U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

NUREG-1556
Volume 16, Rev. 1

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees

Draft Report for Comment

Office of Nuclear Material Safety and Safeguards

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Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees

Draft Report for Comment

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COMMENTS ON DRAFT REPORT

Any interested party may submit comments on this report for consideration by the NRC staff. Comments may be accompanied by additional relevant information or supporting data. Please specify the report number NUREG–1556, Volume 16, Revision 1, in your comments, and send them by the end of the comment period specified in the *Federal Register* notice announcing the availability of this report.

Addresses: You may submit comments by any one of the following methods. Please include Docket ID **NRC-2015-0252** in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the U.S. Nuclear Regulatory Commission (NRC) Web site and on the Federal rulemaking Web site http://www.regulations.gov.

Federal Rulemaking Website: Go to http://www.regulations.gov and search for documents filed under Docket ID **NRC-2015-0252**. Address questions about NRC dockets to Carol Gallagher at (301) 415-3463 or by e-mail at Carol.Gallagher@nrc.gov.

Mail comments to: Cindy Bladey, Chief; Rules, Announcements, and Directives Branch (RADB), Division of Administrative Services, Office of Administration; Mail Stop: OWFN–12–H8, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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ABSTRACT

This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses. 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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This NUREG contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0044; 3150-0014; 3150-0017; 3150-0016; 3150-0001; 3150-0010; 3150-0020; 3150-0009; 3150-0008; 3150-0132; and 3150-0120.

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FOREWORD

The U.S. Nuclear Regulatory Commission's (NRC's) NUREG–1556 technical report series provides a comprehensive source of 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

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

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

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

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Division of Material Safety, State, Tribal and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards

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ABBREVIATIONS

AEA	Atomic Energy Act
Bq	becquerel
CFR	Code of Federal Regulations
Ci	curie
GBq	gigabecquerel
GL	generally licensed or general license
kBq	kilobecquerel
MBq	megabecquerel
NMSS	Office of Nuclear Material Safety and Safeguards
µCi	microcurie
mCi	millicurie
NRC	U.S. Nuclear Regulatory Commission
OMB	Office of Management and Budget
PII	Personally Identifiable Information
RIS	Regulatory Issue Summary
RSO	radiation safety officer
SSD	sealed source and device
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.

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

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

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

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

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

2 AGREEMENT STATES

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

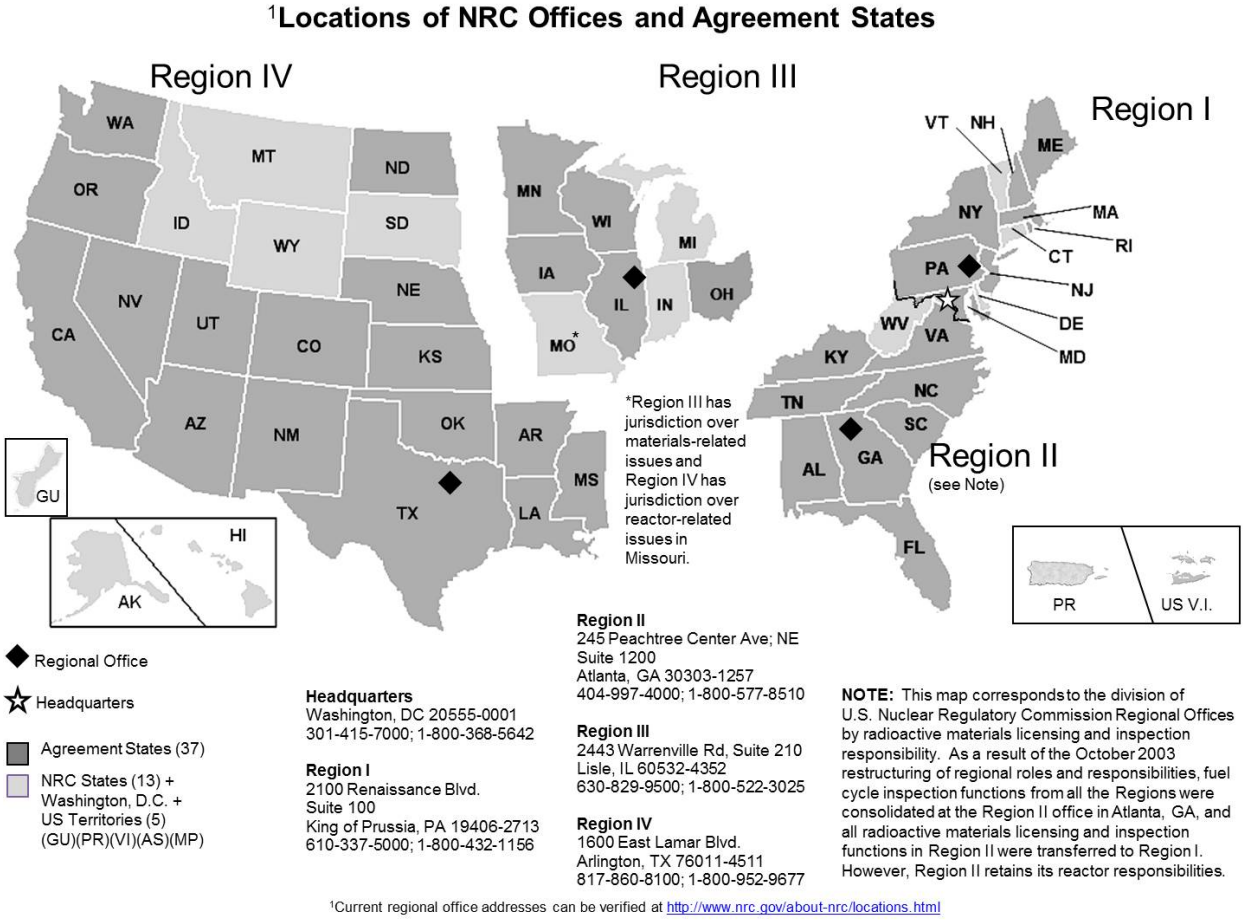


Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

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

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

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

Table 2-1. Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency, regardless of location (except 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

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

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	**Regulatory Agency**
Non-Federal entity on federally recognized Indian Tribal land	NRC[3]
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State	Agreement State
Non-Federal entity in Agreement State	Agreement State[4]
Non-Federal entity in Agreement State at federally controlled site **not** subject to exclusive Federal jurisdiction	Agreement State[4]
Non-Federal entity in Agreement State at federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor	NRC
Non-Federal entity in Agreement State using radioactive materials **not** directly connected with Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor	Agreement State[4]
Import and export of material	NRC

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

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

[4]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")

- commitment to provide information to employees regarding deliberate misconduct provisions (10 CFR 30.10, 10 CFR 40.10, and 10 CFR 70.10, "Deliberate misconduct")

- commitment to obtaining the NRC's prior written consent before transferring control of the license (see Section 11.1 of this report)

- notification of the appropriate NRC Regional Administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy [10 CFR 30.34(h), 10 CFR 40.41(f), and 10 CFR 70.32(a)(9)], as discussed further in Section 11.2, "Notification of Bankruptcy Proceedings," of this report

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

3.2 Safety Culture

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

"Nuclear safety culture" is defined in the NRC's safety culture policy statement (76 FR 34773; June 14, 2011) as "the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment." Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal-conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). Refer to Table 3-1 for the traits of a positive safety culture from NRC's safety culture policy statement.

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

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, NRC's safety culture policy statement and traits are not incorporated into the regulations.

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

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

Table 3-1. Traits of a Positive Safety Culture

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

4 APPLICABLE REGULATIONS

It is the applicant's, 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"

- 10 CFR Part 171 "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC"

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

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

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

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

Table 4-1. General Licenses and Associated GL Distribution Requirements

General License		GL Distribution Requirements	
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 32.51a	Same: Conditions of licenses
10 CFR 31.6	General license to install devices generally licensed in 10 CFR 31.5	10 CFR 32.52	Same: Material transfer reports and records
		10 CFR 32.210	Registration of product information

Table 4-1. General Licenses and Associated GL Distribution Requirements (Continued)			
General License		**GL Distribution Requirements**	
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

Table 4-1. General Licenses and Associated GL Distribution Requirements (Continued)			
General License		**GL Distribution Requirements**	
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

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

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

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

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

As no new manufacture or initial distribution of products for use under this general license is allowed, these products will not be discussed further in this document. However, for completeness, Appendix D of this NUREG includes a table of requirements applicable to 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.

NUREG−1556, Volume 12 provides information on applications for manufacturing and distribution.

5.2 Licensing and Sealed Source and Device Registration

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

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

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

An SSD evaluation is *not* required for devices and products authorized under 10 CFR 31.8, 10 CFR 31.11, 10 CFR 40.22, 10 CFR 40.25, or 10 CFR 70.19. In these cases, the safety of 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.

Licensees must conduct their programs in accordance with the following:

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

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

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

5.3 Types of Generally Licensed Products

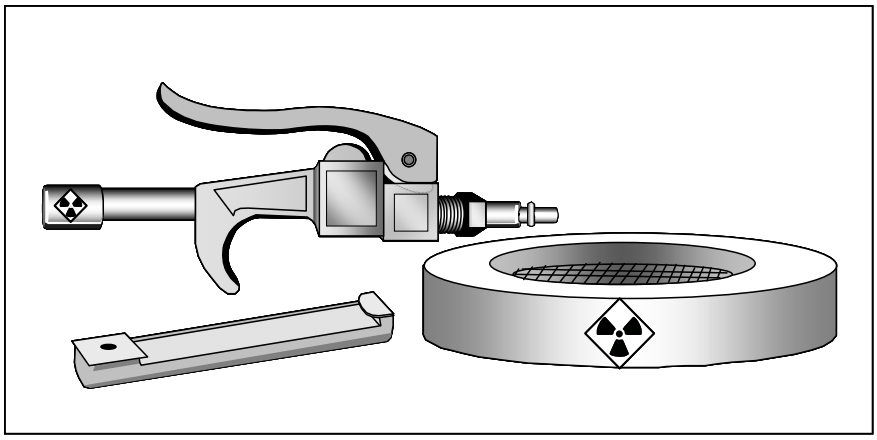
This section lists the applicable regulations and some examples under each of materials, products, or devices that may be distributed under a GL distribution license and possessed by a general licensee.

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

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

10 CFR 31.7 Luminous Safety Devices for Use in Aircraft

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



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092000

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.*

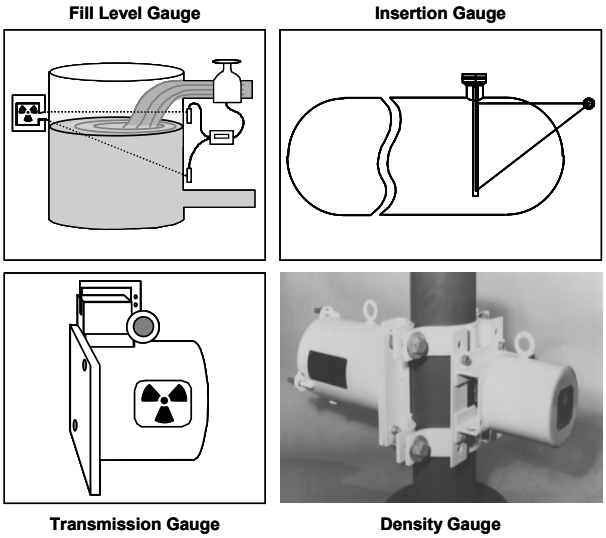

Figure 5-3. Fixed Gauging Devices. *Certain nuclear gauges can be possessed under* 10 CFR 31.5.

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.*

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

- single source not to exceed 0.185 megabecquerels (MBq) [5 microcuries (µCi)] at any 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.*

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

- each device not to exceed 50 µCi [1.85 MBq]

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

- iodine-125 not to exceed 10 µCi [370 kBq]
- iodine-131 not to exceed 10 µCi [370 kBq]
- carbon-14 not to exceed 10 µCi [370 kBq]
- tritium not to exceed 50 µCi [1.85 MBq]
- cobalt-57, not to exceed 10 µCi [370 kBq]
- iron-59 not to exceed 20 µCi [740 kBq]
- selenium-75 not to exceed 10 µCi [370 kBq]
- mock iodine-125 not to exceed 0.05 µCi [1.85 kBq] of iodine-129 and 0.005 µCi [185 Bq] of americium-241

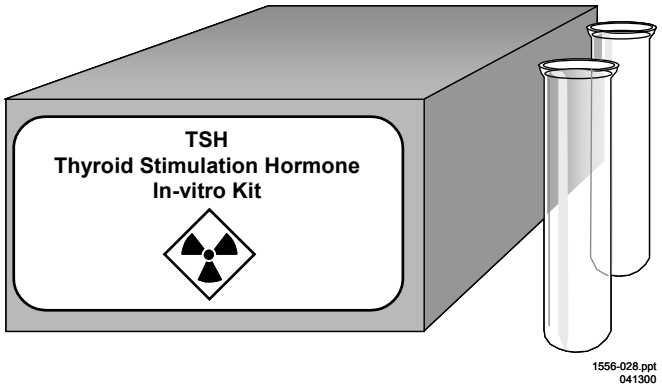

Figure 5-7. In Vitro Kit. *Certain in vitro kits used in medicine, veterinary medicine, hospitals, and clinical laboratories are authorized under 10 CFR 31.11.*

10 CFR 40.22 Small quantities of source material

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

Example: depleted uranium used as radiation shielding for an accelerator

10 CFR 70.19 General license for calibration or reference sources

- at any one time, at any one location of storage or use, no more than 5 µCi [185 kBq] of plutonium in the form of calibration or reference sources

5.4 Identifying and Protecting Sensitive Information

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

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

- Proprietary Information/Trade Secrets: If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Appendix M of this NUREG provides a checklist for requests for withholding proprietary information from public disclosure.

- Personally Identifiable Information: Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII, and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act

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

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

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

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

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

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

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

Any part of a license application or information provided by a licensee or applicant that the NRC determines should be withheld from public disclosure will be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program," and the licensee or applicant will be notified in writing that NRC plans to honor the request. Management Directive 12.6 is available electronically on the NRC's Web site: 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.

5.5 Foreign Vendors

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

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

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

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

6.3 Paper Applications

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

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

> Applications must be signed by the applicant, licensee, or a person duly authorized as required by 10 CFR 30.32(c), 10 CFR 40.31(b), or 10 CFR 70.22(d) (see Section 8.8, "Certification").

Please note that if it is necessary when filing for a license to reference information contained in other licensees' file(s) or registration certificate(s), whether current or inactive, the information should be submitted, in its entirety, as part of the application.

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

6.4 Electronic Applications

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

7 APPLICATION AND LICENSE FEES

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

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

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

8 CONTENTS OF AN APPLICATION

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

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

8.1 Item 1: License Action Type

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

Type of Action	License No.
[ ] A. New License	Not Applicable
[ ] B. Amendment	XX-XXXXX-XX
[ ] C. Renewal	XX-XXXXX-XX

Check box A for a new license request. Note that a pre-licensing visit may be conducted prior to issuance of the license.

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

Check box C for a renewal of an existing license and provide the license number. See "License Amendments and Renewals" in Chapter 11 of this report.

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

8.2 Item 2: Name and Mailing Address of Applicant

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

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

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

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

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

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

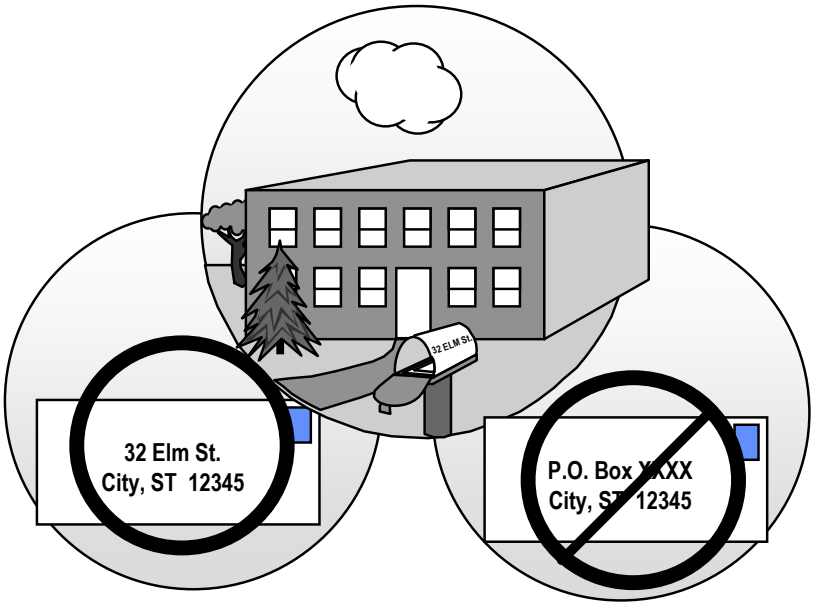

Figure 8-1. Location of Distribution

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

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

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

8.4 Item 4: Person To Be Contacted About This Application

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

8.5 Item 5: Radioactive Material

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

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

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

8.7 Item 12: License Fees

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

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

8.8 Item 13: Certification

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

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

***Notes**:*

- It is a criminal offense to knowingly and willfully make a false statement or representation on an application or correspondence (18 U.S.C. 1001).

- When an application references commitments, those items will be incorporated into the license and, therefore, become binding regulatory requirements.

9 DETAILS OF INFORMATION REQUIRED FOR THE SPECIFIC TYPES OF GL DISTRIBUTION LICENSES

This chapter provides instructions for applicants specific to each type of generally licensed (GL) product and its associated licensing provisions. Some of this guidance applies to the application for Sealed Source and Device (SSD) registration of the product when applicable.

9.1 10 CFR 32.51: Requirements for Distribution of Devices for Use Under 10 CFR 31.5 (Certain Measuring, Gauging, or Controlling Devices)

Regulations: 10 CFR 20.1901, 10 CFR 20.1201(a), 10 CFR 31.5, 10 CFR 31.6, 10 CFR 32.24, 10 CFR 32.51, 10 CFR 32.51a, 10 CFR 32.52, 10 CFR 32.210

Criteria: 10 CFR 32.51 provides the requirements for applications for a specific license to manufacture or initially transfer devices containing byproduct material to persons generally licensed under 10 CFR 31.5 or equivalent regulations of an Agreement State.

The applicant must obtain a specific license under Title 10 of the *Code of Federal Regulations* (10 CFR) 32.51 and a registration certificate under 10 CFR 32.210 in order to distribute devices for use under the general license in 10 CFR 31.5.

Paragraph (a)(1) of 10 CFR 32.51 indicates that the applicant must satisfy the general requirements of 10 CFR 30.33. These requirements are addressed separately in guidance on obtaining a possession license.

Paragraph (a)(2) of 10 CFR 32.51 requires the submission of sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiological protection.
- Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in a year a dose in excess of 10 percent of the annual limits specified in 10 CFR 20.1201(a).
- Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in 10 CFR 32.24.

The dose assessment submitted to demonstrate that the criteria of 10 CFR 32.51(a)(2)(ii) and (a)(2)(iii) are met must be consistent with other information submitted about the device under 10 CFR 32.51 and 32.210(c).

Paragraph (a) of 10 CFR 20.1201 establishes the annual limits for occupational exposures for adult workers at licensed facilities. The primary criterion is a total effective dose equivalent of

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

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

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

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

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

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

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

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

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

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

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

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

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

Discussion:

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

Dose evaluations

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

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

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

Dose evaluation for additional tasks

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

Prototype testing

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

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

Quality control/quality assurance

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

Informing customers

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

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

Response From Applicant:

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

- all of the specific information required about the device(s) one intends to distribute

- a dose assessment addressing all of the appropriate scenarios to demonstrate that the device meets the safety criteria in 10 CFR 32.51(a)(2)(ii) and (a)(2)(iii), which references the table in 10 CFR 32.24

- information on quality control and information on product labeling (actual example labels are helpful)

- information on the safety instructions that will be provided to recipients

- when seeking longer testing intervals for general licensees, submit sufficient information to demonstrate that such longer interval is justified by performance characteristics and by design features that affect the probability or consequences of leakage from the device or failure of the on-off mechanism and indicator

- when seeking authorization for general licensees to perform certain service activities, as described in 10 CFR 32.51(c), submit the written instructions to be followed by the general licensee, the estimated calendar quarter doses associated with such activities, and the basis for these estimates

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

- "We will transfer only devices that are manufactured consistent with all of the statements in the application, as approved by the NRC and referenced in the registration certificate and the license."

- "We will transfer devices only to persons authorized to use such devices, either by the general license in 10 CFR 31.5, or by an equivalent general license if the potential recipient is in an Agreement State."

- "We will provide information to customers prior to purchase, in accordance with 10 CFR 32.51a(a) and (b)."

- "We will provide quarterly transfer reports in accordance with 10 CFR 32.52(a) and (b) and will maintain records in accordance with 10 CFR 32.52(c)."

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

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

Regulations: 10 CFR 31.7, 10 CFR 32.53, 10 CFR 32.54, 10 CFR 32.55, 10 CFR 32.56, 10 CFR 32.210

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

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

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

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

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

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

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

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

(i) The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions, which are likely to be encountered in normal use and handling of the device.

(ii) The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it.

(iii) The device is so designed that it cannot easily be disassembled.

(iv) Prototypes of the device have been subjected to and have satisfactorily passed the required tests.

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

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

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

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

- Applicants should submit [in accordance with 10 CFR 32.210(c)] a sample or drawing of the typical or generic label consistent with the requirements of 10 CFR 32.54(a), or propose using the alternative approach in 10 CFR 32.54(b), which allows for some of the information to be included in an accompanying leaflet.

- The information on quality assurance/quality control submitted under 10 CFR 32.53(b)(5) must be consistent with the requirements of 10 CFR 32.55, which specify certain aspects of quality assurance.

- The requirements for material transfer reporting are specified in 10 CFR 32.56. Information concerning the reporting requirements is not required to be included in the application, because the requirements are fully specified in the regulations. Details concerning recordkeeping and annual reporting requirements appear in Appendix I of this NUREG.

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

Discussion:

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

Prototype tests

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

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

Acceptable prototype testing procedures

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

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

Step 1. The internal temperature of the test chamber is reduced to −62 °C [−80 °F], and the device is maintained for at least 1 hour at this temperature at atmospheric pressure.

Step 2. The internal temperature of the test chamber is raised to −54 °C [−65 °F] and maintained until the temperature of the device has stabilized at −54 °C [−65 °F] at atmospheric pressure.

Step 3. The atmospheric pressure of the chamber is reduced to 83 millimeters of mercury absolute pressure, while the chamber temperature is maintained at −54 °C [−65 °F].

Step 4. The internal temperature of the chamber is raised to −10 °C [+14 °F] and maintained until the temperature of the device has stabilized at −10 °C [+14 °F], and the internal pressure of the chamber is then adjusted to atmospheric pressure. The test chamber door is then opened in order that frost will form on the device, and it remains open until the frost has melted but not long enough to allow the moisture to evaporate. The door is then closed.

Step 5. The internal temperature of the chamber is raised to +85 °C [185 °F] at atmospheric pressure. The temperature of the device is stabilized at +85 °C [185 °F] and maintained for 2 hours. The device is then visually inspected to determine the extent of any deterioration.

Step 6. The chamber temperature is reduced to +71 °C [160 °F] at atmospheric pressure. The temperature of the device is stabilized at +71 °C [160 °F] for a period of 30 minutes.

Step 7. The chamber temperature is reduced to +55 °C [130 °F] at atmospheric pressure. The temperature of the device is stabilized at this temperature for a period of 4 hours.

Step 8. The internal temperature of the chamber is reduced to +30 °C [86 °F] and the pressure to 138 millimeters of mercury absolute pressure and stabilized. The device is maintained under these conditions for a period of 4 hours.

Step 9. The temperature of the test chamber is raised to +35 ºC [95 °F], and the pressure is reduced to 83 millimeters of mercury absolute pressure and stabilized. The device is maintained under these conditions for a period of 30 minutes.

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

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

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

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

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

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

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

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

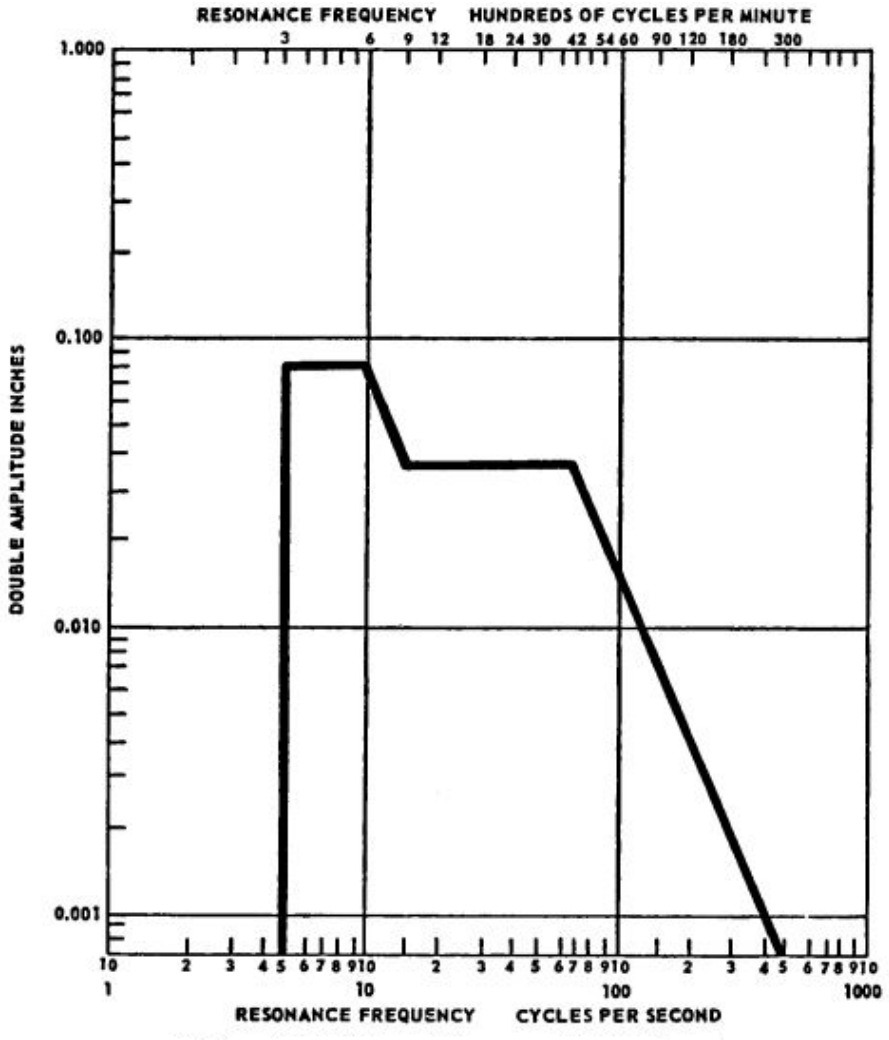

Figure 9-1. Amplitude of Vibration at Resonance Frequency

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

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

Quality assurance/quality control

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

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

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

- tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion

- inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the required criteria for finding a unit defective

Acceptable sampling test procedures

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

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

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

Labeling

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

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

Informing customers

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

Response From Applicant:

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

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

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

- "We will transfer only devices that are manufactured consistent with all of the statements in the application, as approved by the NRC and referenced in the registration certificate and the license."
- "We will label devices, as outlined in this application and in accordance with 10 CFR 32.54."
- "We will conduct quality assurance/quality control, as outlined in this application and in accordance with 10 CFR 32.55."
- "We will maintain records and provide annual material transfer reports, in accordance with 10 CFR 32.56."

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

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

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

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

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

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

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

(1) chemical and physical form and maximum quantity of americium 241 or radium-226 in the source

(2) details of construction and design

(3) details of the method of incorporation and binding of the americium-241 or radium-226 in the source

(4) procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use

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

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

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

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

Paragraph (d) of 10 CFR 32.57 specifies the findings that the NRC must make for any type of source containing more than 0.005 μCi [185 Bq] of americium-241 or radium-226 before issuing the license:

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

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

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

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

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

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

Discussion:

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

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

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

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

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

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

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

Labeling

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

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

Acceptable quality control procedures

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

Informing customers

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

Response From Applicant:

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

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

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

- “We will transfer only sources that are manufactured consistent with all of the statements in the applications as approved by the NRC and referenced in the license.”

- “We will ensure that all sources are leak tested, as required by 10 CFR 32.59.”

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

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

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

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

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

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

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

(i) chemical and physical form and maximum quantity of strontium-90 in the device

(ii) details of construction and design of the source of radiation and its shielding

(iii) radiation profile of a prototype device

(iv) procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use

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

(vi) description of labeling to be affixed to the device

(vii) instructions for handling and installation of the device

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

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

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

(i) The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions, which are likely to be encountered in normal use and handling of the device.

(ii) The strontium-90 is incorporated or enclosed, so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem [5 mSv] in a year under ordinary circumstances of use.

(iii) The device is so designed that it cannot be easily disassembled.

(iv) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by 10 CFR 32.61(f).

(v) Quality control procedures have been established to satisfy the requirements of 10 CFR 32.62.

Paragraph (f) of 10 CFR 32.61 specifies certain aspects of the required prototype tests, including that at least five prototypes of the device must be tested.

The information submitted under 10 CFR 32.61(b)(4) must demonstrate that the devices have met the prototype testing requirements of 10 CFR 32.61(f).

Conditions for any license issued under 10 CFR 32.61 appear in 10 CFR 32.62, which specifies certain aspects of quality assurance, including that *all* devices must be visually inspected and leak tested via one of two specified dry wipe tests.

- The information submitted under 10 CFR 32.61(b)(5) forms the basis for meeting 10 CFR 32.62 and must be consistent with those requirements.

Discussion:

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

<u>Acceptable prototype testing procedures for ice detection devices</u>

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

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

(ii) *Vibration tests*. The device is subjected to vibration tests, as described for luminous aircraft safety devices.

(iii) *Shock test*. The device is subjected to the shock test described for luminous aircraft safety devices.

(iv) *Hermetic seal and waterproof test*. On completion of all other tests described above, the device is immersed in 30 inches [76 cm] of water for 24 hours and shows no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water is then be reduced to 1 inch [2.54 cm] of mercury. Lowered pressure is maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is longer. Pressure is then increased to normal atmospheric pressure. Any visible evidence of physical contact between the water and the strontium-90 is to be considered leakage.

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

Acceptable sampling procedures for ice detection devices containing strontium-90

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

Subject each unit in the sample to the following tests:

(i) Each device is immersed in 30 inches [76 cm] of water for 24 hours and shows no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water is then reduced to 1 inch [2.54 cm] of mercury. Lowered pressure is maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is longer. Pressure is then increased to normal atmospheric pressure. Any device which leaks, as evidenced by physical contact between the water and the strontium-90, must be considered as a defective unit.

(ii) The immersion test water from the preceding test is measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of the original amount of strontium-90 in any device, the device must be considered as a defective unit.

Labeling

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

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

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

Informing customers

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

Response From Applicant:

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

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

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

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

- "We will label devices, as outlined in this application and in accordance with 10 CFR 32.61(d)."

- "We will conduct quality control/quality assurance procedures, as outlined in this application and in accordance with 10 CFR 32.62."

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

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

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

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

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

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

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

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

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

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

- iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75 not exceeding 10 µCi [370 kBq]
- tritium not exceeding 50 µCi [1.85 MBq]
- iron-59 not exceeding 20 µCi [740 kBq]
- mock iodine-125 not exceeding 0.05 µCi [1.85 kBq] of iodine-129 and 0.005 µCi [0.18 kBq] of americium-241

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

Labeling

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

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

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

Informing customers

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

Response From Applicant:

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

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

- "We will transfer only kits that are manufactured consistent with all of the statements in the applications, as approved by the NRC and referenced in the license."

- "We will transfer kits only to those authorized under the general license by having a license issued under 10 CFR Part 35 or a validated NRC Form 483. For those in Agreement States, we will follow 10 CFR 30.41 and determine whether an equivalent general license and registration form is provided by the State, or, if not, that the recipient is specifically authorized to receive it under the specific license."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Discussion:

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

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

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

<u>Dose assessment</u>

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

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

Prototype testing

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

Product labeling

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

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

Quality control/quality assurance

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

Response From Applicant:

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

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

- information on the unique benefits that will accrue to the public because of the usefulness of the product or device

- an adequate dose assessment to demonstrate that the device/product meets the safety criteria in 10 CFR 40.34(a)(2)

- information on quality control and information on product labeling (actual example labels are helpful)

- information on the safety instructions that will be provided to recipients

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

- "We will transfer only devices (or products) that are manufactured consistent with all of the statements in the applications as approved by the NRC and referenced in the license."

- "We will provide information to customers in accordance with 10 CFR 40.35(d). Before its installation in each product or device, we will impress the depleted uranium with the following legend clearly legible through any plating or other covering: 'Depleted Uranium.'"

- "We will provide annual material transfer reports in accordance with 10 CFR 40.35(e) and will maintain records in accordance with 10 CFR 40.35(e)(3)."

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

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

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

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

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

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

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

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

- The information on labeling submitted under 10 CFR 40.54(b) will supply the basis for meeting the requirements of 10 CFR 40.55(a) and should be consistent with those requirements.

- The information on quality control submitted under 10 CFR 40.54(b) will form the basis for meeting the requirements of 10 CFR 40.55(b).

- The details of how information will be provided to customers submitted under 10 CFR 40.54(b) should comply with the requirements of 10 CFR 40.55(c).

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

Discussion:

Product labeling

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

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

Acceptable quality control procedures

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

Informing customers

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

Response From Applicant:

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

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

- "We will label our product as described in this application and in accordance with 10 CFR 40.55(a)."
- "We will conduct quality control as outlined in this application as approved by the NRC and in accordance with 10 CFR 40.55(b)."
- "We will provide the appropriate information to customers in accordance with 10 CFR 40.55(c)."
- "We will maintain records and provide annual material transfer reports in accordance with 10 CFR 40.55(d)."

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

Regulations: 10 CFR 70.19, 10 CFR 70.39

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

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

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

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

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

(ii) details of construction and design

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

(iv) procedures for and results of prototype testing of sources that are designed to contain more than 0.005 µCi [185 Bq] of plutonium to demonstrate that the plutonium contained

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

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

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

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

Paragraph (a)(4) specifies findings that the NRC must make before issuing the license for any type of source containing more than 0.005 µCi [185 Bq] of plutonium:

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

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

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

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

Discussion:

Prototype Testing

If the calibration or reference source(s) contains more than 0.005 µCi [185 Bq] of plutonium, the applicant must submit the procedures for and the results of prototype testing for consideration. Prototype testing is specified in 10 CFR 70.39(a)(5).

Product labeling

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

Quality control procedures

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

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

Informing customers

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

Response From Applicant:

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

- all the specific information required as to the source(s) one intends to distribute, including results of prototype testing and details on quality control

- information on source or storage container labeling, including information on the safe use and storage (actual example labels are helpful)

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

- "We will transfer only sources that are manufactured consistent with all of the statements in the applications, as approved by the NRC and referenced in the license."

- "We will transfer sources only to specifically licensed persons. For those in Agreement States, we will follow 10 CFR 70.42, and determine whether an equivalent general license is provided by the State, or, if not, that the recipient is specifically authorized to receive it under a specific license."

10 DEFICIENCIES IN THE APPLICATION

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

Normally, the NRC expects the applicant to respond within 30 days of the date of the request. Applicants may request an extension of time in order to respond to any correspondence or request for additional information about its application, provided the NRC determines that there is good cause and the additional time requested is reasonable. Applicants may make these requests in writing or via telephone. Typically, the reviewer notifies the applicant by telephone 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.

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

11.1 Timely Notification of Transfer of Control

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

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

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

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

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

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

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

11.2 Notification of Bankruptcy Proceedings

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

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

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

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

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

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.

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.”

APPENDIX A

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

APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION FORM 313

1

U.S. Nuclear Regulatory Commission Form 313

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

NRC FORM 313 (02-2016)
10 CFR 30, 32, 33, 34
35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 02/29/2016**

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 Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

SEND APPLICATIONS TO:

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

IF YOU ARE LOCATED IN:

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

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

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

SEND APPLICATIONS TO:

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

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

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - ☐ A. NEW LICENSE
   - ☐ B. AMENDMENT TO LICENSE NUMBER _____
   - ☐ C. RENEWAL OF LICENSE NUMBER _____

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

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

BUSINESS TELEPHONE NUMBER | BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

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

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

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

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY _____ AMOUNT ENCLOSED $ _____

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE | SIGNATURE | DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

NRC FORM 313 (02-2016)

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

APPENDIX C

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.

(2) *Problem Identification and Resolution*—Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.

(3) *Personal Accountability*—All individuals take personal responsibility for safety.

(4) *Work Processes*—The process of planning and controlling work activities is implemented so that safety is maintained.

(5) *Continuous Learning*—Opportunities to learn about ways to ensure safety are sought out and implemented.

(6) *Environment for Raising Concerns*—A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.

(7) *Effective Safety Communication*—Communications maintain a focus on safety.

(8) *Respectful Work Environment*—Trust and respect permeate the organization.

(9) *Questioning Attitude*—Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

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

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

APPENDIX D

TABLES OF APPLICABLE REQUIREMENTS FOR EACH GENERAL LICENSE

Tables of Applicable Requirements for Each General License

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		
	Subject	**Applicable Regulation**
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)

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)		
	Subject	**Applicable Regulation**
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

Table D–2. Regulatory Requirements for Luminous Safety Devices for Use in Aircraft Generally Licensed Under 10 CFR 31.7		
	Subject	**Applicable Regulation**
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

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		
	Subject	**Applicable Regulation**
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

Table D–4. Regulatory Requirements for a General License for Strontium-90 in Ice Detection Devices Under 10 CFR 31.10		
	Subject	**Applicable Regulation**
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

Table D–5. Regulatory Requirements for Byproduct Material for Certain *In Vitro* Clinical or Laboratory Testing Generally Licensed Under 10 CFR 31.11		
	Subject	**Applicable Regulation**
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

Table D–6. Regulatory Requirements for a General License for Certain Items and Self-Luminous Devices Containing Radium-226 Under 10 CFR 31.12		
	Subject	**Applicable Regulation**
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

Table D–7. Regulatory Requirements for Source Material Generally Licensed Under 10 CFR 40.22		
	Subject	**Applicable Regulation**
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

Table D–8. Regulatory Requirements for Source Material Generally Licensed Under 10 CFR 40.25		
	Subject	**Applicable Regulation**
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

Table D–9. Regulatory Requirements for Special Nuclear Material Generally Licensed Under 10 CFR 70.19		
	Subject	**Applicable Regulation**
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

APPENDIX E

INFORMATION TO BE PROVIDED TO CUSTOMERS (GENERAL LICENSEES)

Information to be Provided to Customers (General Licensees)

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

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

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

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

Information to be Supplied to Customers in Agreement States

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

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

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

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

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

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

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

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

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

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

The licensee must provide the following information:

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

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

- Minimize exposure by applying the basic radiation safety principles of time, distance, and shielding.[*]

[1]Minimizing the time spent around radioactive material, as well as maximizing the distance and the shielding between persons and the radioactive material.

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

- Wear gloves and laboratory coats when handling liquid or powdered radioactive material.

- Securely store all radioactive materials when not in use.

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

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

NRC FORM 244 (01-2016)

APPENDIX F

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

Recordkeeping and Material Transfer Reports for Distributors Licensed Under 10 CFR 32.51, Including NRC Form 653–Transfers of Industrial Devices Report

Quarterly Material Transfer Reports for 10 CFR 32.51 Licensees

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

- Name and license number of the specific licensee submitting the report [10 CFR 32.52(a)(7)].

- Name and address of *each* general licensee, including intermediate persons, to which a device was transferred.

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

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

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

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

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

- Name, title, and telephone number of each general licensee's responsible individual.

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

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

- Date of transfer.

- Type, model number, and serial number of the device transferred.

- Quantity and type of byproduct material contained in the device.

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

Important Notes on Transfer Reports

Licensees should note the following information about transfer reports:

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

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

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

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

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

Recordkeeping

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

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

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U. S. NUCLEAR REGULATORY COMMISSION

TRANSFERS OF INDUSTRIAL DEVICES REPORT (TO GENERAL LICENSEES)

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

APPROVED BY OMB: NO. 3150-0001 **EXPIRES: 05/31/2016**

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.

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

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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

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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

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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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

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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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

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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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

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

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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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

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 *(No P.O. Boxes, include Zip Code)*

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

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APPENDIX G

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

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).

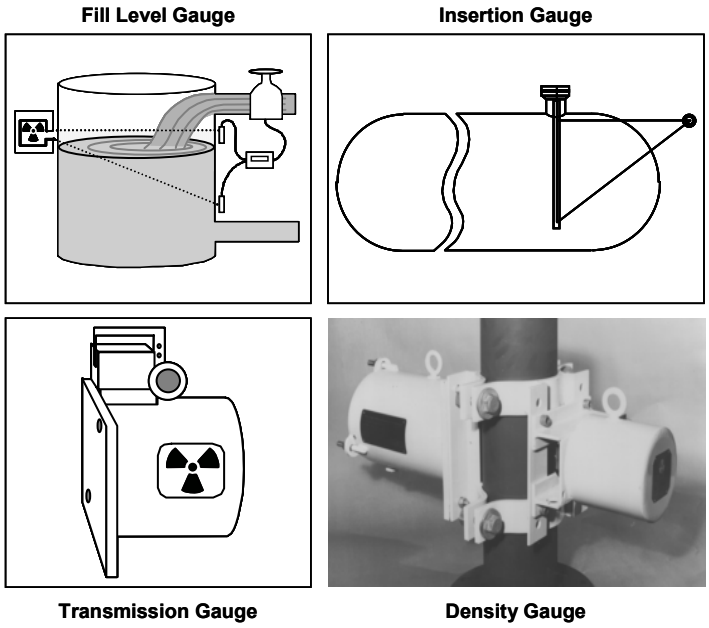

Figure G–1. Fixed Gauges. *Certain fixed nuclear gauges may be possessed and used under the general license in Title 10 of the Code of Federal Regulations (10 CFR) 31.5, "Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere."*

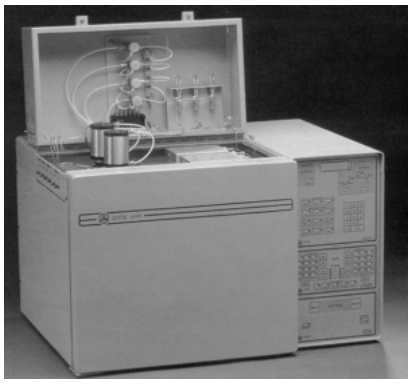

Figure G–2. Gas Chromatograph Unit. *Certain gas chromatograph units (detector cells) used for analysis of chemical composition can be possessed under the general license in 10 CFR 31.5.*

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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.)*

2. What is a 10 CFR 31.5 general licensee?

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

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

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

4. Which GL devices are subject to NRC registration?

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

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

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

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

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

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

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

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

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

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

7. What are the requirements for a GL device?

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

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)**

Type of Report	Contents of Report	Frequency	Send to
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 (*Note:* 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
Report of incidents (*Note:* 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.)	Written report includes the following: • description of the event, including probable cause, and the equipment manufacturer and model number • exact location of the event • isotopes, quantities, and chemical and physical form of the licensed material • date and time of the event • corrective actions and results of evaluations or assessments • radiation exposures to individuals	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
Report of lost or stolen devices	Written report includes the following: • description of the licensed material • description of the circumstances under which the loss or theft occurred • disposition of the licensed material • radiation exposure to individuals • actions to recover the material • actions to prevent recurrence	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)	Administrator of the appropriate NRC regional office

Additional Reporting Requirements for GL Devices Subject to Registration

Type of Report	Contents of Report	Frequency	Send to
Registration	The following information and any other information specifically requested by the NRC: • name and mailing address • information about each device: the manufacturer or initial transferor, model number, serial number, radioisotope, and activity • name, title, and telephone number of the responsible individual • address where the device(s) is used or stored or both • certification that the information concerning the device(s) has been verified through a physical inventory and check of the label • certification by the responsible individual that he or she is aware of the requirements of the general license (***Note**:* This information should be submitted using NRC Form 664.)	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

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

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

9. Is there reciprocity for GL devices?

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

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

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

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

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

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

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

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

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

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

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

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

14. Who can answer additional questions?

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

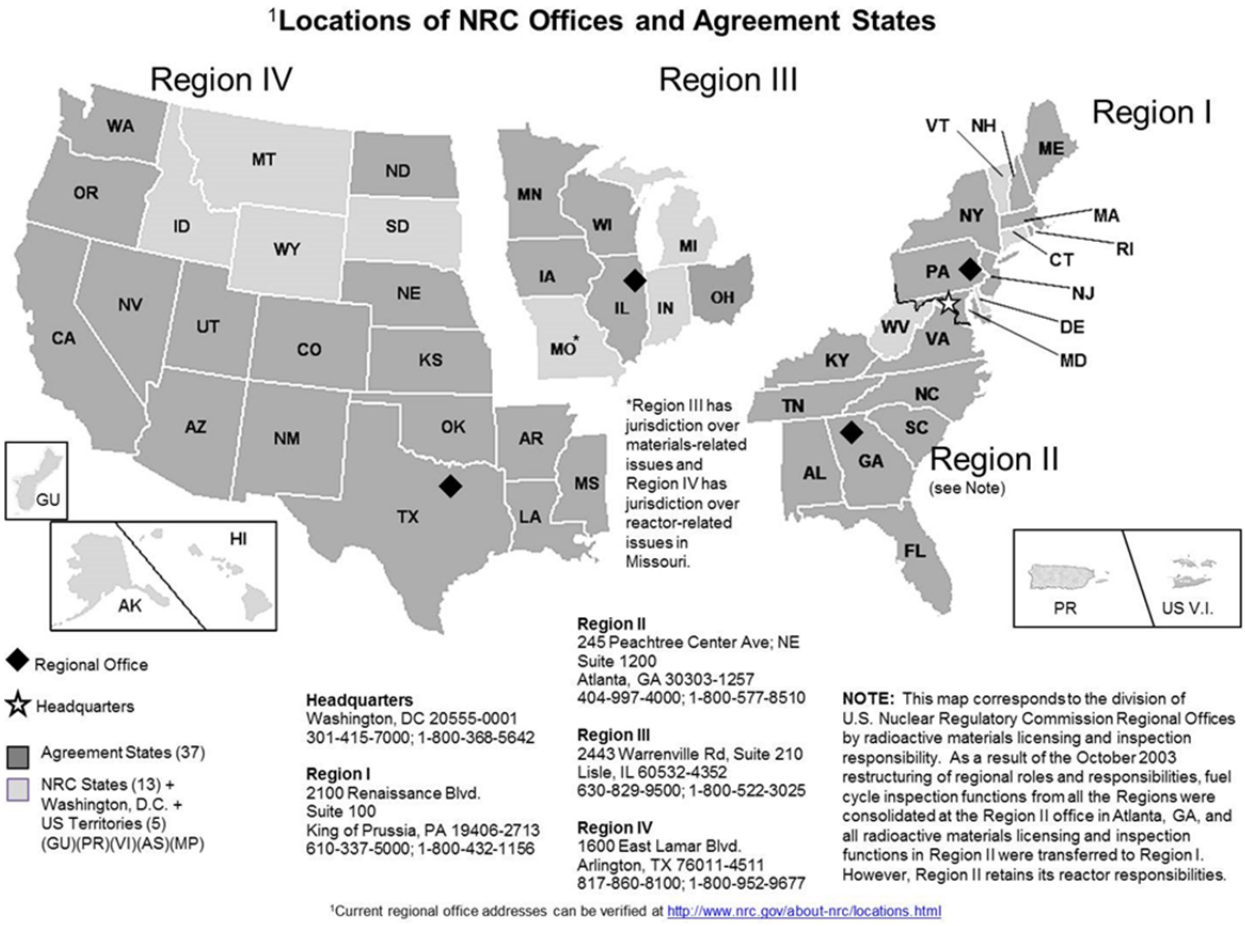
Note that States where the NRC has jurisdiction are called non-Agreement States. States where the NRC has given the State the authority to regulate the use of radioactive material are called Agreement States.

15. What other requirements apply?

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

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

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



[1]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

APPENDIX H

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

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.

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

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)	Written report includes the following: • description of the event, including probable cause, and the equipment manufacturer and model number • exact location of the event • isotopes, quantities, and chemical and physical form of the licensed material • date and time of the event • corrective actions and the results of evaluations or assessments • radiation exposures to individuals	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	Written report includes the following: • description of the licensed material • description of the circumstances under which the loss or theft occurred • disposition of the licensed material • radiation exposure to individuals • actions to recover the material • actions to prevent recurrence	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)	Administrator of the appropriate NRC regional office

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

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

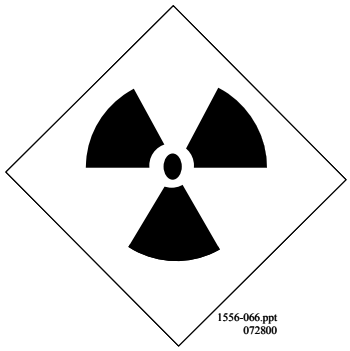


Figure H–2. Radiation Symbol

6. How can I tell if it is working?

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

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

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

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

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

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

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

8. Can broken signs contaminate buildings and require cleanup?

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

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

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

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

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

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

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

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

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

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

13. To whom can I go with additional questions?

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

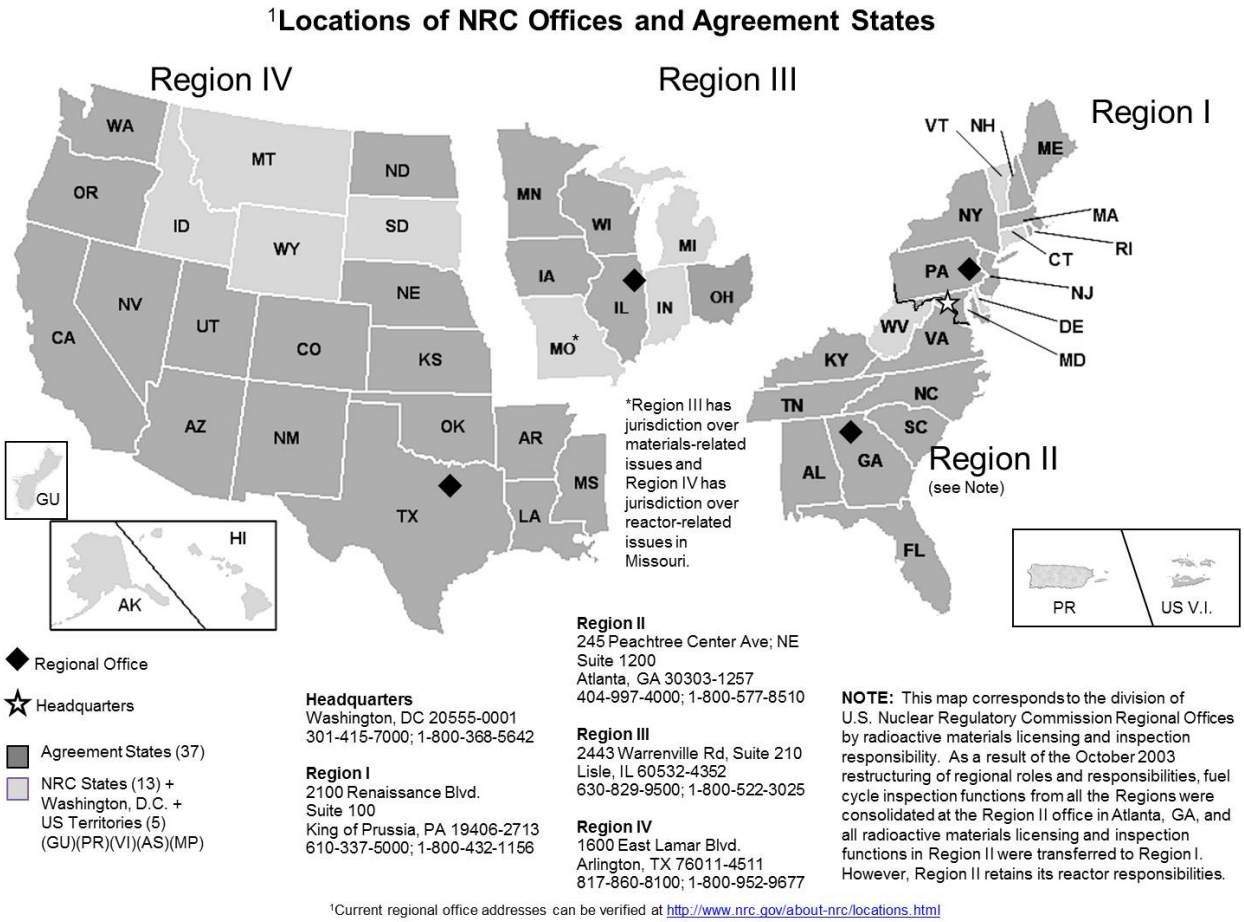


Figure H–3. Locations of NRC Offices and Agreement States

14. What other requirements apply?

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

APPENDIX I

RECORDKEEPING AND MATERIAL TRANSFER REPORTS FOR THOSE LICENSED UNDER 10 CFR 32.53, 10 CFR 40.34, AND 10 CFR 40.54

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

Distribution of Aircraft Safety Devices

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

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

The report must include the following information:

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

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

Key Points on Transfer Reports

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

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

Recordkeeping

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

Distribution of Certain Industrial Products or Devices Containing Depleted Uranium

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

- name and address of each general licensee

- the address should be the mailing address of the location of use of the product or device or, for products and devices that are portable, the mailing address of the primary place of storage of the device

- name or position or both of an individual who may constitute a point of contact between the Commission and the general licensee

- type and model number of the device transferred

- quantity of depleted uranium contained in the product or device.

Important Notes on Transfer Reports

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

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

Recordkeeping

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

Distribution of "Small Quantities of Source Material" to General Licensees

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

- Name, address, and license number of the person who transferred the source material.

- Name and address of each general licensee to which more than 50 grams of source material was transferred (distributed) in a calendar quarter.

- Name or position or both and telephone number of the general licensee's responsible agent.

- Type, physical form, and quantity of source material transferred.

- Total quantity of each type and physical form of source material transferred (distributed) in the reporting period to all such GL recipients. This means totals to all 10 CFR 40.22 GLs and Agreement State equivalent GLs, including that transferred to those who received less than 50 grams.

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

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

Important Notes on Transfer Reports

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

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

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

Recordkeeping

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

APPENDIX J

U.S. NUCLEAR REGULATORY COMMMISSION FORM 483

1

U.S. Nuclear Regulatory Commission Form 483

NRC FORM 483 (03-2015) — **U.S. NUCLEAR REGULATORY COMMISSION**

APPROVED BY OMB: NO. 3150-0038 **EXPIRES: 02/28/2018**

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.

REGISTRATION CERTIFICATE -- *IN VITRO TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE*

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.

1. NAME AND ADDRESS OF APPLICANT *(See Instruction 3.B. below)*

TELEPHONE NUMBER (Include Area Code):

2. APPLICATION *(Check one box only)*

I hereby apply for a registration number pursuant to 10 CFR 31, Section 31.11, for use of byproduct materials for:

- ☐ Myself, a duly licensed physician authorized to disperse drugs in the practice of medicine.
- ☐ The above-named clinical laboratory.
- ☐ The above named hospital.
- ☐ Veterinarian in the practice of veterinary medicine.

INSTRUCTIONS

A. Submit this form to:

Licensing Branch (T-8 E24)
Division of Materials Safety & State Agreements
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

(At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.)

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.

4. REGISTRATION

REGISTRATION NUMBER:

(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.)

5. If place of use is different from address listed above, give complete address.

6. CERTIFICATION

I hereby certify that:

A. All information in this registration certificate is true and complete.

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.

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.

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.

PRINTED OR TYPED NAME AND TITLE OF APPLICANT	SIGNATURE	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. 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.

NRC FORM 483 (03-2015)

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.

[1] Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

NOTES

[1] 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.

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

[3] 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/

APPENDIX K

QUESTIONS AND ANSWERS ABOUT THE 10 CFR 40.22 GENERAL LICENSE

Questions and Answers About the 10 CFR 40.22 General License

1. What is a 10 CFR 40.22 general licensee?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Paragraph 40.22(b) requires that persons receiving, possessing, using, or transferring source material in accordance with a general license comply with the following: (1) they are prohibited from administering the source material or its radiation to human beings; (2) they may not abandon the source material and must dispose of it under the requirements in 10 CFR 40.22(b)(2)(i) and (ii); (3) they are subject to the provisions in 10 CFR 40.1 through 40.10, 40.41(a) through (e), 40.46, 40.51, 40.60 through 40.63, 40.71, and 40.81; (4) they must respond to written requests from the NRC for information; and (5) they may not export the source material, except in accordance with 10 CFR Part 110.

- Paragraph 40.22(c) requires that activities be conducted so as to minimize contamination of the facility and the environment.

- Paragraph 40.22(d) exempts a general licensee from the requirements of 10 CFR Parts 19, 20, and 21, with certain noted exceptions.

- Paragraph 40.22(e) states that no person may initially transfer or distribute source material to persons generally licensed, unless authorized by a specific license issued in accordance with 10 CFR 40.54, "Requirements for License to Initially Transfer Source Material for Use Under 10 CFR 40.22."

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

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

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

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

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

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

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

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

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

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

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

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

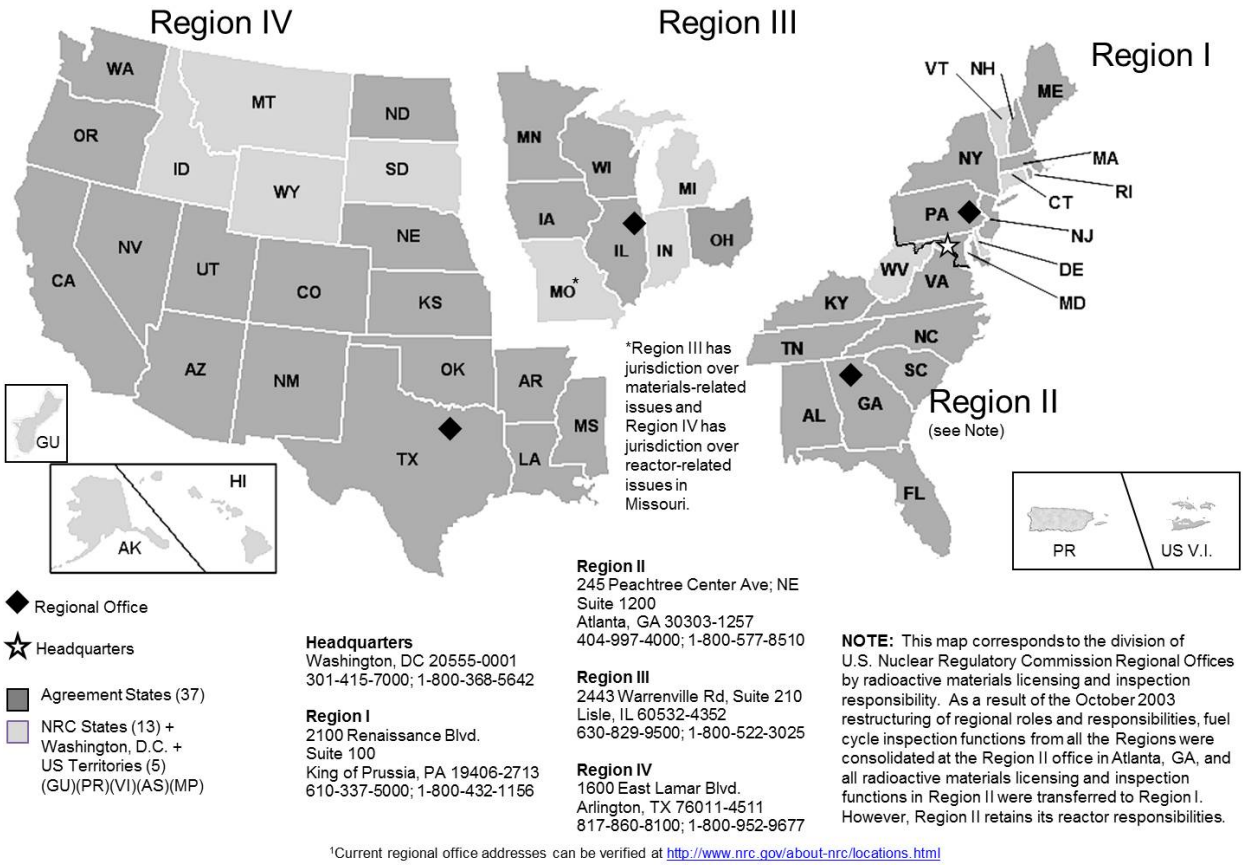
Yes, but only under the provisions of 10 CFR 40.22(b)(5) and 10 CFR 40.51(b)(6) (i.e., in accordance with 10 CFR Part 110). A specific license issued under 10 CFR 40.54 is not required for initial distributions that are directly exported.

14. Who can answer additional questions?

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

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

[1]Locations of NRC Offices and Agreement States



[1]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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX L

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

NRC Form 664—General License Registration Form for Certain Devices 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.

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

Radionuclide	Activity greater than or equal to:
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

Radionuclide	Code for form	Radionuclide	Code for form
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

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 Registration Number **SECTION 1 - GENERAL LICENSEE INFORMATION**

GL - ☐☐☐☐☐☐ - ☐☐

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: ☐☐☐☐☐ - ☐☐☐☐

For NRC Use Only
(Do not write here)

Category: ☐☐

Packet Receipt Date (MMDDYYYY)

☐☐☐☐☐☐☐☐

Accession Number

☐☐☐☐☐☐☐☐☐☐

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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:

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Address Line 1:

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Address Line 2:

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

City:

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

State: ☐☐ Zip Code: ☐☐☐☐☐ - ☐☐☐☐

GL - ______ - __

Date ________

SECTION 2

PAGE 1 OF ____

SECTION 2 - DEVICES SUBJECT TO REGISTRATION

Our records indicate that you have these devices. Please update the information as necessary.

NRC Device Key ________ (Internal Control Number)

Distributor/Distributed By:

Distributor License Number:

Manufacturer Name:

Device Model (Not Source Model):

Device Serial Number:

☐ Not in possession of device (Also complete Section 4)

Transfer Date: MM/DD/YYYY

MM DD YYYY

	Isotope (e.g., AM241)	Activity (e.g., 100)	Unit (e.g., mCi)
1.			
2.			
3.			
4.			
5.			
6.			

GL - [ ][ ][ ][ ][ ][ ] - [ ][ ]

Date _____

SECTION 2

PAGE ___ OF ___

SECTION 2 - DEVICES SUBJECT TO REGISTRATION

Our records indicate that you have these devices. Please update the information as necessary.

NRC Device Key _____ (Internal Control Number)

Distributor/Distributed By:

[ ]

Distributor License Number:

[ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

Manufacturer Name:

[ ]

Device Model (Not Source Model):

[ ]

Device Serial Number:

[ ]

☐ Not in possession of device (Also complete Section 4)

Transfer Date: MM/DD/YYYY

[ ][ ] MM [ ][ ] DD [ ][ ][ ][ ] YYYY

	Isotope (e.g., AM241)	Activity (e.g., 100)	Unit (e.g., mCi)
1.	[ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ]
2.	[ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ]
3.	[ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ]
4.	[ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ]
5.	[ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ]
6.	[ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ]

GL - ☐☐☐☐☐☐ - ☐☐

Date ____________

SECTION 3 - ADDITIONAL DEVICES SUBJECT TO REGISTRATION

Provide information about other devices you have that are subject to registration. Do not report specifically licensed devices.

Manufacturer Name

Initial Transferor Name

Initial Transferor License Number (if known)

Device Model Number (Not Source Model)

Device Serial Number

How acquired and date (e.g., from a distributor/ manufacturer, other licensee, other source)?

☐ Manufacturer/Initial Transferor listed above
☐ Other General License
☐ Other Source

Date Transferred: MM DD YYYY

	Isotope (e.g., AM241)	Activity (e.g., 100)	Unit (e.g., mCi)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

GL - ☐☐☐☐☐☐ - ☐☐

SECTION 4

Date _____

PAGE 1 OF ___

SECTION 4 - NOT IN POSSESSION OF DEVICE

Provide information about devices listed in Section 2 or 6, but no longer in your possession.

Part 1

NRC Device Key *(from Section 2 or 6)* _____

Transfer Date ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Location of the Device:

- ☐ Whereabouts Unknown *(Complete Part 1 only)*
- ☐ Never Possessed the Device *(Complete Part 1 only)*
- ☐ Returned to Manufacturer *(Complete Part 1 only)*
- ☐ Transferred to another general licensee *(Complete Parts 2 and 3)*
- ☐ Transferred to a Specific Licensee (not the manufacturer) *(Complete Part 2)*

Part 2

License Number of Recipient (if transferred to a specific licensee)

☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Company Name:

Department:

Address Line 1:

Address Line 2:

City:

State: ☐☐ Zip Code: ☐☐☐☐☐ - ☐☐☐☐

Part 3 Enter the name of the individual responsible for this device.

Last Name:

First Name: Middle Initial: ☐

Telephone Number: ☐☐☐ - ☐☐☐ - ☐☐☐☐ Extension ☐☐☐☐☐

Title

GL - ☐☐☐☐☐☐ - ☐☐

Date _____

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/

_____ _____

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.

GL - [| | | | |] - [|]

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:	

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:	

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:	

▲ ▲

GL - ______ - __

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: ______

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: ______

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: ______

APPENDIX M

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

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:

☐	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
☐	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should **not** be marked as proprietary.
☐	An affidavit that:
☐	Is notarized.
☐	Clearly identifies (such as by name or title and date) the document to be withheld.
☐	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.
☐	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.
☐	Provides a rational basis for holding the information in confidence.
☐	Fully addresses the following issues:
☐	Is the information submitted to, and received by, the NRC in confidence? Provide details.
☐	To the best of the applicant's knowledge, is the information currently available in public sources?
☐	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
☐	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.

NRC FORM 335
(12-2010)
NRCMD 3.7

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

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11545 Rockville Pike
Rockville, MD 20852

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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.)
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Volume 16
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