58.

5 Applicants may submit actual copies of labels to be used on products or a generic label or  
6 statement indicating that the required information will be contained on the label. Submission of  
7 generic labels or statements would allow licensees to change other information on the labels,  
8 such as brand names or telephone numbers, without having to amend their license. In addition,  
9 applicants should describe how labels will be adhered and how labels will remain legible during  
10 normal conditions of use.

11 Acceptable quality control procedures

12 These procedures should address the determination of quantity and how these determinations  
13 are made and used for labeling and recording transactions. The applicant should provide  
14 assurance, with a reasonable tolerance, that quantities will be as labeled and not exceed the  
15 quantity limit of 10 CFR 32.57(c). For example, the quantity of material in sealed sources used  
16 to calibrate equipment may be assured if the sources are traceable to the National Institute of  
17 Standards and Technology. Applicants may also commit to adhering to a particular standard for  
18 quality assurance, such as an International Organization of Standardization or American  
19 National Standards Institute standard. Quality control should also address ensuring that  
20 sources or storage containers all have the required labels.

21 Informing customers

22 There are no regulations requiring that distributors inform their customers of the requirements  
23 of the general license in 10 CFR 31.8. As these customers are also specifically licensed for  
24 other radioactive material, they should be aware of NRC regulations. However, Appendix D of  
25 this NUREG provides a table of regulations applicable to 10 CFR 31.8 general licensees  
26 (Table D-3) that might be made available to customers.

27 **Response From Applicant:**

28 An applicant should provide sufficient information relating to the design, manufacture, labeling  
29 or marking, and in some cases, prototype testing, and proposed quality control procedures, to  
30 demonstrate that the sources will meet any applicable quantity limit levels set forth in the  
31 regulations and that the byproduct material is properly contained in the source.

- 32 • Provide all of the specific information required as to the sources to distribute, including  
33 information on quality control and on source and container labeling.

34 To confirm understanding of responsibilities as a licensee, submit the following or substantially  
35 similar statements:

- 36 • “We will transfer only sources that are manufactured consistent with all of the statements  
37 in the applications as approved by the NRC and referenced in the license.”
- 38 • “We will ensure that all sources are leak tested, as required by 10 CFR 32.59.”

- 1 • “We will transfer sources only to specifically licensed persons. For those in Agreement  
2 States, we will follow 10 CFR 30.41, and determine whether an equivalent general  
3 license is provided by the State, or, if not, that the recipient is specifically authorized to  
4 receive it under the specific license.”

5 **9.4 10 CFR 32.61: Requirements for Distribution of Ice-Detection Devices**  
6 **Containing Strontium-90**

7 **Regulations:** 10 CFR 20.1901(a), 10 CFR 31.10, 10 CFR 32.61, 10 CFR 32.62,  
8 10 CFR 32.210

9 **Criteria:** Applicants for a specific license to manufacture or initially transfer ice-detection  
10 devices containing strontium-90 for distribution to persons generally licensed under  
11 10 CFR 31.10 apply under 10 CFR 32.61.

12 The applicant must obtain a specific license under 10 CFR 32.61 and a registration certificate  
13 under 10 CFR 32.210 to distribute devices for use under the general license in 10 CFR 31.10.

14 Paragraph (a) of 10 CFR 32.61 indicates that the applicant must satisfy the general  
15 requirements of 10 CFR 30.33. These requirements are addressed separately in a  
16 possession license.

17 Paragraph (b) of 10 CFR 32.61 requires the submission of sufficient information regarding each  
18 type of device, pertinent to evaluation of the potential radiation exposure, including:

- 19 (i) chemical and physical form and maximum quantity of strontium-90 in the device  
20 (ii) details of construction and design of the source of radiation and its shielding  
21 (iii) radiation profile of a prototype device  
22 (iv) procedures for and results of prototype testing of devices to demonstrate that the  
23 strontium-90 contained in each device will not be released or be removed from the  
24 device under the most severe conditions likely to be encountered in normal handling  
25 and use  
26 (v) details of quality control procedures to be followed in manufacture of the device  
27 (vi) description of labeling to be affixed to the device  
28 (vii) instructions for handling and installation of the device

29 After receiving the application, the NRC may require the submittal of additional information,  
30 including experimental studies and tests, to facilitate a determination of the safety of the device.

31 Paragraph (d) of 10 CFR 32.61 specifies labeling requirements. Information submitted under  
32 10 CFR 32.61(b)(6) concerning labeling must be consistent with the requirements of  
33 10 CFR 32.61(d).

34 Paragraph (e) of 10 CFR 32.61 specifies the findings that the NRC must make before issuing  
35 the registration certificate or the license:

- 1 (i) The method of incorporation and binding of the strontium-90 in the device is such that  
2 the strontium-90 will not be released from the device under the most severe conditions,  
3 which are likely to be encountered in normal use and handling of the device.
- 4 (ii) The strontium-90 is incorporated or enclosed, so as to preclude direct physical contact  
5 by any individual with it and is shielded so that no individual will receive a radiation  
6 exposure to a major portion of his body in excess of 0.5 rem [5 mSv] in a year under  
7 ordinary circumstances of use.
- 8 (iii) The device is so designed that it cannot be easily disassembled.
- 9 (iv) Prototypes of the device have been subjected to and have satisfactorily passed the tests  
10 required by 10 CFR 32.61(f).
- 11 (v) Quality control procedures have been established to satisfy the requirements of  
12 10 CFR 32.62.
- 13 Paragraph (f) of 10 CFR 32.61 specifies certain aspects of the required prototype tests,  
14 including that at least five prototypes of the device must be tested.
- 15 The information submitted under 10 CFR 32.61(b)(4) must demonstrate that the devices have  
16 met the prototype testing requirements of 10 CFR 32.61(f).
- 17 Conditions for any license issued under 10 CFR 32.61 appear in 10 CFR 32.62, which specifies  
18 certain aspects of quality assurance, including that *all* devices must be visually inspected and  
19 leak tested via one of two specified dry wipe tests.
- 20 • The information submitted under 10 CFR 32.61(b)(5) forms the basis for meeting  
21 10 CFR 32.62 and must be consistent with those requirements.

## 22 **Discussion:**

23 An applicant may request to have models listed as a series on the registration certificate. In  
24 order to have the models listed as a series, the design and construction of the models in the  
25 series should have similarities. Applicants should provide detailed engineering drawings of  
26 each basic device that contain overall dimensions, maximum and minimum dimensions,  
27 tolerances, materials of construction, and differences between models in the series.

### 28 Acceptable prototype testing procedures for ice detection devices

29 The devices must be subjected to tests that adequately take into account the individual,  
30 aggregate, and cumulative effects of environmental conditions expected in service that could  
31 adversely affect the effective containment of strontium-90, such as temperature, moisture,  
32 absolute pressure, water immersion, vibration, shock, corrosion, and weathering. The NRC has  
33 previously accepted the following procedures for prototype testing of ice detectors, with each  
34 device being subjected to all of the tests.

- 35 (i) *Temperature-altitude test.* The device is placed in a test chamber as it would be used in  
36 service. A temperature-altitude condition schedule is followed, as outlined in Step 1  
37 through Step 10 of the temperature-altitude test for luminous aircraft safety devices.

- 1 (ii) *Vibration tests.* The device is subjected to vibration tests, as described for luminous  
2 aircraft safety devices.
- 3 (iii) *Shock test.* The device is subjected to the shock test described for luminous aircraft  
4 safety devices.
- 5 (iv) *Hermetic seal and waterproof test.* On completion of all other tests described above, the  
6 device is immersed in 30 inches [76 cm] of water for 24 hours and shows no visible  
7 evidence of physical contact between the water and the strontium-90. Absolute  
8 pressure of the air above the water is then be reduced to 1 inch [2.54 cm] of mercury.  
9 Lowered pressure is maintained for 1 minute or until air bubbles cease to be given off by  
10 the water, whichever is longer. Pressure is then increased to normal atmospheric  
11 pressure. Any visible evidence of physical contact between the water and the  
12 strontium-90 is to be considered leakage.

13 These procedures were previously required to be used for prototypes of ice detection devices  
14 because the devices were designed for use on airplanes. However, if ice detectors are  
15 developed for other uses, prototype tests must be designed to represent environmental  
16 conditions expected in service for the projected use(s). If expected conditions are significantly  
17 less extreme and the testing conditions limited accordingly, it should be clear that the devices  
18 are designed specifically for the intended purpose and not easily adapted for use in more  
19 severe conditions, such as on an airplane.

20 Acceptable sampling procedures for ice detection devices containing strontium-90

21 In addition to the visual inspection and specified dry wipe test that must be conducted on all  
22 devices, additional testing must be carried out on samples of lots. These tests on lot samples  
23 must adequately take into account the individual, aggregate, and cumulative effects of  
24 environmental conditions expected in service that could possibly affect the effective containment  
25 of strontium-90, such as absolute pressure and water immersion. The NRC has found the  
26 following procedures for sampling testing of lots acceptable.

27 Subject each unit in the sample to the following tests:

- 28 (i) Each device is immersed in 30 inches [76 cm] of water for 24 hours and shows no visible  
29 evidence of physical contact between the water and the strontium-90. Absolute  
30 pressure of the air above the water is then reduced to 1 inch [2.54 cm] of mercury.  
31 Lowered pressure is maintained for 1 minute or until air bubbles cease to be given off by  
32 the water, whichever is longer. Pressure is then increased to normal atmospheric  
33 pressure. Any device which leaks, as evidenced by physical contact between the water  
34 and the strontium-90, must be considered as a defective unit.
- 35 (ii) The immersion test water from the preceding test is measured for radioactive material. If  
36 the amount of radioactive material in the immersion test water is greater than 0.1 percent  
37 of the original amount of strontium-90 in any device, the device must be considered as a  
38 defective unit.

39 Labeling

40 Labeling requirements of 10 CFR 32.61(d) are highly specific. However, applicants should also  
41 describe how labels will be adhered and how labels will remain legible during normal conditions

1 of use. In this case, the normal conditions of use are expected to cover a significant range of  
2 environmental conditions.

3 Applicants should submit a sample or drawing of the typical or generic label.

4 Informing customers

5 There are no regulations requiring that distributors inform their customers of the requirements of  
6 the general license in 10 CFR 31.10. However, Table D-4 of Appendix D of this NUREG  
7 presents a listing of all requirements applicable to general licensees under 10 CFR 31.10, which  
8 may be made available to customers for information.

9 **Response From Applicant:**

10 An applicant should submit sufficient information regarding each type of device pertinent to  
11 evaluation of the potential radiation exposure.

- 12 • Provide all of the specific information required as to the devices to distribute.

13 To confirm understanding of responsibilities as a licensee, submit the following or substantially  
14 similar statements:

- 15 • “We will transfer only devices that are manufactured consistent with all of the statements  
16 in the applications, as approved by the NRC and referenced in the registration certificate  
17 and the license.”

- 18 • “We will label devices, as outlined in this application and in accordance with  
19 10 CFR 32.61(d).”

- 20 • “We will conduct quality control/quality assurance procedures, as outlined in this  
21 application and in accordance with 10 CFR 32.62.”

22 Additional guidance pertaining to obtaining the registration certificate under 10 CFR 32.210 is  
23 provided in NUREG-1556, Volume 3.

24 **9.5 10 CFR 32.71: Requirements for Distribution of In Vitro Kits Under**  
25 **10 CFR 31.11**

26 **Regulations:** 10 CFR 20.1901(a), 10 CFR 20.2001, 10 CFR 30.41(d), 10 CFR 31.11,  
27 10 CFR 32.71

28 **Criteria:** Applicants for a specific license to manufacture or distribute byproduct material for  
29 certain in vitro clinical or laboratory testing for distribution to persons generally licensed under  
30 10 CFR 31.11 apply under 10 CFR 32.71.

31 A specific license under 10 CFR 32.71 must be obtained, in order to distribute in vitro kits for  
32 use under the general license in 10 CFR 31.11. Note that an SSD registration certificate is not  
33 required for in vitro kits.

1 Paragraph (a) of 10 CFR 32.71 indicates that the applicant must satisfy the general  
2 requirements of 10 CFR 30.33. These requirements are addressed separately in a  
3 possession license.

4 Paragraph (b) of 10 CFR 32.71 specifies the radionuclides and quantities that can be distributed  
5 in the form of prepackaged in vitro kits. The quantity limits are also stated directly in the general  
6 license of 10 CFR 31.11 and so cannot be overwritten by any provision of the distribution  
7 license or any specific exemption granted under 10 CFR 30.11.

8 Paragraphs (c), (d), and (e) of 10 CFR 32.71 specify labeling requirements, including  
9 information that may be provided in leaflets or brochures that accompany the packages.  
10 Certain aspects of the labeling requirement are a condition of the general license itself in  
11 10 CFR 31.11(d)(2) and so cannot be overwritten by any provision of the distribution license or  
12 any specific exemption granted under 10 CFR 30.11.

13 Paragraph (c)(2) of 10 CFR 32.71 specifically requires the inclusion of the radiation symbol  
14 described in 10 CFR 20.1901(a).

15 **Discussion:** The byproduct material must be prepared for distribution in prepackaged units  
16 consisting of any one of the following:

- 17 • iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75 not exceeding 10  $\mu$ Ci  
18 [370 kBq]
- 19 • tritium not exceeding 50  $\mu$ Ci [1.85 MBq]
- 20 • iron-59 not exceeding 20  $\mu$ Ci [740 kBq]
- 21 • mock iodine-125 not exceeding 0.05  $\mu$ Ci [1.85 kBq] of iodine-129 and 0.005  $\mu$ Ci  
22 [0.18 kBq] of americium-241

23 These kits are used for a variety of clinical tests, which include Schillings tests, red cell survival  
24 tests, hormone evaluations, and thyroid stimulating hormone tests.

## 25 Labeling

26 Labeling requirements of 10 CFR 32.71(c), (d), and (e) are highly specific and allow some of the  
27 specific information to appear in a leaflet or brochure that accompanies the package. In  
28 addition, applicants should describe how labels will be adhered and how labels will remain  
29 legible during normal conditions of use.

30 Applicants should submit a sample or drawing of the typical or generic label and a sample  
31 of any leaflet or brochure to be used in conjunction with the label to provide all  
32 required information.

33 This label, leaflet, or brochure must contain adequate information about the precautions to be  
34 observed in handling and storing such byproduct material. For mock iodine-125 reference or  
35 calibration sources, the information must also contain directions for disposing of waste in  
36 accordance with 10 CFR 20.2001, "General Requirements." Usually, compliance with this latter  
37 requirement is achieved by transfer to an authorized recipient.

1 Informing customers

2 There are no regulations requiring that distributors inform their customers of the requirements of  
3 the general license in 10 CFR 31.11. As they are either specifically licensed under 10 CFR  
4 Part 35 or must be preregistered with the NRC, they should be aware of NRC regulations.  
5 However, Appendix D of this NUREG provides a table of regulations applicable to 10 CFR 31.11  
6 general licensees (Table D-5), which might be made available to customers. In accordance  
7 with 10 CFR 31.11(f), except for mock iodine-125 sources, any person using byproduct material  
8 under this general license is exempt from the requirements in 10 CFR Parts 19, 20, and 21,  
9 including the requirements on the disposal of licensed material. The distribution licensees may  
10 wish to inform their customers of this exemption.

**Note:** The distributor of GL in vitro kits must not transfer materials to a general licensee unless the general licensee is licensed under 10 CFR Part 35 or has a properly completed NRC Form 483 (Appendix J of this NUREG) on file with the NRC. Distributors can verify this information by obtaining a copy of the specific licensee's Part 35 license or the general licensee's validated NRC Form 483. An NRC Form 483 has been validated if the NRC has assigned it a registration number. Alternative methods for verification appear in 10 CFR 30.41(d).

11 **Response From Applicant:**

12 Applicants should submit the following: Information on the types of prepackaged kits planned to  
13 distribute, which demonstrates that the products to be transferred will meet all applicable  
14 limitations in 10 CFR 31.11(a) and (d) and 32.71(b) through (e). This should include an actual  
15 package label, leaflet, or brochure for each type of prepackaged kit.

16 To confirm understanding of responsibilities as a licensee, submit the following or substantially  
17 similar statements:

- 18 • "We will transfer only kits that are manufactured consistent with all of the statements in  
19 the applications, as approved by the NRC and referenced in the license."
- 20 • "We will transfer kits only to those authorized under the general license by having a  
21 license issued under 10 CFR Part 35 or a validated NRC Form 483. For those in  
22 Agreement States, we will follow 10 CFR 30.41 and determine whether an equivalent  
23 general license and registration form is provided by the State, or, if not, that the recipient  
24 is specifically authorized to receive it under the specific license."

25 **9.6 10 CFR 40.34: Requirements for Distribution of Certain Industrial**  
26 **Products or Devices Containing Depleted Uranium**

27 **Regulations:** 10 CFR 20.1201(a), 10 CFR 40.25, 10 CFR 40.34, and 10 CFR 40.35

28 **Criteria:** Applicants for a specific license to manufacture or initially transfer industrial products  
29 and devices containing depleted uranium for use under 10 CFR 40.25 or equivalent regulations  
30 of an Agreement State apply under 10 CFR 40.34.

1 A specific license under 10 CFR 40.34 must be obtained, in order to distribute industrial  
2 products and devices for use under the general license in 10 CFR 40.25. Note that an SSD  
3 registration certificate is not required.

4 Paragraph (a)(1) of 10 CFR 40.34 indicates that the applicant must satisfy the general  
5 requirements of 10 CFR 40.32. These requirements are addressed separately in a  
6 possession license.

7 Paragraph (a)(2) of 10 CFR 40.34 requires the submission of sufficient information relating to  
8 the design, manufacture, prototype testing, quality control procedures, labeling or marking,  
9 proposed uses, and potential hazards of the industrial product or device to provide reasonable  
10 assurance that possession, use, or transfer of the depleted uranium in the product or device is  
11 not likely to cause any individual to receive in a year a radiation dose in excess of 10 percent of  
12 the annual limits specified in 10 CFR 20.1201(a).

13 A dose assessment should be submitted to demonstrate that the criteria of 10 CFR 40.34(a)(2)  
14 are met. The assumptions made in that assessment should be consistent with other information  
15 submitted about the product or device

16 Paragraph (a) of 10 CFR 20.1201 establishes the annual limits for occupational exposures for  
17 adult workers at specifically licensed facilities. The primary criterion is a total effective dose  
18 equivalent of 5 rem [0.05 Sv]. Additional limits apply to individual organs and tissues. Thus, for  
19 a whole body external exposure, the criterion for possession, use, and transfer of products or  
20 devices under 10 CFR 40.25 is that no person is likely to receive a dose in a year of more than  
21 500 mrem [5 mSv]. For nonuniform exposure and for potential intakes from breakdown of the  
22 plating or other covering, individual organ and tissue limits may also need to be considered. As  
23 such dose assessments would normally need to involve some conservatism to cover  
24 uncertainties in the assumptions, generally those working with GL products/devices should not  
25 regularly be exposed to more than 100 mrem [1 mSv]/year.

26 Paragraph (a)(3) of 10 CFR 40.34 requires the submission of sufficient information regarding  
27 the industrial product or device and the presence of depleted uranium for a mass-volume  
28 application in the product or device to provide reasonable assurance that unique benefits will  
29 accrue to the public because of the usefulness of the product or device.

30 Paragraph (b) of 10 CFR 40.34 indicates that if the unique benefits of an industrial product or  
31 device are questionable, the NRC will approve an application for a specific license only if the  
32 product or device is found to combine a high degree of utility and low probability of uncontrolled  
33 disposal and dispersal of significant quantities of depleted uranium into the environment.

34 Paragraph (c) of 10 CFR 40.34 indicates that the NRC may deny an applicant for a specific  
35 license under this paragraph if the end uses of the industrial product or device cannot be  
36 reasonably foreseen.

37 Conditions for any license issued under 10 CFR 40.34 appear in 10 CFR 40.35.

38 The purposes for the information required to be submitted under 10 CFR 40.34 include:

39 • Information submitted under 10 CFR 40.34(a)(2) concerning quality control will form the  
40 basis for meeting the requirements of 10 CFR 40.35(a).

1 • Information submitted concerning labeling will form the basis for meeting the  
2 requirements of 10 CFR 40.35(b) and (c) and should be consistent with those  
3 requirements.

4 Applicants should provide a copy of the information packet to be sent to customers when  
5 transferring products or devices [required by 10 CFR 40.35(d)]. Details concerning information  
6 to be provided to customers can be found in Appendix E of this NUREG.

7 The requirements for records and reporting are specified in 10 CFR 40.35(e). Information  
8 concerning the recordkeeping and reporting requirements are not required to be included in the  
9 application, because the requirements are fully specified in the regulations. Details concerning  
10 recordkeeping and annual transfer reporting requirements appear in Appendix I of this NUREG.

11 Paragraph (f) of 10 CFR 40.35 also requires that those distributors required to submit  
12 emergency plans by 10 CFR 40.31(i) follow the emergency plan approved by the NRC. It also  
13 addresses changes to the plan that may be made without prior NRC approval and when prior  
14 approval is necessary. No additional information is required to be submitted at the time of  
15 application under 10 CFR 40.34 as a result of this requirement.

#### 16 **Discussion:**

17 The general license in 10 CFR 40.25 is limited to depleted uranium contained in industrial  
18 products or devices for the purpose of providing a concentrated mass in a small volume of the  
19 product or device. Examples of such mass-volume applications are shielding in accelerators  
20 and in all types of X-ray units, and balance weights in tool holders, boring bars, drill collars,  
21 momentum wheels, and crankshafts.

22 To distribute products containing depleted uranium as GL devices, the applicant must describe  
23 the unique benefits that will accrue to the public because of the usefulness of the product as a  
24 result of the presence of depleted uranium for a mass-volume application in the product or  
25 device. Unique benefit means that the demonstrated usefulness of the industrial product or  
26 device is enhanced by the physical properties of a concentrated mass of depleted uranium in a  
27 small volume of the product or device. When such use offers a clear advantage, even of a  
28 limited degree, over other materials, the "unique" property will be considered to be satisfied.

29 Paragraph (c) of 10 CFR 40.34 reserves the right for the NRC to exercise its judgment in  
30 denying a license application when the end use of a product cannot be reasonably foreseen.  
31 This criterion is related to the ability to project how people are likely to be exposed to the  
32 radioactive material within or the radiation produced by a product, as well as the conditions  
33 under which the product would be used. This provision, along with paragraph (b) of  
34 10 CFR 40.34, also allows the NRC to ensure that the uses of depleted uranium in products  
35 are justified.

#### 36 Dose assessment

37 The regulations in 10 CFR Part 40 do not require devices containing depleted uranium to be  
38 reviewed and approved through the SSD registry. However, applicants must submit information  
39 on the design, manufacture, prototype testing, quality control procedures, labeling or marking,  
40 proposed uses, and potential hazards of the industrial product or device to provide reasonable  
41 assurance that the possession, use, or transfer of the depleted uranium in the product or device  
42 are not likely to cause any individual to receive in a year a radiation dose in excess of

1 10 percent of the annual limits specified in 10 CFR 20.1201(a). Products or devices that may  
2 cause an individual to receive radiation doses in excess of these limits are not eligible for  
3 distribution to general licensees. In developing scenarios for the dose assessment, the  
4 distributor should be able to make reasonable assumptions about the industries or market  
5 segment(s) that they expect to serve with their product(s) and how the product(s) will be used,  
6 as well as the likely conditions of use. The reviewer needs to determine if the assumptions  
7 presented are indeed reasonable. This determination becomes particularly important if the  
8 projected doses are approaching an applicable limit.

#### 9 Prototype testing

10 Applicants should determine an appropriate method to demonstrate the product/device's ability  
11 to maintain its integrity when subjected to the most severe conditions of normal use.  
12 Procedures for prototype testing should adequately take into account the individual, aggregate,  
13 and cumulative effects of environmental conditions expected in service that could adversely  
14 affect the effective containment of the depleted uranium, such as temperature, moisture,  
15 absolute pressure, water immersion, vibration, shock, wear, and weathering. Following each  
16 test exposing the device to the various conditions, the device should be evaluated for  
17 removable surface contamination. The results of testing should be taken into account in the  
18 dose assessment.

#### 19 Product labeling

20 Before installing depleted uranium in any product or device, the depleted uranium must be  
21 impressed with the words "Depleted Uranium" and the impression must be clearly legible  
22 through any plating or covering, in accordance with 10 CFR 40.35(c).

23 Applicants may submit actual copies of labels used on products, or a generic label or statement  
24 indicating that the required information will be contained on the label. Submission of generic  
25 labels or statements would allow licensees to change other information on the labels, such as  
26 brand names or telephone numbers, without having to amend their license. In addition,  
27 applicants should describe how labels will be adhered and how labels will remain legible during  
28 normal conditions of use.

#### 29 Quality control/quality assurance

30 Quality control should include ensuring that products or devices all have the required labels.  
31 Quality control should also address ensuring that required information is provided to each  
32 customer, including for transactions conducted over the Internet.

#### 33 **Response From Applicant:**

34 An applicant should provide sufficient information relating to the design, manufacture, prototype  
35 testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of  
36 the product/device(s), and conditions of handling, storage, and use of product/device(s) to  
37 demonstrate that the product will meet the safety criteria set forth in the regulations. This  
38 must include:

- 39 • all of the specific information required as to the product(s) or device(s) intended  
40 to distribute

- 1 • information on the unique benefits that will accrue to the public because of the  
2 usefulness of the product or device
- 3 • an adequate dose assessment to demonstrate that the device/product meets the safety  
4 criteria in 10 CFR 40.34(a)(2)
- 5 • information on quality control and information on product labeling (actual example labels  
6 are helpful)
- 7 • information on the safety instructions that will be provided to recipients

8 To confirm understanding of responsibilities as a licensee, submit the following or substantially  
9 similar statements:

- 10 • “We will transfer only devices (or products) that are manufactured consistent with all of  
11 the statements in the applications as approved by the NRC and referenced in the  
12 license.”
- 13 • “We will provide information to customers in accordance with 10 CFR 40.35(d). Before  
14 its installation in each product or device, we will impress the depleted uranium with the  
15 following legend clearly legible through any plating or other covering: ‘Depleted  
16 Uranium.’”
- 17 • “We will provide annual material transfer reports in accordance with 10 CFR 40.35(e)  
18 and will maintain records in accordance with 10 CFR 40.35(e)(3).”

19 **9.7 10 CFR 40.54: Requirements for Distribution of Small Quantities of**  
20 **Source Material**

21 **Regulations:** 10 CFR 40.22, 10 CFR 40.54, and 10 CFR 40.55

22 **Criteria:** Applicants for a specific license to initially distribute source material to general  
23 licensees under 10 CFR 40.22 or equivalent regulations of an Agreement State apply under  
24 10 CFR 40.54.

25 A specific license under 10 CFR 40.54 must be obtained, in order to distribute industrial  
26 products and devices for use under the general license in 10 CFR 40.25. Note that an SSD  
27 registration certificate is not required, even if one is intending to distribute sealed sources.

28 Paragraph (a) of 10 CFR 40.54 indicates that the applicant must satisfy the general  
29 requirements of 10 CFR 40.32. These requirements are addressed separately in a  
30 possession license.

31 Paragraph (b) of 10 CFR 40.54 requires the submission of sufficient information on the methods  
32 to be used for quality control, labeling, and providing safety instructions to recipients.

33 Conditions for any license issued under 10 CFR 40.54 appear in 10 CFR 40.55.

34 The purposes for the information required to be submitted under 10 CFR 40.54 include:

- 1 • The information on labeling submitted under 10 CFR 40.54(b) will supply the basis for  
2 meeting the requirements of 10 CFR 40.55(a) and should be consistent with those  
3 requirements.
- 4 • The information on quality control submitted under 10 CFR 40.54(b) will form the basis  
5 for meeting the requirements of 10 CFR 40.55(b).
- 6 • The details of how information will be provided to customers submitted under  
7 10 CFR 40.54(b) should comply with the requirements of 10 CFR 40.55(c).

8 Paragraph (d) of 10 CFR 40.55 specifies the requirements for records and reporting.  
9 Information concerning the recordkeeping and reporting requirements are not required to be  
10 included in the application, because the requirements are fully specified in the regulations.  
11 However, the applicant needs to be aware of these responsibilities. Details concerning  
12 recordkeeping and annual reporting requirements can be found in Appendix I of this NUREG.

### 13 **Discussion:**

#### 14 Product labeling

15 The requirements for product labels appear in 10 CFR 40.55(a). Labels must include the type  
16 of source material (uranium and/or thorium), quantity of material, and the words “radioactive  
17 material.” Applicants should describe how the various types of sources or packaging  
18 (e.g., glass vials) will be labeled.

19 Applicants may submit actual copies of labels to be used on products, or a generic label or  
20 statement indicating that the required information will be contained on the label. Submission of  
21 generic labels or statements would allow licensees to change other information on the labels,  
22 such as brand names or telephone numbers, without having to amend their license.

#### 23 Acceptable quality control procedures

24 These procedures should address the determination of quantity and/or concentration and how  
25 these determinations are made and used for labeling and recording transactions. The applicant  
26 should provide assurance, with a reasonable tolerance, that users would not receive larger  
27 quantities or concentrations than they are expecting. Applicants may submit a quality  
28 assurance program instead of or in conjunction with a quality control program. Typically,  
29 applicants commit to adhering to a particular standard for quality assurance, such as an  
30 International Organization of Standardization or American National Standards Institute standard.  
31 Quality control should also address ensuring that required information is provided to each  
32 customer before the first transfer of the source material in a year, including for transactions  
33 conducted over the Internet.

#### 34 Informing customers

35 Applicants should provide a copy of the information packet to be sent to customers when  
36 transferring products or devices [required by 10 CFR 40.55(c)]. Details concerning information  
37 to be provided to customers can be found in Appendix E of this NUREG. In addition,  
38 Appendix K of this NUREG provides guidance in the form of questions and answers that may  
39 assist in answering questions that the applicant or their customers may have concerning the  
40 general license in 10 CFR 40.22.

1 **Response From Applicant:**

2 An applicant should provide information relating to quality control and product labeling and the  
3 content of brochures, including information on the safety instructions that will be provided to  
4 recipients. (Also provide copies of prototypes or actual labels).

5 To confirm understanding of responsibilities as a licensee, submit the following or substantially  
6 similar statements:

7 • "We will label our product as described in this application and in accordance with  
8 10 CFR 40.55(a)."

9 • "We will conduct quality control as outlined in this application as approved by the NRC  
10 and in accordance with 10 CFR 40.55(b)."

11 • "We will provide the appropriate information to customers in accordance with  
12 10 CFR 40.55(c)."

13 • "We will maintain records and provide annual material transfer reports in accordance  
14 with 10 CFR 40.55(d)."

15 **9.8 10 CFR 70.39: Requirements for Distribution of Calibration or**  
16 **Reference Sources Containing Plutonium**

17 **Regulations:** 10 CFR 70.19, 10 CFR 70.39

18 **Criteria:** Applicants for a specific license to manufacture or initially transfer plutonium to  
19 general licensees under 10 CFR 70.19 apply under 10 CFR 70.39.

20 A specific license under 10 CFR 70.39 must be obtained, in order to distribute calibration or  
21 reference sources for use under the general license in 10 CFR 70.19. Note that an SSD  
22 registration certificate is not required for calibration or referenced sources to be used under the  
23 general license in 10 CFR 70.19 nor is it required for such sources to be used under a  
24 specific license.

25 Paragraph (a)(1) of 10 CFR 70.39 indicates that the applicant must satisfy the general  
26 requirements of 10 CFR 70.23. These requirements are addressed separately in a  
27 possession license.

28 Paragraph (a)(2) of 10 CFR 70.39 requires the submission of sufficient information on each  
29 type of calibration or reference source pertaining to the evaluation of potential radiation  
30 exposure, including:

31 (i) chemical and physical form and maximum quantity of plutonium in the source

32 (ii) details of construction and design

33 (iii) details of the method of incorporation and binding of the plutonium in the source

34 (iv) procedures for and results of prototype testing of sources that are designed to contain  
35 more than 0.005  $\mu\text{Ci}$  [185 Bq] of plutonium to demonstrate that the plutonium contained

1 in each source will not be released or be removed from the source under normal  
2 conditions of use

3 (v) details of quality control procedures to be followed in manufacture of the source

4 (vi) description of labeling to be affixed to the source or the storage container for the source

5 After receiving the application, the NRC may require the submittal of additional information,  
6 including experimental studies and tests, to facilitate a determination of the safety of the source.

7 Paragraph (a)(4) specifies findings that the NRC must make before issuing the license for any  
8 type of source containing more than 0.005  $\mu\text{Ci}$  [185 Bq] of plutonium:

9 (i) The method of incorporation and binding of the plutonium in the source is such that the  
10 plutonium will not be released or be removed from the source under normal conditions of  
11 use and handling of the source.

12 (ii) The source has been subjected to and has satisfactorily passed the specified  
13 prototype tests.

14 Paragraph (b) of 10 CFR 70.39 specifies the labeling requirements. Information submitted  
15 under 10 CFR 70.39(a)(2)(vi) on labeling should be consistent with 10 CFR 70.39(b).

16 Paragraph (c) of 10 CFR 70.39 specifies dry wipe test requirements. Information submitted  
17 under 10 CFR 70.39(a)(2)(v) on quality control should include information on testing consistent  
18 with 10 CFR 70.39(c).

## 19 **Discussion:**

### 20 Prototype Testing

21 If the calibration or reference source(s) contains more than 0.005  $\mu\text{Ci}$  [185 Bq] of plutonium, the  
22 applicant must submit the procedures for and the results of prototype testing for consideration.  
23 Prototype testing is specified in 10 CFR 70.39(a)(5).

### 24 Product labeling

25 Applicants may submit actual copies of the labels used on sources, or a generic label or  
26 statement indicating that the required information will be contained on the label. Submission of  
27 generic labels or statements would allow licensees to change other information on the labels,  
28 such as brand names or telephone numbers, without having to amend their license. In addition,  
29 applicants should describe how labels will be adhered and how labels will remain legible during  
30 normal conditions of use.

### 31 Quality control procedures

32 Applicants must submit procedures addressing quality control. These procedures should  
33 address the determination of quantity and how these determinations are made and used for  
34 labeling and recording transactions. The applicant should provide assurance, with a reasonable  
35 tolerance, that quantities of material in the sources will be as labeled. For example, the quantity  
36 of material in sealed sources used to calibrate equipment may be assured if they are traceable

1 to the National Institute of Standards and Technology. Applicants may also commit to adhering  
2 to a particular standard for quality assurance, such as an International Organization of  
3 Standardization or American National Standards Institute standard. The specific dry wipe test  
4 requirements of 10 CFR 70.39(c) should also be addressed, if sources will contain more than  
5 0.1  $\mu\text{Ci}$  [3.7 kBq] of plutonium.

6 Informing customers

7 There are no regulations requiring that distributors inform their customers of the requirements of  
8 the general license in 10 CFR 70.19. As they are also specifically licensed for other radioactive  
9 material, they should be aware of NRC regulations. However, Appendix D of this NUREG  
10 provides a table of regulations applicable to 10 CFR 70.19 general licensees (Table D-9), which  
11 might be made available to customers.

12 **Response From Applicant:**

13 Applicants should submit sufficient information on each type of calibration or reference source  
14 pertaining to the evaluation of potential radiation exposure, including:

- 15 • all the specific information required as to the source(s) one intends to distribute,  
16 including results of prototype testing and details on quality control
- 17 • information on source or storage container labeling, including information on the safe  
18 use and storage (actual example labels are helpful)

19 To confirm understanding of responsibilities as a licensee, submit the following or substantially  
20 similar statements:

- 21 • “We will transfer only sources that are manufactured consistent with all of the statements  
22 in the applications, as approved by the NRC and referenced in the license.”
- 23 • “We will transfer sources only to specifically licensed persons. For those in Agreement  
24 States, we will follow 10 CFR 70.42, and determine whether an equivalent general  
25 license is provided by the State, or, if not, that the recipient is specifically authorized to  
26 receive it under a specific license.”

1

## 10 DEFICIENCIES IN THE APPLICATION

2 In the process of evaluating an application, a reviewer may determine that the applicant has  
3 submitted insufficient information. If this is the case, the reviewer must inform the applicant that  
4 the application information is insufficient and that additional information is necessary for review  
5 of the application. Depending on the type and complexity of the information needed, the  
6 reviewer may obtain the information by sending a formal written request to the applicant or for  
7 simple answers and clarifications, by notifying the applicant of the need for information via  
8 telephone or electronic mail. Submittal of an inadequate or deficient application may delay the  
9 issuance of the license. The U.S. Nuclear Regulatory Commission (NRC) could reject the  
10 application if the applicant fails to provide a prompt or timely response to a noted deficiency in  
11 the application.

12 Normally, the NRC expects the applicant to respond within 30 days of the date of the request.  
13 Applicants may request an extension of time in order to respond to any correspondence or  
14 request for additional information about its application, provided the NRC determines that there  
15 is good cause and the additional time requested is reasonable. Applicants may make these  
16 requests in writing or via telephone. Typically, the reviewer notifies the applicant by telephone  
17 that an extension has been granted and gives the applicant the new proposed response date.



## 11 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the changes take place. The change is not in effect until the amendment has been issued. In general, the licensee must submit an application for an amended license whenever there is a substantive change to text or labels accompanying the product. Substantive changes include such items as a change in the name or address of the licensed distributor, wording required by regulations, or colors used on the hazard warning labels. An application for a license amendment is not needed for minor changes. Minor changes include changes in format; color intensity; typographical corrections; and changes to the distributor's logo, telephone number, e-mail address, or Web site address.

Amending or changing the generally licensed (GL) distribution license may also require amendments to the possession and use license(s) or the device registration certificate(s) (or both) for additions, deletions, or modifications to the models of sealed sources or devices to be distributed. NUREG-1556, Volume 3, provides information on how and when to amend an SSD registration.

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 [see Title 10 of the *Code of Federal Regulations* (10 CFR) 2.109(a), 10 CFR 30.36(a), 10 CFR 40.42(a), and 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, in duplicate, either an the U.S. Nuclear Regulatory Commission (NRC) Form 313 or a letter requesting amendment or renewal.
- Provide the license number and docket number.
- For renewals, provide a complete and up-to-date application, including all applicable items outlined in Appendix B of this NUREG.

Using the suggested wording of responses and committing to use the model procedures in this NUREG will expedite the NRC's review.

Applicants submitting an application for license renewal filed at least 30 days before the expiration date of the license will receive a "Deemed Timely" letter confirming that the application has been filed in a timely manner and the present license will remain in effect until the NRC takes final action on the renewal application. A copy of this letter should be maintained until the amended license is received. If the NRC does not receive a renewal application before the expiration date, the licensee will be without a valid license when the license expires, at which point GL distribution activities are no longer authorized and the licensee must cease all distribution activities until a new license can be obtained. The licensee must then submit an application package for a new license.

1 Licensees not wishing to renew their GL distribution license should send a letter to the NRC  
2 before the expiration date of the license with a request to terminate the license (see Chapter 13  
3 for additional guidance).

#### 4 **11.1 Timely Notification of Transfer of Control**

5 **Regulation:** 10 CFR 30.34(b), 10 CFR 40.46, 10 CFR 70.36

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

9 **Discussion:** Transferring control may be the result of mergers, buyouts, or majority stock  
10 transfers. Although it is not the NRC's intent to interfere with the business decisions of  
11 licensees, under 10 CFR 30.34(b), 10 CFR 40.46, or 10 CFR 70.36 and the Atomic Energy Act,  
12 licensees must obtain prior NRC written consent before transferring control of the license to  
13 ensure the following:

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

22 Most of these matters relate to the transfer of the possession license. With respect to the  
23 distribution license, the main issue would be to coordinate the action with the transfer of the  
24 possession license and ensure that the appropriate possession license is in place before  
25 transfer of the distribution license. In addition, there may be such considerations as the training  
26 and experience of persons responsible for ensuring that only products that meet all of the  
27 approved specifications are transferred for use under the respective general license.

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

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

1 **11.2 Notification of Bankruptcy Proceedings**

2 **Regulations:** 10 CFR 30.34(h), 10 CFR 40.41(f), 10 CFR 70.32(a)(9)(i)

3 **Criteria:** Immediately following the filing of a voluntary or involuntary petition for bankruptcy for  
4 or against a licensee, the licensee must notify the appropriate NRC Regional Administrator, in  
5 writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

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

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

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



## 12 APPLICATIONS FOR EXEMPTIONS

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

**Discussion:** Various sections of the NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, "Application for exemptions"; 10 CFR 20.2301, "Applications for exemptions"; 10 CFR 30.11, "Specific exemptions"; 10 CFR 40.14, "Specific exemptions"; and 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. Requests for exemptions submitted to the NRC must identify the regulation for which the exemption is being requested and include a justification for the requested exemption.

Until the NRC has granted an exemption in writing, the NRC expects strict compliance with all applicable regulations.
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### 13 TERMINATION OF ACTIVITIES

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.36, 10 CFR 40.42, or 10 CFR 70.38, generally licensed (GL) distribution licensees may request termination of their U.S. Nuclear Regulatory Commission (NRC) license at any time. Licensees should notify NRC within 60 days of its decision to permanently cease distribution or within 24 months after distribution has ceased. The NRC generally issues separate licenses for distribution and for possession and use of radioactive material. The request to terminate the distribution license may occur prior to decommissioning and must occur prior to termination of any associated possession licenses.

In accordance with 10 CFR 32.211, a holder of a registration certificate who no longer intends to manufacture or initially transfer a sealed source or device shall request inactivation of the registration certificate. Such a request must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. This applies whether or not the licensee (certificate holder) is authorized to distribute other exempt products and may not be terminating their exempt distribution license. If this cessation of activity is associated with the termination of the license, the request for inactivation of registration should state the intent to terminate the license, giving the specific license number.

**Note:** A license is not terminated until the NRC takes action to terminate the license; therefore, an application for license termination does not relieve the licensee from its obligations to comply with NRC regulations and the terms and conditions of the license, until such time as the license is terminated in writing by the NRC.

**Note:** For distribution licenses issued under 10 CFR 32.51, 10 CFR 32.53, 10 CFR 40.34, and 10 CFR 40.54, there are material transfer reporting requirements, which are either quarterly or annual. These requirements include that if no transfers of byproduct or source material have taken place, the report must so indicate. Regardless of the actual due date for the final report, final reports to the NRC and the Agreement States should be submitted as soon as possible after all distribution has ceased to expedite termination of the distribution license. The NRC will issue a termination notice upon request only after receiving the final transfer report and determining that required reports have also been submitted to the Agreement States.

After the license is terminated (or has expired), the former distribution licensee may no longer initially transfer for sale or distribution any remaining or new products or materials.

Termination of the distribution license does not relieve the licensee from any obligations or requirements related to terminating any associated possession license issued by the NRC. This would include requirements related to residual contamination at the site. GL distribution licensees that intend to terminate their possession and use activities, as well, are also responsible for notifying the appropriate NRC regional office concerning the disposition of the possession license and all radioactive material and for providing records of deposition, etc., to the NRC. For information on termination of possession and use licenses, refer to NUREG-1556, Volume 12, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution."



1

**APPENDIX A**

2

**DOCUMENTS CONSIDERED IN THE PREPARATION OF THIS REPORT**



## Documents Considered in the Preparation of this Report

Document Identification	Title	Date
NUREG-1556, Volume 16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licenses	12/2000
IN 2009-18	Information Notice 2009-18, "Performance of Required Shutter Checks and Reporting of Gauge Shutter Failures"	9/18/2009
IN 2011-09	Information Notice 2011-09, "Fixed Gauge Shutter Failures Due to Operating in Harsh Working Environments"	5/18/2011
ML112150558	Interim Guidance for Implementation of the Final Rule, Requirements for Distribution of Byproduct Material in 10 CFR Parts 30, 31, 32, 40, and 70	6/2012
ML13051A824	Guidance for Implementation of the Final Rule "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions," 10 CFR Parts 30, 40, 70, 170, and 171	5/29/2013



1

**APPENDIX B**

2

**U.S. NUCLEAR REGULATORY COMMISSION FORM 313**



# U.S. Nuclear Regulatory Commission Form 313

Please use the most current version of this form, which may be found at:

<http://www.nrc.gov/reading-rm/doc-collections/forms/>

<p><b>NRC FORM 313</b> (02-2016) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40</p> <p style="text-align: center;"><b>U.S. NUCLEAR REGULATORY COMMISSION</b></p> <p style="text-align: center;"><b>APPLICATION FOR MATERIALS LICENSE</b></p>	<p><b>APPROVED BY OMB: NO. 3150-0120</b></p> <p><small>Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE0B-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></p>	<p style="text-align: right;"><b>EXPIRES: 02/29/2016</b></p>			
<p><b>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.</b></p>					
<p><b>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</b></p> <p style="font-size: small;">MATERIALS SAFETY LICENSING BRANCH DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001</p> <p><b>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</b></p> <p><b>IF YOU ARE LOCATED IN:</b></p> <p>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,</p> <p><b>SEND APPLICATIONS TO:</b></p> <p style="font-size: small;">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</p>	<p><b>IF YOU ARE LOCATED IN:</b></p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, <b>SEND APPLICATIONS TO:</b></p> <p style="font-size: small;">MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352</p> <p>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,</p> <p><b>SEND APPLICATIONS TO:</b></p> <p style="font-size: small;">NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511</p>				
<p><b>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.</b></p>					
<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</p>				
<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>BUSINESS TELEPHONE NUMBER _____ BUSINESS CELLULAR TELEPHONE NUMBER _____</p> <p>BUSINESS EMAIL ADDRESS _____</p>				
<p>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.</p>					
<p>5. RADIOACTIVE MATERIAL</p> <p style="font-size: small;">a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>				
<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>	<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.</p>				
<p>10. RADIATION SAFETY PROGRAM.</p>	<p>9. FACILITIES AND EQUIPMENT.</p>				
<p>12. LICENSE FEES (Fees required only for new applications, with few exceptions*) <i>(See 10 CFR 170 and Section 170.31)</i></p>	<p>11. WASTE MANAGEMENT.</p> <p>FEE CATEGORY <input type="text"/> AMOUNT ENCLOSED \$ <input type="text"/></p>				
<p>13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.</p> <p>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.</p> <p>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.</p>					
<p>CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE</p>	<p>SIGNATURE</p>	<p>DATE</p>			
<p><b>FOR NRC USE ONLY</b></p>					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
APPROVED BY			\$	DATE	

1 **Note:** U.S. Nuclear Regulatory Commission (NRC) Form 313 does not include Title 10 of the  
2 *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear  
3 Material," on the form, but the NRC would like applicants to complete the form if they wish to  
4 distribute or initially transfer special nuclear materials.

1

**APPENDIX C**

2

**SAFETY CULTURE POLICY STATEMENT**



# Safety Culture

The Safety Culture Policy Statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011, and can be found at <http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf>. It is also posted in the U.S. Nuclear Regulatory Commission's (NRC's) Agencywide Documents Access and Management System under Accession No. ML11146A047.

## Safety Culture Policy Statement

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

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

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

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

The following are traits of a positive safety culture:

- (1) *Leadership Safety Values and Actions*—Leaders demonstrate a commitment to safety in their decisions and behaviors.

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

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

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

1

**APPENDIX D**

2

**TABLES OF APPLICABLE REQUIREMENTS FOR EACH  
GENERAL LICENSE**

3



## Tables of Applicable Requirements for Each General License

<b>Table D-1. Regulatory Requirements for Certain Detecting, Measuring, and Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere Generally Licensed Under 10 CFR 31.5</b>		
	<b>Subject</b>	<b>Applicable Regulation</b>
1	Report theft or loss of licensed material	10 CFR 20.2201
2	Notification of incidents	10 CFR 20.2202
3	Prohibition on introducing exempt concentrations	10 CFR 30.14(d)
4	Terms and conditions of licenses	10 CFR 30.34(a)-(e)
5	Bankruptcy notification	10 CFR 30.34(h)
6	Transfer of byproduct material	10 CFR 30.41
7	Reporting requirements	10 CFR 30.50
8	Records	10 CFR 30.51
9	Inspections	10 CFR 30.52
10	Tests	10 CFR 30.53
11	Modification and revocation of licenses and registration certificates	10 CFR 30.61
12	Right to cause the withholding or recall of byproduct material	10 CFR 30.62
13	Violations	10 CFR 30.63
14	Terms and conditions	10 CFR 31.2
15	Categories of users and types of devices	10 CFR 31.5 (a) and (b)(1)
16	Receipt of device	10 CFR 31.5(b)(2)
17	Labels on device	10 CFR 31.5(c)(1)
18	Testing	10 CFR 31.5(c)(2)
19	Testing and service	10 CFR 31.5(c)(3)
20	Records of testing	10 CFR 31.5(c)(4)
21	Malfunction of or damage to the device	10 CFR 31.5(c)(5)
22	Abandonment	10 CFR 31.5(c)(6)
23	Device export restrictions	10 CFR 31.5(c)(7)
24	Restrictions on and reporting of transfers of the device	10 CFR 31.5(c)(8)
25	Transfer of the device to a general licensee	10 CFR 31.5(c)(9)
26	Other regulations: Which are applicable?	10 CFR 31.5(c)(10)
27	Respond to written requests from NRC	10 CFR 31.5(c)(11)
28	Appointment of a responsible person	10 CFR 31.5(c)(12)

<b>Table D-1. Regulatory Requirements for Certain Detecting, Measuring, and Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere Generally Licensed Under 10 CFR 31.5 (Continued)</b>		
	<b>Subject</b>	<b>Applicable Regulation</b>
29	Register appropriate devices	10 CFR 31.5(c)(13)(i)
30	Annual registration of the device	10 CFR 31.5(c)(13)(ii) and 10 CFR 31.5(c)(13)(iii)
31	Report changes in mailing address	10 CFR 31.5(c)(14)
32	Do not hold devices not in use more than 2 years	10 CFR 31.5(c)(15)
33	No manufacture or import authorized	10 CFR 31.5(d)
34	Maintenance of records	10 CFR 31.21
35	Violations	10 CFR 31.22
36	Civil penalties	10 CFR 31.23

<b>Table D-2. Regulatory Requirements for Luminous Safety Devices for Use in Aircraft Generally Licensed Under 10 CFR 31.7</b>		
	<b>Subject</b>	<b>Applicable Regulation</b>
1	Reports of theft or loss of licensed material	10 CFR 20.2201
2	Notification of incidents	10 CFR 20.2202
3	Prohibition on introducing exempt concentrations	10 CFR 30.14(d)
4	Terms and conditions of licenses	10 CFR 30.34(a)-(e)
5	Transfer of byproduct material	10 CFR 30.41
6	Reporting requirements	10 CFR 30.50
7	Records	10 CFR 30.51
8	Inspections	10 CFR 30.52
9	Tests	10 CFR 30.53
10	Modification and revocation of licenses and registration certificates	10 CFR 30.61
11	Right to cause the withholding or recall of byproduct material	10 CFR 30.62
12	Violations	10 CFR 30.63
13	Terms and conditions	10 CFR 31.2
14	Specifics of general license	10 CFR 31.7(a)
15	Other regulations: Which are applicable?	10 CFR 31.7(b)
16	Authorization restrictions of the device	10 CFR 31.7(c)-(e)
17	Maintenance of records	10 CFR 31.21
18	Violations	10 CFR 31.22
19	Criminal penalties	10 CFR 31.23

<b>Table D-3. Regulatory Requirements for Americium-241 and Radium-226 in the Form of Calibration or Reference Sources Generally Licensed Under 10 CFR 31.8</b>		
	<b>Subject</b>	<b>Applicable Regulation</b>
1	Notices, instructions and reports to workers: inspection and investigations	10 CFR Part 19
2	Standards for protection against radiation	10 CFR Part 20
3	Reporting of defects and noncompliance	10 CFR Part 21
4	Prohibition on introducing exempt concentrations	10 CFR 30.14(d)
5	Terms and conditions of licenses	10 CFR 30.34(a)-(e)
6	Transfer of byproduct material	10 CFR 30.41
7	Reporting requirements	10 CFR 30.50
8	Records	10 CFR 30.51
9	Inspections	10 CFR 30.52
10	Tests	10 CFR 30.53
11	Modification and revocation of licenses	10 CFR 30.61
12	Right to cause the withholding or recall of byproduct material	10 CFR 30.62
13	Violations	10 CFR 30.63
14	Terms and conditions	10 CFR 31.2
15	Specification of and limitation of general license to specific licensees	10 CFR 31.8(a)-(b)
16	Other regulations: Which are applicable?	10 CFR 31.8(c)
17	Quantity limits and other restrictions	10 CFR 31.8(c)(1)-(5)
18	Limits to authorization	10 CFR 31.8(d)-(e)
19	Maintenance of records	10 CFR 31.21
20	Violations	10 CFR 31.22
21	Criminal penalties	10 CFR 31.23

<b>Table D-4. Regulatory Requirements for a General License for Strontium-90 in Ice Detection Devices Under 10 CFR 31.10</b>		
	<b>Subject</b>	<b>Applicable Regulation</b>
1	General requirements for waste disposal	10 CFR 20.2001
2	Reports of theft or loss of licensed material	10 CFR 20.2201
3	Notification of incidents	10 CFR 20.2202
4	Prohibition on introducing exempt concentrations	10 CFR 30.14(d)
5	Terms and conditions of licenses	10 CFR 30.34(a)-(e)
6	Transfer of byproduct material	10 CFR 30.41
7	Records, inspections, tests, and reports	10 CFR 30.50
8	Records	10 CFR 30.51
9	Inspections	10 CFR 30.52
10	Tests	10 CFR 30.53
11	Modification and revocation of licenses	10 CFR 30.61
12	Right to cause the withholding or recall of byproduct material	10 CFR 30.62
13	Violations	10 CFR 30.63
14	Terms and conditions	10 CFR 31.2
15	General license for strontium-90 in ice detection devices	10 CFR 31.10(a)
16	Damage and servicing	10 CFR 31.10(b)(1)
17	Labels	10 CFR 31.10(b)(2)
18	Other regulations: Which are applicable?	10 CFR 31.10(b)(3)
19	Limits to authorization	10 CFR 31.10(c)
20	Maintenance of records	10 CFR 31.21
21	Violations	10 CFR 31.22
22	Criminal penalties	10 CFR 31.23

<b>Table D–5. Regulatory Requirements for Byproduct Material for Certain <i>In Vitro</i> Clinical or Laboratory Testing Generally Licensed Under 10 CFR 31.11</b>		
	<b>Subject</b>	<b>Applicable Regulation</b>
1	General requirements for waste disposal	10 CFR 20.2001
2	Reports of theft or loss of licensed material	10 CFR 20.2201
3	Notification of incidents	10 CFR 20.2202
4	Prohibition on introducing exempt concentrations	10 CFR 30.14(d)
5	Terms and conditions of licenses	10 CFR 30.34(a)-(e)
6	Transfers of byproduct material	10 CFR 30.41
7	Reporting requirements	10 CFR 30.50
8	Records	10 CFR 30.51
9	Inspections	10 CFR 30.52
10	Tests	10 CFR 30.53
11	Modification and revocation of licenses	10 CFR 30.61
12	Right to cause the withholding or recall of byproduct material	10 CFR 30.62
13	Violations	10 CFR 30.63
14	Terms and conditions	10 CFR 31.2
15	Specifics of general license	10 CFR 31.11(a), (c)(3), (d)
16	Criteria for use	10 CFR 31.11(b)
17	Quantity limits	10 CFR 31.11(c)(1)
18	Storage	10 CFR 31.11(c)(2)
19	Transfers	10 CFR 31.11(c)(4)
20	Disposal	10 CFR 31.11(c)(5)
21	Report changes	10 CFR 31.11(e)
22	Other regulations: Which are applicable?	10 CFR 31.11(f)
23	Maintenance of records	10 CFR 31.21
24	Violations	10 CFR 31.22
25	Criminal penalties	10 CFR 31.23

<b>Table D-6. Regulatory Requirements for a General License for Certain Items and Self-Luminous Devices Containing Radium-226 Under 10 CFR 31.12</b>		
	<b>Subject</b>	<b>Applicable Regulation</b>
1	Disposal of certain byproduct material	10 CFR 20.2008
2	Prohibition on introducing exempt concentrations	10 CFR 30.14(d)
3	Terms and conditions of licenses	10 CFR 30.34(a)-(e)
4	Transfers of byproduct material	10 CFR 30.41
5	Inspections	10 CFR 30.52
6	Tests	10 CFR 30.53
7	Modification and revocation of licenses	10 CFR 30.61
8	Right to cause the withholding or recall of byproduct material	10 CFR 30.62
9	Violations	10 CFR 30.63
10	Terms and conditions	10 CFR 31.2
11	General license for certain items and self-luminous products containing radium-226	10 CFR 31.12(a)
12	Other regulation: Which are applicable?	10 CFR 31.12(b)
13	Possible damage reporting	10 CFR 31.12(c)(1)
14	Abandonment and disposal	10 CFR 31.12(c)(2)
15	Export	10 CFR 31.12(c)(3)
16	Disposal	10 CFR 31.12(c)(4)
17	Respond to written requests from NRC	10 CFR 31.12(c)(5)
18	Limits to authorization	10 CFR 31.12(d)
19	Maintenance of records	10 CFR 31.21
20	Violations	10 CFR 31.22
21	Criminal penalties	10 CFR 31.23

<b>Table D-7. Regulatory Requirements for Source Material Generally Licensed Under 10 CFR 40.22</b>		
	<b>Subject</b>	<b>Applicable Regulation</b>
1	General requirements for waste disposal	10 CFR 20.2001
2	Radiological criteria for unrestricted use	10 CFR 20.1402
3	Limits to authorization (Quantity limits of the general license?)	10 CFR 40.22(a)
4	Prohibition against applying to human beings	10 CFR 40.22(b)(1)
5	Abandonment and disposal	10 CFR 40.22(b)(2)
6	Other regulations: Which are applicable?	10 CFR 40.22(b)(3)
7	Respond to written requests from NRC	10 CFR 40.22(b)(4)
8	Export	10 CFR 40.22(b)(5)
9	Minimize contamination and residual source material	10 CFR 40.22(c)
10	Exemption from most of Parts 19, 20, and 21 if not specifically licensed	10 CFR 40.22(d)
11	Prohibition of initial distribution without authorizing license	10 CFR 40.22(e)
12	Terms and conditions of licenses	10 CFR 40.41(a)-(e)
13	Inalienability of licenses	10 CFR 40.46
14	Transfer of source or byproduct material	10 CFR 40.51
15	Restrictions on the use of Australian-obligated source material	10 CFR 40.56
16	Reporting requirements	10 CFR 40.60
17	Records	10 CFR 40.61
18	Inspections	10 CFR 40.62
19	Tests	10 CFR 40.63
20	Modification and revocation of licenses	10 CFR 40.71
21	Violations	10 CFR 40.81

<b>Table D–8. Regulatory Requirements for Source Material Generally Licensed Under 10 CFR 40.25</b>		
	<b>Subject</b>	<b>Applicable Regulation</b>
1	General requirements for waste disposal	10 CFR 20.2001
2	Radiological criteria for unrestricted use	10 CFR 20.1402
3	Authorizing provision	10 CFR 40.25(a)
4	Restricted to being manufactured or distributed by authorized specific licensee	10 CFR 40.25(b)
5	Registration	10 CFR 40.25(c)(1)
6	Update registration	10 CFR 40.25(c)(2)
7	Limitations on processing and treatments	10 CFR 40.25(d)(1)
8	Abandonment	10 CFR 40.25(d)(2)
9	Disposal	10 CFR 40.25(d)(3)
10	Report transfers	10 CFR 40.25(d)(4)
11	Exemption from Parts 19, 20, and 21	10 CFR 40.25(e)
12	Terms and conditions of licenses	10 CFR 40.41(a)–(e)
13	Inalienability of licenses	10 CFR 40.46
14	Transfer of source or byproduct material	10 CFR 40.51
15	Restrictions on the use of Australian-obligated source material	10 CFR 40.56
16	Reporting requirements	10 CFR 40.60
17	Records	10 CFR 40.61
18	Inspections	10 CFR 40.62
19	Tests	10 CFR 40.63
20	Modification and revocation of licenses	10 CFR 40.71
21	Violations	10 CFR 40.81

<b>Table D-9. Regulatory Requirements for Special Nuclear Material Generally Licensed Under 10 CFR 70.19</b>		
	<b>Subject</b>	<b>Applicable Regulation</b>
1	Notices, instructions, and reports to workers: inspection and investigations General requirements for waste disposal	10 CFR Part 19
2	Standards for protection against radiation	10 CFR Part 20
3	Reporting of defects and noncompliance	10 CFR Part 21
4	General license restricted to specific licensees	10 CFR 70.19(a)
5	Restricted to being manufactured or distributed by authorized specific licensee	10 CFR 70.19(b)
6	Other regulations: Which are applicable? and other requirements including authorization limit for one location	10 CFR 70.19(c)
7	Conditions of license	10 CFR 70.32
8	Reporting requirements	10 CFR 70.50
9	Inspections	10 CFR 70.55
10	Tests	10 CFR 70.56
11	Modification and revocation of licenses	10 CFR 70.81
12	Suspension and operation in war or national emergency	10 CFR 70.82
13	Violations	10 CFR 70.91
14	Reports of loss or theft or attempted theft or unauthorized production of special nuclear material	10 CFR 74.11
15	Recordkeeping	10 CFR 74.19

1

**APPENDIX E**

2

**INFORMATION TO BE PROVIDED TO CUSTOMERS  
(GENERAL LICENSEES)**

3



## 1 Information to be Provided to Customers (General Licensees)

### 2 Requirements of 10 CFR 32.51a for Distributors to 10 CFR 31.5

3 Those licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) 32.51 are required  
4 to provide information to their generally licensed (GL) customers before transfer of devices, in  
5 accordance with 10 CFR 32.51a(a) and (b). The intent is for the customer to be aware of this  
6 information and make an informed decision before making a commitment to purchase (i.e., so  
7 they can consider the requirements associated with the GL and the costs of disposal of the  
8 device in making a decision to purchase).

9 For end users in U.S. Nuclear Regulatory Commission (NRC) jurisdiction GL under  
10 10 CFR 31.5, the licensee or intermediate person must ensure that the end user receives the  
11 following information:

- 12 • a copy of 10 CFR 30.51, "Records;" 10 CFR 31.2, "Terms and conditions;" 10 CFR 31.5,  
13 10 CFR 20.2201, "Reports of theft or loss of licensed material;" and 10 CFR 20.2202,  
14 "Notification of incidents"
- 15 • a list of services that can only be performed by a specific licensee
- 16 • information on acceptable disposal options and estimated cost of disposal
- 17 • an indication that the NRC's policy is to issue high civil penalties for improper disposal

### 18 Information to be Supplied to Customers in Agreement States

19 If the customer plans to use the device in an Agreement State jurisdiction, the licensee should  
20 provide the customer with a copy of the applicable State regulations and the name, address,  
21 and telephone number of the contact at the relevant Agreement State regulatory agency. A  
22 copy of the NRC regulations listed under "Regulations" above can be substituted for the  
23 Agreement State regulations, with a note that the device is regulated by the Agreement State  
24 regulations. Information about NRC's policy for high civil penalties for improper disposal need  
25 not be included in this case.

26 Although the regulations allow copies of NRC's regulations to be provided in lieu of copies of the  
27 relevant Agreement State, the compatibility category of 10 CFR 31.5 has changed since that  
28 regulation was issued, meaning there may not be equivalent provisions in all States.  
29 Distributors need to keep informed concerning the applicable regulations in each Agreement  
30 State at least to the extent of determining whether their device is covered by an equivalent  
31 general license. It would be advisable to provide copies of relevant regulations for the particular  
32 State, but at a minimum, distributors must verify that the recipient is authorized to receive  
33 the device.

34 **Note:** Licensees can also give Appendix G or H of this NUREG to customers for their  
35 information. These appendices contain useful information about GL devices in an easy-to-read  
36 question and answer format. Appendix G of this NUREG may be helpful to a wide range of  
37 general licensees, and Appendix H of this NUREG may be helpful to general licensees that use  
38 self-luminous exit signs. Appendix D of this NUREG also contains a table listing regulations  
39 applicable to these general licensees in NRC jurisdiction (Table D-1).

1 Requirements of 10 CFR 40.35(d) for Distributors to 10 CFR 40.25

2 Those licensed under 10 CFR 40.34 are required by 10 CFR 40.35(d) to provide information to  
3 their GL customers when transferring devices for use under 10 CFR 40.25 or equivalent  
4 Agreement State provisions. The intent is for the customer to be aware of this information  
5 (i.e., the requirements associated with the general license) and to be able to complete  
6 applicable registration requirements. The licensee must provide the following information:

- 7 • a copy of the general license contained in 10 CFR 40.25
- 8 • a copy of NRC Form 244

9 If the customer plans to use the device in an Agreement State's jurisdiction, the licensee should  
10 provide the customer with a copy of the equivalent State general license and any Agreement  
11 State certificate. Copies of 10 CFR 40.25 and NRC Form 244 can be substituted for the  
12 Agreement State general license, with a note that the device is regulated by the Agreement  
13 State under regulations substantially the same as 10 CFR 40.25. Although not required by  
14 regulation, providing the name, address, and telephone number of the contact at the relevant  
15 Agreement State regulatory agency is advisable so that customers will be able to meet  
16 registration requirements in a timely manner.

17 **Note:** Table D-8 of Appendix D of this NUREG also contains a table listing regulations  
18 applicable to these general licensees, which may also be provided to customers for information.

19 **Requirements of 10 CFR 40.55(c) for Distributors to 10 CFR 40.22**

20 Those licensed under 10 CFR 40.54 are required by 10 CFR 40.55(c) to provide information to  
21 their GL customers before the first transfer in each calendar year to each particular recipient.

22 The licensee must provide the following information:

- 23 • a copy of 10 CFR 40.22 and 10 CFR 40.51, or relevant equivalent Agreement  
24 State provisions
- 25 • appropriate radiation safety precautions and instructions relating to the handling, use,  
26 storage, and disposal of source material

27 What is adequate and appropriate safety instruction depends on the amount and type of  
28 material the user is obtaining. For dispersible materials, it is particularly important to address  
29 means of minimizing the intake of the material. Instructions should include general statements  
30 about radiation safety such as the following:

- 31 • Minimize exposure by applying the basic radiation safety principles of time, distance,  
32 and shielding.\*

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<sup>1</sup>Minimizing the time spent around radioactive material, as well as maximizing the distance and the shielding between persons and the radioactive material.

1 • Prohibit eating, drinking, smoking, and applying cosmetics in areas of use.

2 • Wear gloves and laboratory coats when handling liquid or powdered  
3 radioactive material.

4 • Securely store all radioactive materials when not in use.

5 Applicants under 10 CFR 40.54 must describe how they will ensure that this information is  
6 provided to customers before transfer of the source material, including for transactions  
7 conducted over the Internet.

8 **Note:** Licensees can also give Appendix K of this NUREG to this report to customers for their  
9 information. That appendix contains useful information about the small quantities general  
10 license in an easy-to-read question and answer format. Table D-7 of Appendix D of this  
11 NUREG also contains a table listing regulations applicable to general licensees under  
12 10 CFR 40.22.

NRC FORM 244  
(01-2016)  
10 CFR 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0031 EXPIRES: 01/31/2019



**REGISTRATION CERTIFICATE --  
USE OF DEPLETED  
URANIUM UNDER GENERAL LICENSE**

Estimated burden per response to comply with this mandatory collection request: 1 hour. NRC requires this information to identify the general licensees and to facilitate subsequent communication. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0031), 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.

**Section 40.25 of 10 CFR Part 40 establishes a general license authorizing the use of depleted uranium contained in industrial products or devices for mass-volume applications. Submit NRC form 244 within 30 days after the first receipt or acquisition of such depleted uranium.**

**1. INSTRUCTIONS:**

- A. Print or type the name and address of the registrant (including ZIP Code) for whom this form is filed in Box 3 below.
- B. Submit this form in duplicate to:  
Director, Office of Federal and State Materials and Environmental Management Programs  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555-0001
- with a copy to the appropriate Regional Administrator at the address listed on the reverse.
- (NRC will assign a file number, and a copy of this form will be returned to you.)

2. I hereby file NRC Form 244 pursuant to 10 CFR 40.25, for use of depleted uranium contained in industrial products or devices for mass-volume applications.

3. NAME AND ADDRESS OF REGISTRANT FOR WHOM THIS FORM IS FILED (Include Zip Code)

4. FILE NUMBER (Leave blank - to be assigned by NRC)

**5. INDIVIDUAL DULY AUTHORIZED TO ACT FOR AND ON BEHALF OF THE REGISTRANT IN SUPERVISING THE PROCEDURES**

A. NAME

B. TITLE

C. ADDRESS

D. TELEPHONE NUMBER

E. FACSIMILE TELEPHONE NUMBER

F. E-MAIL ADDRESS

**6. CERTIFICATION**

I hereby certify that:

- A. All information in this registration certificate is true and complete.
- B. This registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 10 CFR 40.25(a) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium.
- C. I understand that Commission regulations require that any changes in information furnished by a registrant on this registration certificate be reported in writing to the Director, Office of Federal and State Materials and Environmental Management Programs, with a copy to the appropriate Regional Administrator at the address listed on the reverse, within 30 days after the effective date of such change.
- D. I understand that the registrant is required to comply with the provisions of Section 40.25 of the NRC's regulation 10 CFR Part 40 (reprinted on the reverse side of this form) with respect to all depleted uranium which the registrant receives, acquires, uses, or transfers under the general license for which this registration certificate is filed with the U. S. Nuclear Regulatory Commission.

E. PRINTED OR TYPED NAME AND TITLE OF PERSON FILING FORM

F. SIGNATURE

G. DATE

**WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.**

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**APPENDIX F**

**RECORDKEEPING AND MATERIAL TRANSFER REPORTS  
FOR DISTRIBUTORS LICENSED UNDER 10 CFR 32.51,  
INCLUDING NRC FORM 653—TRANSFERS OF INDUSTRIAL  
DEVICES REPORT**



1           **Recordkeeping and Material Transfer Reports for Distributors Licensed**  
2           **Under 10 CFR 32.51, Including NRC Form 653—Transfers of Industrial**  
3           **Devices Report**

4           **Quarterly Material Transfer Reports for 10 CFR 32.51 Licensees**

5           Licensees are required to file a report with the U.S. Nuclear Regulatory Commission (NRC)  
6           within 30 days of the end of each calendar quarter, in accordance with Title 10 of the *Code of*  
7           *Federal Regulation* (10 CFR) 32.52. They may use NRC Form 653 (see copy in this Appendix)  
8           to submit these quarterly reports. Alternatively, licensees may use another report format, as  
9           long as the report includes the following information:

- 10          •       Name and license number of the specific licensee submitting the report  
11                [10 CFR 32.52(a)(7)].
- 12          •       Name and address of *each* general licensee, including intermediate persons, to which a  
13                device was transferred.

14                This address is to be the mailing address of the location of use of the device. For  
15                devices that are portable, this address is the mailing address of the primary place of  
16                storage of the device.

17                When a customer has multiple locations of use, each location of use should be listed as  
18                a separate transfer, with the corresponding mailing address of each location of use  
19                (unless the multiple locations are contained within the same business campus or  
20                industrial complex). For example, an applicant transfers generally licensed (GL) devices  
21                to Company A at two different locations (Plant 1 and Plant 2). Company A is considered  
22                as two separate general licensees, one for each location of use. In other words,  
23                Company A-Plant 1 is considered a separate general licensee from Company A-Plant 2.  
24                The applicant should report both general licensees to which a device was transferred.

25                Different facilities at the same industrial complex or business campus are not considered  
26                separate locations.

27                If there is no mailing address for the location of use, an alternative address for the  
28                general licensee should be submitted, along with information on the actual location of  
29                use. (This might be the case, if the device is used on a pipeline.)

30                Reports to the NRC should only include transfers of devices for which the place of use is  
31                within the NRC’s jurisdiction or, for portable devices, the primary place of storage of the  
32                device is within the NRC’s jurisdiction. (See Chapter 2 for details on NRC jurisdiction.)

- 33          •       Name, title, and telephone number of each general licensee’s responsible individual.

34                The responsible individual must be an individual designated by the general licensee to  
35                be responsible for having knowledge of and the authority to take required actions to  
36                ensure the day-to-day compliance with the appropriate regulations and requirements.  
37                Each general licensee must designate only one responsible individual per location.  
38                However, a responsible individual can be assigned to more than one general licensee.  
39                This individual is not necessarily someone who works on site at the place of use of the

1 device and is not necessarily conducting all required actions, but he or she is  
2 responsible for ensuring that required actions are taken.

3 • Date of transfer.

4 • Type, model number, and serial number of the device transferred.

5 • Quantity and type of byproduct material contained in the device.

6 Licensees must also submit a report containing the same information outlined above to the  
7 responsible Agreement State agency for transfers to or from general licensees in each  
8 Agreement State. However, a report of no transfers during the reporting period is only required  
9 if an Agreement State requests it. [10 CFR 32.52(b)]

#### 10 Important Notes on Transfer Reports

11 Licensees should note the following information about transfer reports:

12 • If one or more “intermediate persons” will temporarily possess the device at the intended  
13 place of use before the intended end user takes possession, the report must include the  
14 same information for each intermediate person as for the intended user and clearly  
15 designate that person as an intermediate person. The term “intermediate persons”  
16 means a person, company, or corporation that will temporarily possess the device at an  
17 intended place of use before its possession by the intended user. Such temporary  
18 possession includes a manufacturer transferring devices to a distributor or electrical  
19 contractor. For example, if XYZ Building Company owns an office building during its  
20 construction and the building contains self-luminous tritium exit signs (GL devices),  
21 XYZ Building Company is the intermediate person. When XYZ Building Company sells  
22 the office building to Company 123, then Company 123 becomes the general licensee.  
23 Note that an intermediate person should not hold a device in storage for longer than  
24 2 years, unless quarterly physical inventories of these devices are performed while they  
25 are in standby. [10 CFR 31.5(c)(15)].

26 • If a company will be a warehouseman before delivery to the final destination, the  
27 warehouseman is exempted under 10 CFR 30.13, “Carriers,” to the extent that the  
28 company stores the GL device for the end user. The company’s name does not need to  
29 be documented on the transfer report. For example, Company A purchases a tritium exit  
30 sign through Electric Company X (a warehouseman) for use at a particular location L,  
31 which is currently under construction. Electric Company X can store the exit sign at its  
32 place of business before shipment to its final destination. The distributor (specific  
33 licensee with license for distribution) must list the general licensee as Company A at  
34 location L on the quarterly transfer report. The distributor cannot ship the exit sign to  
35 Electric Company X without knowing the buyer of the sign from Electric Company X  
36 (i.e., the end user or general licensee company name and location of use). Also, the  
37 distributor cannot ship multiple signs to Electric Company X for it to maintain in stock for  
38 resale, unless Electric Company X has a specific license for possession and distribution  
39 of GL devices.

40 • If a GL-distribution licensee receives a device from a 10 CFR 31.5 general licensee, the  
41 report must note this and identify the general licensee by name and address; the type,  
42 model number, and serial number of the device received; the date of receipt; and, in the

1 case of devices not initially transferred by the reporting licensee, the name of the  
2 manufacturer or initial transferor. [10 CFR 32.52(a)(3)] If using NRC Form 653, these  
3 receipts are to be included on the portion identified as 653A.

- 4 • If no transfers or receipts were made during the reporting period, the licensee must file a  
5 report of no activity, except that such reports should only be sent to Agreement States  
6 that request reports of no activity. [10 CFR 32.52(a)(6), 10 CFR 32.52(b)(7)] If a  
7 GL-distribution licensee makes a change(s) to a device possessed under 10 CFR 31.5,  
8 such that the label must be changed to update required information, the report must  
9 identify the general licensee, the device, and the change to information on the device  
10 label. [10 CFR 32.52(a)(4)] If the licensee uses NRC Form 653 to report these changes,  
11 then they should report the changes on NRC Form 653B.

## 12 Recordkeeping

13 In accordance with 10 CFR 32.52(c), licensees must maintain the information on all  
14 10 CFR 31.5 (and equivalent Agreement State licensees) transfers and receipts that support the  
15 reports described above for 3 years after the recorded event.

16 In the event the licensee files for bankruptcy or requests termination of the license, the licensee  
17 must make available to the various regulatory agencies, upon request, records of the final  
18 disposition of devices. [10 CFR 32.51a(e)]



**TRANSFERS OF INDUSTRIAL  
DEVICES REPORT  
(TO GENERAL LICENSEES)**

Estimated burden per response to comply with this mandatory collection request: 36 minutes. NRC requests quarterly reports to keep apprised of device movements. Send comments regarding the 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 Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0001), 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.

(Continue on NRC Form 653, 653A or 653B, as appropriate)

**For each "licensee" to whom a device(s) has been transferred during the reporting period, supply the following:**

NAME OF VENDOR	REPORTING PERIOD	
	FROM	TO
LICENSE NUMBER		

**INTERMEDIATE PERSON(S) (if any)**

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

**GENERAL LICENSEE INFORMATION**

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE (No P.O. Boxes, include Zip Code)		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

**INFORMATION ON DEVICE(S) TRANSFERRED**

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

**INTERMEDIATE PERSON(S) (if any)**

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

**GENERAL LICENSEE INFORMATION**

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE(No., P.O. Boxes, include Zip Code)		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

**INFORMATION ON DEVICE(S) TRANSFERRED**

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

**TRANSFERS OF INDUSTRIAL DEVICES REPORT  
 (TO GENERAL LICENSEES) (continued)**

**INTERMEDIATE PERSON(S) (if any)**

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

**GENERAL LICENSEE INFORMATION**

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE (No P.O. Boxes, include Zip Code)		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

**INFORMATION ON DEVICE(S) TRANSFERRED**

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

**INTERMEDIATE PERSON(S) (if any)**

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

**GENERAL LICENSEE INFORMATION**

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE (No P.O. Boxes, include Zip Code)		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

**INFORMATION ON DEVICE(S) TRANSFERRED**

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

**TRANSFERS OF INDUSTRIAL DEVICES REPORT  
 (TO GENERAL LICENSEES) (continued)**

**INTERMEDIATE PERSON(S) (if any)**

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

**GENERAL LICENSEE INFORMATION**

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

**INFORMATION ON DEVICE(S) TRANSFERRED**

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

**INTERMEDIATE PERSON(S) (if any)**

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

**GENERAL LICENSEE INFORMATION**

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>		
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE		
TITLE OF RESPONSIBLE INDIVIDUAL			

**INFORMATION ON DEVICE(S) TRANSFERRED**

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

**TRANSFERS OF INDUSTRIAL DEVICES REPORT (FROM GENERAL LICENSEES)**  
For each "licensee" from whom a device(s) has been received during the reporting period, supply the following:

GENERAL LICENSEE INFORMATION				
NAME OF GENERAL LICENSEE			MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>	
INFORMATION ON DEVICE(S) RECEIVED				
DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)
GENERAL LICENSEE INFORMATION				
NAME OF GENERAL LICENSEE			MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>	
INFORMATION ON DEVICE(S) RECEIVED				
DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)
GENERAL LICENSEE INFORMATION				
NAME OF GENERAL LICENSEE			MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>	
INFORMATION ON DEVICE(S) RECEIVED				
DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)
GENERAL LICENSEE INFORMATION				
NAME OF GENERAL LICENSEE			MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>	
INFORMATION ON DEVICE(S) RECEIVED				
DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

**TRANSFERS OF INDUSTRIAL DEVICES REPORT (FROM GENERAL LICENSEES)(continued)**

For each "licensee" from whom a device(s) has been received during the reporting period, supply the following:

GENERAL LICENSEE INFORMATION				
NAME OF GENERAL LICENSEE			MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>	
INFORMATION ON DEVICE(S) RECEIVED				
DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)
GENERAL LICENSEE INFORMATION				
NAME OF GENERAL LICENSEE			MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>	
INFORMATION ON DEVICE(S) RECEIVED				
DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)
GENERAL LICENSEE INFORMATION				
NAME OF GENERAL LICENSEE			MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>	
INFORMATION ON DEVICE(S) RECEIVED				
DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)
GENERAL LICENSEE INFORMATION				
NAME OF GENERAL LICENSEE			MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>	
INFORMATION ON DEVICE(S) RECEIVED				
DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

**TRANSFERS OF INDUSTRIAL DEVICES REPORT (LABEL CHANGES)**

For each device for which required label information has been changed, supply the following:

GENERAL LICENSEE USER INFORMATION	
NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>

INFORMATION ON DEVICE(S) RECEIVED							
TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION	
NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>

INFORMATION ON DEVICE(S) RECEIVED							
TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION	
NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>

INFORMATION ON DEVICE(S) RECEIVED							
TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION	
NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>

INFORMATION ON DEVICE(S) RECEIVED							
TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

**TRANSFERS OF INDUSTRIAL DEVICES REPORT (LABEL CHANGES)(continued)**

For each device for which required label information has been changed, supply the following:

GENERAL LICENSEE USER INFORMATION							
NAME OF GENERAL LICENSEE USER				MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>			
INFORMATION ON DEVICE(S) RECEIVED							
TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS
GENERAL LICENSEE USER INFORMATION							
NAME OF GENERAL LICENSEE USER				MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>			
INFORMATION ON DEVICE(S) RECEIVED							
TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS
GENERAL LICENSEE USER INFORMATION							
NAME OF GENERAL LICENSEE USER				MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>			
INFORMATION ON DEVICE(S) RECEIVED							
TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS
GENERAL LICENSEE USER INFORMATION							
NAME OF GENERAL LICENSEE USER				MAILING ADDRESS AT THE LOCATION OF USE <i>(No P.O. Boxes, include Zip Code)</i>			
INFORMATION ON DEVICE(S) RECEIVED							
TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

1

**APPENDIX G**

2

**GUIDANCE FOR 10 CFR 31.5 GENERAL LICENSEES  
(QUESTIONS AND ANSWERS)**

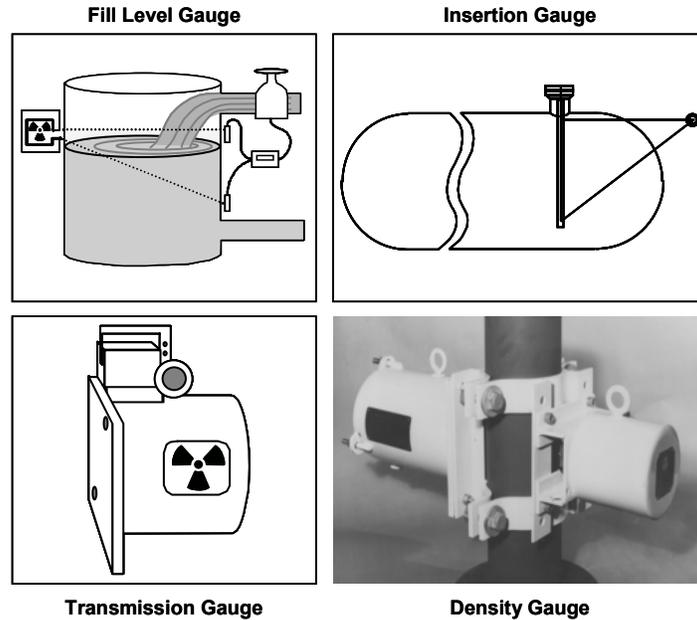
3



# Guidance for 10 CFR 31.5 General Licensees (Questions and Answers)

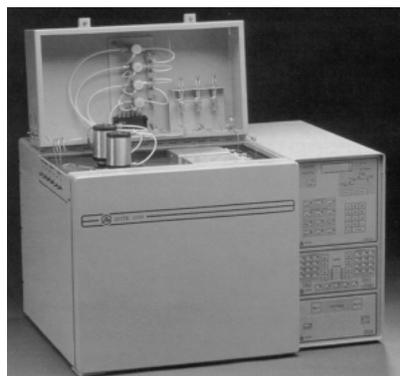
## 1. What is a generally licensed (GL) device?

Generally licensed (GL) devices contain source or byproduct material or both and are typically used to detect, measure, or control the density, level, or chemical composition of various items. Examples of such devices are density gauges, fill-level gauges (see Figure G-1), gas chromatographs (see Figure G-2), and static elimination devices. Another type of GL device is a self-luminous exit sign (see Figure G-3).



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060500

**Figure G-1. Fixed Gauges.** *Certain fixed nuclear gauges may be possessed and used under the general license in Title 10 of the Code of Federal Regulations (10 CFR) 31.5, "Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere."*



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092000

**Figure G-2. Gas Chromatograph Unit.** *Certain gas chromatograph units (detector cells) used for analysis of chemical composition can be possessed under the general license in 10 CFR 31.5.*



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092000

**Figure G–3. Self-Luminous Exit Sign.** *Certain self-luminous, tritium exit signs can be possessed under 10 CFR 31.5. (Typical devices initially contain 25 curies of tritium per sign.)*

1    **2.    What is a 10 CFR 31.5 general licensee?**

2           A general licensee is a company or person who uses or stores a GL device. The  
3           device is obtained through an authorized transfer from the device manufacturer or  
4           distributor or by a change of company ownership whereby the device remains in use at  
5           a particular location. If a device is received through unauthorized means, contact the  
6           regulatory authority immediately (see Question 14).

7    **3.    What is U.S. Nuclear Regulatory Commission (NRC) annual registration of**  
8    **GL devices?**

9           The NRC requires that certain devices authorized in 10 CFR 31.5 be registered each  
10          year. Registration of the device depends upon the type and quantity of radioactive  
11          material in the device (see Questions 4 and 6). Registration involves completing  
12          NRC Form 664, “General Licensee Registration,” when requested and returning it to  
13          the NRC.

14   **4.    Which GL devices are subject to NRC registration?**

15          Devices that are subject to NRC registration are devices used or stored or both in an  
16          NRC jurisdiction that contain, at the time of manufacture, at least 370 megabecquerels  
17          (MBq) [10 millicuries (mCi)] of cesium-137, 3.7 MBq [0.1 mCi] of strontium-90 or  
18          radium-226, or 37 MBq [1 mCi] of cobalt-60, americium-241, or any other transuranic  
19          [i.e., element with an atomic number greater than that of uranium (92)].

20          Tritium exit signs and gas chromatographs are not subject to registration.

21          Persons generally licensed by an Agreement State who have devices meeting the  
22          registration criteria are not subject to NRC registration requirements if the devices are  
23          used in areas of NRC jurisdiction for less than 180 days in any calendar year.

24          See Question 14 for a listing of States where the NRC has jurisdiction (non-Agreement  
25          States), as well as a listing of States where the NRC has given the State the authority  
26          for regulating use of radioactive material (Agreement States).

1 **5. How do I know if I have a GL device?**

2 If you have a device of a type described in Question 1 above, look at the labels on the  
3 device, if any. GL devices should have labels containing such words as “Caution—  
4 Radioactive Material” or “The receipt, possession, use, and transfer of the device  
5 are subject to a general license” and identifying the radioactive material, such as  
6 “5 millicuries of cesium-137” or “1 mCi of Am-241.”

7 Also, review any paperwork (such as manuals or brochures) that you received with the  
8 device. These documents can provide you with information on the radioactivity  
9 contained within the device and whether or not the device is subject to NRC  
10 regulations. If you are still unsure, contact the manufacturer or distributor of the device  
11 for help. If the manufacturer is not available, contact the NRC (see Question 14).

12 Possession or use of similar devices may require a specific license. Manufacturers or  
13 distributors cannot transfer specifically licensed devices to customers who do not have  
14 a specific license to possess such a device. The customer should apply to the NRC or  
15 the appropriate Agreement State for a specific license.

16 **6. How do I know if I have a GL device that is subject to annual registration?**

17 The device manufacturer should be able to answer questions about the registration of  
18 any devices you have purchased. You can also look at the label on the device for the  
19 identification of the radioisotope and quantity of radioactive material. If the device  
20 contains the type and quantity of material indicated in Question 4, then it is subject to  
21 registration by the NRC.

22 **7. What are the requirements for a GL device?**

23 GL devices used within an NRC jurisdiction are subject to the NRC regulations listed in  
24 10 CFR 31.5. General licensees are required to appoint a responsible individual who  
25 knows about the requirements and have the authority to carry out the necessary  
26 duties to comply with the regulatory requirements. The five tables below summarize  
27 these requirements.

28 **Routine Maintenance**

Ensure that all labels affixed to the device stay attached to the device.
Comply with the instructions and precautions provided on the labels, including any referenced documents such as operating and service manuals.
If required, perform leak tests every 6 months, in accordance with the manufacturer’s instructions or as required by the regulations (unless the device is in storage or unless otherwise indicated on the label), and maintain leak test records for 3 years.

If required, perform shutter tests every 6 months, in accordance with the manufacturer's instructions or regulatory requirements (unless the device is in storage or unless otherwise indicated on the label), and maintain shutter test records for 3 years. Fixed gauges routinely operate in a continuous mode with the shutter open, exposing the radioactive source inside. This increases the chances of corrosion and the buildup of rust or debris to affect the ability of the shutter to close. Therefore, licensees should consider more frequent shutter tests by taking into account such factors as the accessibility of the gauge (e.g., the gauge is mounted 100 feet above the ground), indications that a shutter may have a buildup of debris, whether any components are beginning to corrode, "sticking" or "binding" of the shutter during closure, and the potential for employees to be exposed should a shutter get stuck in the open position.

**1 Requirements if the Device Becomes Damaged or Fails a Shutter or Leak Test**

Suspend operation of the device.

Have the device repaired or properly disposed of by the manufacturer, distributor, or other person holding a specific license to repair or dispose of it.

Within 30 days, provide the NRC a brief description of the event and remedial actions taken. If measured contamination is greater than 185 becquerels [0.005 microcuries] or is likely to have resulted from the event, develop and submit a plan to the NRC for ensuring that the premises and environs are acceptable for unrestricted use.

**2 Additional Actions To Be Taken in the Case of Significant Damage to the Device**

Notify the person who is responsible for overseeing use of devices containing byproduct material. Immediately secure the area and keep people away from the device until the situation is assessed and radiation levels are known. If equipment is involved, isolate it until it is determined there is no contamination present. Perform first aid for any injured individuals, but remove them from the area only when medically safe to do so.

Arrange for a radiation survey to be conducted, as soon as possible, by a knowledgeable person using an appropriate radiation survey meter. This person could be a representative of a manufacturer or distributor, a local emergency responder, a consultant, or a licensee employee using a radiation survey meter. To accurately assess the radiation hazard, it is essential that the person performing the survey is competent in the use of a radiation survey meter.

In addition to any required notification of the NRC, you may report any incident to the NRC by calling the NRC's Emergency Operations Center at (301) 816-5100. The center is staffed 24 hours a day and accepts collect calls. Local authorities may also be able to provide assistance.

1 **Reporting Requirements (Applicable to All 10 CFR 31.5 General Licensees)**

<b>Type of Report</b>	<b>Contents of Report</b>	<b>Frequency</b>	<b>Send to</b>
Transfer or disposal report	Identification of device by manufacturer's (or initial transferor's) name; model number and serial number; name, address, and license number of the recipient; and date of transfer	Within 30 days of transfer or export	Director of NMSS Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Transfer report for change of ownership (where the device remains in use at a particular location)	Manufacturer's (or initial transferor's) name; model number and serial number; name and address of the transferee; and name, title, and telephone number of the responsible individual for the transferee	Within 30 days of transfer	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Report if the device becomes damaged or fails a shutter or leak test	Brief description of the event and remedial actions taken and a plan (if contamination is measured or likely) for ensuring that the premises and environs are acceptable for unrestricted use	Within 30 days of occurrence	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Report a change in the name of the licensee	New name of the general licensee	Within 30 days of occurrence	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Report of change of mailing address of the location of use ( <i>Note:</i> In the case of portable devices, this only applies to the mailing address of the device's primary place of storage.)	New mailing address for the location where the device is used or stored	Within 30 days after moving the device	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001

Type of Report	Contents of Report	Frequency	Send to
<p>Report of incidents (<i>Note:</i> An NRC licensee that possesses a fixed gauge with a shutter that cannot be closed must notify the NRC within 24 hours of any such incident, in accordance with 10 CFR 30.50(b)(2). In addition, in accordance with 10 CFR 30.50(c)(2), the licensee must follow the initial report within 30 days with a written report describing the circumstances that led to the shutter failure and the corrective actions taken.)</p>	<p>Written report includes the following:</p> <ul style="list-style-type: none"> <li>• description of the event, including probable cause, and the equipment manufacturer and model number</li> <li>• exact location of the event</li> <li>• isotopes, quantities, and chemical and physical form of the licensed material</li> <li>• date and time of the event</li> <li>• corrective actions and results of evaluations or assessments</li> <li>• radiation exposures to individuals</li> </ul>	<p>Telephone report immediately or within 24 hours of occurrence per 10 CFR 30.50; written report within 30 days of the telephone report per 10 CFR 30.50</p>	<p>Administrator of the appropriate NRC regional office</p>
<p>Report of lost or stolen devices</p>	<p>Written report includes the following:</p> <ul style="list-style-type: none"> <li>• description of the licensed material</li> <li>• description of the circumstances under which the loss or theft occurred</li> <li>• disposition of the licensed material</li> <li>• radiation exposure to individuals</li> <li>• actions to recover the material</li> <li>• actions to prevent recurrence</li> </ul>	<p>Telephone report immediately or within 30 days of occurrence per 10 CFR 20.2201(a); written report within 30 days of the telephone report per 10 CFR 20.2201(b)</p>	<p>Administrator of the appropriate NRC regional office</p>

1 **Additional Reporting Requirements for GL Devices Subject to Registration**

Type of Report	Contents of Report	Frequency	Send to
Registration	<p>The following information and any other information specifically requested by the NRC:</p> <ul style="list-style-type: none"> <li>• name and mailing address</li> <li>• information about each device: the manufacturer or initial transferor, model number, serial number, radioisotope, and activity</li> <li>• name, title, and telephone number of the responsible individual</li> <li>• address where the device(s) is used or stored or both</li> <li>• certification that the information concerning the device(s) has been verified through a physical inventory and check of the label</li> <li>• certification by the responsible individual that he or she is aware of the requirements of the general license</li> </ul> <p>(<b>Note:</b> This information should be submitted using NRC Form 664.)</p>	Annual	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001, or as otherwise indicated in the request for registration
Bankruptcy	Notification of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the U.S. Code	Immediately following the filing of a voluntary or involuntary petition for bankruptcy	Administrator of the appropriate NRC regional office

1 **8. Can I relocate my device(s) from one location to another?**

2 Some GL devices have been approved for installation and relocation by the general  
3 licensee; however, this does not apply to all GL devices. You should contact the  
4 manufacturer or distributor to determine whether your device(s) has been approved for  
5 relocation and installation by the general licensee.

6 **9. Is there reciprocity for GL devices?**

7 No, there is no reciprocity provision applicable to general licensees. If a general  
8 licensee obtains a device in an Agreement State and wishes to use the device within an  
9 NRC jurisdiction, it must do so under 10 CFR 31.5. In this case, the general license in  
10 10 CFR 31.5 applies automatically without application for license or other permission as  
11 long as the device has been manufactured and distributed appropriately. The general  
12 licensee is subject to the provisions of 10 CFR 31.5, including registration requirements.  
13 However, NRC registration is not required for a general licensee using a device in NRC  
14 jurisdiction for less than 180 days in any calendar year.

15 The general license in 10 CFR 31.5 only applies within NRC jurisdiction. General  
16 licensees intending to move from one jurisdiction to another should contact the  
17 applicable regulatory authority (i.e., the NRC or the particular Agreement State) before  
18 moving, to determine the applicable regulations in their jurisdictions. Not all  
19 jurisdictions have a general license, and specific provisions of the general license may  
20 vary among jurisdictions.

21 **10. I am an Agreement State general licensee. Does the NRC allow me to use my GL**  
22 **device at temporary jobsites within an NRC jurisdiction?**

23 Yes. For portable devices, such as devices used for demonstration purposes, which  
24 may be transported from an Agreement State to an NRC jurisdiction, use of the device  
25 in an NRC jurisdiction is permitted as long as the general licensee follows the  
26 requirements of 10 CFR 31.5.

27 **11. Would an Agreement State allow me to use my GL device at temporary jobsites**  
28 **within that Agreement State's jurisdiction?**

29 For devices that may be transported from one Agreement State to another, or from an  
30 NRC jurisdiction to an Agreement State, use of the device comes under the regulations  
31 of the Agreement State where the device is being used. Be sure to know the  
32 requirements in the area where you are using the device by contacting the particular  
33 Agreement State. Some Agreement States currently require that the device be  
34 registered or specifically licensed before it can be used in that State.

35 **12. How can I get rid of a GL device?**

36 GL devices can only be transferred (for disposal or to obtain a replacement device) to  
37 (1) a person holding a specific license under 10 CFR Part 30, "Rules of General  
38 Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 32,  
39 "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing  
40 Byproduct Material," or equivalent Agreement State regulations, such as the device  
41 manufacturer, or (2) a person holding a specific license that authorizes waste collection,

1 such as a waste broker. A GL device can be transferred to other specific licensees only  
2 with prior written approval of the NRC.

3 A GL device can only be transferred to another general licensee if the GL device  
4 remains at a particular location. The transferor must give the new general licensee  
5 copies of 10 CFR 30.51, "Records;" 10 CFR 31.2, "Terms and Conditions;"  
6 10 CFR 31.5, 10 CFR 20.2201, "Reports of Theft or Loss of Licensed Material;"  
7 10 CFR 20.2202, "Notification of Incidents;" and any safety documents identified in the  
8 device label.

9 **13. Can I keep a device that I am not using?**

10 GL devices containing byproduct materials not in use can only be stored for 2 years.  
11 After 2 years, the device must be properly transferred. During this period of nonuse,  
12 the shutter must be locked in the closed position. Devices kept in standby for future  
13 use are excluded from the 2-year time limit if the general licensee performs a quarterly  
14 physical inventory of the device while it is in standby status. The general licensee must  
15 continue to annually register the device and pay the appropriate fees.

16 **14. Who can answer additional questions?**

17 Call the device manufacturer, who should be able to assist you. If the manufacturer is  
18 no longer in business, or if you cannot contact the manufacturer, call the appropriate  
19 NRC regional office or Agreement State for assistance. See Figure G-4 for the  
20 telephone numbers for the NRC regional offices.

21 Note that States where the NRC has jurisdiction are called non-Agreement States.  
22 States where the NRC has given the State the authority to regulate the use of  
23 radioactive material are called Agreement States.

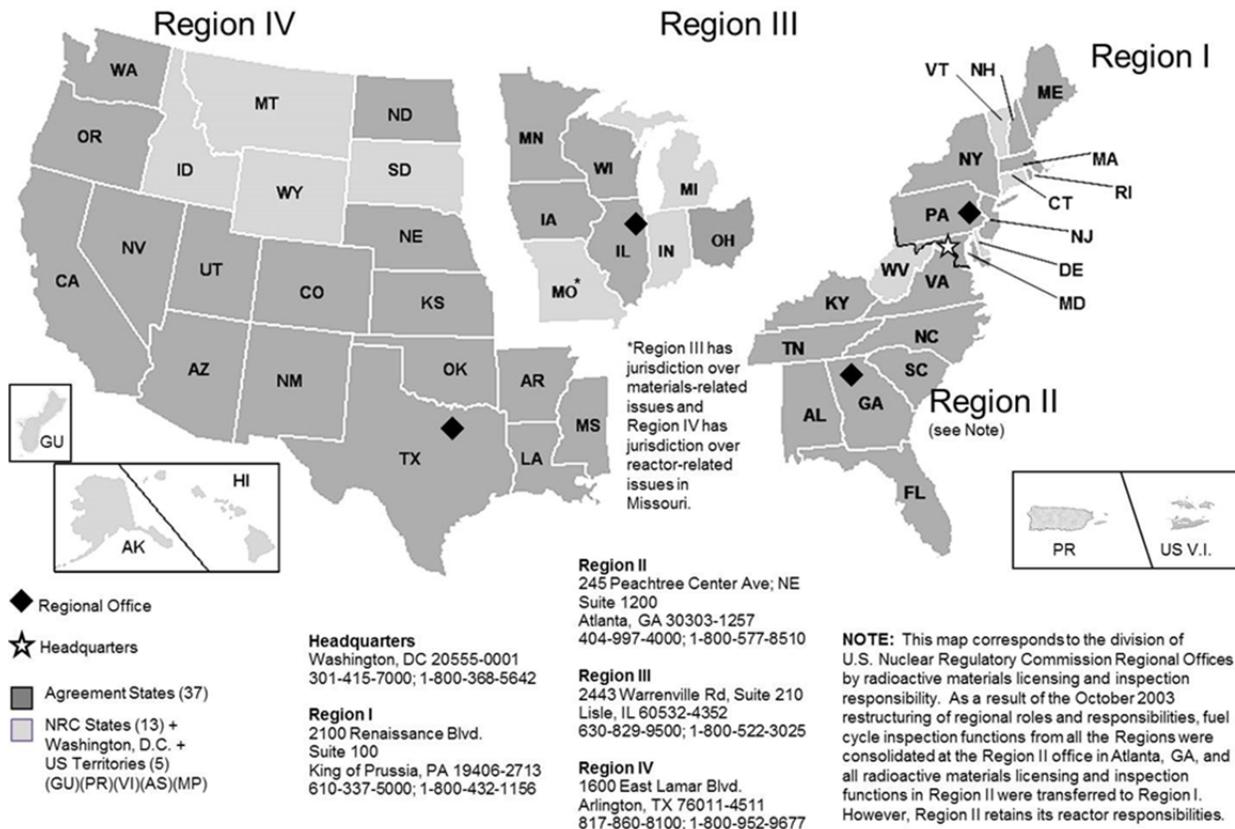
24 **15. What other requirements apply?**

25 Persons who possess devices listed in 10 CFR 31.5 are exempt from the requirements  
26 of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and  
27 Investigations;" 10 CFR Part 20, "Standards for Protection against Radiation;" and  
28 10 CFR Part 21, "Reporting of Defects and Noncompliance," with the exception of the  
29 provisions in 10 CFR 20.2201 and 10 CFR 20.2202. These persons are subject to the  
30 following sections of 10 CFR Part 30: 30.1 through 30.10, 30.14(d), 30.34(a) to (e),  
31 30.41, 30.50 to 30.53, and 30.61 to 30.63.

32 **16. My company has a specific license for the use of radioactive material and also**  
33 **has GL devices. Do I have to include these devices on my inventory of**  
34 **radioactive materials?**

35 No, you do not have to include GL devices on the inventory that is required by your  
36 specific license. However, many companies have chosen to keep track of their devices,  
37 along with their specifically licensed material, through periodic inventory.

<sup>1</sup>Locations of NRC Offices and Agreement States



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

<sup>1</sup>Current regional office addresses can be verified at <http://www.nrc.gov/about-nrc/locations.html>  
**Figure G-4. Locations of NRC offices and Agreement States**

1

## **APPENDIX H**

2

### **GUIDANCE ON SELF-LUMINOUS EXIT SIGNS (QUESTIONS AND ANSWERS)**

3



# Guidance on Self-Luminous Exit Signs (Questions and Answers)

## 1. What is a self-luminous exit sign?

A self-luminous exit sign (see Figure H–1) is a nonelectrical product that uses radioactive tritium (H–3) gas to produce light. Specifically, the signs contain light sources that consist of glass tubes that are internally coated with phosphor and filled with tritium gas. Tritium is an isotope of hydrogen that emits low-energy beta radiation in the form of electrons. These electrons excite the phosphor, causing the glass tubes to continuously emit light.



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**Figure H–1. Self-Luminous Exit Sign.** *Certain self-luminous, tritium exit signs can be possessed under Title 10 of the Code of Federal Regulations (10 CFR) 31.5, “Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.” (Typical devices initially contain 25 curies of tritium per sign.)*

## 2. Do I need to obtain or apply for a license to use a self-luminous exit sign?

No. Self-luminous exit signs are generally licensed (GL) by the U.S. Nuclear Regulatory Commission (NRC). The companies, institutions, or individuals that use these signs do not apply for a license; they are automatically considered “general licensees” of the NRC and must follow NRC requirements for the use of the signs. The NRC maintains a database of general licensees and the locations of the self-luminous exit signs.

However, the distributors of self-luminous exit signs are specifically licensed by the NRC or an Agreement State. They provide information to the NRC so that the agency can maintain the database of self-luminous exit sign owners.

## 3. What is a 10 CFR 31.5 “general licensee”?

Any company, institution, or person conducting business who uses, stores, or possesses a self-luminous exit sign acquired in an authorized manner is a general licensee.

## 4. What are the obligations of a general licensee?

As a general licensee using a self-luminous exit sign, you must appoint an individual responsible for fulfilling the regulatory requirements listed in 10 CFR 31.5. In general, these requirements are the following:

- You *cannot* remove the labeling or radioactive symbol on the sign.
- You *cannot* abandon a self-luminous exit sign.

- 1 • You must properly dispose of a self-luminous exit sign by transferring it to a  
2 manufacturer or radioactive waste broker specifically licensed by the NRC or an  
3 Agreement State.
- 4 • Any lost, stolen, or broken sign(s) must be reported to the NRC.
- 5 • You *cannot* give away or sell the self-luminous exit sign to another individual,  
6 company, or institution unless the device is to remain in use at a particular  
7 location (e.g., if it is included in a transfer of ownership of a building). In the case  
8 of such a transfer, you are obligated to pass on a copy of the regulatory  
9 requirements to the new general licensee *and* you must notify the NRC.
- 10 • You must inform the NRC of a company name change or change of address.
- 11 • You must make certain reports, summarized in the table below.

## 12 Reporting Requirements

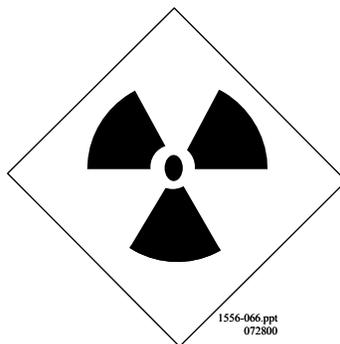
Type of Report	Contents of Report	Frequency	Send to
Disposal or transfer report	Identification of the device by the manufacturer's (or initial transferor's) name, model number, and serial number; name, address, and license number of the recipient; and date of transfer	Within 30 days of transfer or disposal	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Transfer report for change of ownership (where device remains in use at a particular location)	Manufacturer's (or initial transferor's) name, model number, and serial number; name and address of the transferee; and name, title, and telephone number of the responsible individual for the transferee	Within 30 days of transfer	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Report if device becomes damaged	Brief description of the event and remedial actions taken	Within 30 days of occurrence	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Report change in the name of the licensee	New name of general licensee	Within 30 days of occurrence.	Director of NMSS, Attn: GLTS, U.S. NRC, Washington, DC 20555-0001

Type of Report	Contents of Report	Frequency	Send to
Report change of address	New mailing address of the location where the device is used or stored	Within 30 days after moving the device.	Director of NMSS Attn: GLTS, U.S. NRC, Washington, DC 20555-0001
Incidents (e.g., fires, explosions)	<p>Written report includes the following:</p> <ul style="list-style-type: none"> <li>• description of the event, including probable cause, and the equipment manufacturer and model number</li> <li>• exact location of the event</li> <li>• isotopes, quantities, and chemical and physical form of the licensed material</li> <li>• date and time of the event</li> <li>• corrective actions and the results of evaluations or assessments</li> <li>• radiation exposures to individuals</li> </ul>	Telephone report immediately or within 24 hours of occurrence per 10 CFR 30.50; written report within 30 days of the telephone report per 10 CFR 30.50	Administrator of the appropriate NRC regional office

Type of Report	Contents of Report	Frequency	Send to
Report of lost or stolen devices	<p>Written report includes the following:</p> <ul style="list-style-type: none"> <li>• description of the licensed material</li> <li>• description of the circumstances under which the loss or theft occurred</li> <li>• disposition of the licensed material</li> <li>• radiation exposure to individuals</li> <li>• actions to recover the material</li> <li>• actions to prevent recurrence</li> </ul>	<p>Telephone report immediately or within 30 days of occurrence per 10 CFR 20.2201(a); written report within 30 days of the telephone report per 10 CFR 20.2201(b)</p>	<p>Administrator of the appropriate NRC regional office</p>

1 **5. How do I identify a self-luminous exit sign?**

2 All self-luminous exit signs are required to have a durable, visible label affixed to the sign  
3 that identifies it as containing radioactive material. The label will contain the words  
4 “Caution—Radioactive Material” and may also include the radiation symbol (Figure H–2).  
5 In addition, the label will include the name of the manufacturer (or initial transferor), the  
6 product model number, the serial number, and the quantity of tritium contained.



**Figure H–2. Radiation Symbol**

1   **6.   How can I tell if it is working?**

2           Because self-luminous exit signs will not appear to be lit in ambient light conditions, they  
3           must be viewed in darkness to evaluate their performance. When viewed in the dark, all  
4           letters should be visible. If the letters are clearly legible and uniformly lit, the sign is  
5           functioning properly.

6           If the luminance appears to be uniformly low, check the Underwriters Laboratories (UL)  
7           label to determine the expiration date of the sign. If the sign has passed its expiration  
8           date, it no longer meets the luminance requirements of the applicable fire or building  
9           code. Contact the manufacturer for replacement and disposal information.

10          If any letter(s) or part(s) of a letter(s) is not lit when viewed in the dark, the sign is not  
11          functioning properly. This may mean that the sign has been damaged and that one or  
12          more of the internal light sources has been damaged. In this case, contact the  
13          manufacturer immediately for return instructions.

14   **7.   What should I do if a sign is broken or damaged?**

15          Most signs that are broken do not cause a release of tritium. If a sign is excessively  
16          damaged, the tritium gas could be released and would dilute rapidly in the air. Keep in  
17          mind that for this to occur, the outer frame and inner protective housing would also have  
18          to be damaged. The area should be evacuated and ventilated to avoid unnecessary  
19          exposure to the radioactive material. The material does not pose any immediate health  
20          hazard to workers at the location or to members of the public. However, the sign would  
21          be expected to have relatively high levels of tritium on it and should be properly  
22          handled. To avoid spreading contamination, do not move the sign into other areas  
23          before disposal.

24          Contact the manufacturer for directions on the proper handling of the damaged sign, as  
25          well as proper shipping and disposal. If you do not know who the manufacturer is,  
26          carefully look on the sign itself for the name and telephone number of the manufacturer.  
27          If you still cannot identify a manufacturer, call the NRC to request assistance in dealing  
28          with the broken sign.

29          Typically, manufacturers will advise a procedure such as the following: Wear rubber  
30          gloves and eye protection since you may come in contact with broken glass or  
31          radioactive material or both. Wipe the entire surface of the sign with a paper towel.  
32          Wrap the sign, paper towel, and gloves in a plastic bag (i.e., garbage bag) and tape it  
33          closed. Wash your hands with soap and water. Wrap the sign a second time in a plastic  
34          bag (i.e., garbage bag) and tape it closed. Wash your hands with soap and water.  
35          Place each sign in a sturdy carton. Use filler materials to ensure a tight, rattle-free fit.  
36          Tape the seal flaps and seams. Label the carton: "**RADIOACTIVE.**" Place this package  
37          into a second sturdy cardboard carton and include a piece of paper with the following  
38          words: "**This package conforms to the conditions and limitations specified in**  
39          **49 CFR 173.424 for radioactive material, excepted package-instruments or articles,**  
40          **UN2911.**" Use filler materials to ensure a tight fit. Tape the seal flaps and seams. DO  
41          NOT label this outer carton "RADIOACTIVE." Before shipping, contact the manufacturer  
42          whose name appeared on the sign label. Make a report to the NRC (see the table of  
43          reporting requirements in Question 4).

1 **8. Can broken signs contaminate buildings and require cleanup?**

2 Yes. If the sign is severely damaged and mishandled, the contamination can be spread  
3 throughout a room or building—wherever the sign traveled. If contamination occurs,  
4 appropriate cleanup must be performed by a person specifically authorized by the NRC  
5 for this activity. Keep in mind that for this to occur, the outer frame and inner protective  
6 housing would have to be damaged and the sign mishandled. To avoid spreading  
7 contamination, follow the instructions in Question 7.

8 **9. Do I need a license to sell self-luminous exit signs?**

9 In order to transfer exit signs for sale or distribution to customers, you must obtain a  
10 specific NRC license for distribution under 10 CFR 32.51.

11 **10. Can I throw a self-luminous exit sign in the trash?**

12 No. It is unlawful to abandon or dispose of self-luminous exit signs except by transfer to  
13 a manufacturer or other person specifically licensed by the NRC. Most manufacturers  
14 will accept the return of any self-luminous exit signs.

15 It is important that these signs be properly disposed of and that they not be abandoned,  
16 because they can end up damaged. They can also end up in the hands of  
17 individuals who do not know that they are radioactive and who may inadvertently  
18 contaminate themselves.

19 **11. Can I give away or sell my self-luminous exit sign to someone else?**

20 No, you cannot transfer the sign to someone else. The only exception is when the sign  
21 remains in use at a particular location, such as when a building is sold. In the specific  
22 case of a change of ownership in which a GL device remains in use at a particular  
23 location, the new owner will become the new general licensee. You are then obligated  
24 to provide a copy of the regulatory requirements to the new general licensee, and you  
25 must notify the NRC.

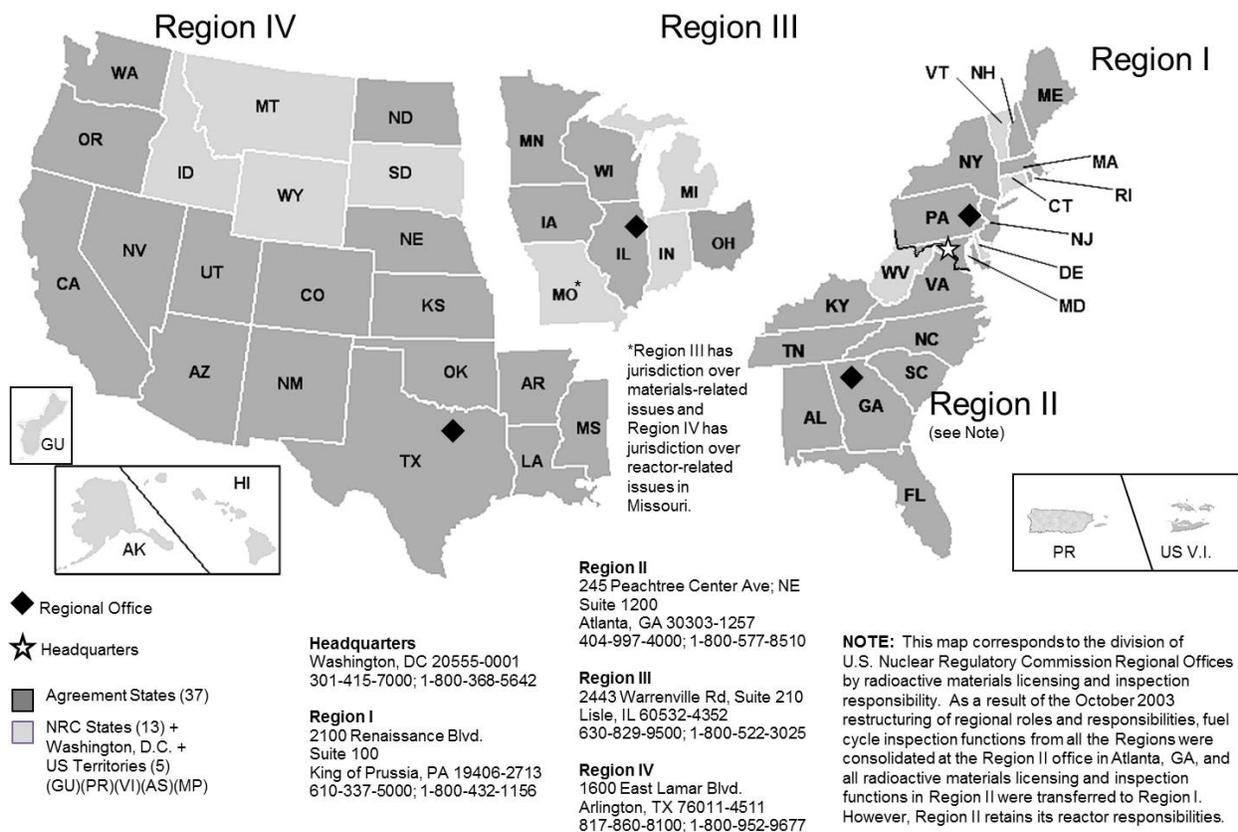
26 **12. My company has a specific license for the use of radioactive material and also has  
27 self-luminous exit signs. Do I have to include the signs in my inventory of  
28 radioactive materials?**

29 No, you do not have to include these signs in the inventory that is required by your  
30 specific license. However, many companies have chosen to keep track of their signs,  
31 along with their specifically licensed material, through periodic inventory.

32 **13. To whom can I go with additional questions?**

33 Call the product manufacturer, who should be able to assist you. You may also call the  
34 appropriate NRC regional office or Agreement State for assistance. Figure H-3 provides  
35 the telephone numbers for the NRC regional offices.

<sup>1</sup>Locations of NRC Offices and Agreement States



**Figure H-3. Locations of NRC Offices and Agreement States**

1 **14. What other requirements apply?**

2 Persons who possess devices listed in 10 CFR 31.5 are exempt from the requirements  
 3 of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and  
 4 Investigations;" 10 CFR Part 20, "Standards for Protection against Radiation;" and  
 5 10 CFR Part 21, "Reporting of Defects and Noncompliance," with the exception of the  
 6 provisions in 10 CFR 20.2201 and 20.2202. They are subject to the following sections of  
 7 10 CFR Part 30: 30.1 through 30.10, 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.53,  
 8 and 30.61 to 30.63.



1

**APPENDIX I**

2

**RECORDKEEPING AND MATERIAL TRANSFER REPORTS FOR THOSE**

3

**LICENSED UNDER 10 CFR 32.53, 10 CFR 40.34, AND 10 CFR 40.54**



1 **Recordkeeping and Material Transfer Reports for Those Licensed Under**  
2 **10 CFR 32.53, 10 CFR 40.34, and 10 CFR 40.54**

3 **Distribution of Aircraft Safety Devices**

4 For products distributed to general licensees under 10 CFR 31.7, and equivalent general  
5 licensees of Agreement States, 10 CFR 32.56, "Same: Material Transfer Reports," requires the  
6 specifically licensed distributor to file an annual report with the NRC by July 30 of each year,  
7 covering the year ending June 30.

8 The address for reporting to the NRC must include "ATTN: Document Control Desk/GLTS."

9 The report must include the following information:

- 10 • name of each general licensee to which a device(s) was transferred (distributed)
- 11 • types and numbers of each product transferred (distributed)
- 12 • quantity of tritium or promethium-147 contained in each type of product
- 13 • total quantity of tritium or promethium-147 transferred (distributed)

14 The report should also identify the specific licensee submitting the report (the distributor) and  
15 the specific license number.

16 Key Points on Transfer Reports

17 If no transfers or receipts were made during the reporting period, the licensee must file a report  
18 of no activity.

19 Licensees must also submit a report containing the same information outlined above to the  
20 responsible Agreement State agency for transfers to general licensees in Agreement  
21 States. However, a report of no transfers during the reporting period is only required if an  
22 Agreement State requests it.

23 Recordkeeping

24 Recordkeeping for transfers is required by 10 CFR 30.51. Records of transfers must be kept at  
25 least 3 years following the transfer.

26 **Distribution of Certain Industrial Products or Devices Containing Depleted Uranium**

27 For products distributed to general licensees under 10 CFR 40.25 and equivalent general  
28 licensees of Agreement States, the specifically licensed distributor is required under  
29 10 CFR 40.35(e) to file a report with the NRC within 30 days after the end of each calendar  
30 quarter that covers the previous calendar quarter. The report must include the following  
31 information:

- 32 • name and address of each general licensee

- 1 • the address should be the mailing address of the location of use of the product or device  
2 or, for products and devices that are portable, the mailing address of the primary place  
3 of storage of the device
- 4 • name or position or both of an individual who may constitute a point of contact between  
5 the Commission and the general licensee
- 6 • type and model number of the device transferred
- 7 • quantity of depleted uranium contained in the product or device.

8 Important Notes on Transfer Reports

9 If no transfers were made during the reporting period, the licensee must file a report of  
10 no activity.

11 Licensees must also submit a report containing the same information outlined above to the  
12 responsible Agreement State agency for transfers to general licensees in Agreement States. If  
13 no transfers were made during the reporting period to a particular Agreement State, the licensee  
14 must report this.

15 Recordkeeping

16 Those licensed under 10 CFR 40.34 are required by 10 CFR 40.35(e)(3) to keep records of all  
17 information concerning each transfer for 3 years following the date of transfer.

18 **Distribution of “Small Quantities of Source Material” to General Licensees**

19 For products and materials distributed to general licensees under 10 CFR 40.22, *and equivalent*  
20 *general licensees of Agreement States*, 10 CFR 40.55(d) requires the specifically licensed  
21 distributor to file an annual report with the NRC by January 31 of each year covering the  
22 previous calendar year. The report must include the following information:

- 23 • Name, address, and license number of the person who transferred the source material.
- 24 • Name and address of each general licensee to which more than 50 grams of source  
25 material was transferred (distributed) in a calendar quarter.
- 26 • Name or position or both and telephone number of the general licensee’s  
27 responsible agent.
- 28 • Type, physical form, and quantity of source material transferred.
- 29 • Total quantity of each type and physical form of source material transferred (distributed)  
30 in the reporting period to all such GL recipients. This means totals to all 10 CFR 40.22  
31 GLs and Agreement State equivalent GLs, including that transferred to those who  
32 received less than 50 grams.

33 The responsible agent is an individual designated by the general licensee to be responsible for  
34 having knowledge of and authority to take required actions to ensure day-to-day compliance  
35 with the appropriate regulations and requirements. This individual is not necessarily someone

1 who works on site at the place of use of the material and is not necessarily conducting all  
2 required actions, but he or she is responsible for ensuring that required actions are taken.

3 Important Notes on Transfer Reports

4 Reports to the NRC must include information on transfers made nationally, not just to NRC  
5 general licensees.

6 If no transfers or receipts were made during the reporting period, the licensee must submit a  
7 report of no activity.

8 Licensees must also submit a report containing the same information outlined above to the  
9 responsible Agreement State agency for transfers to general licensees in Agreement  
10 States. However, a report of no transfers to that State during the reporting period is only  
11 required if an Agreement State requests it.

12 Recordkeeping

13 Those licensed under 10 CFR 40.54 are required by 10 CFR 40.55(e) to keep records of all  
14 information concerning each transfer for 1 year following its inclusion in a report.



1

**APPENDIX J**

2

**U.S. NUCLEAR REGULATORY COMMISSION FORM 483**



# U.S. Nuclear Regulatory Commission Form 483

<p><b>NRC FORM 483</b> (03-2015)</p>	 <p><b>U.S. NUCLEAR REGULATORY COMMISSION</b></p>	<p><b>APPROVED BY OMB: NO. 3150-0038</b></p>	<p><b>EXPIRES: 02/28/2018</b></p> <p><small>Estimated burden per response to comply with this mandatory collection request: 8 minutes. The validated registration serves as evidence to suppliers of byproduct material that the registrant is entitled to receive the byproduct material. 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 Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0038), 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></p>
<p><b>REGISTRATION CERTIFICATE -- IN VITRO TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE</b></p>			
<p>Section 31.11 of 10 CFR 31 establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine to possess certain small quantities of byproduct material for in vitro clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NRC Form 483 and received from the Commission a validated copy of NRC Form 483 with a registration number.</p>			
<p>1. NAME AND ADDRESS OF APPLICANT <i>(See Instruction 3.B. below)</i></p>		<p><b>2. APPLICATION</b> <i>(Check one box only)</i></p> <p>I hereby apply for a registration number pursuant to 10 CFR 31, Section 31.11, for use of byproduct materials for:</p> <p><input type="checkbox"/> Myself, a duly licensed physician authorized to disperse drugs in the practice of medicine.</p> <p><input type="checkbox"/> The above-named clinical laboratory.</p> <p><input type="checkbox"/> The above named hospital.</p> <p><input type="checkbox"/> Veterinarian in the practice of veterinary medicine.</p>	
<p>TELEPHONE NUMBER <i>(Include Area Code):</i></p>		<p><b>4. REGISTRATION</b></p> <p><b>REGISTRATION NUMBER:</b></p> <div style="border: 1px solid black; height: 60px; width: 100%;"></div> <p><i>(If this an initial registration, leave this space blank -- number to be assigned by NRC. If this is a change of information from a previously registered general license, include your registration number.)</i></p>	
<p><b>INSTRUCTIONS</b></p> <p>A. Submit this form to:</p> <p style="margin-left: 40px;">Licensing Branch (T-8 E24) Division of Materials Safety &amp; State Agreements U.S. Nuclear Regulatory Commission Washington, DC 20555-0001</p> <p>(At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.)</p> <p>B. In the box above, print or type the name, address (including ZIP Code), and telephone number of the registrant physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine for whom or for which this registration form is filed.</p>		<p>5. If place of use is different from address listed above, give complete address.</p>	
<p>I hereby certify that:</p> <p style="text-align: center;"><b>6. CERTIFICATION</b></p> <p>A. All information in this registration certificate is true and complete.</p> <p>B. The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of 10 CFR 31.11. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.</p> <p>C. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director of Federal and State Materials and Environmental Management Programs within 30 days from the effective date of such change.</p> <p>D. I have read and understand the provisions of Section 31.11 of NRC regulations 10 CFR 31 (on page 2 of this form); and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the U.S. Nuclear Regulatory Commission.</p>			
<p>PRINTED OR TYPED NAME AND TITLE OF APPLICANT</p>		<p>SIGNATURE</p>	<p>DATE</p>
<p><b>WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. 1001 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.</b></p>			

**CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 10 CFR 31.11**

**§31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.**

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

- (1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.
- (2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.
- (3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.
- (4) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.
- (5) Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings, or animals.
- (6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.
- (7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.
- (8) Cobalt-57, in units not exceeding 0.37 megabecquerel (10 microcuries) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) A person shall not receive, acquire, possess, use, or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

- (1) Has filed NRC Form 483, "Registration Certificate --In Vitro Testing with Byproduct Material Under General License," with the Director, Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 30.6(a) of this chapter, and has received from the Commission a validated copy of NRC Form 483 with a registration number assigned; or
- (2) Has a license that authorizes the medical use of byproduct material that was issued under part 35 of this chapter.
- (c) A person who receives, acquires, possesses, or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:
  - (1) The general licensee shall not possess at any one time, under the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 7.4 megabecquerels (200 microcuries).

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in paragraph (a)(7) of this section as required by § 20.2001.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, or before November 30, 2007, and the provisions of a specific license issued by a State with comparable provisions to § 32.71 that authorize manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State or the State with comparable provisions to § 32.71.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package: 1

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

NAME OF MANUFACTURER

(e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director, Office of Federal and State Materials and Environmental Management Programs, any changes in the information furnished by him in the "Registration Certificate --In Vitro Testing With Byproduct Material Under General License." Form NRC-483. The report shall be furnished within 30 days after the effective date of such change.

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of parts 19, 20, and 21, of this chapter with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202.

<sup>1</sup> Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

**NOTES**

<sup>1</sup> A State to which certain regulatory authority over radioactive material has been transferred by formal agreement, pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

<sup>2</sup> Material generally licensed under this section prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

<sup>3</sup> A new triplicate set of this Registration Certificate, NRC Form 483, may be used to report any change of information furnished by a registrant as required by §31.11(e).

If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 31.11 are required, file NRC Form 313, "Application for Materials License," to obtain a specific byproduct material license. Copies of application and registration forms may be obtained by e-mail request at Forms.Resource@nrc.gov or at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/>

1

**APPENDIX K**

2

**QUESTIONS AND ANSWERS ABOUT THE 10 CFR 40.22  
GENERAL LICENSE**

3



1           **Questions and Answers About the 10 CFR 40.22 General License**

2    **1.    What is a 10 CFR 40.22 general licensee?**

3           A 10 CFR 40.22 general licensee is a commercial or industrial firm; research,  
4           educational, or medical institution; or Federal, State, or local government agency that  
5           receives, possesses, uses, or transfers small quantities of source material in the forms  
6           and quantities described in 10 CFR 40.22(a)(1)–(3) for research, development,  
7           educational, commercial, or operational purposes. If you believe you have received  
8           source material through unauthorized means, contact your regulatory authority  
9           (see Question 14).

10   **2.    Who is considered to be a person for the purposes of the 10 CFR 40.22**  
11    **general license?**

12           Section 40.4 defines a person to be “[a]ny individual, corporation, partnership, firm,  
13           association, trust, estate, public or private institution, group...and any legal successor,  
14           representative, agent, or agency of the foregoing.” Section 40.22, though, clearly lists a  
15           subset of persons for whom the 10 CFR 40.22 general license is applicable. For  
16           example, the omission of “individuals” as an authorized class in 10 CFR 40.22 means  
17           that an individual may not possess source material under a 10 CFR 40.22 general license  
18           and would instead need to apply for a specific license.

19           A “person” authorized under 10 CFR 40.22 is not necessarily the largest entity in a class  
20           of the listed users. A separate general license is applicable to each unit of the entity that  
21           is physically separate from other units. The purpose of the physical separation is to  
22           make it unlikely that more than the allowed amount of source material could be brought  
23           together in a single location. As such, the NRC has normally considered separate  
24           facilities operated by the same entity to be separate general licensees, even if both  
25           facilities are in different parts of the same city. Use and storage locations within the  
26           same building, complex, or campus are considered the same location.

27   **3.    What is a small quantity of source material under 10 CFR 40.22?**

28           Under 10 CFR 40.22, a “small quantity” of source material means the following: (1) not  
29           more than 1.5 kilograms (kg) [3.3 pounds (lb)] of uranium and thorium in dispersible  
30           forms at any one time and not more than a total of 7 kg [15.4 lb] of uranium and thorium  
31           in dispersible forms in any one calendar year (any material processed by the general  
32           licensee that alters the chemical or physical form of the material containing source  
33           material must be accounted for as a dispersible form, even after processing is  
34           completed); and (2) not more than a total of 7 kg [15.4 lb] of uranium and thorium at one  
35           time and not more than a total of 70 kg [154 lb] of uranium and thorium in any one  
36           calendar year. Although the latter possession limits include source material possessed in  
37           a dispersible form, they do not increase the amount of uranium and thorium that is  
38           allowed to be possessed in a dispersible form and instead represent the total amount of  
39           uranium and thorium in both dispersible and nondispersible forms that you may possess  
40           at any one time and receive in total over a calendar year.

41           An exception to the limits applies for uranium removed during the treatment of drinking  
42           water and for source material used at laboratories for the purpose of determining the  
43           concentration of uranium and thorium contained within the material being analyzed. For

1 these two activities, a person operating under the 10 CFR 40.22 general license may  
2 possess a total of up to 7 kg [15.4 lb] of uranium and thorium at one time and up to 70 kg  
3 [154 lb] during a calendar year, regardless of form or process.

4 **4. What are uranium and thorium in their natural isotopic concentrations?**

5 Uranium and thorium in their natural isotopic concentrations have not undergone  
6 processing to separate or enrich individual isotopes of radionuclides. Chemical  
7 processes alone do not change the isotopic concentration. However, some variation in  
8 the ratios of certain radionuclides exists in natural uranium or thorium, depending on the  
9 time after chemical separation. Only thorium-232 (Th-232) and thorium-228 (Th-228)  
10 are normally present in significant amounts in naturally occurring thorium. These two  
11 isotopes are of equal activity abundance at the time of chemical separation, with a  
12 negligible mass abundance of Th-228. Some thorium-230 (Th-230) may be present,  
13 depending on the uranium content of the source ore. The normal content of natural  
14 uranium is 99.27 percent U-238, 0.72 percent U-235, and 0.0055 percent uranium-234  
15 (U-234) by mass. Additional information may be found in Section 3.1 of NUREG-1717,  
16 "Systematic Radiological Assessment of Exemptions for Source and Byproduct  
17 Materials," issued June 2001.

18 **5. May I possess separated isotopic concentrations of uranium or thorium under the**  
19 **10 CFR 40.22 general license?**

20 Other than depleted uranium (primarily U-238), you may not possess uranium or thorium  
21 that has been separated by isotope under the 10 CFR 40.22 general license. Instead,  
22 you would need to apply for a specific license to possess those isotopes. Additionally,  
23 for isotopes of uranium or thorium that are produced only as a result of a reaction in a  
24 nuclear reactor or by an accelerator, you would need to apply for a specific license under  
25 10 CFR Part 30 for the possession and use of byproduct material for those isotopes of  
26 uranium and thorium.

27 **6. Are there any restrictions on processing or using source material under the**  
28 **10 CFR 40.22 general license?**

29 As long as you meet and continue to meet the conditions for possession of source  
30 material, as stated in 10 CFR 40.22(a), there are only a few restrictions on how you may  
31 process or use the source material: (1) you may not administer the source material  
32 (or radiation from it) either externally or internally to human beings; (2) you may not  
33 concentrate or extract uranium or thorium in ores if the primary purpose of the process is  
34 to concentrate or extract the source material because you would create waste, which is  
35 considered 11e.(2) byproduct material and would require a specific license to possess;  
36 and (3) you may not isotopically separate any of the isotopes of uranium or thorium,  
37 because then you would possess uranium or thorium no longer in its natural isotopic  
38 concentration. For example, you could melt depleted uranium and pour it into various  
39 forms and shapes under the 10 CFR 40.22 general license, as long as you were doing it  
40 for research, development, educational, commercial, or operational purposes and  
41 possessed less than 1.5 kg of source material at any one time and did not receive or  
42 process more than 7 kg of source material in any calendar year.

1 **7. With what requirements must I comply if I have source material generally licensed**  
2 **under 10 CFR 40.22?**

3 The NRC's requirements for using source material under the general license for small  
4 quantities of source material are contained or referenced in 10 CFR 40.22(b) through (e),  
5 and are summarized as follows:

- 6 • Paragraph 40.22(b) requires that persons receiving, possessing, using, or  
7 transferring source material in accordance with a general license comply with the  
8 following: (1) they are prohibited from administering the source material or its  
9 radiation to human beings; (2) they may not abandon the source material and  
10 must dispose of it under the requirements in 10 CFR 40.22(b)(2)(i) and (ii);  
11 (3) they are subject to the provisions in 10 CFR 40.1 through 40.10, 40.41(a)  
12 through (e), 40.46, 40.51, 40.60 through 40.63, 40.71, and 40.81; (4) they must  
13 respond to written requests from the NRC for information; and (5) they may not  
14 export the source material, except in accordance with 10 CFR Part 110.
- 15 • Paragraph 40.22(c) requires that activities be conducted so as to minimize  
16 contamination of the facility and the environment.
- 17 • Paragraph 40.22(d) exempts a general licensee from the requirements of  
18 10 CFR Parts 19, 20, and 21, with certain noted exceptions.
- 19 • Paragraph 40.22(e) states that no person may initially transfer or distribute source  
20 material to persons generally licensed, unless authorized by a specific license  
21 issued in accordance with 10 CFR 40.54, "Requirements for License to Initially  
22 Transfer Source Material for Use Under 10 CFR 40.22."

23 **8. What is considered to be "dispersible" uranium and thorium?**

24 Source material is considered to be dispersible if it is in a form that can be readily  
25 ingested or inhaled (i.e., could be breathed in or swallowed by accident). For example,  
26 the material would be considered to be dispersible if it were in a form of a powder or  
27 liquid. For the purposes of the general license in 10 CFR 40.22, source material in solid  
28 form, but small enough to inadvertently ingest, such as small pellets or beads, would also  
29 be considered to be dispersible.

30 **9. What activities would be considered as altering the chemical or physical form of**  
31 **the source material?**

32 Any activity that changes the size or composition of the material containing the uranium  
33 or thorium would be considered as altering its chemical or physical form. This would  
34 include activities such as grinding or cutting the material, heating the material to the  
35 extent it results in off-gassing, melting, or making other chemical changes to the material  
36 containing the uranium or thorium (even if the uranium or thorium itself is not affected).  
37 Activities such as encapsulating the material in another material (as long as the original  
38 material is not changed) or division of already separated pieces (e.g., rocks from sand)  
39 would not be considered changing the physical or chemical form of the source material.

1 **10. Must I contact the NRC before possessing source material under the**  
2 **10 CFR 40.22 general license?**

3 No. You are not required to notify the NRC that you want to possess or use source  
4 material under the 10 CFR 40.22 general license. However, when you cease  
5 operations under the 10 CFR 40.22 general license and if you have identified significant  
6 source material contamination, you must notify the NRC about the contamination under  
7 the requirements in 10 CFR 40.22(c).

8 **11. May I initially transfer or distribute source material under my general license to**  
9 **other persons who are generally licensed?**

10 No. You may only initially transfer or distribute source material under a specific license  
11 issued under 10 CFR 40.54. As stated in 10 CFR 40.22(e), no person may initially  
12 transfer or distribute source material to persons generally licensed unless authorized by a  
13 specific license issued in accordance with 10 CFR 40.54 or equivalent provisions of an  
14 Agreement State.

15 Most persons possessing source material under the 10 CFR 40.22 general license are  
16 expected to receive source material directly from a specific licensee authorized for initial  
17 distribution or from another 10 CFR 40.22 general licensee who received the source  
18 material from a specific licensee. However, because uranium or thorium can be  
19 extracted from or concentrated in previously unlicensed materials or directly from its  
20 place in nature, the processor could initially possess the source material under the  
21 10 CFR 40.22 general license without receiving it from another licensee. Examples of  
22 such activities would include processing for other minerals from ores and the extraction of  
23 uranium from drinking water. Under these situations, any initial transfer of such source  
24 material to another 10 CFR 40.22 general licensee would require a specific license  
25 authorizing distribution; however, if the transfer were to someone for possession under  
26 the exemption in 10 CFR 40.13(a) or to a specific licensee (e.g., a licensed disposal site),  
27 no specific license authorizing distribution would be needed (see 10 CFR 40.51(b)(1)–(7),  
28 “Transfer of source or byproduct material”).

29 **12. How do I know if the source material that I am transferring would be used under**  
30 **10 CFR 40.22, thus requiring me to obtain a specific license before I can initially**  
31 **transfer the source material?**

32 You should directly contact the recipient to determine if the recipient is authorized to  
33 receive the source material and whether it is receiving the material under a general  
34 license, a specific license, or other authorization. If you determine that the recipient will  
35 possess the source material under a general license and you plan to initially transfer the  
36 source material to the recipient for possession under the general license, you are  
37 required to obtain a specific license, in accordance with 10 CFR 40.22(e) and  
38 10 CFR 40.54. If you prefer not to obtain a license under 10 CFR 40.54, you could  
39 require the recipient to obtain a specific license authorizing the possession of the source  
40 material prior to any transfer. If the recipient obtains or already has a specific license  
41 authorizing the possession and use of the source material to be transferred, you are  
42 required to verify that the recipient’s license authorizes receipt of the type, form, and  
43 quantity of source material to be transferred using a method indicated in  
44 10 CFR 40.51(d). In this case, you would not need to obtain a specific license issued in  
45 accordance with 10 CFR 40.22(e) and 10 CFR 40.54.

1 **13. May I export the generally licensed source material that I have for sale or disposal?**

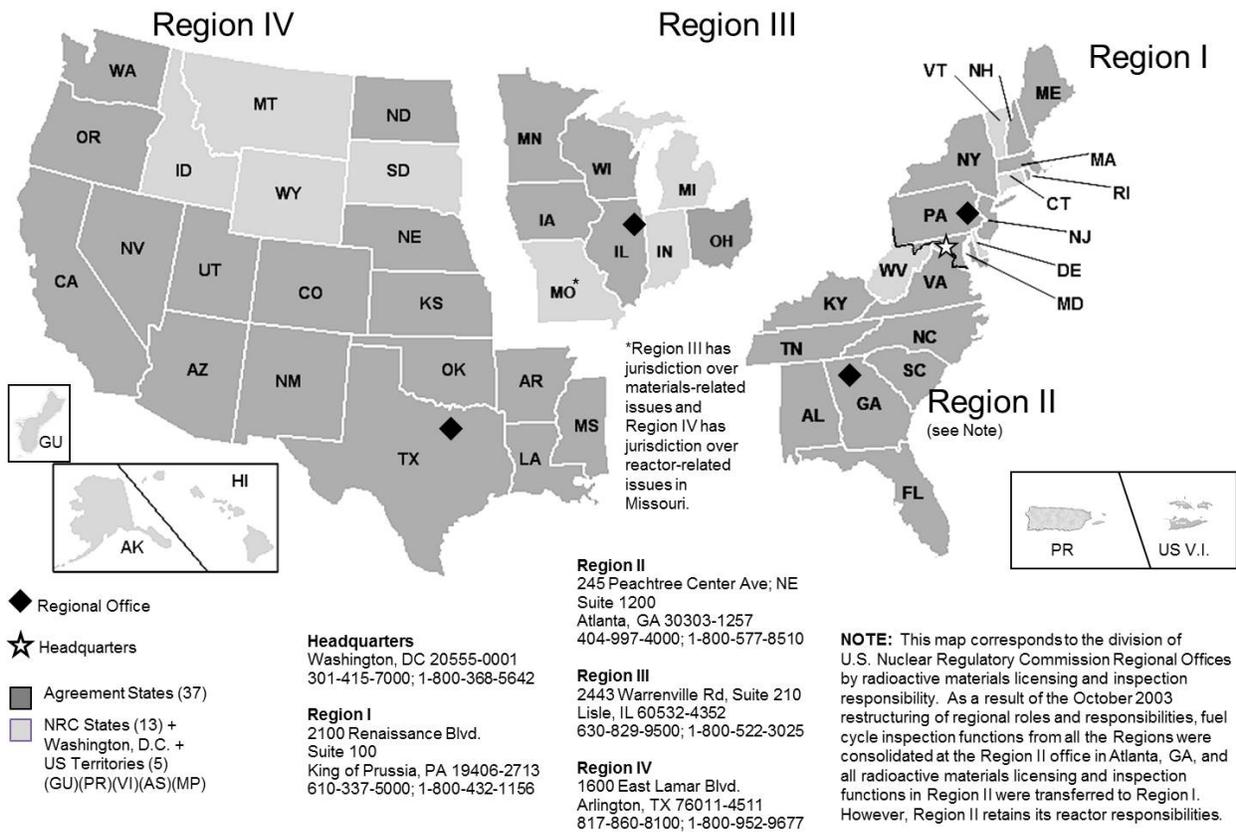
2 Yes, but only under the provisions of 10 CFR 40.22(b)(5) and 10 CFR 40.51(b)(6) (i.e., in  
3 accordance with 10 CFR Part 110). A specific license issued under 10 CFR 40.54 is not  
4 required for initial distributions that are directly exported.

5 **14. Who can answer additional questions?**

6 Call the distributor, who should be able to assist you. If the distributor is no longer in  
7 business or if you cannot contact the distributor, call the appropriate NRC regional office  
8 or Agreement State for assistance. See Figure K-1 for the telephone numbers for the  
9 NRC regional offices.

10 Note that States where the NRC has jurisdiction are called non-Agreement States.  
11 States where the NRC has given the State the authority to regulate the use of  
12 radioactive material are called Agreement States.

<sup>1</sup>Locations of NRC Offices and Agreement States



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

**Figure K-1. Locations of NRC Offices and Agreement States**

1 **15. How do I determine if there is significant contamination at my facility because of**  
2 **my operations under the 10 CFR 40.22 general license?**

3 The NRC expects that evidence of significant contamination can be made through visual  
4 inspection (e.g., there are particulates remaining from operations on surfaces such as  
5 floors, glove boxes, vents, etc.), as well as through the review of historical information  
6 about the quantities of materials used, how they were processed, and whether spills  
7 occurred. If there is doubt as to whether remaining contamination may be considered to  
8 be significant, the licensee should consult with the NRC or a health physics consultant.

9 **16. Whom at the NRC should I call to consult about the appropriateness of sampling**  
10 **and restoration activities to ensure that any contamination or residual source**  
11 **material is not likely to result in exposures that exceed the limits in**  
12 **10 CFR 20.1402, “Radiological Criteria for Unrestricted Use”? What if I am located**  
13 **in an Agreement State? Can I expect the NRC contact to explain how to sample**  
14 **and what kind of restoration might be necessary?**

15 While 10 CFR 40.22 requires notifying the Director of the Office of Nuclear Material  
16 Safety and Safeguards (NMSS), you may also wish to contact and discuss these matters  
17 with NRC regional staff, as they may be able to provide more detailed information.  
18 Paragraph (b)(2) of 10 CFR 40.5, “Communications,” indicates which States and  
19 territories are handled by the various regional offices. Those in Agreement States  
20 should contact their State regulator. Information on which States are Agreement States  
21 and their contacts can be found at <https://scp.nrc.gov> (click on your State). NRC or  
22 Agreement State staff may be able to advise whether sampling or cleanup is necessary,  
23 or how and where to locate a health physics contractor.

24 **17. Can you suggest some approaches for conducting operations at my facility so as**  
25 **to minimize contamination of my facility and the environment?**

26 Appropriate procedures and facility designs for minimizing contamination depend on the  
27 quantities of materials used, their chemical and physical form, and what processes are  
28 conducted with the material. Minimizing contamination can be achieved with good  
29 “housekeeping” practices, such as cleaning up spills of liquids, powders, or residues from  
30 grinding promptly before they are tracked around a facility. Procedures should be  
31 designed to reduce the likelihood of spills and to contain materials when there are spills,  
32 such as not leaving containers open unnecessarily, conducting operations on nonporous  
33 surfaces, and using absorbent covers on laboratory counter surfaces when liquids are  
34 being handled. Any release of source material to the site should be avoided.

35 Those general licensees using larger quantities of liquids or otherwise dispersible  
36 materials may already be using survey equipment for operational purposes; monitoring  
37 and recordkeeping may be useful in some cases in order to identify contamination to  
38 clean up promptly or to improve procedures, as well as to aid in any eventual cleanup  
39 when activities involving source material are completed. Glove boxes not only reduce  
40 intakes while processes are taking place but also contain particulates that may otherwise  
41 be spread more widely or released to the environment. Contaminating inaccessible  
42 areas, such as buried piping, should be avoided. Using dispersible forms of source  
43 material in dedicated areas, separate from other processes, may be appropriate in  
44 some circumstances.

1 The examples discussed above are illustrative only, and are not intended to provide  
2 complete instruction on how to minimize contamination. If a general licensee is not  
3 confident in its ability to determine the best approaches to avoid significant contamination  
4 of its premises or the environment, the licensee could hire a health physics consultant.

5 **18. When I am permanently ceasing operations at my site, may I leave any**  
6 **contamination behind? If so, how much residual contamination is**  
7 **considered allowable?**

8 The preference would be for no contamination to be left behind. In accordance with the  
9 provisions of 10 CFR 40.22(c), when activities involving generally licensed source  
10 material are permanently ceased at a site, if evidence of significant contamination is  
11 identified (see Q14 in this Appendix), the Director of NMSS must be notified by one of the  
12 methods listed in 10 CFR 40.5(a). You may, at that time, consult with the NRC staff on  
13 the appropriateness of sampling and restoration activities to ensure that any  
14 contamination or residual source material is not likely to result in exposures that exceed  
15 the limits in 10 CFR 20.1402. If significant amounts of contamination from your operation  
16 resulting in exposures above the levels found in 10 CFR 20.1402 are discovered after  
17 you vacate a site, you may be liable for costs associated with the cleanup of such  
18 contamination.

19 **19. If there is residual contamination at my site, must I notify the NRC before I**  
20 **permanently cease operations with source material and leave the site?**

21 If you identify or are concerned that there may be significant contamination remaining at  
22 the site at the cessation of operations, you must notify the NRC before you leave the site.  
23 When you contact the NRC, you may consult with the NRC staff to determine what  
24 actions, if any, you may need to take. The NRC, at its option, may decide to inspect the  
25 facility after all decommissioning is completed to better ensure protection of public health  
26 and safety.

27 **20. What must I do if I want to get rid of my generally licensed source material?**

28 In accordance with the provisions of 10 CFR 40.22(b)(2), if you wish to get rid of  
29 generally licensed source material, you must dispose of it in one of the following ways:  
30 (1) a cumulative total of 0.5 kg of source material in solid, nondispersable form may be  
31 transferred each calendar year to persons receiving the material for permanent disposal,  
32 as allowed by other Federal and State agencies; (2) the source material may be disposed  
33 of in accordance with 10 CFR 20.2001, "General Requirements;" or (3) the source  
34 material may be transferred to another person in accordance with 10 CFR 40.51  
35 (e.g., given to a person authorized to receive the material under license).

36 **21. I plan to sell my business, and I possess and use source material as a 10 CFR**  
37 **40.22 general licensee as part of my business. As paragraph 10 CFR 40.22(b)(3)**  
38 **indicates that I am subject to 10 CFR 40.46, "Inalienability of Licenses," do I need**  
39 **to get NRC approval before I sell the business?**

40 If the business of using the source material is continuing, the new owner would need to  
41 individually qualify for the general license in 10 CFR 40.22 (i.e., meet the constraints of  
42 the general license—in particular, be a commercial or industrial firm, research,  
43 educational, or medical institution or a Federal, State, or local government agency) or

1 would need to be a specific licensee authorized to possess the source material. There is  
2 no transfer of your authority under the general license. If the new owner fits either of  
3 these cases, no NRC permission or notification is required. Otherwise, 10 CFR 40.46  
4 would not allow you to transfer the business to someone not covered by 10 CFR 40.22 or  
5 an appropriate specific license without NRC consent, and you should contact the NRC for  
6 further direction.

7 If no use of the source material by the new business is anticipated, 10 CFR 40.22(b)(2)  
8 and (c) would apply, and the source material should be disposed of and any  
9 contamination dealt with before transfer of the business.

10 **22. Paragraph 10 CFR 40.22(b)(3) indicates that I am subject to recordkeeping**  
11 **requirements under 10 CFR 40.61, “Records.” However, certain paragraphs in**  
12 **10 CFR 40.61 require me to retain records until the Commission terminates the**  
13 **license. Does the Commission normally terminate 10 CFR 40.22 general licenses?**  
14 **Will the NRC notify me that I am no longer considered to be a general licensee?**

15 In the case of a general license, no termination of license procedure takes place. Some  
16 of the records retention periods in 10 CFR 40.61 are tied to the termination of a specific  
17 license and, thus, those requirements do not apply. For a general licensee, records  
18 retention would be tied to active possession of the source material [e.g., normally 3 years  
19 after the date of transfer or disposal of the source material, per 10 CFR 40.61(a)(1)].  
20 Generally, as the NRC does not actually issue an individual license to each general  
21 licensee, the NRC would not notify you that you no longer are a general licensee.

1

**APPENDIX L**

2

**NRC FORM 664—GENERAL LICENSE REGISTRATION FORM FOR  
CERTAIN DEVICES LISTED IN 10 CFR 31.5**

3



1 **NRC Form 664—General License Registration Form for Certain Devices**  
2 **Listed in 10 CFR 31.5**



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

TO: Users of Devices Subject to General License Registration  
SUBJECT: ANNUAL REGISTRATION OF GENERALLY LICENSED DEVICES

The U.S. Nuclear Regulatory Commission (NRC) requires annual registration of certain devices that are possessed under the general license issued in Section 31.5 of Title 10 U.S. Code of Federal Regulations (10 CFR 31.5). Devices subject to registration include those containing the radioactive material and activity listed in Table 1 of the attached NRC Form 664. You are receiving this notice because NRC records indicate that you have one or more such devices. Information about the general license registration program is available NRC website at <http://www.nrc.gov/materials/miau/miau-reg-initiatives/gen-license.html>

Note that under 10 CFR 31.5(c)(11), the attached General Licensee Registration Package must be completed, signed, and returned to the NRC within 30 days from the date of this letter. Read all of the instructions prior to completing the package. Mail the completed package in the enclosed envelope to:

Director, Office of Nuclear Material Safety  
and Safeguards  
ATTN: GLTS  
U.S. Nuclear Regulatory Commission  
Washington DC 20555-0001

**Registration Fee:** Commission regulations (10 CFR 170.31, Category 3Q) require that you submit a registration fee with each registration on an annual basis. The registration fee is subject to change yearly, and you are required to submit the fee that is in effect as of the date of this letter. An invoice for the current amount due will be sent to you under separate cover. If you have any questions about the fee or the invoice, please contact the License Fee Billing Help Desk at (301) 415-7554 or e-mail at [fees.resource@nrc.gov](mailto:fees.resource@nrc.gov).

NRC amended 10 CFR Parts 170.11 and 170.31 to provide that 10 CFR Part 170 fees be assessed to Federal agencies, where applicable, in accordance with the Energy Policy Act of 2005. Therefore, those Federal facilities required to register certain generally licensed devices in their possession will be required to pay the annual registration fee.

Attachment: NRC Form 664 -- General Licensee Registration and Instructions

Sincerely,

Hector Rodriguez-Luccioni, PhD  
U.S. Nuclear Regulatory Commission  
Office of Nuclear Material Safety  
and Safeguards  
Division of Materials Safety, States, Tribal  
and Rulemaking Programs  
Materials Safety Licensing Branch

**INSTRUCTIONS FOR COMPLETING NRC FORM 664  
"GENERAL LICENSEE REGISTRATION"**

Review all six sections of this registration form. If any information is incorrect or missing, make corrections in the applicable boxes. If you have more devices than space provided in the form, **copy the form before starting, as needed.** Use black ink and print in **CAPITAL LETTERS.** Start information in the first box provided. If the information contains a number with a dash (-) or a decimal point (.), include the dash or decimal point as an individual character. Use the "ø" character to represent the number 0 (zero).

Verify information about the devices by reviewing the label on the outside of the device. **For safety reasons, DO NOT TRY TO TAKE APART any device to verify this information.** If you are uncertain how to identify the device's label, contact the device's manufacturer or an authorized service agent for this information. Also, contact the manufacturer for any additional information about NRC requirements. You may also review 10 CFR 31.5 and other applicable regulations on the NRC web site at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>, or review specific information about the general licensee project at <http://www.nrc.gov/materials/miau/miau-reg-initiatives/gen-license.html>

**Note to specific licensees:** If you believe the device(s) listed on the registration form are possessed under your specific license, then verify the device label does not state the device is subject to a general license. If the labels indicate the device is subject to a general license, then complete the registration form as instructed below. If not, complete the registration as instructed below, however, in Section 2, follow the instructions for "not in possession of device" and complete one Section 4 page per device transferred to your specific license.

**Section 1 - General Licensee Information.** Provide the requested information about you, the general licensee.

On Page 1, provide the street address/location where your device(s) are used. For portable devices, provide the storage location. P.O. Box addresses are not allowed.

Do not write in the box marked **For NRC Use Only**

On Page 2, provide the name, telephone number, and title of the individual responsible for your device(s), and a mailing address where correspondence about your device(s) can be sent. The mailing address should be specific to the physical location where the devices are used and/or stored (P.O. boxes may be used if this is the only available mailing address). The individual indicated in this section as responsible for your device(s) must also verify and sign the form in Section 5.

**Section 2 - Devices Subject to Registration.** This section lists each device subject to registration and in your possession, according to NRC records. Devices subject to registration include those containing at least one of the radionuclides listed in Table 1, with the activity indicated, at the time of manufacture.

**Table 1. Criteria for Registration**

<b>Radionuclide</b>	<b>Activity greater than or equal to:</b>
Strontium-90, Radium-226	3.7 megabecquerel (0.1 millicurie)
Cobalt-60, Curium-244, Americium-241, Californium-252	37 megabecquerel (1 millicurie)
Cesium-137	370 megabecquerel (10 millicurie)

Use the codes from Table 2 when correcting isotope information for devices in this section. If you do not possess a device on this list, blacken the "not in possession of device" circle, and provide the relevant information in Section 4. Note that each device is assigned a unique six-digit number called the NRC Device Key.

**Table 2. Isotope Codes for Sections 2 and 3**

<b>Radionuclide</b>	<b>Code for form</b>	<b>Radionuclide</b>	<b>Code for form</b>
Americium-241	AM241	Curium-244	CM244
Californium-252	CF252	Strontium-90	SR90
Cesium-137	CS137	Radium-226	RA226
Cobalt-60	CO60		

**Section 3 - Additional Devices.** If you have other generally licensed devices (not listed in Section 2) that meet the conditions for registration listed in Table 1, provide information about each additional device. **Before starting, copy this section as needed for your additional devices.** Also indicate how you acquired each device by blackening the proper circle.

When entering isotope and unit information for your device(s), use the codes listed in Table 2 of Section 2 for isotope information, and use the codes from Table 3 for unit information:

**Table 3. Unit Codes for Section 3**

Unit	Code for form	Unit	Code for form
picocurie	PCI	becquerel	BQ
nanocurie	NCI	kilobecurel	KBQ
microcurie	UCI	megabecurel	MBQ
millicurie	MCI	gigabecurel	GBQ
curie	CI	terabecurel	TBQ
pound	LB	microgram	UG
		milligram	MG
kilogram	KG	gram	G

**Section 4 - Not in Possession of Device.** Use this section to report any devices that are listed in Sections 2 or 6, but that you no longer possess. **Before starting, copy this section as needed for additional devices that are not in your possession.** Enter the NRC Device Key, as listed in Section 2 or 6. Blacken the circle (choose only one) that best describes the disposition of the device and complete the rest of the section as appropriate.

**Section 5 - Certification and Signature.** The responsible individual must certify, sign, and date Section 5.

**Section 6 - Devices Not Subject to Registration.** This list contains information about devices that NRC records indicate are in your possession, but are **not subject to registration**. If you no longer have one or more of the listed devices, you are required to make a transfer report to NRC in accordance with 10 CFR 31.5(c)(8) or (9), as applicable. You may use Section 4 for this purpose. This section does not list any static eliminators containing polonium-210 (Po-210), or luminous exit signs containing tritium (H-3). These devices are not subject to registration, and are not included in this section in an effort to reduce the length of this form.

**RETURN THE COMPLETED FORM IN THE ENCLOSED LARGE ENVELOPE WITH PROPER POSTAGE.**

GL -       -

Date \_\_\_\_\_

NRC FORM 664  
(07-2015)  
10 CFR 31.5

SECTION 1  
PAGE 1 of 2

U.S. NUCLEAR REGULATORY COMMISSION

### GENERAL LICENSEE REGISTRATION

APPROVED BY OMB: NO. 3150-0198

OMB EXPIRATION DATE: 04/30/2016

Estimated burden per response to comply with this mandatory collection request: 20 minutes. NRC will use this information to track general licensees and their devices to ensure a higher level of device accountability. 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 Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0198), 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.

Complete all six sections of this registration form. If any of the preprinted information is incorrect, provide the changes in the applicable boxes. USE CAPITAL LETTERS.

#### General License SECTION 1 - GENERAL LICENSEE INFORMATION

##### Registration Number

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Enter the company name and street address for the physical location of use for the device(s). For portable devices, specify the primary storage location. Do not use P. O. Boxes.

Company Name:

Department:

Address Line 1:

Address Line 2:

City:

State:

Zip Code:

<b>For NRC Use Only</b> <i>(Do not write here)</i>	
Category:	<input type="text"/>
Packet Receipt Date (MMDDYYYY)	<input type="text"/>
Accession Number	<input type="text"/>



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Date \_\_\_\_\_

**SECTION 1 - GENERAL LICENSEE INFORMATION (Continued)**

**Enter the name, telephone number, and title of the person who is the responsible individual for the device(s).**

Last Name:

First Name:

Middle Initial:

Telephone:

 -  - 

Extension:

Title:

**Enter the mailing address where correspondence regarding your device(s) should be sent.**

Department:

Address Line 1:

Address Line 2:

City:

State:

Zip Code:

 - 









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Date \_\_\_\_\_

SECTION 5  
PAGE 1 of 1

**SECTION 5 - CERTIFICATION**

I hereby certify that:

- A. All information contained in this registration is true and complete to the best of my knowledge and belief.
- B. A physical inventory of the devices subject to registration has been completed and the device information on this form has been checked against the device labeling.
- C. I am aware of the requirements of the general license, provided in 10 CFR 31.5.  
(Copies of applicable regulations may be viewed at the NRC web site at [www.nrc.gov/reading-rm/doc-collections/cfr/](http://www.nrc.gov/reading-rm/doc-collections/cfr/))

\_\_\_\_\_  
SIGNATURE - RESPONSIBLE INDIVIDUAL *(Listed in Section 1)*

\_\_\_\_\_  
DATE

**WARNING: FALSE STATEMENTS MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL ASPECTS. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY WRONG STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER IN ITS JURISDICTION.**



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Date \_\_\_\_\_

**SECTION 6 - DEVICES NOT SUBJECT TO REGISTRATION**

**NRC Device Key:**  **Manufacturer License No.:**   
**Manufacturer Name:**   
**Model Number:**  **Serial No.:**  **Transfer Date:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**

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**NRC Device Key:**  **Manufacturer License No.:**   
**Manufacturer Name:**   
**Model Number:**  **Serial No.:**  **Transfer Date:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**

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**NRC Device Key:**  **Manufacturer License No.:**   
**Manufacturer Name:**   
**Model Number:**  **Serial No.:**  **Transfer Date:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**

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Date \_\_\_\_\_

SECTION 6  
PAGE \_\_\_\_\_ OF \_\_\_\_\_

**SECTION 6 - DEVICES NOT SUBJECT TO REGISTRATION**

**NRC Device Key:**  **Manufacturer License No.:**   
**Manufacturer Name:**   
**Model Number:**  **Serial No.:**  **Transfer Date:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**

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**NRC Device Key:**  **Manufacturer License No.:**   
**Manufacturer Name:**   
**Model Number:**  **Serial No.:**  **Transfer Date:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**

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**NRC Device Key:**  **Manufacturer License No.:**   
**Manufacturer Name:**   
**Model Number:**  **Serial No.:**  **Transfer Date:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**   
**Isotope:**  **Activity:**  **Unit:**

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1

**APPENDIX M**

2

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

3



1  
2

## Checklist for Requests to Withhold Proprietary Information From Public Disclosure (Under 10 CFR 2.390)

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

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



**BIBLIOGRAPHIC DATA SHEET**

(See instructions on the reverse)

1. REPORT NUMBER  
(Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)  
NUREG-1556, Volume 16,  
Revision 1  
DRAFT

2. TITLE AND SUBTITLE  
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3. DATE REPORT PUBLISHED

MONTH	YEAR
June	2016

4. FIN OR GRANT NUMBER

5. AUTHOR(S)  
Ujagar Bhachu, Gary Comfort, Vanessa Cox, Farrah Gaskins, Robert Gattone, Catherine Mattsen, and Megan Shoher

6. TYPE OF REPORT

Technical

7. PERIOD COVERED (Inclusive Dates)

December 2000 to June 2016

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

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

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

Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

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

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

NUREG-1556  
Volume 16  
Distribution  
Generally Licensed (GL) Material, Products, or Devices  
Licensee

13. AVAILABILITY STATEMENT

unlimited

14. SECURITY CLASSIFICATION

(This Page)

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unclassified

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16. PRICE



Federal Recycling Program





**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
WASHINGTON, DC 20555-0001  
\_\_\_\_\_  
OFFICIAL BUSINESS



**NUREG-1556, Vol. 16  
Revision 1, Draft**

**Consolidated Guidance About Materials Licenses: Program-Specific Guidance  
About Licenses Authorizing Distribution to General Licensees**

**June 2016**