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

NUREG-1556
Volume 3, Rev. 2

Consolidated Guidance About Materials Licenses

Applications for Sealed Source and Device Evaluation and Registration

Final Report

Office of Nuclear Material Safety and Safeguards

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Consolidated Guidance About Materials Licenses

Applications for Sealed Source and Device Evaluation and Registration

Final Report

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ABSTRACT

This technical report contains information intended to provide guidance to applicants for requests for sealed source or device safety evaluations and registrations. It also provides the U.S. Nuclear Regulatory Commission (NRC) reviewers of such requests with the information and materials necessary to determine that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information on applicable regulations and industry standards, general policies and procedures affecting evaluation and registration, how and where to file a request, the application review process, and how to draft and modify a registration certificate.

Paperwork Reduction Act Statement

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 3150-0043; 3150-0044; 3150-0014; 3150-0035; 3150-0017; 3150-0016; 3150-0001; 3150-0015; 3150-0007; 3150-0010; 3150-0158; 3150-0214; 3150-0130; 3150-0020; 3150-0009; 3150-0008; 3150-0036.

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The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

FOREWORD

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

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

The current document, NUREG–1556, Volume 3, Revision 2, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," is intended for use by applicants, licensees, and NRC staff. This revision provides a general update to the previous information contained in NUREG–1556, Volume 3, Revision 1, issued April 2004.

This report takes a risk-informed, performance-based approach to evaluating sealed sources and devices (SSDs). 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 SSD designs, safety evaluations, and registrations. NUREG–1556, Volume 3, Revision 2, 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 NRC staff to make the determinations needed to issue a registration certificate or continue a safety evaluation for a sealed source or device.

The comments received during the comment period for NUREG–1556, Volume 3, Revision 2, were summarized and addressed in a document that can be located on the NRC's Agencywide Documents and Management System (ADAMS) under ML15055A343. Access to ADAMS is available on the public Web site at: http://www.nrc.gov/reading-rm/adams.html. The comments received by NRC included general corrections and comments to add references for sources or devices containing byproduct material.

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ACKNOWLEDGMENTS

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

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ABBREVIATIONS

ADAMS	Agencywide Documents Access and Management System
ALARA	as low as is reasonably achievable
Am-241	americium-241
ANSI	American National Standards Institute
ASQ	American Society for Quality
Bq	becquerel
CFR	*Code of Federal Regulations*
Ci	curie(s)
cm	centimeter(s)
DOT	U.S. Department of Transportation
EPAct	Energy Policy Act of 2005
FDA	U.S. Food and Drug Administration
FR	*Federal Register*
GPO	Government Printing Office
GBq	gigabecquerel(s)
h	hour
HDE	humanitarian device exemption
IAEA	International Atomic Energy Agency
IDE	investigational device exemption
IMPEP	Integrated Materials Performance Evaluation Program
in.	inch(es)
IN	Information Notice
IRB	Internal Review Board
ISO	International Organization of Standardization
kBq	Kilobecquerels
Kr-85	krypton-85
MML	Master Materials Licensee
MBq	megabecquerel(s)
mCi	millicurie(s)
MOU	Memorandum of Understanding
mrem	millirem
MSTR	Division of Material Safety, State, Tribal, and Rulemaking Programs
NARM	Naturally Occurring Radioactive Material or Accelerator-Produced Radioactive Material
NMED	Nuclear Material Events Database
NMSS	Nuclear Material Safety and Safeguards
NORM	Naturally Occurring Radioactive Material
NRC	U.S. Nuclear Regulatory Commission
NSSDR	National Sealed Source and Device Registry
OCFO	Office of the Chief Financial Officer
OMB	Office of Management and Budget
PII	Personally Identifiable Information
PMA	premarket approval
Pr-147	promethium-147
QA	quality assurance
QC	quality control

Ra-226	radium-226
RIS	Regulatory Issue Summary
SSD	sealed source and device
Sr-90	strontium-90
µCi	microcurie(s)
U.S.C.	United States Code
µSv	microsievert(s)

1 PURPOSE OF REPORT

This report provides guidance to applicants on submitting requests to the U.S. Nuclear Regulatory Commission (NRC) for radiation safety evaluation and registration of sealed sources and devices (SSDs) containing byproduct material and provides the NRC with criteria for evaluating such applications. In addition, it is designed to provide the reviewer of such requests with the guidance, information, and materials necessary to make a determination that the product is acceptable for licensing purposes. The report provides the applicants and reviewers with information on applicable regulations and industry standards, general policies and procedures affecting evaluation and registration, how and where to file a request, the application review process, and how to draft and modify a registration certificate.

Radiation safety programs for the use of byproduct material as an SSD are structured on the presumption that the byproduct material will not breach its containment and contaminate the environment or unnecessarily expose individuals to radiation. This presumption depends largely upon the adequacy of the containment properties of the sealed sources or devices in withstanding the stresses imposed by the environment in which they are possessed and used.

The NRC maintains the National Sealed Source and Device Registry (NSSDR or the Registry) of radiation safety information on SSDs containing byproduct material. Agreement States also provide information on their radiation safety evaluations to the NRC for the Registry. Both the NRC and the Agreement States use the information in the Registry. Thus, a vendor needs to provide detailed information about its SSD only to a single agency, and the results of the radiation safety evaluation will be available for use in granting licensing approval to users of the device throughout the U.S.

Any information collection activities mentioned in this document are contained as requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 2,19, 20, 21, 30, 31, 32, 34, 35, 36, 37, 39, 40, 70, 71, 110, 170, and 171, which provide the regulatory basis for this document.

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 for certain activities, including performing safety evaluations of byproduct material, which are used, possessed, or distributed by persons within their borders. Any applicant, other than a Federal entity, who wishes to apply for a sealed sources and devices (SSD) registration certificate 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.

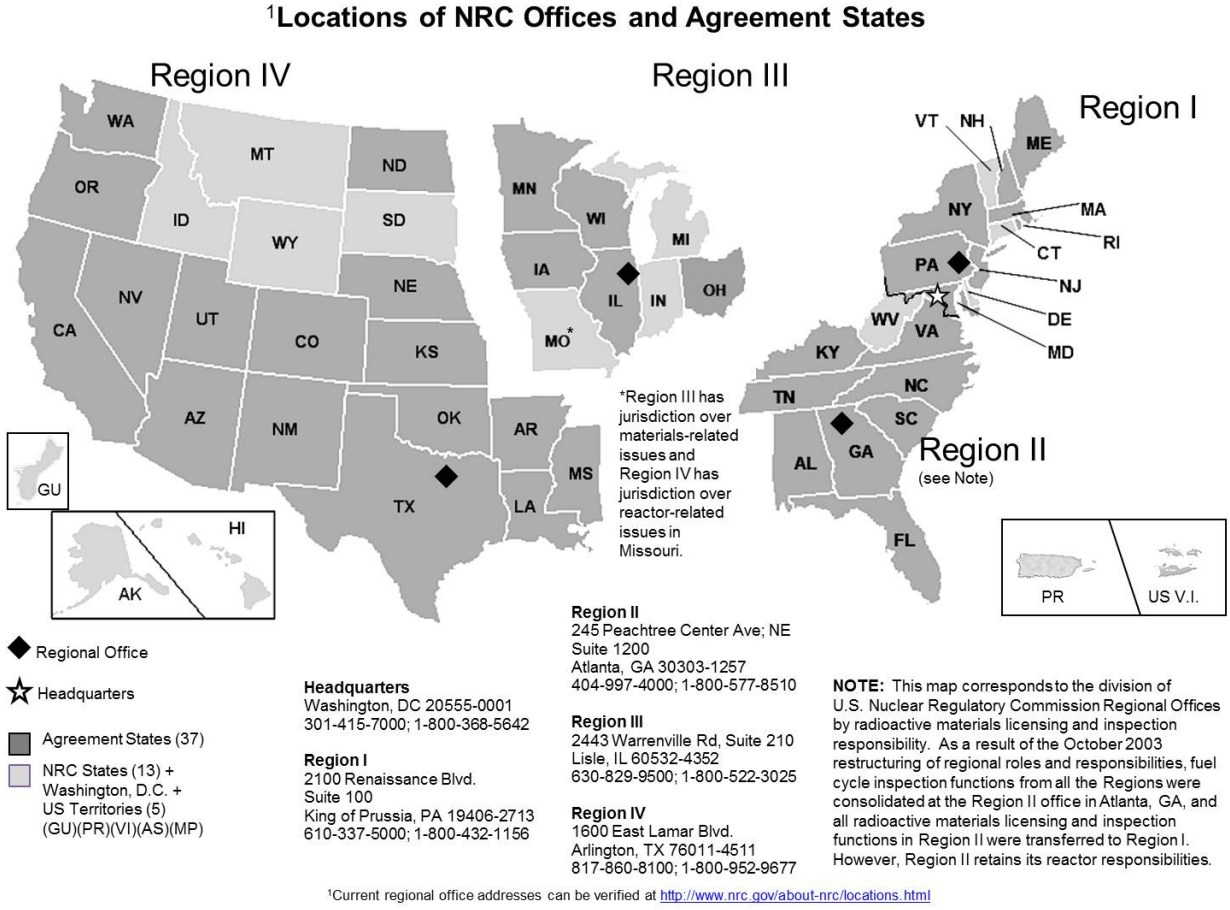

Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

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.[1]

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

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

Fourteen 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. In these States, the NRC regulates applicants and registration certificate holders in the same manner as those located in a non-Agreement State. Applicants from those Agreement States should contact the NRC's NMSS.

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

Table 2-1. Who Evaluates Sealed Sources and Devices?

Applicant and Its Location	Regulatory Agency
Distributor of products to persons exempt from licensing regardless of location	NRC
Federal agency regardless of location	NRC
Non-Federal entity in non-Agreement State, District of Columbia, or U.S. territory or possession	NRC
Non-Federal entity in Agreement State with authority to issue sealed source and device registration certificates	Agreement State
Non-Federal entity in Agreement State that does not have authority to issue sealed source and device registration certificates	NRC

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

When an Agreement State issues a registration certificate, the State forwards a copy of the registration certificate to the NRC Division of Material Safety, State, Tribal, and Rulemaking Programs (MSTR). MSTR performs an administrative review of each certificate, including an examination for gross errors or omissions and ensuring that the first page of the certificate contains all necessary information. The NRC incorporates the certificate into the National Sealed Source and Device Registry. If the NRC identifies any administrative problems or errors with an Agreement State registration certificate, the NRC resolves them directly with the Agreement State.

Agreement State regulations are compatible with NRC regulations. However, Agreement State regulations may vary from NRC regulations. As such, SSDs registered by an Agreement State may have requirements that vary from those in NRC regulations. The NRC and Agreement States' SSD programs are evaluated under the NRC's Integrated Materials Performance Evaluation Program. The purpose of the evaluation is to ensure that the state program is adequate to protect public health and safety compatibly with the National Materials Program.

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 increased safety and compliance.

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

3.1 Commitments and Responsibilities

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

- To ensure that records and all information provided to the NRC are complete and accurate (10 CFR 30.9, "Completeness and accuracy of information")
- To affirm licensee's knowledge about the contents of the application
- To apply for a registration certificate amendment if the information provided in the application or contained in the certificate is modified or changed; registration certificate holders must comply with the information in the registration certificate until the certificate is amended
- To provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to ensure that the registration certificate holder meets its regulatory requirements
- To report defects or noncompliances, in accordance with regulations
- To comply with the requirement that the registration certificate holder is required to manufacture or distribute the product, in accordance with the following:
  - the statements and representations contained in the application for safety review and registration;
  - the provisions of the registration certificate; and
  - NRC regulations.

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

3.2 Safety Culture

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

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

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

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, NRC's safety culture policy statement and traits are not incorporated into the regulations. Many of the safety culture traits may be inherent to an organization's existing radiation safety practices and programs. For instance, applications for SSD registrations must include details of the quality control program, as indicated in 10 CFR 32.210(f)(1), that will be implemented to ensure that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. The need to establish and maintain a quality control program 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) and "Problem Identification and Resolution" (issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance).

Refer to Appendix H 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 sealed source and device (SSD) evaluations. These parts 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 (NRC's) online library at http://www.nrc.gov/reading-rm.html. For viewing in a browser, the following list includes a direct link 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 34 "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations"
- 10 CFR Part 35 "Medical Use of Byproduct Material"
- 10 CFR Part 36 "Licenses and Radiation Safety Requirements for Irradiators"
- 10 CFR Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- 10 CFR Part 39 "Licenses and Radiation Safety Requirements for Well Logging"
- 10 CFR Part 40 "Domestic Licensing of Source Material"
- 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 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 Printing 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* (FR).

The regulations in 10 CFR 30.32(g) and 10 CFR 32.210, "Registration of product information," codify the current and longstanding practice whereby vendors of sealed sources of radioactive material and devices containing sealed sources submit the radiation safety information necessary to perform an independent, technical safety evaluation and to obtain registration of radiation safety information on certain SSDs. The specific provisions in 10 CFR 30.32(g) require a license applicant to either make reference to a registered SSD or provide the information necessary to perform a safety evaluation of the SSD. 10 CFR 32.210 outlines the NRC safety evaluation and registration criteria and clarifies the regulatory responsibility of registration certificate holders of products for which the NRC evaluates and registers radiation safety information.

A license applicant may submit an application to manufacture and/or distribute products to be used by specific licensees, general licensees, or an exempt or custom user. Current regulations require that manufacturers and distributors register with the Commission most products used under a specific or general license issued in accordance with 10 CFR Part 30 or 10 CFR Part 31.

If the NRC deems registration of a product design to be necessary, the applicant must provide the information called for in 10 CFR 32.210, and the NRC will evaluate the application in the same manner as all registration applications.

The products listed in Sections 4.1–4.6 of this chapter are used by persons exempt from licensing requirements or used in accordance with a general license, and the NRC has determined that registration of the product design is necessary. In addition to the general registration criteria in 10 CFR 32.210, the regulations require that the products meet certain specific requirements. These specific requirements are listed in Sections 4.1–4.6 and need to be addressed during the product evaluation.

Some specifically licensed products are required, by regulation, to meet certain specific requirements in addition to the general registration criteria provided in 10 CFR 32.210. The

specific requirements for these products are listed in Sections 4.7–4.10 and need to be addressed during the product evaluation.

An SSD that contains naturally occurring or accelerator-produced radioactive material [Naturally Occurring Radioactive Material (NORM) or Naturally Occurring Radioactive Material or Accelerator-Produced (NARM), respectively] is under the regulatory jurisdiction of the NRC. The NRC maintains the National Sealed Source and Device Registry (NSSDR) that includes information about such materials. The applications for registration and amendments for sealed sources or devices containing NORM/NARM sources must be filed with the NRC. The NRC will place a copy of the source and design registrations in the NSSDR.

4.1 Self-Luminous Products Containing Tritium, Krypton-85, or Promethium-147 for Use by Persons Exempt From Licensing Requirements

Under 10 CFR 30.19, "Self-luminous products containing tritium, krypton-85, or promethium-147," persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued under 10 CFR 32.22, "Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer." Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, which must be addressed during the product evaluation are listed below:

Area To Be Addressed	Applicable 10 CFR Regulations
Design	30.19(a) & (c), 32.22(a)
Maximum Radiation Levels	32.22(a)(2)(vi)
Maximum Dose Commitments	32.22(a)(2)(xiii) & (xiv)
Labeling	32.25(b)
Registration	30.19(b)

The registration certificate should list all models of each type of product that are distributed. Some models may be designed and fabricated as a series. In order to have the model listed as a series, there should be similarities in the design and construction of the devices. Applicants should provide detailed engineering drawings of each basic device series containing the overall dimensions; the minimum and maximum dimensions for each series type; the tolerances, description, and identification of the construction materials; and the source mounting configuration(s) to be used with each series type. This information should be provided for each type of material used, such as steel, aluminum, or plastic. The application should include a list of the differences between the models in that series.

NUREG–1556, Volume 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses," contains the design and prototype testing requirements. Acceptable procedures that test for leaking tritium vial sources may include swipe testing as well as brightness, light output, or immersion testing, based on the rates of tritium leakage over a specific time period. Further guidance on exempt distribution licenses can be found in NUREG–1556, Volume 8.

The regulations in 10 CFR 32.25(b) require that each unit is marked or labeled so that the person licensed under 10 CFR 32.22 can be identified. Identification can be the full name of the licensee, its registered trademark, or its exempt distribution license number.

The use of tritium, krypton-85 (Kr-85), and promethium-147 (Pr-147) in toys, novelties, adornments, or similar consumer products is considered a frivolous use of radioactive material. The regulations do not allow issuing registration certificates for such applications or for applications in which the end use of the product cannot be reasonably foreseen [10 CFR 30.19(c) and 10 CFR 32.22(b)]. Although foreign countries may permit the devices to be commercially distributed, such devices cannot be distributed in the U.S., as delineated in the NRC Consumer Products Policy Statement (79 FR 2907; January 16, 2014).

Figure 4-1. Watches and Aiming Sights. *Watches and aiming sights are products distributed to persons exempt from licensing under 10 CFR 30.19, self-luminous products containing tritium, Kr-85, or Pr-147.*

4.2 Gas and Aerosol Detectors Containing Byproduct Material for Use by Persons Exempt From Licensing Requirements

Under 10 CFR 30.20, "Gas and aerosol detectors containing byproduct material" persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued under 10 CFR 32.26, "Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer." Therefore, the requirements for product evaluation are imposed on the person to be licensed to manufacture or initially transfer the product. Specific requirements imposed on the product design that must be addressed during the product evaluation are listed below:

Area To Be Addressed	Applicable 10 CFR Regulations
Design	30.20(a), 32.26[1]

[1]10 CFR 32.26 is applicable to applications to manufacture, process, or produce devices designed to protect health, safety, or property or to initially transfer such products for use under 10 CFR 30.20. Gas and aerosol detectors designed to detect explosives or chemical agents are examples of devices that may be licensed for distribution in accordance with the regulations in 10 CFR 32.26.

Maximum Radiation Levels	32.26(b)(6)
Maximum Dose Commitments	32.26(b)(13) & (14)
Labeling	32.29(b)[2]
Registration	30.20(b)

Further guidance on exempt distribution licenses can be found in NUREG–1556, Volume 8.

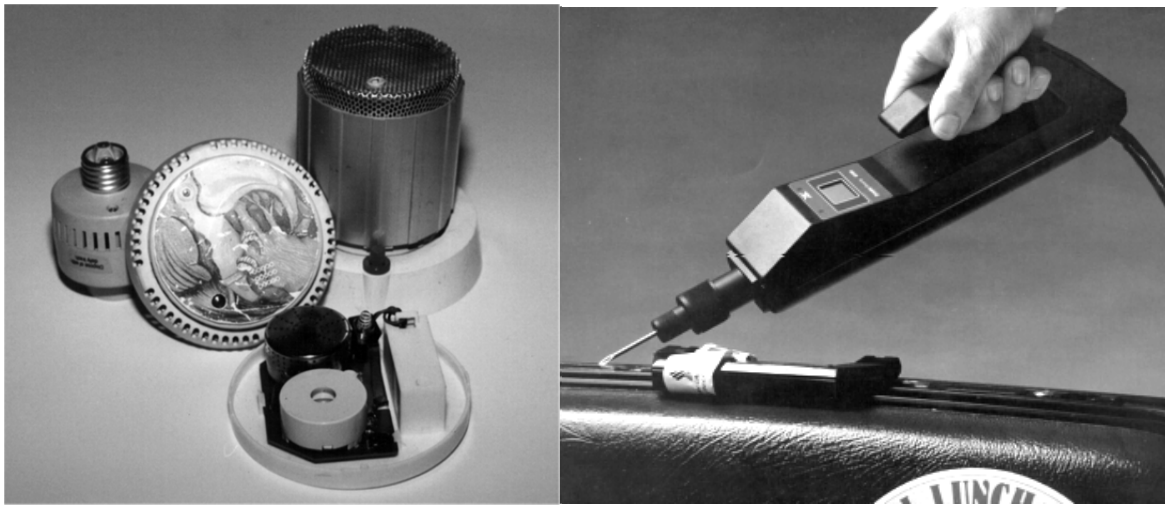

Figure 4-2. Smoke and Chemical Agent Detectors. *Smoke and chemical agent detectors are products distributed to persons exempt from licensing under 10 CFR 30.20, "Gas and aerosol detectors containing byproduct material."*

4.3 Industrial Devices for Use by Persons Exempt From Licensing Requirements

Certain industrial devices are exempt from licensing requirements by the user under 10 CFR 30.22(a). These are industrial 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 an ionized atmosphere. However, manufacturers and distributors of these products need to apply for a license and a sealed source and device registration under 10 CFR 32.30.

Further guidance on exempt distribution licenses can be found in NUREG–1556, Volume 8.

4.4 Devices Used Under the General License in 10 CFR 31.5

Under 10 CFR 31.5, "Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere," persons may use certain devices in accordance with a general license so long as the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.51, "Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture or initially transfer," and 10 CFR 32.51a, "Same: Conditions of license." The devices used under the

[2]10 CFR 32.29(b) requires identification of the person licensed under 10 CFR 32.26. Identification can be the full name of the licensee, the registered trademark, or the NRC exempt distribution license number.

general license include devices designed for the purpose of producing light or an ionized atmosphere or for detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition. The requirements for product evaluation are imposed on the person to be licensed to manufacture or initially transfer the product. Further guidance on general licenses can be found in NUREG–1556, Volume 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licensees Authorizing Distribution to General Licensees." Specific requirements imposed on the product design that must be addressed during the product evaluation are listed below:

Area To Be Addressed	Applicable 10 CFR Regulations
Design	31.5(a), 32.51(a)(2)(i)
Maximum Dose Commitments	32.51(a)(2)(ii) & (iii)
Labeling	32.51(a)(3)
Leak Testing	32.51(b)
Testing and Servicing	32.51(b) & (c)
Installation, Use, and Removal	32.51 (c)
Device Registration	32.51(a)(6)

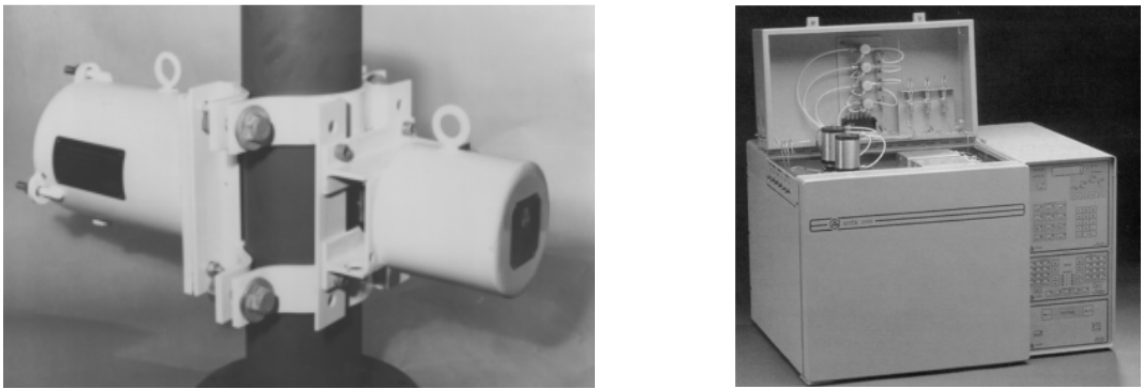

Figure 4-3. 10 CFR 31.5 General License. *Density gauges and gas chromatograph devices are products used under 10 CFR 31.5 general license.*

For generally licensed products containing certain byproduct materials in quantities of concern, the reviewer must be aware that the NRC or Agreement State security requirements are also applicable. The reviewer should include a Reviewer's Note in the device registration regarding the security requirements and should also coordinate the issuance of the registration certificate with the NRC Regional Office or Agreement State licensing staff.

The security requirements apply to the use and transport of International Atomic Energy Agency (IAEA) Category 1 and Category 2 quantities of radioactive material, which the NRC considers to be risk-significant and, therefore, to warrant additional protection. Category 1 and Category 2 thresholds are based on quantity thresholds established in the IAEA Code of Conduct on the Safety and Security of Radioactive Sources. The NRC's security requirements for byproduct material in quantities of concern are in 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

To determine whether the Part 37 requirements are applicable, see the threshold quantities listed in 10 CFR Part 37, Appendix A. The sum of fractions method is to be used to evaluate combinations of multiple sources or multiple radionuclides. Refer to the footnote to Part 37,

Appendix A, Table 1, "Calculations Concerning Multiple Sources or Multiple Radionuclides," for a description of the sum of fractions method and instructions for applying this method.

4.5 Luminous Safety Devices Used in Aircraft Under 10 CFR 31.7

Under 10 CFR 31.7, "Luminous safety devices for use in aircraft," persons may use luminous safety devices containing not more than 10 curies (Ci) of tritium or not more than 300 millicuries (mCi) of Pr-147, in accordance with a general license, so long as the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.53, "Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer." Therefore, the requirements for product evaluation are imposed on the person to be licensed to manufacture or initially transfer the product. Specific requirements imposed on the product design that must be addressed during the product evaluation are listed below:

Area To Be Addressed	Applicable 10 CFR Regulations
Design	32.53(c) & (d)
Prototype Testing[3]	32.53(d)(4)
Units Required for Prototype Testing	32.53(e)
Labeling	32.54
Quality Control	32.55
Registration	32.53(f)

Figure 4-4. 10 CFR 31.7 General License. *Safety devices, such as exit signs, containing tritium or Pr-147 and used in aircraft, may be licensed for use under a 10 CFR 31.7 general license.*

4.6 Ice Detection Devices Containing Strontium-90

Under 10 CFR 31.10, "General license for strontium-90 in ice detection devices," persons may use ice-detection devices containing strontium-90, in accordance with a general license, so long as the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.61, "Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer." Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements imposed on the product design that must be addressed during the product evaluation are listed below:

[3]See NUREG–1556, Volume 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees," for guidance on prototype testing for generally licensed devices under 10 CFR 31.7 or 10 CFR 31.10.

Area To Be Addressed	Applicable 10 CFR Regulations
Design	32.61(c) & (e)
Labeling	32.61(d)
Prototype Testing[4]	32.61(e)(4)
Quality Control	32.61(e)(5), 32.62
Registration	32.61(g)

4.7 Radiography Equipment

Persons specifically licensed to perform industrial radiographic operations are only authorized to use equipment that meets the requirements of 10 CFR Part 34. The vendor or custom user of the equipment may demonstrate that the equipment meets these requirements as part of the evaluation and registration of the equipment. Therefore, during an evaluation of radiography equipment, the items listed below must be addressed:

Area To Be Addressed	Applicable 10 CFR Regulations
Design	34.20(a), 34.22
Source Assemblies	34.20(b)(3)
Transport Containers	34.20(b)(2)
Associated Equipment	34.20(b)(2), 34.20(c)
Leak Testing	34.27
Labeling	34.20
Prototype Testing	34.20
Maximum Radiation Levels	34.20, 34.21

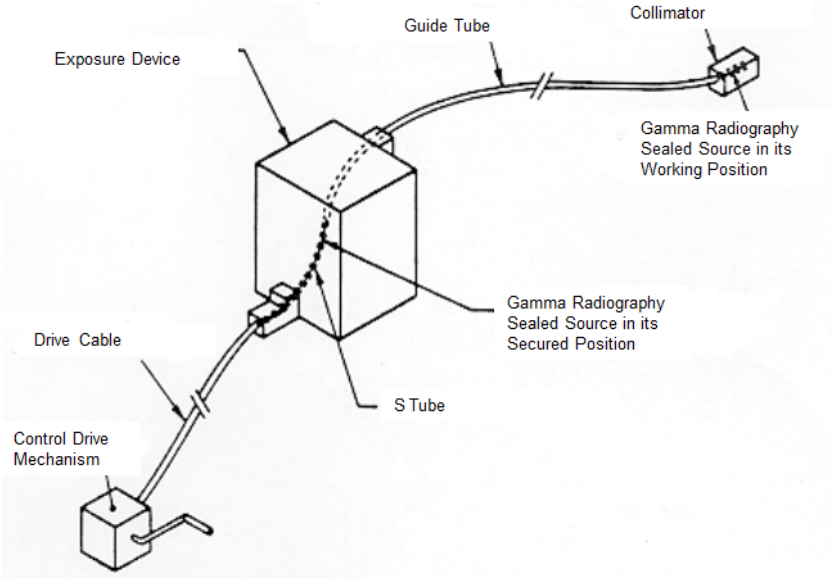

Figure 4-5. Radiography Equipment. *Radiography equipment, such as the equipment shown above, must meet the requirements of 10 CFR Part 34.*

[4]See NUREG–1556, Volume 16, "Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees," for guidance on prototype testing for generally licensed devices under 10 CFR 31.7 or 10 CFR 31.10.

NUREG–1556, Volume 2, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Industrial Radiography Licenses,” provides guidance to an applicant preparing an industrial radiography license application. This guidance also identifies the requirements for the maintenance and inspection of radiography cameras and associated equipment.

There is no requirement to identify associated equipment in an SSD certificate. As a matter of convenience, an SSD applicant may include on the certificate the description of associated equipment that is compatible with the radiographic source or device.

The NRC has discontinued the practice of registering associated equipment, because the agency determined that the Commission’s regulations do not require the registration of associated equipment (see notice published in the *Federal Register*, 68 FR 41757; July 15, 2003).

The regulations in 10 CFR 34.20, “Performance requirements for industrial radiography equipment,” require a licensee to use industrial radiography equipment that has been manufactured and tested to meet radiation safety design and performance criteria in accordance with a national consensus standard [American National Standards Institute (ANSI) N43.9, successor to ANSI N432-1980, which is referenced in 10 CFR 34.20, “Gamma Radiography–Specifications for Design and Testing of Apparatus”]. The life cycle test in the standard is an evaluation of the endurance of a source or device. To test the life cycle of an industrial radiography source or exposure device, all components of the industrial radiography system (including the associated equipment) must be assembled and operated for the duration of the test.

4.8 Well-Logging Equipment

Persons specifically licensed to perform well-logging operations are only authorized to use equipment that meets the requirements of Subpart C, “Equipment,” of 10 CFR Part 39, “Licenses and Radiation Safety Requirements for Well Logging.” For well-logging equipment, only the sealed sources are evaluated and registered, not the logging devices [i.e., logging sources or source holders (bullnoses)]. One requirement is that the licensed material be as insoluble and nondispersible as practicable. The vendor or custom user of the equipment may demonstrate that the equipment meets the requirements as part of the evaluation and registration of the equipment. Further guidance can be found in NUREG–1556 Volume 14, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses.” During an evaluation of well-logging equipment, the items listed below must be addressed:

Area To Be Addressed	Applicable 10 CFR Regulations
Labeling	39.31(a)
Leak Testing	39.35
Design	39.41(a)(1) & (2)
Prototype Testing	39.41(a)(3)

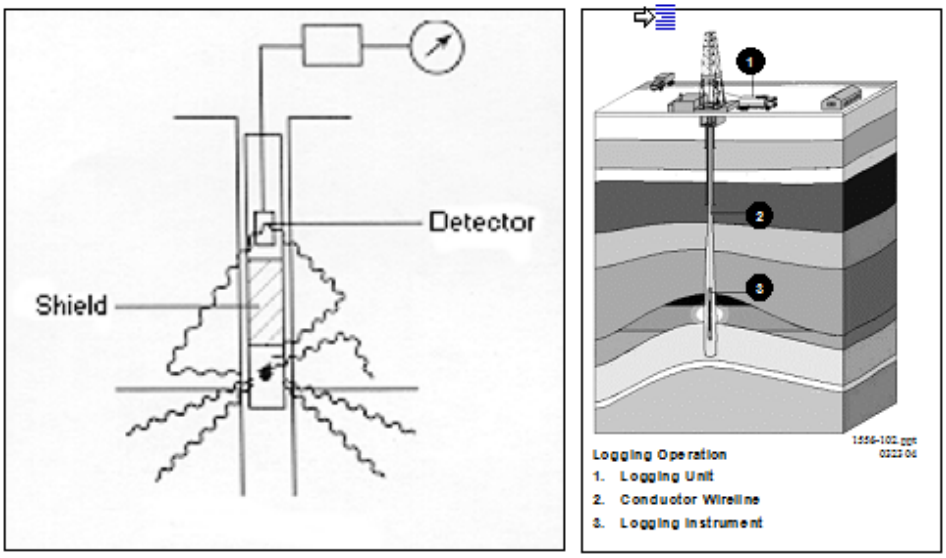

Figure 4-6. Well-Logging Operations. *Sealed sources used in well-logging operations must meet the requirements of 10 CFR Part 39*.

4.9 Irradiators

Irradiators are classified into four different categories. These categories are Category I (self-contained dry source storage), Category II (panoramic dry source storage), Category III (wet source self-contained irradiator), and Category IV (wet source storage panoramic irradiator). Specific ANSI standards to consider when determining irradiator classification and use are outlined in Appendix F.

For example, sealed sources in wet irradiators (ANSI Categories III and IV) must meet the requirements of 10 CFR 36.21, "Performance criteria for sealed sources," in addition to those in 10 CFR 32.210. One such requirement is that the licensed material be as insoluble and nondispersible as practical if used in a wet source storage or wet source change irradiator. The vendor or custom user of the sealed sources may demonstrate that the sealed sources meet the requirements as part of the evaluation and registration of the sealed source. Therefore, during an evaluation of irradiator sources, the items listed below must be addressed:

Area To Be Addressed	Applicable 10 CFR Regulations
Design	36.21(a)(2), (3), & (4)
Leak Testing	36.59
Prototype Testing	36.21(a)(5)

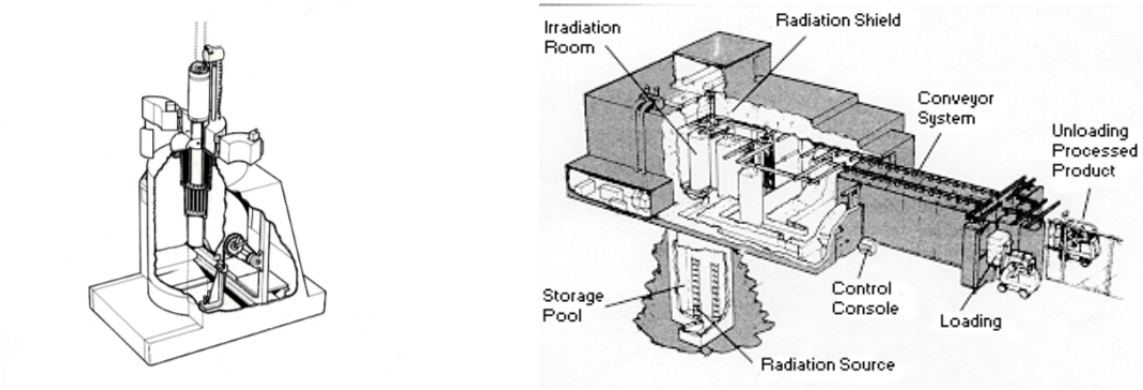

Figure 4-7. Irradiators. *The NRC evaluates Left: (1) Category I (self-shielded) irradiators, both the source and the device, and Right: (2) sealed sources used in Categories II, III, and IV irradiators.*

4.10 Sealed Sources and Devices for Medical Use

Under 10 CFR 35.49, "Suppliers for sealed sources or devices for medical use," only SSDs that are manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," may be used for medical purposes. Sources used in medical applications must also meet the provisions of 10 CFR 32.210. Calibration, transmission, and reference sources in 10 CFR 35.65(a) and 10 CFR 35.65(b) used by medical licensees must also meet the requirements in 10 CFR 32.74. Further guidance can be found in NUREG–1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." During an evaluation of sources for medical uses, the items listed below must be addressed:

Area To Be Addressed	**Applicable 10 CFR Regulations**
Labeling	32.74(a)(2)(viii) & (a)(3)
Leak Testing	32.74(b)
Registration	32.74(a)(4)

Teletherapy sources are an exception to the above requirement. Specifically, teletherapy sources do not need to meet the requirements of 10 CFR 32.74. However, 10 CFR 35.49(c) indicates that these sources do need to be manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30.

Before evaluation of a sealed source or device for medical use, the applicant must provide proof of U.S. Food and Drug Administration (FDA) approval. Sealed sources are evaluated either as part of the medical device or separately when they can be interchanged in several devices. FDA uses the term "device" for both sealed sources and devices.

The NRC will not issue a sealed source and device registration without one of the following four FDA approvals:

(1) Premarket Notification [510(k)]

A 510(k) notification is a premarketing submission made to the FDA to demonstrate that the device to be marketed is safe and effective and is substantially equivalent to other devices currently marketed.

(2) Premarket Approval (PMA)

A PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III[5] medical devices. Class III devices are those that support or sustain human life; are of substantial importance in preventing the impairment of human health; or present a potential, unreasonable risk of illness or injury.

(3) Humanitarian Device Exemption (HDE)

An HDE application is similar in both form and content to a PMA application, but a humanitarian use device is exempt from the effectiveness requirements of a PMA. A humanitarian use device is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the U.S. per year.

(4) Investigational Device Exemption (IDE)

An IDE allows the investigational device to be used in order to collect the safety and effectiveness data required to support a PMA application or a 510(k) submission to the FDA. Either an Internal Review Board (IRB) alone or both an IRB and FDA can approve an IDE.

Manufacturers are not required to have IDE devices reviewed for inclusion in the NSSDR. If an IDE device is not registered, only broad-scope licensees having an IRB may participate in the clinical trials of the device, and they are required to perform their own safety analysis.

In support of the SSD application, applicants should provide the following documentation of FDA review and approval:

- Type of FDA approval [510(k), PMA, HDE, or IDE]
- Sealed source activity for patient treatment approved by FDA (if applicable)
- Any specific conditions or limitations imposed by FDA that users should know

Documentation may consist of a copy of the information provided to FDA for review, or a document with the information issued by FDA. These references are included in the SSD for information only; and therefore, the NRC and Agreement States do not review them.

Class I medical devices (e.g., dose calibration sources, radioactive rulers and markers, nuclear flood source phantoms, as listed in 21 CFR 892) do not require a distributor to obtain premarket clearance from FDA prior to marketing. Such Class I devices are exempt from the 510(k) premarket approval under 21 CFR 807, Subpart E. Therefore, device registrations can be issued in such cases without the FDA premarket approvals listed above. It must be noted that,

[5]The FDA classifies medical devices under its regulations in 21 CFR into three classes: Class I, Class II, and Class III. The device classification will determine the controls and regulations that apply to each class. Device classification depends on the intended use of the device and indications of use.

at times, the distributor does submit a 510(k) submission for Class I devices to the FDA. There may be reasons other than meeting regulations [e.g., the distributor may wish to be able to state that its device has a 510(k) clearance for purely marketing reasons]. In that case, if the distributor submits a 510(k) request to the FDA, the FDA will review the device even though the regulations do not require it. Master Materials Licensees may not perform their own SSD review. A broad-scope permitted under a master materials license may perform its own safety analysis for SSDs for their own use but not for commercial distribution, as described in 10 CFR 33.13(c)(3)(iii).

Section 5.1.2, “Products Used in Research and Development or by Broad Scope Licensees,” of this document contains additional information on broad-scope licenses.

5 GENERAL POLICIES AND PROCEDURES

5.1 Sealed Source and Device Designs That Do Not Require Evaluation and Registration

The provisions of 10 Code of Federal Regulation (CFR) 30.32(g) apply to all sealed sources and devices to be used by the U.S. Nuclear Regulatory Commission (NRC)-specific licensees. Under 10 CFR 32.210, sealed sources and devices (SSDs) must be registered. Exceptions to this are given in 10 CFR 32.210(g). Also, the possession and use of certain products do not require NRC or Agreement State evaluation and registration of the product. This section describes when sources and devices are not required to be registered. In these cases, an alternative evaluation of the safety of the product is made in evaluating the license application.

5.1.1 Calibration and Reference Sources

Calibration and reference sources may be licensed without registration by the NRC or Agreement States if the sources do not exceed the following, as specified in 10 CFR 32.210(g)(1):

- For beta and/or gamma emitting material—37 megabecquerel (MBq) [1 mCi]
- For alpha emitting material—0.37 MBq [10 microcuries (μCi)]

To license these sources, license reviewers need to identify the isotope in Item 6 of the NRC materials license (NRC Form 374), use the statement “calibration or reference sources” in Item 7, and state the maximum quantity for each source in Item 8. Both the possession and distribution of the product to specific licensees may be authorized.

Note that energy compensation sources, when used in the well-logging industry, must meet the requirements of 10 CFR 32.210 [see the provisions of 10 CFR 39.41(f)], even if they have an activity level of less than 37 MBq [1 mCi].

Sources that are below the activity limits but are designed to be used for medical diagnosis will need a safety evaluation. This is in accordance with 10 CFR 35.500, “Use of sealed sources for diagnosis,” which requires that only those sealed sources that are approved in the SSD Registry shall be used for diagnostic purposes.

Calibration and reference sources to be used under the general license in 10 CFR 31.8, “Americium-241 and Radium-226 in the Form of Calibration or Reference Sources,” are not required to be registered.

Some of the byproduct material distributed for use under the exemption in 10 CFR 30.18, “Exempt quantities,” may be used in calibration and reference sources. The manufacture and commercial distribution of these sources are licensed under 10 CFR 32.18, “Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.” These sources are not required to be registered under 10 CFR 32.210.

The NRC does not authorize combining, also referred to as “bundling,” exempt quantity sources in products for commercial distribution under 10 CFR 30.18(e). NRC Generic Letter 99-01, “Recent Nuclear Material Safety and Safeguards Decision on Bundling Exempt Quantities,” dated May 3, 1999, clarifies the NRC’s position on bundling. In some specific applications, the use of multiple calibration sources is permitted, as specified by the provisions of

10 CFR 30.15(a)(9). This use is limited to ionizing radiation instruments with internal calibration or standardization sources. To manufacture and distribute a device with multiple internal calibration sources, the applicant must satisfy the applicable requirements for licensing 10 CFR 32.14, "Certain items containing byproduct material; requirements for license to apply or initially transfer."

Figure 5-1. Calibration and Reference Sources. *Calibration and reference sources may not need NRC or Agreement State registration.*

5.1.2 Products Used in Research and Development or by Broad Scope Licensees

Sealed sources that are intended only for use under research and development or devices containing sealed sources that are intended only for use under research and development or broad-scope licenses need not be registered by the NRC or the Agreement State:

- For unregistered sources or registered sealed sources not possessed and used in accordance with the registration, the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material.

- For registered sealed sources contained in unregistered devices, the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form.

The NRC has granted broad-scope licensees the authority to use SSDs that have been fabricated by or obtained from licensed vendors without prior NRC or Agreement State review and registration. However, broad-scope licensees also have the responsibility for appropriately evaluating the SSD and conducting activities responsibly and safely. For example, for Type A specific licensees of broad scope, 10 CFR 33.13(c)(3)(iii) requires the radiation safety committee to review and approve these safety evaluations. This is especially important with the advent of emerging medical technologies used under 10 CFR Part 35. U.S. Food and Drug Administration (FDA) reviews for medical efficacy of products cannot be substituted for these safety evaluations. The reviews should determine whether a source or device can be used safely from a radiological standpoint and whether adequate radiological protection can be provided for its intended use at the institution. These reviews should be commensurate with the

level of risk that could be reasonably anticipated from the source or device for its intended use and likely accident conditions. The licensee is responsible for performing these reviews; obtaining any necessary design and test information from the vendor; and, if needed, conducting operational tests or other tests to discover and evaluate potential radiation safety hazards.

If a research and development or broad-scope licensee wishes to transfer a SSD to another specific licensee, then the recipient must meet the criteria listed above, or the sealed source or device must be registered in accordance with 10 CFR 32.210. The specific licensee must be in compliance with the licensing requirements in 10 CFR Part 30, prior to transfer.

5.1.3 Custom Sealed Sources or Devices

SSDs containing sealed sources built to the unique specifications of a given user (i.e., custom SSDs) are not required to be sent to the NRC or the Agreement State for registration if (i) they contain less than 7.4 gigabecquerels (GBq) [200 mCi] of radioactive material or less than 740 GBq [20 Ci] of tritium, and (ii) the licensing reviewer has made a determination that the applicant is qualified by training and experience and has adequate facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form [refer to 10 CFR 32.210(g)(2)]. Thus, the applicant would not have to rely on the intrinsic safety of the SSD to demonstrate compliance with 10 CFR 30.33, "General requirements for issuance of specific licenses." Custom SSDs that contain an activity greater than that listed above must be submitted to the NRC or the Agreement State for evaluation and registration.

To license these custom SSDs, license reviewers need to identify the isotope in Item 6 of the material license (NRC Form 374); use the statement "custom source" (for unregistered sources) or "sealed source" (for registered sealed sources), including a unique identifier (e.g., drawing or model number) if possible, in Item 7; and state the maximum quantity of radionuclide, per source or device, in Item 8. In Item 9 (authorized use), license reviewers need to describe, as clearly as possible, the actual use of the custom source or device (e.g., "for use in a Model A analyzer custom built for the licensee by ABC Company in Anytown" or "custom source for use in XYZ Model 100 gauge").

The authorization to use sources or devices of the types described above (that have not been evaluated and registered by the NRC or the Agreement State) applies only to the custom user of the product. Licensees with custom SSDs should inactivate the custom registration, in accordance with Section 13.4, "Transfers to Inactive Status," of this guidance document when the sources or devices are permanently disposed of, placed in permanent storage, or transferred to another licensee that has obtained its own custom registration or that has broad-scope authorization.

Because custom evaluations encompass specific safety features and operating procedures for each location of use, a new custom evaluation must be performed when devices are planned to be transferred to another custom user. The new custom user must provide all the necessary information needed to perform the safety evaluation, prior to receiving the custom device.

5.1.4 Items Containing Byproduct Material Listed in 10 CFR 30.15

Under 10 CFR 30.15, "Certain items containing byproduct material," persons are exempted from licensing requirements for the possession, use, transfer, or ownership of certain specified products. These products must be initially transferred, in accordance with a specific license

issued pursuant to 10 CFR 32.14. Products containing radioactive material to be used under the exemption in 10 CFR 30.15 are not required to undergo a SSD-safety evaluation. Devices qualifying for a product-specific exemption may be distributed without an SSD certificate. 10 CFR 30.15 lists the items for which registration is optional, such as timepieces, marine compasses, electron tubes, and ionization chamber smoke detectors containing not more than 1 µCi of americium-241 (Am-241) per detector in the form of a foil.

5.2 Custom Users

A "custom user" is a user of a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant. Custom users are specifically identified on the first page of registration certificates. Either the custom user or the vendor may make the request for the safety evaluation and registration of the product. Regardless of the applicant, the custom registration is made to unique specifications; therefore, the custom user must meet all commitments made in the application and registration certificate. In some cases, a limited number of different NRC or Agreement State licensees may be custom users of, and may register, the same product. However, a custom user may acquire and/or use more than one product.

5.3 As Low As Is Reasonably Achievable

The NRC's requirements to establish programs, procedures, and engineering controls for achieving doses that are as low as is reasonably achievable (ALARA) are in 10 CFR 20.1101, "Radiation protection programs." Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," explains the NRC's position on this subject. Although these requirements apply to possession and use of radioactive material, applicants should consider the ALARA philosophy when designing and constructing SSDs to avoid unnecessary exposures during installation, maintenance, repair, and use of the SSD. Regulatory Guide 8.10 may be useful to applicants for establishing and following an ALARA philosophy during the design of an SSD.

5.4 Naturally Occurring or Accelerator-Produced Radioactive Material (NARM)

The NRC has jurisdiction over discrete sources of radium-226 (Ra-226), accelerator-produced radioactive materials, and other discrete sources of naturally occurring radioactive material, as required by the Energy Policy Act (EPAct) of 2005. Before enactment of the EPAct, certain States, including non-Agreement States, issued registrations for some SSDs containing Ra-226 or NARM. These registration certificates of SSDs were transitioned from State jurisdiction to NRC jurisdiction.

The NRC should receive all applications for radiation safety evaluation and registration of SSDs that contain NARM. In accordance with the EPAct, the NRC amended the definition of byproduct material under NRC regulations in 10 CFR 30.4, "Definitions," to include Ra-226 sources and NARM. The NRC will perform a review of these SSDs containing these byproduct materials and will issue certificates to manufacturers and distributors in NRC States and certain Agreement States who have not taken over the responsibility for evaluation and registration of SSDs.

5.5 Foreign Vendors

Foreign vendors present a unique situation in that the NRC has no jurisdiction over foreign entities. The provisions of 10 CFR 110.53(a) require a foreign vendor to establish an address in the U.S. to which the NRC can correspond and serve papers, as necessary to accomplish its mission. Accordingly, the NRC accepts applications with a U.S. address from a foreign vendor and issues the registration certificate to the U.S. representative of the foreign vendor. The registration certificate designates the U.S. representative as the distributor of the product and lists the foreign vendor as the manufacturer. Section 10.1, "Summary Information," of this report provides further information on these designations. The U.S. distributor's responsibilities include the implementation of a quality assurance (QA) program to ensure that the imported products are in accordance with the statements made in support of the registration certificates. In addition, the NRC inspects the distributor of the product to determine if the products distributed in the U.S. are in accordance with the statements made in support of the registration certificates.

5.6 Use of International or Foreign Standards

In some cases, an applicant may wish to test a product in accordance with an international or foreign standard. In order for the NRC to find this acceptable, the applicant should first demonstrate, and the reviewer must confirm, that the standard meets or exceeds any specific regulatory requirements (e.g., compliance with ANSI N432-1980 for radiography equipment). To determine if the international or foreign standard is acceptable, the applicant and reviewer should each review the requirements and acceptance criteria of the standard based on the normal and likely accident conditions associated with the use, handling, storage, and transport of the product. The foreign or international standard may be compared with an applicable U.S. standard to determine the acceptability of the standard. The applicant and reviewer may need to exercise professional judgment to make this determination.

If a foreign standard is used, the applicant should submit copies of both the original and English translation of the standard with the application.

5.7 Medical Application—U.S. Food and Drug Administration–NRC Memorandum of Understanding

The FDA and the NRC signed a Memorandum of Understanding (MOU)[1] to coordinate existing FDA and NRC regulatory programs for medical devices, drugs, and biological products that make use of byproduct, source, or special nuclear materials. The principal statute under which the FDA regulates devices is the Federal Food and Drug and Cosmetic Act, as amended by the Safe Medical Devices Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices Act of 1992.

Under the MOU, the agencies agree to promptly inform each other whenever they receive a report or otherwise become aware of any potential public health problems involving products of mutual regulatory concern. Further, the agencies will share information to the extent practicable. For the NRC, this includes information used for product evaluations and approvals and information related to any incidents involving product failures. The NRC should notify the FDA in writing when the NRC begins an evaluation of a medical product, whether it is for a new

[1]The MOU was published in the *Federal Register* on December 23, 2002 (62 FR 15740).

product or for an amendment to an existing product. The notification should include the company, product model number, and the scope of the request. NRC policy precludes the approval of a medical sealed source or device unless the applicant has submitted a copy of the Premarket Approval (PMA) or Form 510(k), issued by the FDA. If the application does not include the PMA or FDA Form 510(k), the applicant will be instructed to contact the FDA and obtain the appropriate approval.

Applicants needing information on the FDA requirements may contact the FDA at the following address:

Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
WO66-4521
Silver Spring, MD 20993
Tel: 800-638-2041 or 301-796-7100

5.8 Computer Software

The NRC safety evaluations concentrate only on those systems that control fundamental safety processes, such as checking an interlock, source, or shielding position and the functionality of position indicators. Software applications that deal with process controls are not part of the product evaluation. The coding of the software is not reviewed independently, but the safety function of the software system is demonstrated by the prototype tests conducted for normal use and likely accident conditions (see Section 10.5, “Prototype Testing”). The reviewer will determine whether, if such systems fail (e.g., a power failure), the sealed source or shielding would return to, or remain in, the fully shielded position.

5.9 Registration Certificate Revocation

Registration certificates may be revoked if (i) the source or device is found to be unsafe for use, (ii) the licensee fails to provide the required registration fees, (iii) the licensee is out of business, or (iv) the NRC finds that the applicant provided false statements regarding the source to the NRC, the FDA, or other government entity.

If it is determined that an SSD evaluated by the issuing agency (NRC or the Agreement State) may pose an undue hazard when used in accordance with the conditions of the registration certificate and that corrective actions cannot be implemented or agreed upon between the registration certificate holder and the issuing agency, then the issuing agency may modify or remove the registration certificate from the National Sealed Source and Device Registry (NSSDR) and may issue orders modifying licenses to all persons licensed to use the SSD. In such a case, the NRC will remove the active registration certificate from the NSSDR and replace it with an inactive registration certificate. The NRC staff will notify the Agreement States to make them aware of the NRC’s actions concerning the SSD.

5.10 Incidents and Defects

The NRC assesses incidents and defects involving products evaluated and registered by the NRC to determine whether the integrity or adequacy of the product was compromised. The assessment involves a re-evaluation of the product to determine its integrity and adequacy, taking into account the causes of the incident or defect. If the NRC determines that a generic

product fault exists, it will notify the registration certificate holder and take appropriate actions, affecting both products currently in use and newly manufactured products. In addition, the NRC will re-evaluate similar products to ensure that they are not susceptible to the same type of faults.

Usually, incidents caused by abnormal or unauthorized use of the product would be considered licensing issues and would not require a re-evaluation of the product. Instead, a review of the user of the product would be initiated.

The NRC keeps on file certain information concerning incidents involving products evaluated by the agency for use in performing future evaluations of the products involved and products similar to those involved.

Regarding failures to comply with the terms of the registration certificates or the existence of a defect, the provisions of 10 CFR 21.21, "Notification of failure to comply or existence of a defect and its evaluation," apply. Specifically, failures and defects must be reported to the NRC and, if required, to the Agreement State (not all Agreement States have this requirement). The Office of Nuclear Security and Incident Response is the NRC office responsible for receiving, compiling, and distributing incident reports to the appropriate NRC Office. The NRC staff will conduct a safety evaluation of the failure or defect in a manner similar to the process described above for incidents.

Furthermore, the NRC has established a database to collect information on incidents, failures, and defects involving radioactive materials. This database is the Nuclear Material Events Database (NMED). The Office of Nuclear Material Safety and Safeguards (NMSS) is the responsible office for adding the data to NMED.

5.11 Proprietary Information

The NRC may make available to the public registration certificates and information, such as applications, contained in the background files for the registration certificates. Persons may request access to this information in accordance with 10 CFR 9.23, "Requests for Records."

An application should not include proprietary information (i.e., information not to be disclosed to the public) unless it is the only means to adequately describe the radiation safety properties of the product. If an application contains information marked as "proprietary," "confidential," "restricted," or "is the express property of Company X," the reviewer needs to determine whether the information is necessary to perform the safety evaluation. If the information is not necessary, it should be returned to the applicant.

If the information is necessary, the reviewer needs to ensure that the applicant has submitted a formal request for withholding the information, in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." The applicant must request withholding at the time it submits the document and must comply with the document marking and affidavit requirements in 10 CFR 2.390. The reviewer needs to evaluate the applicant's request for withholding against the requirements in 10 CFR 2.390. Appendix E to this report includes a checklist for reviewing requests for withholding information from public disclosure.

If the request is rejected, in whole or in part, the reviewer needs to give the applicant the option to withdraw the information or application. If the applicant decides not to withdraw the information or application, the reviewer needs to notify the applicant in writing that the request

for withholding has been rejected and that the reviewer will disregard any references concerning the proprietary status of the information.

Any part of the application that the reviewer has determined should be withheld from public disclosure should be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program," and the applicant should be notified in writing that the NRC plans to honor the request. However, the notification needs to inform the applicant that the NRC may have cause to review the determination in the future if, for example, the scope of a Freedom of Information Act request includes the information. In all review situations, if the NRC needs additional information from the applicant or makes a determination adverse to the initial determination, the applicant will be notified in advance of any public disclosure.

Further guidance for withholding proprietary information from public disclosure is available in NRC Information Notice 2009-07, "Withholding Proprietary Information from Public Disclosure."

5.12 Identifying and Protecting Sensitive Information

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

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

- **Proprietary Information/Trade Secrets**: See Section 5.11, "Proprietary Information." Failure to follow the guidance in Section 5.11 could result in disclosure of the proprietary information to the public or substantial delays in processing the application.

- **Personally Identifiable Information**: Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice 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—Withhold Under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 22, 2005, which can be found on the NRC's Generic Communications webpage under "Regulatory Issue Summaries": http://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Additional information on procedures and any updates is available at http://www.nrc.gov/reading-rm/sensitive-info.html.

5.13 Transportation

This document does not cover detailed requirements for the transportation of devices and sealed sources. The NRC's transportation requirements are established in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." An application for radiation safety evaluation and registration of a SSD, as discussed in this document, does not include a detailed description of packaging and transportation procedures to demonstrate compliance with 10 CFR Part 71.

Any vendor who has questions about the specific requirements for transportation should contact the appropriate NRC Region or the NRC's Inspection and Operations Branch, Division of Spent Fuel Management, at (301) 415-7000, to obtain assistance. Any person involved in the transportation of any NRC-licensed radioactive material package must comply with the applicable regulations of the U.S. Department of Transportation (DOT) in 49 CFR, "Transportation." Certificates of Compliance for Type B transportation packages can be found at http://www.rampac.energy.gov. The DOT approves applications for Special Form Certificates.

Although neither the NRC nor Agreement States evaluate packaging or transportation requirements during SSD evaluations, the evaluation does consider the effects of the packaging or transportation on the normal use and operation of the product. Specifically, the NRC or the Agreement State evaluates the effects of normal conditions experienced during transport (e.g., extreme temperatures, vibration) on the SSD. Applicants should consider these effects when designing the products and packaging for transport.

The packaging certification requirements for Type A packages are ultimately placed on the shipper in accordance with 49 CFR Part 173, "Shippers—General Requirements for Shipments and Packagings," Subpart I, "Class 7 (Radioactive) Materials." The device registration may include this information. The NRC evaluates Type B packages separately.

6 HOW TO FILE

No special form is required for applications for sealed source or device (SSD) evaluations. However, to facilitate the review process, applicants for an SSD evaluation are encouraged to follow the instructions in this chapter.

6.1 General/Format

To standardize the format of an application for an SSD, applicants are encouraged to perform the following steps:

- Review the applicable regulations and use the most recent guidance, including this document, in preparing an application.

- Submit all documents, including all drawings if practicable, printed on standard 8-1/2 inch × 11 inch or legal paper. If the submission of larger documents is necessary, the documents should be folded to 8-1/2 inches × 11 inches.

- Number all pages in an application, consecutively. If revisions are necessary after an application has been submitted, submit revised or replacement pages that show the date of the revision or the revision number. Indicate supplemental pages submitted for insertion alphanumerically (e.g., 12a, 12b).

- Submit an original, signed application. Include an electronic copy when feasible. Retain a copy of the registration application for future reference.

6.2 Content

To standardize the content of an application for an SSD, applicants are encouraged to perform the following steps:

- Complete the “Summary Data” section of the form in Appendix A of this report.

- Attach the application to the “Summary Data” information. The order of the information in the application should correspond to the appropriate subsection in Chapter 10, “Application and Review Process,” of this report.

- Use the checklist included in Appendix A as a guide to determine whether all necessary information has been provided.

- Include drawings that are suitable for inclusion in the registration certificate and that provide an overall representation of the product and its safety features. The U.S. Nuclear Regulatory Commission (NRC) and the Agreement States prefer both paper copies and electronic versions of the labels, diagrams, and photographs that are intended for insertion into the registration certificate.

- Identify drawings, descriptive sales literature, or similar documents when they are submitted as part of an application, such as by marking the materials individually and listing them on a cover sheet for the application or listing them as enclosures to the letter that transmits the application.

- Submit a copy of the user operating manual and safety instructions. In accordance with 10 CFR 32.210(c), these documents should provide the end user with sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

- Identify the safety-related components and assembly methods used to contain and shield the source of radiation. Submit the engineering drawings as identified in Section 6.3, "Engineering Drawings."

- Address the safety-related items in the applicant's QA/Quality Control program to identify potential defects or noncompliance during the fabrication process.

- Avoid submitting proprietary information unless it is absolutely necessary. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.390 and see Section 5.11, "Proprietary Information," of this document for additional details.

- Include a clear, concise presentation of the information necessary for the evaluation, avoiding ambiguous and conflicting statements and wordy descriptions that do not contribute to a technical review.

- Use terms in the application as they are defined in NRC regulations and national consensus standards, as applicable. Define all abbreviations and acronyms.

6.3 Engineering Drawings

The engineering drawings that are submitted with an application should include safety-related details; they should not be fabrication-level drawings. The drawings should include the following details:

- A drawing number, revision number, company name, title, scale, and date, clearly indicating references to parts or other drawings and whether drawings have been reduced or enlarged.

- One or several isometric projection diagrams showing components pertinent to radiation safety, such as shielding material, shielding thickness, on/off mechanisms and indicators, label location, and assembly methods.

- Source mounting and safety features, dimensions, tolerances, and a list of materials of construction. The diagrams may be included in the SSD registration certificate.

- Overall details of the safety-related components (e.g., outer housing, secondary shielding, C-frames, and environmental control systems).

- Complete details for safety-related components (e.g., primary containment, primary shielding, safety features, regulatory requirements).

- Materials of construction [e.g., raw materials, manufactured components, dimensions/tolerances, assembly methods (welds, bolts, screws), and manufacturing/production processes].

- Data sheets on the chemical, physical, and mechanical properties of materials with a foreign designation.
- Function/operation of the product.
- Safety features (e.g., return springs, interlocks).
- On/Off mechanisms and indicators.
- Source containment and shielding, including movement (e.g., shutters, movable source).
- Installation and mounting (including whether the device is fixed, mobile, or portable).
- Air gaps that could allow radiation exposures and barriers/guards (accessibility of the radiation beam during use).
- Tamper-resistant construction/hardware.

Engineering drawings should be in English. To facilitate preparing an application on a product manufactured outside the U.S., the applicant may elect to write or otherwise affix the English translation directly on an engineering drawing.

It may be advantageous to submit the product (without radioactive material) or a part of the product with the application. For example, a vendor of radiography equipment may elect to submit a "pigtail" connector (used to join the source assembly to the drive cable) as a means of clarifying the related engineering drawings and operating instructions. Large pieces of equipment should not be submitted because of handling and storage limitations at the NRC offices.

If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.390 and see Section 5.11, "Proprietary Information," of this document for additional details.

6.4 Transfer to Electronic Format

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

- Submit printed or typewritten—not handwritten—text on smooth, crisp paper that will feed easily into the scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura.
- Use an 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 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 WHERE TO FILE

Applicants located in States or territories subject to the U.S. Nuclear Regulatory Commission (NRC) jurisdiction wishing to register a sealed source or device (SSD) may file an application with the NRC by submitting the application to the following address:

U.S. Nuclear Regulatory Commission
Materials Safety Licensing Branch
Office of Nuclear Material Safety and Safeguards
ATTN: SSDR
Washington, DC 20555-0001

Please note that the above address is different from that of the appropriate NRC Region to which persons would apply for authority to possess and use radioactive material under a manufacturing and distribution license.

The above address cannot accept mail requiring the receiver's signature (e.g., express mail). Mail requiring the receiver's signature should be sent to the following address:

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Division of Material Safety, State, Tribal, and Rulemaking Programs
Materials Safety Licensing Branch
Two White Flint North
11545 Rockville Pike
North Bethesda, MD 20852-2738

Applicants in locations subject to Agreement State jurisdiction who wish to apply for safety evaluation and registration of an SSD should file the application with the appropriate Agreement State agency, not the NRC. However, some Agreement States do not issue registration certificates. Chapter 2, "Agreement States," of this report identifies which Agreement States do not issue registration certificates. In those cases, submit applications to register an SSD with the NRC at the address identified above.

8 REGISTRATION FEES

Each application for which a fee is specified must be accompanied by the appropriate fee, including applications for new registration certificates. Refer to 10 *Code of Federation* (10 CFR) 170.31, "Schedules 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 the registration certificate until the fee payment 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. Currently, no fees are required for amendments of registration certificates.

Most NRC registration certificate holders are also subject to annual fees; refer to 10 CFR 171.16, "Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC." Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for registration certificate holders 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 to the Office of the Chief Financial Officer at NRC Headquarters in Rockville, Maryland, (301) 415-7554. Information about fees may also be obtained by calling NRC's toll free number, (800) 368-5642, extension 415-7554. The e-mail address is Fees.Resource@nrc.gov.

9 DOCUMENT FLOW

9.1 Application Receipt and Assignment to a Reviewer

Applicants usually submit requests for safety evaluations of sealed sources or devices (SSD) directly to the Office of Nuclear Material Safety and Safeguards (NMSS)/ Material Safety, State, Tribal, and Rulemaking (MSTR) or the Agreement State. However, applications may be submitted to other U.S. Nuclear Regulatory Commission (NRC) divisions or offices (e.g., as part of a licensing action) and forwarded to MSTR as a technical assistance request. For example, the NRC Regions and other divisions within NMSS may receive requests as part of a license request, or the Office of the Chief Financial Officer (OCFO) may receive a request to make a registration certificate inactive. The processing of the application is the same in all cases.

The NRC staff submitting technical assistance requests concerning SSD issues to MSTR should follow the procedures in NUREG–1556, Volume 20, "Guidance About Administrative Licensing Procedures."

When the NRC or the Agreement State receives an application, an acceptance review is performed to determine whether the application contains sufficient information to initiate a more thorough review. If the information is not sufficient, the entire package may be returned to the applicant for resubmission of a complete application.

As specified by the internal procedures of the NRC, applications are logged into the SSD action tracking system to await assignment to a reviewer. Each action receives a unique tracking number. Assignment to a reviewer is determined on a first-in basis. An application may be assigned a higher priority, based on the following considerations: (i) whether there is a dire need for the product to protect public health and safety; (ii) whether the product would provide a currently unavailable benefit to society; or (iii) whether commercial hardship is likely to be experienced by the applicant if the evaluation process is delayed. Requests for higher priority should include adequate justification for why the application should be assigned a higher priority.

While an application is awaiting assignment to an NRC reviewer, OCFO receives copies of the cover letter to the application and of NRC Form 567 for verification that the appropriate application fees have been received. OCFO will return NRC Form 567 to MSTR indicating whether the appropriate fees have been collected. MSTR may start an evaluation of a SSD before fees are collected; however, the NRC will not issue final approval of the product until the application fees are paid in full.

9.2 Expedited Reviews

9.2.1 NRC-Expedited Reviews on the Basis of National Security

The NRC will give an application high priority and expedite the review if the product or device is necessary for protecting national security. The following five criteria should be met for a review to be expedited:

(1) The U.S. military or a Federal agency (e.g., U.S. Customs and Border Protection, Federal law enforcement agencies) makes a request for expedited review directly to the NRC.

(2) The appropriate agency official makes a request in writing (e-mail is acceptable) to the appropriate Branch Chief or higher-level management.

(3) The requesting agency should state that national security is at stake and briefly, and in general terms, describe the use of the product. A detailed description that could disclose sensitive information is not necessary. The NRC will expedite the review for security reasons, not for business reasons.

(4) There is no alternative product, an alternative product would be too costly, or the pursuit of an alternative product would result in significant setbacks to plans or schedules.

(5) The requesting agency commits to providing the necessary oversight of the applicant to ensure both of the following:

a. The application is of sufficient quality and provides the necessary information to support an expedited review.

b. The applicant is responsive to NRC requests for information.

In conducting the expedited review, NRC reviewers should be able to conclude, with reasonable assurance, that regulatory requirements are met. However, the rigor of the review should be commensurate with the risk that the product poses to public health and safety. The reviewer should exercise engineering judgment in determining that the product is safe and does not pose a risk to public health and safety.

9.2.2 NRC-Expedited Reviews for Reasons Other Than National Security

An application may be assigned a higher priority upon request. Requests for higher priority should include adequate justification, as indicated. The company president or chief executive officer of the applicant should make the request in writing to the appropriate NRC manager and include the following information:

- If the justification for expedited review is the dire need for the product to protect public health and safety, the request should indicate that the product provides a currently unavailable benefit to society. The applicant should provide details of the need, including (i) who directly benefits from the use of the product, (ii) how they benefit, (iii) how existing products fail to provide that benefit, (iv) why the review must be accomplished in less than the normal review time, and (v) when the product is needed.

- If the justification for expedited review is commercial hardship, the request should describe the commercial hardship that the applicant is likely to experience if the evaluation process is delayed. The applicant should provide details of the hardship, including (i) who is affected by the hardship, (ii) how they are affected (e.g., bankruptcy, layoffs) and why completion of the action is the only way to avoid that effect, (iii) why the review should be accomplished in less than the normal review time, and (iv) when it is needed.

9.3 Responsibilities of the Reviewer

The reviewer is responsible for performing the technical evaluation of the product; ensuring that the product meets all applicable standards and regulations; corresponding with the applicant to

obtain additional information, if necessary; generating the registration certificate; and ensuring that the application is reviewed and signed by two persons having signatory authority. In addition, the reviewer needs to identify any complex policy issues and bring them to management's attention.

In some cases, the adequacy of an element of the product design may not be readily evident. As a result, the reviewer may need to exercise professional judgment about the adequacy and safety of the product design. The reviewer should discuss such judgment with the applicant and document it in a note to the registration file.

Once the evaluation is complete and if a registration certificate is issued, the reviewer should send a copy of the registration certificate to the applicant. The reviewer should forward the registration certificate (including a cover letter to the applicant and a technical assistance request response, if applicable) and all information used in support of the evaluation to the registration assistant for distribution and filing.

Chapter 2, "Agreement States," of this report discusses the NRC's role in the review of Agreement State registration certificates.

9.4 Inclusion in the Sealed Source and Device Computerized Registration System

All newly issued registration certificates are submitted by the issuing agency to the NRC to be added to the National Sealed Source and Device Registry. Once in the system, certificate information can be located by searching on any item that is included in the certificate (see Section 12.2, "First Page Information," of this report). The NMSS Web site contains the registrations at http://nrc-stp.ornl.gov/ssdr.html. Access to the computerized registration system is limited to the NRC and select Agreement State staff for licensing and inspection activities.

Members of the public, who need a copy of the registration certificate, should contact the manufacturer/distributor of the SSD.

10 APPLICATION AND REVIEW PROCESS

Applicants requesting safety evaluations should use the items discussed in this chapter to verify that the application has sufficient information for the reviewers to determine whether the design of the product is adequate for its proposed uses.

Applicants are encouraged to follow the instructions in Chapter 6, "How to File," and use Appendix A to this report as a guideline when submitting applications. Applicants may complete the "Summary Data" section of the form in Appendix A and use the checklist in the appendix to ensure that they have addressed all items listed in this chapter. The balance of the application should be attached to the copy of the form in the appendix. Reviewers may opt to use the checklist to verify that the applicant has addressed all items listed in this chapter.

Note that certain regulations include specific requirements applicable to the evaluation and registration of products. Chapter 4, "Applicable Regulations," lists these regulations, and each regulation also is listed at the end of the applicable topic discussion in this chapter. The regulatory requirements take precedence over the general guidance provided in this document. Applicants must ensure, and reviewers must verify, that all regulatory requirements are met.

The checklist in Appendix A is not considered an all-inclusive review document. It is designed to highlight important aspects of the application. Further detail on and review of specific areas of the application may be necessary.

10.1 Summary Information

10.1.1 Manufacturer and Distributor

Applications must include the complete names and addresses of both the manufacturer and distributor of the product. The same person may be both the manufacturer and the distributor. However, if different, the distributor should apply for the evaluation. The distributor will be responsible for meeting the requirements associated with the registration, whether the information is supplied by the distributor or by the manufacturer on behalf of the distributor.

In some cases, a manufacturer may distribute the product(s) through more than one distributor. Foreign manufacturers may also use more than one distributor for marketing their products in the U.S. In such cases, the U.S. Nuclear Regulatory Commission (NRC) issues a separate vendor code and registration certificate to each of the distributors in order to distinguish between them and maintain traceability of the product(s). Appendix B to this report provides further details on vendor codes. The reviewer should obtain a commitment from the distributor that each product will be distributed with a unique serial number.

Distribution activities are normally classified as either "distribution" or "redistribution." "Distribution" applies to those sealed sources or devices (SSD) initially manufactured or transferred (or both), under 10 CFR Part 32 or under equivalent Agreement State requirements, by the manufacturer for use or resale. Distribution requires evaluation and registration of the product according to the guidance in this document. "Redistribution" refers to those materials received from the initial manufacturer/distributor and transferred to another person licensed to possess the product without any alteration of the product, labeling, packaging, or other contents. Redistribution generally does not require a separate evaluation/registration of the product, because no alteration to the product occurs with this authorization. If a person wishes to alter the design, labeling, packaging, or other contents of the package, or if one wishes to refurbish

existing devices that have been previously registered, the person must obtain specific approval from the NRC in the form of a specific license and separate evaluation/registration of the SSD.

For redistribution of SSDs, the reviewer should confirm the following:

- SSDs to be redistributed will be obtained from a person licensed, pursuant to 10 CFR 30.41, "Transfer of byproduct material," 10 CFR 32.74, or under equivalent Agreement State requirements, to initially distribute such sources.

- The original design, labeling, packaging, and other contents will not be altered, and redistributed products will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or any other document that provides radiation safety instructions for handling and storing the product.

Remanufactured products, or products with replacement parts identical to the original, can only be distributed under the registration certificate if they are in conformance with the statements and commitments made in support of the registration certificate. When the remanufacturing process introduces components or fabrication methods that differ from those that were used for the issuance of the registration certificate, the licensee must request an amendment of the registration certificate or apply for another registration.

10.1.2 Custom User

Applications should indicate whether the product is intended for use by a custom user. The custom user must be identified by name and complete address. Section 5.2, "Custom Users," provides additional information on custom users.

A product specifically designed and constructed to the order of a single licensee may be considered a custom product. Because there is a single user of the product, the NRC can appropriately consider specific departures from accepted standards from the point of view of compensating qualifications or conditions of use for the particular licensee. Usually, these departures occur in the areas of prototype testing and quality control (QC) procedures.

10.1.3 Other Companies Involved

The application should include the name, complete mailing address, and function of all other companies involved in the manufacture and distribution of the product.

10.1.4 Model Number, Sealed Source or Device Type, and Principal Use Code

The regulations in 10 CFR 30.32(g)(1) require the licensee to identify the source or device by manufacturer and model number, as registered under 10 CFR 32.210. For this reason, the application must clearly state the model number designation for the product. This model number will be listed on the registration certificate for the product and may be listed on licenses of persons applying to use the product. The NRC and Agreement States use the model number to uniquely identify the product.

An applicant may request to have a model listed as a series. In order to have the model 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 source or device series

that contain overall dimensions, maximum and minimum dimensions, tolerances, materials of construction, and differences between models in the series.

The application needs to identify the SSD type as used by the industry (e.g., a level gauge, radiography device, self-shielded irradiator, teletherapy unit) and the principal use code that most accurately describes the product. Appendix C to this report lists principal use codes. This information assists applicants and reviewers in determining the applicable regulations, codes, and standards that affect product registration. The application also must identify whether the device is intended to be used under a specific license, general license, either a specific or general license, or by persons exempt from licensing requirements. If applicable, the applicant and reviewer need to determine which general license or exemption applies for possession and use of the product. The applicant must provide the information needed to make this determination. Section 10.2, "Conditions of Use," discusses this further and addresses the product's conditions of use.

10.1.5 Radionuclides Used in the Product

The applicant must identify all radionuclides that will be used in the product and include the maximum requested activity for each, including loading tolerance. The application must also include the form of the byproduct material, including contaminates or impurities, if applicable. Applicants need not provide information on contaminates or impurities that have little effect on the radiation levels from the sealed source or on how the sealed source will react under extreme environmental conditions.

For evaluations of devices, the applicant must identify whether the associated sealed source is currently registered. If so, the applicant must identify the model number designation and the manufacturer or distributor of the sealed source, as listed on the registration certificate for the sealed source.

10.1.6 Registration of Sources as Part of a Device

If the sealed source is not currently registered, the sealed source must be registered separately or as part of the device. In either case, the applicant must submit sufficient information to register the sealed source, and the reviewer must perform a complete evaluation of the sealed source. If the sealed source is registered as part of the device, the registration certificate for the device should note that the sealed source is not registered separately, is registered as part of the device, and is approved only for use in the device.

10.1.7 Leak Test Frequency

The applicant must provide the maximum time interval between leak tests to be performed on the product. Typically, products must be leak tested at intervals not to exceed 6 months. Leak test procedures must be capable of detecting the presence of 185 becquerels (Bq) [0.005 µCi] of removable contamination.

Products containing only krypton-85, hydrogen-3 (tritium), radioactive gas, isotopes with half-lives of 30 days or less, beta- or gamma-emitting material of no more than 3.7 MBq [100 µCi], or alpha-emitting material of no more than 370 kilobecquerels [10 µCi] are exempt from periodic leak testing requirements. However, a leak test should be performed before initial distribution of the product.

Devices may be approved with leak test intervals greater than 6 months if sufficient information (i.e., operational history, leak test history) is submitted to justify such a request. The regulations should be referenced for additional information about leak testing (Table 10-1).

10.1.8 Certification and Signature of a Management Representative

Individuals acting in a private capacity are required to date and sign the application. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the application. Representatives signing an 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 and responsibilities for the regulatory requirements. The NRC will return all unsigned applications for a proper signature.

All representations made in the application are considered commitments for the manufacturing and distribution of the product. Therefore, those items become part of the manufacturing/distribution license conditions and are subject to regulatory requirements.

10.2 Conditions of Use

The applicant must address, and the reviewer must evaluate, the issues listed under 10 CFR 32.210 (c) and (d), such as the intended use and users of the product and which standards, policies, and regulations are applicable. Applicable standards or regulations may specify prototype testing, labeling, design, maximum external radiation levels, maximum dose commitments, quality assurance (QA)/quality control (QC), or leak testing requirements.

The discussion on the intended use of the product should describe the types of users, the locations of use, the occasions when persons will be near the device and the frequency of these occasions, and the possibility that the device may be used as a component in other products.

The applicant and reviewer must also evaluate the likely environments to which the product will be subjected during normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during use, handling, storage, and transportation (extremes experienced during accident conditions during transportation need not be considered). The applicant and reviewer need to evaluate whether the product will be subject to extreme conditions of corrosion, vibration, impact, puncture, compressive loads, explosion, flooding, poor air quality, excessive high or low temperatures, change in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.

The applicant should provide the estimated working life of the product in terms of time, operational cycles, or other applicable limiting conditions. The reviewer should conduct a safety and risk study of the product's estimated working life to determine whether the estimate is justified based on the information submitted. Inclusion of the working life of the product is important because the working life provides an indication of when servicing or re-evaluation of product integrity may be necessary.

Table 10-1. Leak Testing Requirements

Regulations	Applicability
10 CFR 32.51(b) 10 CFR 31.5(c)(2)–(4)	Devices used under the 10 CFR 31.5 general license
10 CFR 34.27	Sources and devices designed for use in radiography operations

Table 10-1. Leak Testing Requirements	
Regulations	**Applicability**
10 CFR 39.35	Sources used in well-logging operations
10 CFR 36.59	Irradiator operations
10 CFR 35.67(f)(1)-(5)	Brachytherapy sources for medical use
10 CFR 32.74(b)	Sources or devices for medical use

10.3 Construction of the Product

Applicants need to describe construction aspects of the product, including components of the product, materials of construction, dimensions, assembly methods, source containment and shielding, and operation of the product and its safety features. The application should include a brief written description and summary of the construction aspects as well as specific, detailed descriptive data such as engineering drawings and product specification sheets.

The brief written description and summary of the construction aspects should include information on the following:

- Overall operation of the product
- Identification of primary components and safety features
- Type of installation, including method of attachment to its mounting if installed in a fixed location and the means of relocation if portable
- Primary construction materials used for the product's structure and integrity and for its safety features
- Accessibility of the radiation beam during use
- Means of providing containment, radiation safety, and shielding of the radiation source, including shutters or other movable shielding
- Location and operation of on/off or shielded/exposed indicators
- Identification of other design features that protect the product from abuse or tampering

The identification of the product's components and safety features should include a description of the purpose, function, and operation of each. An overall drawing of the product, identifying primary components and safety features and indicating overall dimensions, is useful as a complement to the written description of the product and for providing an understanding of the operation of the product.

Detailed design and construction data should be sufficient to allow the reviewer to fully understand the construction and operation of the product and its components and safety features and to evaluate the product's safety and integrity. This should include detailed written descriptions, complete annotated engineering designs, and/or construction drawings of all safety-related components, specification sheets, and materials lists. The applicant should

describe in detail the mounting and integrity of the radioactive material or sealed source in the product.

Drawings of safety-related parts and components should (1) be fully dimensioned with tolerances, (2) include identification of the safety-related parts, (3) indicate the materials of construction or refer to a materials specification sheet or list, (4) indicate fabrication and assembly methods, and (5) include a drawing number and revision date or number. Parts related to safety include those parts or components that provide primary containment, safety, and shielding of the radioactive material or sealed source. Applicants should also provide drawings and descriptions of nonsafety-related components and parts that contribute to the product's safety or integrity or both. These drawings should include sufficient descriptive information to determine how the components contribute to the safety and/or integrity of the product, how the component is integrated with other components of the product, and whether the nonsafety-related components could degrade the effectiveness or usefulness of safety-related components.

The applicant should describe all special design features that protect the product from abuse, control the hazard from direct or scattered radiation, and discourage unauthorized access to the source. The application should address accessibility of the radiation beam during use, including the size of openings or air gaps that could allow any part of a human body to enter the radiation beam, and any protective measures, additional guards, or installation requirements designed to prevent accessibility of the radiation beam during use.

The reviewer must evaluate how the product is constructed and its integrity. The reviewer must be able to determine the construction of the product from the drawings and written description provided with the application. During the evaluation of product integrity, the reviewer needs to ensure the following:

- The assembly methods (e.g., welds, bolts, screws), including size, materials, and spacing, and materials of construction of the device are sufficient to withstand normal use and likely accident conditions. These include being subjected to corrosive environments, vibration, impact, puncture, compressive loads, explosion, flooding, excessive high or low temperatures, drastic changes in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.

- If construction includes the use of dissimilar materials, that the materials are compatible and corrosion is not likely to occur from contact between the unlike materials (e.g., corrosion is likely when you have direct contact between aluminum and steel, or depleted uranium and steel). In addition, the materials will not cause corrosive environments without direct contact (e.g., Teflon can break down when subjected to radiation and cause a corrosive environment for certain metals).

- Exposure to radiation and to the expected conditions of use will not be detrimental to the materials of construction (e.g., adhesives, lubricants, and gaskets).

- The assembly methods will have no detrimental effects on the product during its fabrication (e.g., heat from welding a holder directly to the sealed source, securing the sealed source by tightening a screw or bolt against the wall of the sealed source).

- The fixed shielding will not move nor easily become dislodged from the device.

- The mounting of the sealed source is such that the sealed source will not unintentionally move during use nor become dislodged from the device, and the mounting sufficiently secures the sealed source against access by unauthorized users.

- All moving parts have adequate spacing to ensure that they will not bind during use. The tolerances of the spacing between the parts should be such that likely changes (e.g., from bending, temperature changes causing expansion or contraction, introduction of foreign materials) will not cause binding that may lead to unintentional exposure of the source.

- The device can be locked in the closed condition (source fully shielded) and cannot be locked in the open condition, if applicable.

- The device contains indicators that clearly identify whether the source shielding is in the open or closed position. If colors are used to identify the open or closed conditions, red should be used for the open condition where exposure could occur and green should be used for the closed condition where the source is “safe” in the shielded position.

- Sufficient safety interlocks, barriers, or guards are included to prevent access to the radiation beam and to prevent exposures in excess of those specified in the regulations (the inclusion of barriers or guards should be included as reviewer notes to alert license reviewers).

- If pneumatic or hydraulic systems are used, that there are appropriate filtration, relief valves, and operating pressures.

- The operation is designed to be fail-safe; that is, loss of power or a failure in the system should cause the shutter to return to, or remain in, the fully shielded position.

- If applicable, that the design of the device uses tamper-resistant hardware or assembly methods. Typically, this is required for devices used by general licensees and persons exempt from licensing.

- If applicable, that the device is hermetically sealed from foreign materials or moisture.

- Sealed sources contain appropriate internal void spacing to ensure accurate leak testing results, if applicable. In addition, void spacing should allow for any thermal expansion of the materials.

- Important note for reviewers: Some devices are distributed as both specifically licensed and general licensed devices. For these devices, the reviewer should clearly differentiate between the specifically licensed design and the generally licensed design in the registration certificate. These differences can include, for example, description of tamper proofing, labeling, and other applicable features.

Product integrity does not necessarily mean that the product will perform its intended uses after it is subjected to an accident or unlikely use conditions. However, the product should still ensure that the byproduct material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20 percent constitutes a compromise of the shielding integrity.

If the request is for an amendment to a source or device model, or if the model is substantially similar to another model, the reviewer should check the NRC's Nuclear Material Events Database (NMED) for events involving the source or model for potential safety issues to address during the review process. These models may be within the same model family, or the application may be referencing a substantially similar model in the prototype testing section.

The regulations should be referenced for additional information about product designs (Table 10-2).

Design requirements for exempt products and for devices to be used under the general license in 10 CFR 31.5 include dose criteria. Therefore, the application for these products must also include dose assessments for both normal use and likely accident conditions. Dose assessments must be consistent with the information submitted about such matters as design, construction, working life, and conditions of use.

10.4 Labeling

Applicants must provide a description of the labeling of the product, including information contained on the label, materials of construction of the label, and how and where the label is attached. The labeling should be sufficiently durable to remain legible for the useful life of the product under normal conditions of use and, for devices, should be in a readily visible location. Applicants should provide samples or copies of the labels as part of the application.

The reviewer must verify that the application includes sufficient information about the product labeling. In addition to applicable regulatory requirements, applicants and reviewers should follow the guidelines outlined below for labeling of products.

10.4.1 Devices

Label devices with the following, as applicable:

- Model number, serial number, isotope, activity, distributor's name, date of assay, and the trefoil symbol or the words "CAUTION—RADIOACTIVE MATERIAL"[1] (or both)
- A statement that the product contains depleted uranium as shielding and that includes the total weight of the uranium, if applicable
- Limiting conditions of use or other information necessary for the safe use of the product, such as servicing instructions, if applicable

10.4.2 Sealed Sources

Labels for sealed sources should include the same information as on a device. However, because of the size of the source, all of the information may not fit. Therefore, the label should contain as much of the information as possible, with the importance of the information serving

[1]The word "danger" may be used in lieu of the word "caution."

Table 10-2. Design Requirements	
Regulations	**Applicability**
10 CFR 30.19(a) and (c) 10 CFR 32.22(a)	Devices used under the 10 CFR 30.19 exemption
10 CFR 30.20(a), 10 CFR 32.26	Devices used under the 10 CFR 30.20 exemption
10 CFR 30.22 (a) 10 CFR 32.30 (b)	Devices used under the 10 CFR 30.22 exemption
10 CFR 31.5(a), 10 CFR 32.51(a)(2)	Devices used under the 10 CFR 31.5 general license
10 CFR 32.53(c) and (d)	Devices used under the 10 CFR 31.7 general license
10 CFR 32.61(c) and (e)	Devices used under the 10 CFR 31.10 general license
10 CFR 32.74 (a)(2)(ii)	Sources and devices for medical use
10 CFR 34.20, 10 CFR 34.23	Sources and devices designed for use in radiography operations
10 CFR 39.41(a)(1) and (2)	Sources used in well-logging operations
10 CFR 36.21(a)(2)(3) and (4)	Sources used in irradiator operations

as the criterion for inclusion. Final approval of the information is left to the discretion of the reviewer. The label should include the following information, in order of importance and with a description of why the information should be displayed:

- **Trefoil Symbol (☢) or the Words "CAUTION—RADIOACTIVE MATERIAL" (or both)**: This information is important if a member of the public finds the source because it alerts the person finding the source that it contains radioactive material. The trefoil symbol is fairly well recognized. Therefore, for small sources where all the information may not fit, the symbol is more important than the words "CAUTION—RADIOACTIVE MATERIAL."

- **Serial Number**: The serial number can usually be traced back to determine the original activity, isotope, date of assay, and the last known user of the source. The current activity can be calculated, given this information. However, to trace the serial number back to this information, either the vendor or the last person possessing the source must be known and in business. The serial number may be important for sources that would be stored in large quantities. This would assist the licensee in maintaining accountability of each source.

- **Distributor's Name or Trademark (i.e., Logo)**: This information is important when trying to locate additional information about the source. Information about the distributor resides in the National Sealed Source and Device Registry (NSSDR). The registration certificate may also identify alternate distributors.

- **Model Number**: The NRC includes the sealed source model numbers in the NSSDR. Therefore, given the model number, the NRC could identify the distributor, possible isotopes, and maximum allowable activities.

- **Isotope, Activity, Date of Assay**: This information could assist trained personnel in responding to an incident involving the source. However, this information could be obtained from other data included on the source, as indicated above, or by analysis and surveying radiation levels around the source.

The reviewer must evaluate whether the labeling is durable, will remain on the product, and will remain legible under normal use conditions throughout the working life of the product.

Engraving or laser etching the information is the preferred method for labeling sealed sources. For devices, the preferred method is a metal label, with the information engraved or etched into the label, and the label attached to the device with screws or rivets. Other materials and methods may be acceptable, depending on the likely environments in which the product will be used.

Labels must be placed so that they are easily visible to the users of a device. The labels should also be designed so that they stay attached to the part of the device that contains the radioactive material. The labels should not be attached to the detector housing or to a barrier or guard. The applicant may elect to have additional labels on the detector housing or on barriers or guards.

The reviewer needs to verify that the labeling does not misinterpret, misrepresent, or lead the user into violating any applicable regulations. For example, devices distributed to specific licensees must not include statements concerning use of the device under a general license.

The regulations should be reviewed for additional information about product labeling (Table 10-3).

10.5 Prototype Testing

An applicant must provide information that verifies that the product design will maintain its integrity when subjected to conditions of normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during installation, use, handling, maintenance, storage, and transportation (only normal conditions during transportation need to be considered). Applicants need to determine an appropriate method to demonstrate the product's ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions. This may include the following:

- **Testing a Prototype of the Product**. A prototype product must be a complete representation of the final product that includes all safety features, shielding, safety markings (if appropriate), and any accessory features or mounting that may have a detrimental effect to the safety and integrity of the product when subjected to normal or likely accident conditions. Prototypes must be constructed from the same materials and to the same dimensions and tolerances as the final product, but the prototype may be a scale representation of the final product. Any variations of the prototype product from the final product must be analyzed for the effect on the test results that the change would be expected to cause (see the discussion of an engineering analysis below).

- **Performing an Engineering Analysis**. An engineering analysis could be conducted in lieu of actual testing unless actual testing is required by the regulations. An engineering analysis consists of a detailed, systematic analysis of the product's design and materials of construction and the processes used in manufacturing the product to

Table 10-3. Labeling Requirements	
Regulations	**Applicability**
10 CFR 32.22(a)(2)(x), 10 CFR 32.25(b)	Devices used under the 10 CFR 30.19 exemption
10 CFR 32.26(b)(10), 10 CFR 32.29(b)	Devices used under the 10 CFR 30.20 exemption
32.30(b)(10) and 32.32(b)	Devices used under the 10 CFR 30.22 exemption
10 CFR 32.51(a)(3)-(5)	Devices used under the 10 CFR 31.5 general license
10 CFR 32.54	Devices used under the 10 CFR 31.7 general license
10 CFR 32.61(b)(6) and (d)	Devices used under the 10 CFR 31.10 general license
10 CFR 34.20	Source and devices designed for use in radiography operations
10 CFR 39.31(a)	Sources used in well-logging operations
10 CFR 32.74(a)(2)(vii) and (viii) and (a)(3)	Sources and devices for manufacturing medical products

determine the product's ability to maintain its integrity when subjected to normal and likely accident conditions. The analysis may consist of calculations, modeling, sample testing, and evaluation. In addition, when evaluating products for which an industry standard is applicable, an engineering analysis may be used to demonstrate that the item would successfully pass the standard tests, if it were subjected to the tests. The conclusions of an engineering analysis should be fully justified with supporting documentation describing the analysis and including calculations or other applicable reference material.

- **Operational History of the Product**. Operational history can cover identical devices (excluding accessory equipment that has no effect on the safety or integrity of the product) used in equivalent or more severe conditions of normal use. This typically includes products used in the U.S. as a custom product or in another country. Operational history should include the environmental and operating conditions, numbers of cycles per year, the results of any known accident conditions, the results and root causes of any known product failures, and the years of use of the product. Operational history must be sufficient to demonstrate that the product would be expected to operate safely and maintain its integrity during the product's intended normal conditions of use. In addition, if operational history is sufficiently comprehensive, it may also be used to demonstrate product integrity for likely accident conditions. However, a product's operational history would not be sufficient to demonstrate the product's ability to operate safely or maintain its integrity if it has never been subjected to the extremes of expected normal use or likely accident conditions.

- **Comparison to a Similar or Equivalent Model Previously Reviewed and Registered**. Information about a similar or equivalent product may be used to demonstrate safety or integrity of the requested product, if the design of the similar or equivalent product and its intended normal and likely accident conditions of use are identical or similar to the requested product or can be related (through engineering analysis) to the requested product's conditions of use. In addition, prototype testing of the similar product may also be submitted if it can be related to the requested product.

The comparison should contain information on the similar or equivalent product, including prototype testing, applicable engineering analyses, or operational history and a detailed discussion and analysis of how this information relates to the requested product. In addition, the comparison must demonstrate that the requested product's ability to operate safely and maintain its integrity is equivalent to or more robust than that of the previously approved product, or that the differences between the products are such that the integrity and safety would not be affected.

Regardless of which approach the applicant chooses to pursue, the reviewer must evaluate whether the applicant has adequately demonstrated that the product will maintain its integrity during normal use and likely accident conditions, and whether the information adequately addresses all concerns about the integrity of the source or device when used in a way the applicant has defined as the normal conditions of use.

If the product is registered for use by a custom user, prototype testing may not be required. This is typical in a situation in which only a limited number of units will be manufactured, usually one or two. Therefore, it may not be feasible to manufacture and test a prototype product that may not be able to be used after testing. Because only one licensee is using the product, that licensee can implement additional administrative controls.

10.5.1 Sources

Typically, for sealed sources, the NRC will only accept actual testing of a prototype unit to demonstrate integrity. This is because the sealed source is the primary containment of the radioactive material. The sealed sources should normally be tested in accordance with American National Standards Institute (ANSI) ANSI N43.6-2007, "Sealed Radioactive Sources, Classification," or International Organization of Standardization (ISO) 2919-1999, "Sealed Radioactive Sources, Classification." When reviewing the testing, the reviewer must evaluate the test methods, procedures, and conditions of the tests and acceptance criteria used by the applicant against the standard. Any variations must be evaluated.

In addition to testing in accordance with an ANSI or ISO standard, the applicant may need to perform additional testing to verify that the source will withstand the conditions of use. For example, long sources may need to be subjected to a bend test, and applicants may need to verify that a source design will withstand corrosive environments.

Depending on the wall thickness of a source, engraving or etching the labeling information may have a detrimental effect on the source integrity. For thin-walled sources, the prototype source should include all engraved or etched labeling before testing.

10.5.2 Devices

When evaluating a device, the reviewer must verify that the sealed source incorporated in the device has achieved the appropriate ANSI N43.6-2007 or ISO 2919-1999 classification for its intended use and is authorized for the activity to be loaded. The registration certificate for the sealed source should include its classification.

Devices should be tested in accordance with applicable industry and consensus standards. Appendix F to this report lists applicable standards.[2] If there is no applicable standard for a product, the applicant and reviewer, using professional judgment, must ensure that the testing performed sufficiently simulates the conditions that may be expected during use, handling, storage, and transport of the product. The applicant and reviewer may obtain useful general guidance from a standard for a comparable source or device.

In addition to the testing recommended in the standards, the applicant and reviewer need to consider other potential use and accident conditions that may affect a particular device's integrity. Devices should be tested to demonstrate that they will maintain their containment integrity and that the necessary safety features remain operable after being subjected to any conditions they are likely to experience.

The testing does not need to verify that a device will operate and perform its intended function after being subjected to accident condition testing. However, the product should still ensure that the byproduct material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20 percent constitutes a compromise of the shielding integrity.

Occasionally, an applicant may indicate that a product has been tested in accordance with a standard that has limited applicability in demonstrating that the product will perform adequately, from a radiological standpoint, during normal use and likely accident conditions. Some examples of such standards are Type 7A package testing, special form testing for sealed sources, and testing to Underwriters Laboratories standards. The reviewer should ensure that the applicant does not rely on this testing alone to demonstrate device integrity; for example, tests in accordance with 10 CFR 71.75, "Qualification of special form radioactive material," are not sufficient by themselves.

The regulations should be referenced for additional information about prototype testing (Table 10-4). Acceptable prototype testing for luminous aircraft safety devices to be used under 10 CFR 31.7 and ice detection devices containing strontium-90 (Sr-90) for use under 10 CFR 31.10 are also addressed in NUREG–1556, Volume 16, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees."

10.6 Radiation Profiles

The applicant should provide the maximum radiation levels around the product when it contains the maximum allowable quantity of each nuclide or combination of nuclides. The applicant should include the maximum radiation levels on the surface of the product, at 5 cm [2 in], 30 cm [12 in], and 100 cm [39 in] from the product. The applicable standard, ANSI-N43.8-2008 *"Classification of Industrial Ionizing Radiation Gauging Devices,"* does not measure dose rates in the beam—only scatter radiation. Any dose rate measurements in the beam path are with the shutter closed. If applicable, the applicant should give radiation levels when the device is in the open and closed conditions and when material is present in the measuring area.

[2]For copies of standards, contact the Health Physics Society, 1313 Dolley Madison Boulevard, Suite 402, McLean, VA 22101, telephone: (703) 790-1745, Web site: http://www.hps.org.

Table 10-4. Requirements for Prototype Testing	
Regulations	**Applicability**
10 CFR 32.53(d)(4) and (e)	Devices used under the 10 CFR 31.7 general license
10 CFR 32.61(e)(4) and (f)	Devices used under the 10 CFR 31.10 general license
10 CFR 34.20	Source and devices designed for use in radiography operations
10 CFR 32.74 (a)(2)(iii)	Sources and devices for medical use
10 CFR 39.41(a)(3)	Sources used in well-logging operations
10 CFR 36.21(a)(5)	Sources used in irradiator operations

Doses during transient conditions and during other conditions of use, such as during calibration, may also need to be reported. The reviewer must verify that the applicant has provided the maximum radiation levels.

Figure 10-1 shows an example of an isodistance around a particular gauge configuration. ANSI N43.8-2008 identifies multiple device types and configurations and the appropriate isodistance contour and setup. When appropriate, the applicant should identify the ANSI N43.8-2008 gauge classification.

Measured radiation levels are preferable, but calculated levels also are acceptable. If the applicant submits measured radiation levels, the reviewer needs to verify that the conditions under which the measurements were taken and the equipment used—including type, window thickness, sensitivity, and valid calibration—are acceptable for the nuclide and quantity included in the product. If the applicant submits calculated levels, the reviewer needs to verify that the calculations were performed in accordance with acceptable methods or standards.

If the applicant takes credit for external shielding or barriers or guards that restrict access to higher radiation areas, the radiation levels at, and at distances from each barrier or guard, need to be reported.

The reviewer needs to verify that radiation levels are reasonable. The levels for gamma emitters should be consistent with the inverse-square law, and levels for nongamma emitters should not. The reviewer also needs to assess whether levels that initially appear unreasonable, such as higher levels farther from the product, are possible because of scatter.

Even though 50 microsieverts per hour (μSv/h) [5 millirem per hour (mrem/h)] at 30.5 cm [12 in] is an industry goal that has been used for many years, in general, there are no maximum external radiation level limitations for sealed sources and specifically licensed devices. Ultimately, the user is responsible for ensuring that the product is used in accordance with 10 CFR Part 20 [e.g., the specific licensee is responsible for ensuring that persons do not receive doses in excess of the occupational limits or limits for members of the public and that occupational exposures are as low as is reasonably achievable (ALARA)].

The regulations should be referenced for additional information about radiation profiles and maximum dose commitments (Table 10-5).

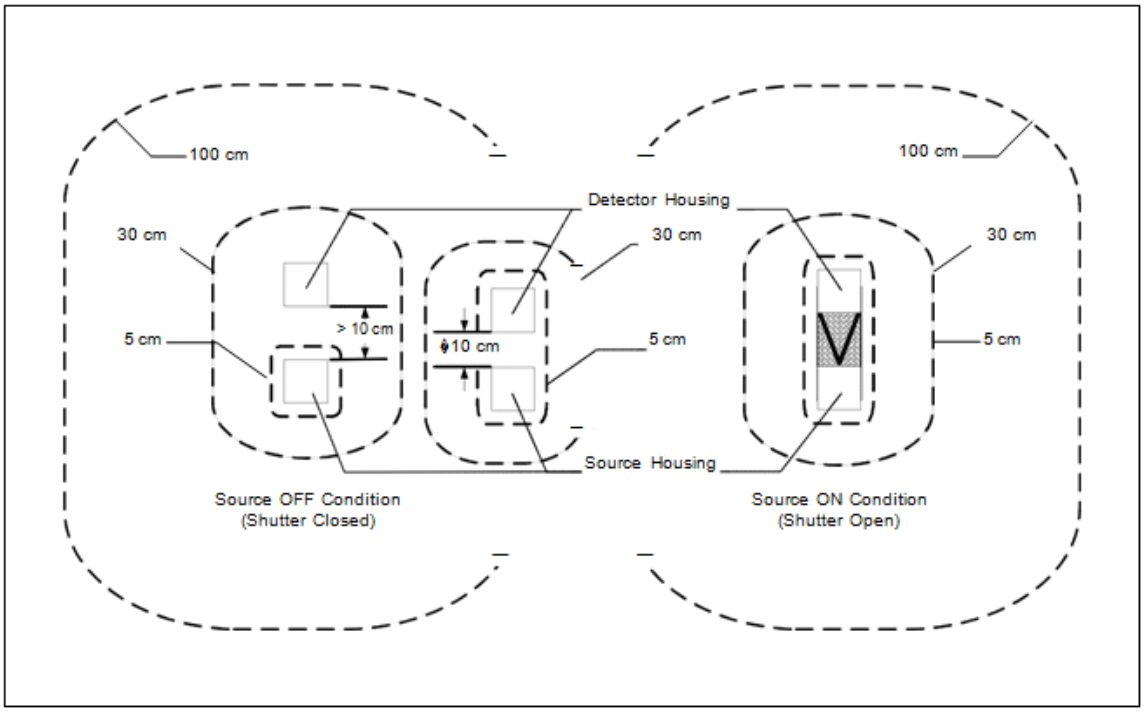

Figure 10-1. Isodistance Contours. *Example of ANSI-N43.8-2008, "Classification of Industrial Ionizing Radiation Gauging Devices," isodistance contour.*

Table 10-5. Requirements for Radiation Levels	
Regulations	**Applicability**
10 CFR 32.22(a)(2)(vi), (xiii), and (xiv)	Devices used under the 10 CFR 30.19 exemption
10 CFR 32.26(b)(6), (13), and (14)	Devices used under the 10 CFR 30.20 exemption
10 CFR 32.30(b)(6)	Devices used under the 10 CFR 30.22 exemption
10 CFR 32.51(a)(2)(ii) and (iii)	Devices used under the 10 CFR 31.5 general license
10 CFR 32.74(a)(2)(iv)	Sources and devices for medical use
10 CFR 34.20 and 10 CFR 34.21	Source and devices designed for use in radiography operations

10.7 Quality Assurance and Quality Control

The applicant must provide details of the QA program that will be implemented to ensure that the product is manufactured and distributed in accordance with the representations made in the application and with the statements contained in the registration certificate for the product. At a minimum, the QA program needs to ensure that (i) the materials of construction and the final assembly meet the design specifications; (ii) the final product is leak tested; (iii) a final radiation profile is performed; (iv) a test is performed that verifies that the product operates as intended, including all safety functions; and (v) a visual and mechanical inspection is performed of

components that are considered related to safety or are expected to be susceptible to failure under extreme or unusual conditions. Some of these inspections may be performed on a sample basis. The reviewer must verify that the applicant has provided adequate information concerning the QA program.

The QA program provides control over all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the SSDs. This puts more emphasis on the overall management structure and on the program that covers construction of the device from the time of initial design through refurbishment.

To evaluate the adequacy of the QA program, the reviewer may use the checklist in Appendix G to this report or other generally accepted guidance.

The NRC staff may consider a QA program that is part of a QA program designed and intended to meet another established standard or requirement, including programs established to meet ISO or ANSI QA program standards, military QA standards, or requirements or regulations established by other U.S. Government agencies [such as the U.S. Food and Drug Administration (FDA)].

SSD vendors frequently use and are accredited in accordance with the international/U.S. QA standard ANSI/ISO/American Society for Quality (ASQ) 9001-2000, "Quality Management Systems—Requirements." The NRC documented its position on the international quality standards in SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," dated July 9, 2003. The paper primarily addresses the applicability of international quality standards to safety-related items of commercial nuclear power plants. However, the conclusions are also applicable for SSDs.

If the vendor of SSDs is accredited to the current standard, the SSD reviewer may accept the certificate of accreditation in lieu of a full set of QA/QC plans or procedures. However, the vendor must make the commitment that the generic QA/QC program includes additional provisions that address the specific issues involved in the fabrication of SSDs, such as the following:

- There is full design conformity in accordance with the statements and commitments submitted in support of the application (including materials of construction, dimensions within stated tolerances, manufacturing methods, assembly methods, and labeling).

- All units are leak tested to 185 Bq [0.005 μCi].

- All units are tested for proper operation of all safety features.

- All units are verified that the radiation levels do not exceed the maximum values stated in the application.

If the product is registered for use by a custom user, submission of a complete QA program may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Because the purpose of a QA program is to ensure that all devices are manufactured to the same specifications, the development and submission of a complete program may not be feasible. Because only one licensee is using the product, that licensee can implement additional administrative controls.

If a vendor is a foreign manufacturer with an affiliate distributor in the U.S., the distributor is responsible for assessing the vendor's QA/QC program performance in accordance with the vendor's established procedures, accepted standards, or guides. The distributor must have an established program for assessing the manufacturer's QA/QC program. This includes an evaluation of the foreign manufacturer's performance, in accordance with these standards at a frequency necessary to ensure that QA is met. The distributor also must maintain records of such audits for future regulatory review.

Specifically, in cases involving foreign manufacturers, the QA/QC functions for fabrication are to be performed at the foreign facility, and the U.S. distributor periodically must audit the foreign facility. Copies of all records must be maintained in the U.S., as specified by the provisions of 10 CFR 110.53(b). With every lot of the product, the foreign manufacturer must forward to the U.S. distributor (i) the leak test results and (ii) copies of documents certifying that the QA/QC commitments made in the application have been met. The U.S. distributor must review and approve the records before the release of the lot. Other QA/QC records must be forwarded to the U.S. location on a periodic basis and must be available upon request in a reasonable time. This policy does not exempt the U.S. distributor from ensuring that all QA/QC functions are performed and from being responsible for ensuring that the product is distributed in accordance with all statements and commitments made in the application and the registration certificate. The SSD reviewer must review and accept the QA/QC plan and procedures at the same level or detail as if the product were manufactured at a U.S. facility.

The reviewer is not responsible for establishing a frequency for QA program audits by the regulatory agency issuing the registration certificate. Audits of the QA program by regulatory agencies do not need to occur on a routine basis, but they may occur if trends indicate generic failures of a product. The applicant should include third-party audits by an unbiased entity as an integral part of the QA program.

The FDA approves devices for medical use before the NRC device evaluation and registration. The FDA requires domestic or foreign manufacturers to have a quality system for the design and production of medical devices intended for commercial distribution in the U.S. Manufacturers must comply with the Good Manufacturing Practices requirements in 21 CFR Part 820, "Quality System Regulation," which covers all aspects of quality management. The FDA's Good Manufacturing Practices requirements are extensive and similar to those of the NRC; therefore, QA programs do not need to be submitted or reviewed for FDA-approved SSDs. An applicant must provide documented proof that the FDA has approved the SSD and that the applicant maintains an FDA-approved QA program. Section 4.10, "Sealed Sources and Devices for Medical Use," discusses types of FDA product approvals.

The regulations should be referenced for additional information about QA and QC (Table 10-6). Acceptable sampling procedures (QC) for luminous aircraft safety devices to be used under 10 CFR 31.7 and ice detection devices containing Sr-90 for use under 10 CFR 31.10 are also addressed in NUREG–1556, Volume 16.

10.8 Installation, Servicing, and Instructions to Users

The applicant should provide any special procedures that need to be followed when the product is installed at the user's facility. These include (i) mounting; (ii) installing interlocks, guards, or barriers; and (iii) determining whether a specific licensee needs to perform the installation. General licensees may be permitted to mount products, depending on their design.

Table 10-6. Requirements for Quality Assurance and Quality Control	
Regulations	**Applicability**
10 CFR 32.55	Devices used under the 10 CFR 31.7 general license
10 CFR 32.61(e)(5), 10 CFR 32.62	Devices used under the 10 CFR 31.10 general license
10 CFR 32.22(a)(2)(xv), 10 CFR 32.25(a)	Self-luminous products (10 CFR 30.19)
10 CFR 32.26(b)(15), 10 CFR 32.29(a)	Gas and aerosol detectors (10 CFR 30.20)
10 CFR 32.30(b)(15)	Certain industrial devices (10 CFR 30.22)
10 CFR 32.51(a)(2)	Certain generally licensed devices (10 CFR 31.5)
10 CFR 32.53(b)(5), 10 CFR 32.55	Luminous devices for aircraft (10 CFR 31.7)
10 CFR 32.61(b)(5) and (e)(5), 10 CFR 32.62	Sr-90 ice detectors (10 CFR 31.10)
10 CFR 32.74(a)(2)(v)	Medical equipment (10 CFR Part 35)
10 CFR 32.210(c)	All sealed sources and devices

An applicant may request that general and specific licensees, without specific authorization under that license, be permitted to mount products. In order for the NRC to grant such a request, the applicant must provide justification for approval (e.g., likely doses to persons mounting the device, why specific training is not necessary to perform mounting) and must provide written procedures that must be followed to mount the product safely. The reviewer must evaluate the adequacy of the procedures. These procedures must indicate the following:

- The product must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the registration certificate.

- The on/off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded.

- The product must be received in good condition (i.e., package is not damaged).

- The product must not require any modification to fit in the proposed location.

The "Limitations and/or Other Considerations of Use" section of the registration certificate must specifically state whether or not general or specific licensees may initially mount the product, in accordance with the manufacturer's instructions, or perform any mounting after moving.

In addition, the applicant should indicate if a specific licensee could only perform other services necessary to support safe use of the products or if a general licensee could also perform them. These include calibration, relocation, leak testing, routine maintenance, radiation surveys, training for users, changing of sources, and final disposal of the byproduct material. The applicant needs to indicate whether the applicant, or the manufacturer or distributor, will provide the necessary services or identify an entity that will provide such services. If the applicant cannot identify an entity that will provide the necessary services, the registration certificate should include this in a reviewer note. However, if the device is to be possessed and used by a general licensee, and the applicant cannot identify an entity that will provide services that cannot be performed by the generally licensed users, the device should not be registered.

Reviewers should recognize that vendors or service companies may discontinue providing services. The NRC is typically notified when a vendor decides that it will no longer provide services.

Registration certificate holders requesting to transfer a registration certificate to inactive status should identify whether they plan to continue to provide services for the registered products or whether they are aware of an entity that will provide services (see Section 13.4, "Transfers to Inactive Status"). The reviewer needs to verify that procedures for servicing the product are adequate, can be performed by the persons indicated by the applicant (e.g., by a general licensee), and do not interfere with or compromise the integrity of the product. As indicated in Chapter 6, "How to File," the applicant should submit a copy of the user operating manual and safety instructions. In accordance with 10 CFR 32.210(c), these documents should provide the end user with "sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property."

The reviewer must verify that the applicant provides the user of the product with the information necessary to safely operate and maintain the product. Such information should include instructions for operation, maintenance, calibration, damage/failure, specific warnings, leak tests, and radiation surveys.

The applicant also should provide information to the user about who may provide services for the product. For devices distributed to general licensees, the applicant must provide specific information, as required under 10 CFR 32.51a. To assist the reviewer in determining whether general licensees may perform certain activities, the applicant must provide an estimate of the dose to a worker for each activity to be performed.

For medical use, 10 CFR 35.67(a) states, "A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer." Therefore, the reviewer needs to verify that these instructions are complete and encompass likely incident or accident conditions.

The reviewer needs to verify that the documentation provided to users of the products does not misinterpret, misrepresent, or otherwise lead the user into violating any applicable regulations (Figure 10-2).

10.9 Safety Evaluation and Concurrence

Concurrence review includes an independent technical review of the materials submitted by the applicant and the documents generated by the initial reviewer. The concurrence review includes evaluation of each area addressed during the initial review (e.g., construction of the product, labeling, and prototype testing), but the concurrence review is not performed to the same level of detail as the initial evaluation review. The concurrence review should focus on ensuring that the product meets all applicable regulations, that the product would not pose any health or safety concerns, and that the registration certification provides an adequate basis for licensing. This concurrence review by a second qualified reviewer is necessary in view of the potential health and safety implications resulting from the widespread distribution of sealed sources and devices.

The regulations below should be referenced for additional information about servicing (Table 10-7).

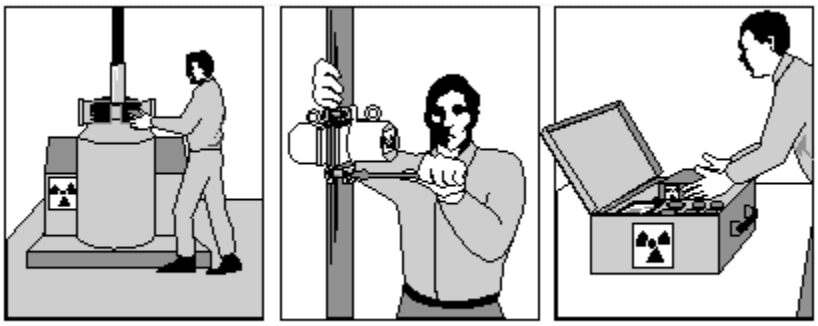

Figure 10-2. Installation and Servicing of Devices. *Applicants must specify the qualifications needed by individuals to perform installation and servicing of devices.*

Table 10-7. Requirements for Servicing of Devices

Regulations	Applicability
10 CFR 32.51(b) and (c)	Devices used under the 10 CFR 31.5 general license
10 CFR 35.605	Installation, maintenance, adjustment, and repair of remote after loaders, teletherapy units, or gamma stereotactic radiosurgery units
10 CFR 35.655	5-year inspection for teletherapy and gamma stereotactic radiosurgery units

11 DEFICIENCIES IN THE APPLICATIONS

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 of information needed, the reviewer may obtain the information by sending a formal written request to the applicant, request a meeting with the applicant, notify the applicant of the need for information via telephone or electronic mail, or obtain the information directly from the applicant during a telephone conversation or via electronic mail. Because of the need to complete the application reviews in a timely manner, the reviewer should perform the actions described in the sections below when addressing deficiencies in applications.

Additional information regarding deficiencies is available in NUREG–1556, Volume 20, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Administrative Licensing Procedures."

11.1 Sending Deficiency Letters to Applicants

Any significant or complex deficiencies in an application for an evaluation must be set forth in a formal deficiency letter to the applicant. The letter to the applicant should request that the applicant respond within a specified number of days from the date of the deficiency letter. The number of days is typically 30 to 60 days, but this depends on the complexity of the information and the level of effort needed by the applicant to respond (e.g., extra time may be needed to perform prototype testing on a product). In addition, the letter should indicate that if the U.S. Nuclear Regulatory Commission (NRC) does not receive a written response[1] to the deficiency letter within the number of days specified in the letter, the reviewer will consider the application as "abandoned" for failure to provide the requested information, "without prejudice" to the resubmission of a complete application, and "close" the application.[2]

The reviewer should take prompt action (i.e., within 5 working days) to close the application after the application has been considered abandoned. The reviewer should notify the applicant, in writing, that the application has been considered abandoned and the reviewer will close the review.

If the NRC receives a response to the deficiency letter after the application has been closed, but less than 1 year from the date of the letter, the application should be assigned a new tracking number and handled as a new application; however, no additional fee may be necessary if the response only requires a continuation of the evaluation. The NRC will not assign a higher priority to the application solely based on the fact that it is a resubmission.

[1]A written response may be by letter, e-mail, or fax from the applicant.

[2]The terms "abandoned," "without prejudice," and "close" are not meant to have legal connotations. As used in this report, "abandoned" means that the applicant for a new license or for an amendment to an existing license has given up its pursuit of the license or amendment. "Without prejudice" means that the applicant can resurrect its application within some reasonable time without having to pay another fee or having its application redocketed. "Close" means that the application is no longer under consideration.

11.2 Meeting With Applicants

Either the NRC or applicants may request meetings to discuss sealed source and device (SSD) applications. The meetings may take place before submission of an application or after submission to discuss items included in a deficiency letter. Meetings between the NRC and applicants may occur at an NRC office or at the applicant's facility, if it is determined that a meeting would enhance the NRC's understanding of the product. Meetings between the NRC and applicants should follow the guidance in NRC Management Directive 3.5, "Attendance at NRC Staff Sponsored Meetings." (ADAMS Accession No. ML112971635)

11.3 Using the Telephone or Electronic Mail To Obtain Additional Information

Reviewers may use the telephone or electronic mail to obtain clarifying information from an applicant. To accelerate the review process, the NRC may use these mechanisms to notify an applicant of simple deficiencies.

However, use of the telephone or electronic mail to notify an applicant of deficiencies must be limited to items that are simple and that can be explained in simple terms. Such items include a request for the model number of a sealed source, the need for an applicant commitment to perform a procedure, or the clarification of a material type or a dimension.

If the deficiency requires a clarification of information provided in the application, it may not be necessary to have the applicant respond in writing. This decision is left to the discretion of the reviewer. However, the applicant's response, whether via the telephone or electronic mail, must be documented and included as part of the application.

In all cases, the person initiating the communication must document the telephone conversation or electronic mail transmitting deficiencies to an applicant. If the applicant does not respond to the issues discussed within 15 calendar days, a reminder letter must be sent to the applicant. The reminder letter is a letter that clearly specifies the deficiencies and must be handled as a typical deficiency letter, with the exception that it includes a statement that the information needs to be received within a specified timeframe or the application will be closed.

11.4 Requesting Response Time Extensions

The NRC may grant a request from an applicant for an extension of time to respond to any correspondence about its application if the agency determines that there is good cause to grant an extension. The request may be in writing, via the telephone, or by e-mail. Typically, the reviewer should respond by telephone to notify the applicant that an extension has been granted. All requests for extensions must be approved by the NRC management and must be documented in a conversation record.

12 CONTENTS OF THE CERTIFICATE

Registration certificates are written in a standard format. This allows license reviewers and inspectors to quickly retrieve the information necessary to perform a license review, perform a site inspection, or respond to incidents involving lost, damaged, and/or abandoned sealed sources or devices.

The registration certificate is a summary of the technical evaluation of the product. It contains summaries of the areas examined during the evaluation process. Appendix D to this report includes standard formats for registration certificates for a sealed source, for a device, and for an exempt device. This chapter provides further clarification of the information included in a registration certificate.

12.1 Header

The header includes the title of the document, the registration number, date of issuance, page numbering, and the sealed source or device (SSD) type. If the certificate is amended or corrected, this is indicated in the title; the page number of each corrected page(s) is listed, or the header notes that the certificate is amended in its entirety. The reviewer assigns the registration number in accordance with the numbering procedures in Appendix B. The issue date is the date the certificate has received both reviewer and concurrence signatures.

12.2 First Page Information

The first page of each certificate includes the model number of the SSD, the name and complete address of the manufacturer and distributor, the manufacturer or distributor and model number for the sealed source incorporated in the device (for devices), isotopes, maximum allowable activity levels, leak test frequency, principal uses (including code and description), and an indication of whether the registered product is designed for custom use. If registered for custom use, the name and address of the custom user are included. This information is entered into the U.S. Nuclear Regulatory Commission (NRC)-maintained, computerized National Sealed Source and Device Registry.

For clarity, there should be only one maximum activity listed for each radionuclide. If there are multiple activity limits or configurations within a family or series of sources or devices, the description section should include the model-specific values.

The following sections describe, in order, the information included in the rest of the certificate for sources and devices, beginning with the second page.

12.3 Description

This section provides a narrative description of the construction of the product, the safety features of the product, ON/OFF indicators, and/or other safety indicators. The description should include the materials of construction and fabrication techniques for safety-related components of the product (e.g., source encapsulation materials, source holder materials, shutter mechanisms, welding process, and device safety-related features, such as tamper-resistant fasteners and locks). The description also includes overall dimensions of the SSD.

Certificates for sealed sources include the chemical and physical forms of the source material. Certificates for devices describe how the sealed source is secured within the device and how the product is protected from its intended environment (e.g., hermetically sealed, fireproof, corrosion resistant).

The revision history for amended registration certificates could also be included in the registration certificate for license reviewers and inspectors. Only the most recent registration certificate is kept on file. A revision history could help license reviewers and inspectors to be aware of changes over time for older devices still in use.

The text may be structured in a format that enhances clarity (e.g., with subheadings).

12.4 Labeling

This section describes how the labeling requirements are fulfilled. It lists the information contained on the label, construction of the label, and how and where the labeling is attached to the product. Any exemptions from labeling requirements or omissions of information typically included on the labels will be noted. A visual representation of the label may be included as an attachment.

12.5 Diagrams

This section lists the diagrams, drawings, sketches, or pictures of the product that are included in the certificate. These are typically included as attachments to the certificate and should include the overall dimensions of the product, the location of the sealed source within the device, and the safety-related features of the product. A person using the certificate, such as an inspector or license reviewer, should be able to identify a device, given the diagrams and the description from the certificate.

12.6 Conditions of Normal Use

This section lists the environmental conditions the product is intended to withstand. It also includes the normal intended uses of the product and any limitations that define these uses. The working life also may be included.

12.7 Prototype Testing

This section describes tests performed on prototypes of the product to demonstrate product integrity when subjected to conditions of normal use and likely accident conditions. If the product was tested in accordance with an applicable industry or consensus standard, this section should state the corresponding classification, as defined by the standard. If the product was tested in accordance with an applicable regulation, this section specifies whether the product satisfactorily met the requirements of the regulation.

If, in lieu of prototype testing a product, an applicant submitted operational history of the product or a similar product or provided an engineering analysis that demonstrates that the product is adequately designed, this section will provide the details of the operational history or engineering analysis and the basis for determining the design to be adequate.

12.8 External Radiation Levels

This section states the maximum radiation levels from the product when loaded with the maximum activity of each nuclide or combination of nuclides. If the manufacturer is unable to provide measured external radiation levels for the product, the certificate lists a conservatively calculated maximum radiation profile. If applicable, the radiation profiles are listed for shutter open and closed conditions. The stated levels are the maximum radiation levels expected from the product and take into consideration factors affecting the levels, such as whether the product is present in the measuring area or whether certain areas around the device are restricted from access. Any significant contaminants that would change the expected radiation levels are stated. The radiation levels listed in this section will include the levels on contact with the product, at 5-, 30-, and 100-cm [2-, 12-, and 39-in] from the product, and in the beam if provided in the application.

Should a device contain a number of isotopes and be designed with a range of dimensions, a distributor may commit to ensuring that the radiation levels do not exceed a specified level. If this is the situation, the certificate needs to include the maximum allowable radiation level and state limitations on the installation of the device.

For devices, the certificate includes the American National Standards Institute (ANSI) N43.8-2008 classification, if available and not included in a prior section.

12.9 Quality Assurance and Quality Control

This section includes a summary of the quality assurance (QA) measures that will be followed to ensure that the product meets all applicable specifications. If the quality control (QC) procedures meet a national or industry standard or regulation or U.S. Food and Drug Administration (FDA's) Good Manufacturing Practices, this fact is specified in this section. If the applicant commits to following a complete QA/QC program, this section may include a short summary of the program and reference that details of the complete program are on file with the NRC. The section also contains a statement reflecting that the NRC has assessed the QA/QC program and deemed it acceptable.

12.10 Limitations and Other Considerations of Use

This section establishes the safety-related limiting conditions imposed on the SSD not already addressed by existing regulations. These may include leak testing, shutter test frequency, special handling, storage or use considerations, environmental conditions, labeling, special-handling procedures and tools, and specific licensing conditions that should be addressed by the license reviewer. This section needs to clearly indicate the services that may be performed by general-licensed users of the products. It also includes a limitation that states that the registration certificate and the information contained within the references shall not be changed without the written authorization of the NRC. Limitations on SSDs can be divided into two categories: (i) limitations placed on the manufacturer or distributor of the SSD and (ii) limitations placed on the user of the SSD. Limitations in the first category are derived from regulations. The second category of limitations is derived from both regulations and conditions imposed by the manufacturer, particular conditions of use that would reduce the radiation safety of the device, and circumstances unique to the sealed source or device that require that the SSD receive a special limitation.

In addition, this section of the certificate may contain reviewer notes. The purpose of such notes is to identify to license reviewers areas of use of the product that cannot be controlled as part of the registration. This alerts the license reviewer to verify that the licensee implements certain administrative procedures before initial use, as part of routine use, or as part of an emergency response to an incident. For example, indicating in a reviewer note that a vendor no longer offers servicing for the product alerts the license reviewer to obtain more than a statement that the vendor will provide services.

12.11 Food and Drug Administration Approval Summary

This section contains the FDA information for SSDs used for medical use. Reviewers do not evaluate the data provided by the applicant. The references provided by the applicant are for information only. Applicants provide proof of the FDA approval type and specific use limitations that are not evaluated by the NRC or Agreement States but that are important for users to know.

12.12 Safety Analysis Summary

This section summarizes the conclusion of the evaluation performed by the reviewer and states that the product is acceptable for certain licensing conditions. This section also typically lists any additional features that the device, surroundings, environment, or accessories may contribute to the integrity or safety of the product. These may include physical constraints such as barriers, fences, or guards and actual use time in terms of radiation exposure resulting from working around the product.

12.13 References[1]

This section incorporates by reference the documents that were submitted in support of the application. These references include applications, letters, faxes, electronic mail messages, and enclosures to such documents. The applicant is required to adhere to the information and commitments included in these references and to retain the references in accordance with applicable records retention requirements.

12.14 Issuing Agency

This section identifies the NRC as the regulatory agency that issued the certificate and includes the date issued and the typed names and signatures of the two persons who reviewed the certificate and all applicable documentation. All certificates include two signatures as part of the QC measures.

12.15 Attachments

This section typically contains diagrams, drawings, sketches, or pictures of the product, as discussed in Section 12.5, “Diagrams.” These enable inspectors to easily identify the devices in the field. The attachments also may contain designations of specific models and their characteristics, such as dimensions and sealed source activities, if a series of devices is registered.

[1]Registration certificates issued by the NRC may include ADAMS accession numbers for documents that are incorporated into the registration certificate by reference.

The header for the attachments is similar to that for the main body of the registration certificate. The header contains the title of the document, registration number, date of issuance, and attachment numbering. The header does not contain the SSD type.

12.16 Dimensions and Use of Dual Units

The NRC's previous metrication policy (SECY-96-098, "Final Policy Statement—Conversion to the Metric System," dated May 7, 1996) provided that documents specific to a registration certificate holder, such as the registration certificate, include dimensions in the units employed by the registration certificate holder. For example if the application used English units, then the registration certificate would also contain the same units.

Guidance on the use of units appears in NUREG–1379, "NRC Editorial Style Guide."

13 MODIFICATIONS TO EXISTING REGISTRATION CERTIFICATES

It is the obligation of the registration certificate holder to keep the registration certificate current. If a registration certificate holder plans to make a change to the registered product that affects the commitments made in the information provided in support of the application or the conditions included in the registration certificate, the registration certificate holder must file for an amendment or correction to the registration certificate. Until the amendment request is approved and the amended certificate is issued, the registration certificate holder is obligated to comply with the information in the certificate. Registration certificate holders are encouraged to anticipate the need for certificate amendments as far in advance as possible.

The registration certificate holder should retain one copy for its records and submit the original certificate to the address specified in Chapter 7, "Where to File." The application should identify the registration certificate by number and should clearly describe the changes and the effects of the changes on the safety properties of the product. References to previously submitted information should be clear and specific and should identify that information by date, document title, and page number.

An application to amend a certificate should be accompanied by the appropriate fee, if applicable [see 10 *Code of Federal Regulation* (CFR) 170.31 for current requirements and Chapter 8, "Registration Fees," of this report for specific guidance]. For medical products, the registration certificate holder must have obtained U.S. Food and Drug Administration (FDA) approval before submitting a request for amendment to the registration certificate.

The request for an amendment or correction needs to address the changes to the product and how the changes affect the original safety evaluation of the product. The reviewer needs to evaluate the changes to determine whether they have any adverse effects on the safety of the product and whether the initial evaluation and the determination of adequacy are still valid. The reviewer needs to look at all aspects of the initial evaluation to determine whether the change would have an effect on another aspect of the evaluation that may not be readily evident. For example, changing a part of the source holder from stainless steel to lead may improve the shielding efficiency, but it may have detrimental effects on how the device will react to accident conditions. The manufacturer may have overlooked this type of detrimental effect.

13.1 Amendments

If the registration certificate holder requests an amendment to the certificate (i.e., it requires a safety evaluation to be performed), the certificate should be amended in its entirety. The certificate header should include, under the title, the following:

(AMENDED IN ITS ENTIRETY)

An amended certificate should be issued when new information is added to the certification file, such as name or address changes. Once the new information is added to the registration, the correspondence should also be added as a reference to the signature page. All pages of the certificate must show the new date of the amendment.

The certificate should be assigned a new issue date, and the certificate should be reissued in its entirety. When appropriate, the reviewer should use bold typeface to highlight the changes to the certificate. In addition, if products that meet the previous design specifications remain in use, reviewers must ensure that previous design information stays in the registration certificate

and must delete sections that are no longer applicable. The reviewer should describe the changes and the effective date of the changes in the description section for historical continuity. The registration certificate also should identify, by date or serial number, when a design change is implemented.

13.2 Correction

If the change only involves corrections to the certificate (i.e., does not require a safety evaluation to be performed), such as adding or clarifying information when such information was already part of the certificate file, or correction of a typographical error identified in the certificate, then only the affected pages of the certificate need to be updated and issued. The corrected page should show the date of the certificate as it was before and also include the date of correction. The reviewer should use bold typeface to make the corrections. Each affected page should include, in the header, under the title, the words "CORRECTED PAGES," the number of each page affected, and the date of the correction, as shown below:

(CORRECTED PAGES 1, 2, and 4—JULY 5, 2000)

The issue date of the certificate should remain the same as the last issue date. It is not necessary to include the letter from the registration certificate holder requesting the correction in the reference section of the certificate.

However, if the correction requires a change to the signature page of the certificate, the certificate should be amended in its entirety. The reviewer may elect to postpone making corrections to the signature page until the registration certificate holder requests an amendment to the certificate, thus requiring a safety evaluation.

13.3 Combining Registration Certificates

Registration certificate holders may ask the U.S. Nuclear Regulatory Commission (NRC) to combine two or more certificates into a single certificate. However, it is NRC policy that a single registration certificate may group together only products that are essentially identical in design, function, and construction and that vary only in a dimensional capacity, in the sources used, or in their application.

Combining registration certificates does not require a safety evaluation. However, the reviewer must determine whether the request meets the Material Safety, State, Tribal, and Rulemaking (MSTR) policy and whether the registration certificates can be administratively combined.

13.4 Transfers to Inactive Status

A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) (SSDs) covered by a particular certificate shall request inactivation of the registration certificate. A request for inactivation of a registration certificate must be made when the distributor has no ongoing intent to distribute the device (i.e., when: (i) there is no ongoing intent to distribute a product and (ii) 2 years have passed since distribution has ceased).

If a registration certificate holder asks the NRC to transfer a registration certificate to inactive status,[1] the registration certificate holder should provide the following:

- The total number of the products sold and the number of products still in use[2]
- The services (including source replacement and availability) the registration certificate holder will still provide to users of the product or the identification of an entity that will provide services. Servicing of devices must be in accordance with all the conditions in the certificate
- A commitment that the registration certificate holder will no longer commercially distribute the product
- Verification that no changes were made to the product since its initial registration or last amendment. If changes have been made, then the new information must be incorporated into the inactivated certificate. However, the changes need not be in a bold typeface because the certificate has a new registration number assigned to it
- The associated specific license number if a distribution license is terminated in accordance with 10 CFR 30.36, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas"

The reviewer should verify that the request for inactivation includes the information noted above and that the background file for the product evaluation is complete and accurate. Because some registrations were issued many years ago, the files may not include all the information that is now needed. Therefore, the reviewer should request that the registration certificate holder submit any and all additional information that would be needed to make a determination that the product is acceptable for licensing purposes. The reviewer should make the reference file as complete as possible.

The reviewer needs to write an updated registration certificate, including the new registration number (see Appendix B for instructions on issuance of inactive registration certificate numbers) and updated information. Directly under the new registration number, the reviewer should insert a reference to the old registration number with the statement, "Supersedes NR-XXXX-D-YYY-S." The reviewer may also refer to the previous registration for clarity or for historical documentation in the text of the registration certificate; for example, the reviewer may place such a reference as a "Reviewer's Note" in the "Limitations and/or Other Considerations of Use" section of the registration certificate. The new certificate will contain a statement that the product will no longer be commercially distributed but may still be approved for licensing purposes. The new registration certificate will replace the old registration certificate and will be used as the basis for continued licensing of the product.

Some registrations contain a series of sources or devices on a single certificate, some of which are being inactivated and others not. In these cases, the existing certificate may be amended by extracting the inactivated models. An inactive certificate containing these models may then be created. In such cases, the inactive certificate should reference the original certificate where

[1]The NRC also will transfer a registration certificate to inactive status if it knows that the registration certificate holder is out of business (see Section 5.9).
[2]If the registration certificate holder does not know the actual number of products sold and still in use, they should provide the best estimate.

the active models remain registered. The amended original certificate must contain updated information on the models that are still active and should reference the inactive certificate for those models that have been inactivated.

Licensees with custom SSDs should inactivate the custom registration when sources or devices are permanently disposed of, placed in permanent storage, or transferred to another licensee that has obtained its own custom registration or that has broad-scope authorization. The licensee should verify the number of SSDs disposed of, placed in permanent storage, or transferred to another licensee and confirm that no changes have been made to the custom product since its initial registration or last amendment.

13.5 Reactivating Inactive Registration Certificates

Vendors may submit requests to reactivate inactive registration certificates. The NRC handles requests to reactivate inactive registration certificates using one of two methods:

(1) If the background information on file with the NRC for the inactive registration certificate is complete and up to date, and the vendor does not request any changes to the information, the vendor may simply submit a letter to the NRC requesting reactivation of the registration certificate. The letter should include commitments that the information on file with the NRC is complete and accurate and that the vendor will abide by all information on file with the NRC. The reviewer must verify that the information is complete before assigning a new registration certificate number and reissuing the certificate.

(2) If the background information on file with the NRC for the inactive registration certificate is incomplete or not up to date, or the vendor requests changes to the information (e.g., changes in the design of the product or manufacturing or distribution procedures), the vendor should submit a complete application for evaluation and registration in accordance with the guidance provided in this document. The reviewer must review and evaluate the application in the same manner as a new application.

Directly under the new registration number, the reviewer should insert a reference to the old registration number with a statement, “Supersedes NR-XXXX-D-YYY-S.” The reviewer may also refer to the previous registration for clarity or for historical documentation in the text of the registration certificate; for example, the reviewer may place such a reference as a “Reviewer’s Note” in the “Limitations and/or Other Considerations of Use” section of the registration certificate.

13.6 Ownership Changes and Corporate Relocations

If a registration certificate holder asks the NRC to transfer a registration certificate because of ownership changes or corporate relocations, the registration certificate holder should perform the following:

- Delineate the facility’s name and location where the products are manufactured.

- Specify the serial number of the last unit that was distributed by the old company before the name or address change, and the number of completed units that were transferred by the old company to be distributed by the new company.

- Provide change of ownership information discussing the transfer of products, records custody, and servicing arrangements for products previously distributed.

- Provide a new label for the devices indicating the new company name and the effective date of the label change.

- Confirm that no changes were made to the product since its initial registration or last amendment.

- Verify that previous commitments made by the old company have not changed.

- Provide details about the quality assurance program under the new ownership or at the new location.

The reviewer should assign a new vendor code when ownership changes. When a product registration is taken over by another vendor, the reviewer should change the registration number to the new vendor and its next sequential unit number (see Appendix B to this report).

14 IDENTIFYING AND REPORTING DEFECTS AND NONCOMPLIANCES AS REQUIRED BY 10 CFR PART 21

Registration certificate holders must adopt appropriate procedures to evaluate deviations in product designs or failures to comply with registration requirements to identify defects or failures to comply that are associated with a substantial safety hazard. A substantial safety hazard is defined in 10 CFR Part 21, "Reporting of Defects and Noncompliance," as a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to 10 *Code of Federal Regulation* (CFR) Parts 30, 40, 50, 60, 61, 70, 71, or 72. However, the U.S. Nuclear Regulatory Commission (NRC) Information Notice (IN) 91-39, "Compliance with 10 CFR Part 21, Reporting of Defects and Noncompliance," dated June 7, 1991, which can be found on the NRC's Generic Communications Web page under INs: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/, indicates that from a radiological perspective, a substantial radiation safety hazard exists if there is a potential for a moderate exposure to, or release of, licensed material. Further, it provides the following for determining moderate exposure or release of licensed material:

- Guidelines for determining moderate exposure:
  - greater than 250 mSv [25 rem] exposure (whole body or its equivalent to other body parts) to occupationally exposed workers in a period of 1 year or less
  - greater than 5 mSv [0.5 rem] exposure (whole body or its equivalent to other body parts) to an individual in an unrestricted area in a period of 1 year or less
- Guidelines for determining the potential for release of licensed material:
  - release of materials in amounts reportable under the provisions of 10 CFR 20.2202(b)(2)

All defects or failures to comply that are associated with, or could lead to, a substantial safety hazard must be reported to the NRC, pursuant to 10 CFR 21.21. In addition, registration certificate holders must meet the posting requirements specified in 10 CFR 21.6, "Posting requirements."

Applicants need not submit copies of the procedures that are necessary to meet the requirements of 10 CFR Part 21. However, applicants should be aware of the need for such procedures, and the NRC will evaluate the procedures during inspections. If a certificate holder identifies a 10 CFR Part 21 defect that results in a design change, an amendment to the registration certificate must be made.

15 GLOSSARY

Active Registration Certificate means a registration certificate for a sealed source or device that may be authorized for initial distribution. It constitutes part of the basis for the NRC and Agreement States to issue licenses.

Active Vendor means a vendor, listed on a registration certificate, that may be authorized to initially distribute the sealed source or device listed on the registration certificate.

Agreement State means a State that has entered into an agreement with the NRC allowing the State to regulate the use of byproduct material within the State. NMSS can provide a complete listing of the current Agreement States, including addresses and points of contacts.

Agreement State Registration Certificate means a registration certificate, issued and maintained by an Agreement State, for a sealed source or device evaluated by the Agreement State.

Applicant means a vendor or custom user of a product that applies for a certificate of registration with the NRC or an Agreement State. The applicant is responsible for ensuring that the information provided in the application is complete and accurate.

Associated Equipment is equipment that is used in conjunction with a device and directly affects the safe use of the device or ensures that the device maintains its integrity (e.g., parts that move a source, control the shielding of a source, control the radiation levels around a device, come in contact with the source). A sealed source or device certificate need not identify associated equipment. As a matter of convenience, an applicant for a sealed source or device may include the description of associated equipment that is compatible with the radiographic source or device on the certificate.

Custom User means a licensee that uses a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant. Typically, no more than two different NRC or Agreement State licensees may be custom users of, and may register, the same product. However, a custom user may acquire or use (or both) more than one product.

Energy Compensation Source means a small sealed source, with an activity not exceeding 3.7 MBq [100 µCi], used in a logging tool to provide a reference standard to maintain the tool's calibration when in use.

Inactive Registration Certificate means a registration certificate for a sealed source or device that may have been authorized for distribution at one time but is no longer authorized for initial distribution. Unless otherwise stated on the registration certificate, the sealed source or device included on an inactive registration certificate still may be authorized for use and may continue to be licensed. The vendor listed on the registration certificate may be authorized to provide service and replacement parts for the sealed source or device and may be authorized to receive the sealed source or device from a user for disposal or redistribution to a licensee. However, the design of the sealed source or device cannot be changed.

The NRC and the Agreement States may continue to issue licenses to persons to use sealed sources or devices that are included on an inactive registration certificate. This typically would occur during renewal of a license. However, the fact that the registration certificate is inactive serves to alert the license reviewer that the user may not be able to find a firm to service the

device or may not be able to find replacement parts. The license reviewer must ensure that emergency procedures, operational support, and services are still applicable.

Inactive Vendor means a vendor that no longer may be authorized to initially distribute the sealed source or device listed on a registration certificate but that may be authorized to provide services for the sealed source or device. (Appendix B uses the term.)

Mounting means physically positioning the product into its permanent location, including installation of fasteners (e.g., mounting bolts). Mounting does not include electrical connection, activation, or operation of the product.

National Sealed Source and Device Registry (NSSDR) is maintained by the NRC and contains sealed source and device registration certificates that are prepared by the NRC and the Agreement States.

Product means any sealed source, device, or associated equipment registered with the NRC or an Agreement State.

Registration Certificate Holder means a vendor or custom user of a product that holds a certificate of registration with the NRC or an Agreement State. The registration certificate holder is responsible for ensuring that the information in the registration certificate is current and correct and that products manufactured or distributed conform with the conditions of the certificate.

Vendor means any person, licensed or unlicensed, who manufactures or distributes products.

Working Life means the time period or operational cycles during which the product is expected to maintain its integrity. The working life should be based on radiotoxicity, total activity, product construction, normal operating environments, likely abnormal conditions, fatigue, and wear.

APPENDIX A

APPLICATION AND REVIEW CHECKLIST

APPLICATION AND REVIEW CHECKLIST for (Acceptance, 1st, or 2nd) Review for SSD 00-000

<table>
<tr><th colspan="3">SUMMARY DATA</th></tr>
<tr><td colspan="2">Name and Complete Mailing Address of the Applicant:</td><td>Name, Title, and Telephone Number of the Individual To Be Contacted If Additional Information or Clarification Is Needed by the NRC:</td></tr>
<tr><td colspan="2">The Applicant Is (check one):</td><td rowspan="5">If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:</td></tr>
<tr><td></td><td>Custom User</td></tr>
<tr><td></td><td>Manufacturer</td></tr>
<tr><td></td><td>Distributor</td></tr>
<tr><td></td><td>Manufacturer and Distributor</td></tr>
<tr><td colspan="2">If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</td><td>Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:</td></tr>
<tr><td colspan="2">Model Number:</td><td>Principal Use Code (see Appendix C):</td></tr>
<tr><td colspan="2" rowspan="5">Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source):</td><td>For Use by:</td></tr>
<tr><td></td><td>Specific Licensees Only</td></tr>
<tr><td></td><td>General Licensees Only</td></tr>
<tr><td></td><td>Both Specific and General Licensees</td></tr>
<tr><td></td><td>Persons Exempt from Licensing</td></tr>
<tr><td colspan="2">Leak-Test Frequency:</td><td rowspan="2">Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):</td></tr>
<tr><td></td><td>Periodic Leak-Testing is Not Required</td></tr>
<tr><td></td><td>6 Months</td><td rowspan="2">Radionuclides and Maximum Activities (including loading tolerance):</td></tr>
<tr><td></td><td>Attached is justification for a leak test frequency of greater than 6 months</td></tr>
<tr><td colspan="3">CERTIFICATION:

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 ABOVE, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10 OF THE CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.</td></tr>
<tr><td colspan="3">Certifying Officer—Typed Name and Title</td></tr>
<tr><td colspan="2">Signature:</td><td>Date:</td></tr>
</table>

CHECKLIST			
Registration Certificate Holder: **Model:**			
DESCRIPTION	**OK/DEF**		**COMMENTS**
	1st Reviewer	**2nd Reviewer**	
DESCRIPTION/CONSTRUCTION			
If the registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?			
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)			
Assembly methods (screw, welds, etc.); verify integrity			
Source mounting (size and integrity) and security			
Is source ANSI classification sufficient (from ANSI N43.6-1997 and ISO 2919): Radiography—Unprotected……..43515 Radiography—In Device ……..43313 Medical—Radiography ……..32312 Medical—γ Teletherapy ……53524 Medical—Brachytherapy ……..53211 Medical—Source Applicators ……..43312 γ Gauges—Unprotected ……..43333 γ Gauges—In Device ……..43232 β Gauges, Low Energy γ Gauges, or X-ray Fluorescence ……..33222 Oil Well Logging ……..56522 Portable Moist/Density ……..43333 Neutron Applications ……..43323 Calibration Source Activity > 30 µCi (1 MBq) ……..22212 γ Irradiators (I) ……..43323 γ Irradiators (II, III) ……..43424 γ Irradiators (IV) ……..53424 Chromatography ……..32211 Static Eliminators ……..22222 Smoke Detectors ……..32222			
Definition of shutter operation (locked in “off” position, not locked in “on” position), fail safe, spacing and tolerances			
On-Off indicators (description, quantity, location)			
Safety interlocks, guards, similar components to prevent access to beam or high radiation levels			
Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium and steel)			
Shielding efficiency and integrity			

CHECKLIST			
Registration Certificate Holder: **Model:**			
DESCRIPTION	**OK/DEF**		**COMMENTS**
	1st Reviewer	**2nd Reviewer**	
For medical devices: Type of FDA approval: • Premarket notification (501(k)) • Premarket approval (PMA) • Investigational Device Exemption (IDE) • Humanitarian Device Exemption (HDE) Type of Medical Use: • Manual brachytherapy, 35.400 • Medical diagnosis, 35.500 • Photon-emitting remote afterloader, 35.600 • Photon-emitting teletherapy unit, 35.600 • Gamma stereotactic radiosurgery unit, 35.600 • Other medical, 35.1000 List of FDA limitations of use provided			
Well logging (10 CFR 39.41) and irradiator (10 CFR 36.21) sources must be as nondispersible and nonsoluble, as practical			
See “ANSI and Other Standards” list for references for particular source/device designs (See Appendix F, e.g., radiography, brachytherapy)			

CHECKLIST			
Registration Certificate Holder: **Model:**			
DESCRIPTION	**OK/DEF**		**COMMENTS**
	1st Reviewer	**2nd Reviewer**	
LABELING			
Complete and final copy of label attached			
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)			
Attachment and location(s)—visible to users?			
Method of attachment is durable and permanent under normal conditions of use			
Contents: Model no., serial no., isotope, activity, manufacturer, date of assay, trefoil symbol, "CAUTION—RADIOACTIVE MATERIAL" (depleted uranium information must be included)			
Is label in compliance with regulatory requirements?			
CONDITIONS OF USE			
Estimated working life of the source/device (years, operational cycles)			
Actions to be taken when product reaches end of its working life			
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)			
How the device will be used			
Meets dose limits of 10 CFR Part 32 for distribution to general licensees or persons exempt from licensing			
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)			
Tests results			
Years of use (See Section 10.5, "Prototype Testing," Operational history of the product)			
Similarities to other sources/devices if they are used as basis			
RADIATION PROFILES			
Survey instrument used (e.g.. type, window thickness, sensitivity, calibration dates)			
Conditions: including environments, scatter (product in beam), and use of guards and shields			

CHECKLIST			
Registration Certificate Holder: **Model:**			
DESCRIPTION	**OK/DEF**		**COMMENTS**
	1st Reviewer	**2nd Reviewer**	
RADIATION PROFILES (CONTINUED)			
Distance from source/surface (per ANSI 538-1979, N43.8 - 2001)			
Shutter Open and Closed/Source Shielded			
Verify that radiation surveys for γ radiation meet inverse squared law.			
Verify that radiation surveys for non-γ radiation have not been calculated using the inverse squared law.			
QUALITY ASSURANCE			
Materials, subassemblies, services			
Assembly methods (screws, welding, etc.)			
Dimensions and tolerances			
Activity, radiation levels, leak tests			
Final inspection			
QA Manual and comparison of other (generally) accepted guidance (e.g., ANSI/ISO/ASQ 9001-2001)			
Additional measures for sealed sources and devices if ANSI/ISO/ASQ 9001-2001 is used			
INSTALLATION			
Fixed, portable, movable, fixed installation but portable source housing			
Inherent shielding, inaccessibility			
Beam access (size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers)			
Mounting integrity			
ACCOMPANYING DOCUMENTATION			
Leak tests results and radiation surveys			
Operation safety instructions, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions, if applicable			
For distribution to general licensees, verify that the listing of NRC Regions and Agreement States is up to date and include copies of all pertinent regulations			

CHECKLIST						
Registration Certificate Holder: **Model:**						
DESCRIPTION				**OK/DEF**		**COMMENTS**
				1st Reviewer	**2nd Reviewer**	
SERVICING						
The following activities may be performed by the persons indicated:						
Activity	By a General Licensee	Only by a Specific Licensee	Will Be Offered by the Applicant			
Installation						
Relocation						
Maintenance						
Repair						
Source Exchange						
Calibration						
Leak Testing						
Radiation Survey						
Training						
FOREIGN VENDORS						
Drop ship						
Who and where is source installed						
Leak test and radiation surveys						
QA in the U.S.						

1st Reviewer Signature: _____ **Date:**

2nd Reviewer Signature: _____ **Date:**

APPENDIX B

ASSIGNING REGISTRATION CERTIFICATE NUMBERS

Assigning Registration Certificate Numbers

Each sealed source or device registration certificate has a unique registration number. The registration number consists of either 10 or 11 characters, as shown below.

NR-XXXX-D-YYY-S

Agency Code (NR): The agency code is a two-letter abbreviation of the agency issuing the certificate. All certificates issued by the U.S. Nuclear Regulatory Commission (NRC) have NR as the agency code.

Vendor Code (XXXX): Each active vendor (who manufactures or distributes products, i.e., manufacturer or distributor) is assigned a unique three- or four-digit number on a nationwide basis. The registration certificate number will use the vendor code for the distributor. If the company is out of business or no longer has an active registration certificate, the vendor is classified as inactive vendor, and the vendor code will be between 800 and 1000 or between 8000 and 9000. The NRC maintains the listing of vendor codes and issues new vendor codes. Reviewers in Agreement States should contact the NRC to obtain the next available vendor code in the National Sealed Source and Device Registry (NSSDR).

Source or Device Code (D): The source or device code is a one-letter code that indicates if a registration certificate is for a sealed source (S), a device (D), or associated equipment (A). The designation (U) is no longer used; it had been used in the past when registrations, which had been issued prior to the establishment of the present-day practice without a clear designation, were transferred into the current system from historical records in the early 1980s.

Unit Number (YYY): The unit number is a separate series of three-digit numbers assigned to registration certificates for each vendor. These numbers are assigned in sequential order starting with 101 for active registration certificates and starting with 801 for inactive registration certificates. A new registration for an existing vendor is assigned the next available unit number. The agency that regulates the vendor typically controls the issuance of unit numbers.

License Code (S): This one-letter code indicates how the source or device has been registered. “S” indicates that it may only be used by specific licensees; “G” indicates it may be used by general licensees; “B” indicates that it is intended to be used by both specific and general licensees; and “E” indicates that it may be used by persons exempt from licensing.

Parts of the registration certificate numbers are changed when a State becomes an Agreement State, or when a vendor moves from a non-Agreement State to an Agreement State, or vice versa. Specifically, the following changes are implemented:

- The agency code (NR) designation is changed to that of the Agreement State.
- The vendor code (XXXX) does not change, because each vendor has a unique number, which applies nationwide.
- The unit number (YYY) is changed to be the next sequential number for the vendor.
- The Source/Device Code (S/D) does not change
- The license code (S) does not change.

APPENDIX C

PRINCIPAL USE CODES AND DEFINITIONS

Principal Use Codes and Definitions

A	***Industrial Radiography***	The examination of the structure of materials by nondestructive methods that use sealed sources of radioactive material.
B	***Medical Radiography***	The process of producing x-ray or gamma ray images to assist in medical diagnoses. This code was discontinued with the revision of 10 CFR Part 35, "Medical Use of Byproduct Material," implementation date of October 24, 2002. The currently used medical codes are listed below.
C	***Medical Teletherapy***	The treatment of disease with gamma radiation from a controlled source of radiation located at a distance from the patient. This code was discontinued with the revision of 10 CFR Part 35, implementation date of October 24, 2002. The currently used medical codes are listed below.
D	***Gamma Gauges***	The use of gamma radiation to measure or control thickness, density, levels, interface location, radiation leakage, or chemical composition.
E	***Beta Gauges***	The use of beta radiation to measure or control thickness, density, levels, interface location, radiation leakage, or chemical composition.
F	***Well Logging***	The lowering and raising of measuring devices or tools that may contain radioactive sources into well bases or cavities for the purpose of obtaining information about the well or adjacent formation.
G	***Portable Moisture Density Gauges***	Portable gauges that use a radioactive sealed source to determine or measure the content or density of material. Includes hand-held and dolly-transported devices with sources.
H	***General Neutron Source Applications***	All applications, except reactor startup and well logging, which use a neutron source. (See NUREG-1556, Volume 14, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses.")
I	***Calibration Sources [Activity greater than 30 µCi (per ANSI 43.6)]***	Sources of a known purity and activity that are used to determine the variation in accuracy of a measuring instrument and to ascertain necessary correction factors.
J	***Gamma Irradiation, Category I***	An irradiation in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volumes undergoing irradiation is not physically possible because of the design of the irradiation.

K	***Gamma Irradiation, Category II***	A controlled human access irradiation in which the sealed source is contained in a dry container constructed of solid materials, is fully shielded when not in use, and is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.
L	***Gamma Irradiation, Category III***	An irradiation in which the sealed source is contained in a storage pool (usually containing water), the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is physically restricted in its designed configuration and proper mode of use.
M	***Gamma Irradiation, Category IV***	A controlled human access irradiation in which the sealed source is contained in a storage pool (usually containing water), is fully shielded when not in use, and is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.
N	***Ion Generators, Chromatography***	The use of an ion-generating source and a device to determine the chemical composition of material.
O	***Ion Generators, Static Eliminators***	The use of an ion-generating source and a device to eliminate static electricity on a surface or a surrounding area.
P	***Ion Generators, Smoke Detectors***	The use of an ion-generating source and a device to detect gases and particles created by combustion.
Q	***Thermal Generator***	The use of a radionuclide and a device to produce heat to produce energy.
R	***Gas Sources***	Sealed sources containing radioactive gas such as krypton-85 or hydrogen-3.
S	***Foil Sources***	Sources that are constructed using thin metal foil. The radioactive material may be secured to the foil in a number of ways, for example, plating, laminating, or cold welding.
T	***Other***	All uses not covered in other non-medical categories.
U	***X-Ray Fluorescence***	Sources and devices that use radioactive material to excite the atoms of samples that in turn emit characteristic X-rays and thereby provide a means for sample analysis.
V	***General Medical Use***	Includes diagnostic sources and devices such as bone mineral analyzers and therapeutic sources and devices such as interstitial needles, therapeutic seeds, and ophthalmic applicators. This code was discontinued with the revision of 10 CFR Part 35, implementation date of October 24, 2002. The currently used medical codes are listed below.
W	***Self-Luminous Light Source***	A source consisting of a radioactive nuclide or nuclides incorporated in solid inactive materials or sealed in a protective envelope and incorporating a phosphor to emit light.

X	***Medical Reference Sources***	Includes calibration, transmission, and references sources, in accordance with 10 CFR 35.65, “Authorization for calibration, transmission, and reference sources.” Includes flood sources, instrument check sources, and spot markers.
Y	***Calibrators***	Devices containing calibration sources that are used to determine the variation in accuracy of a measuring instrument and to determine necessary correction factors.
Z	***Not used***	
AA	***Manual Brachytherapy***	For use in manual brachytherapy, in accordance with 10 CFR 35.400, “Use of sources for manual brachytherapy,” or equivalent Agreement State regulations.
AB	***Medical Diagnosis Sources***	For use in medical diagnosis, in accordance with 10 CFR 35.500, “Use of sealed sources for diagnosis,” or equivalent Agreement State regulations.
AC	***Photon-Emitting Remote Afterloaders***	For use in Photon-Emitting Remote Afterloaders, in accordance with 10 CFR 35.600, “Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit,” or equivalent Agreement State regulations.
AD	***Photon-Emitting Teletherapy Units***	For use in photon-emitting teletherapy units, in accordance with 10 CFR 35.600 or equivalent Agreement State regulations.
AE	***Gamma Stereotactic Radiosurgery Units***	For use in Gamma Stereotactic Radiosurgery Units, in accordance with 10 CFR 35.600 or equivalent Agreement State regulations.
AF	***Other Medical Uses***	For other medical uses that are regulated under 10 CFR 35.1000, “Other medical uses of byproduct material or radiation from byproduct material,” or equivalent Agreement State regulations.

APPENDIX D

STANDARD REGISTRATION CERTIFICATE FORMATS

Standard Registration Certificate Formats

Table of Contents for Standard Registration Certificate Formats

Example 1

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: PAGE 1 of 5

SOURCE TYPE: *Provide a short description of the source type.*

MODEL: *ABC*

MANUFACTURER/DISTRIBUTOR:	*Name* *Street* *City, State, Zip (If manufacturer and distributor are the same, keep subheading as shown. If different, delete the word "manufacturer" from the subheading.)*
MANUFACTURER:	*Name, Street, City, State, Zip (This subheading and information is not necessary if the manufacturer and distributor are the same.)*
ISOTOPE: *List Isotopes*	MAXIMUM ACTIVITY: *XX* Gbq (*XX* mCi) *(Units should be such that the amount is in the 1 to 999 range.)*
LEAK TEST FREQUENCY:	Not Required *or* 6 Months
PRINCIPAL USE:	(…) See Appendix C
CUSTOM SOURCE:	___ Yes ___ No
CUSTOM USER:	*Name* *Street* *City, State Zip* *(Delete entire subsection if not applicable.)*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: PAGE 2 OF 5

SOURCE TYPE: *Provide a short description of the source type.*

DESCRIPTION: *Provide the complete description of the source.*

LABELING:

The source is engraved with the radiation symbol, isotope, activity, model number, serial number, date of assay, name of the distributor, and the words "CAUTION—RADIOACTIVE MATERIAL." The text is *XX* mm (*XX* in.) high and is on the *end/side* of the source capsule.

DIAGRAM:

Reference all attachments to the document, including the total number of attachments.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for use in measuring....

The source may be used in harsh environments but shall not be subjected to environments that exceed its ANSI N542-1977 classification, 97C00000.

The estimated working life of the source is *XX* years.

PROTOTYPE TESTING:

(The reviewers should list either the standard classification and/or actual test results.) A prototype of the Model ABC source was constructed and subjected to the tests provided in ANSI N 43.6-1997 or ISO 2919-1999 and achieved a classification of 96C00000.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: PAGE 3 OF 5

SOURCE TYPE: *Provide a short description of the source type.*

EXTERNAL RADIATION LEVELS:

The following dose rates for the Model ABC source containing 37 Gbq (1.0 Ci) of Am-241:

Table 1

Distance		***Maximum Radiation Level***			
		From Window		***From Sidewall/Back***	
(cm)	***(inches)***	***(μSv/h)***	***(mrem/h)***	***(μSv/h)***	***(mrem/h)***
5	*1.97*				
30	*11.81*				
100	*39.37*				

QUALITY ASSURANCE AND CONTROL:

XXXX Corporation maintains a quality assurance and control program, *which* has *been* deemed acceptable for licensing purposes *by the NRC*. A copy of the program is on file with the NRC. *(For medical sources that have been manufactured under FDA good manufacturing practices, the QA/QC program may not be on file with the NRC.)*

(For medical applications) All manufacturing of the Model XXXX sources/devices and related operations are to be carried out in manufacturing processes consistent with the current Good Manufacturing Practices Final Rule, Quality System Regulation, 21 CFR Part 820, under the supervision of the Quality Assurance group at XXXX Corporation.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The source shall be distributed to persons specifically licensed by the NRC or an Agreement State.
- *(For custom registration)* The source shall only be used by the custom user listed in this certificate, ABC Corporation.
- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: PAGE 4 OF 5

SOURCE TYPE: *Provide a short description of the source type.*

- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. In view that these sources exhibit high dose rates, the sources should be handled by experienced licensed personnel* using adequate handling equipment and procedures.
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 185 Bq (0.005 μCi) of removable contamination.
- The source shall not be subjected to conditions that exceed its ANSI N43.6-1997 or ISO 2919-1999 classification, 96C00000.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

FDA APPROVAL SUMMARY *(For sources in use in accordance with 10 CFR Part 35 or equivalent Agreement State regulations)*:

This source was approved by the U.S. Food and Drug Administration, Approval No., *XXXX*, Form 510(k), dated *MM/DD/YYYY.*

SAFETY ANALYSIS SUMMARY:

Based on review of the Model ABC sealed source, its ANSI classification, and the information and test data cited below, *we {continue to} conclude* that the source is acceptable for licensing purposes.

Furthermore, *we {continue to} conclude* that the source would be expected to maintain its containment integrity for normal conditions of use and accidental conditions, *which* might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: PAGE 5 OF 5

SOURCE TYPE: *Provide a short description of the source type.*

REFERENCES:

The following supporting documents for the Model ABC sealed source are hereby incorporated by reference and are made a part of this registry document.

- XXXX Corporation's application dated December 25, 0000, with enclosures thereto.
- XXXX Corporation's letters dated July 4, 0000, and December 25, 0000, with enclosures thereto.
- XXXX Corporation's facsimiles dated July 4, 0000, and December 25, 0000.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: Reviewer: _____
Name of 1st Reviewer

Date: Concurrence: _____
Name of 2nd Reviewer

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: ATTACHMENT 1 OF X

(Insert Drawings)

(Insert Captions)

Example 2

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 1 OF 8

(For "X", the following designations should be used: "S" for specifically licensed devices, "G" for generally licensed devices, and "B" for both types.)

> *Important note for reviewers: Some devices are distributed as "B" (both specifically licensed and general licensed devices). For these devices, the reviewer should clearly differentiate between the specifically licensed design and the generally licensed design in the registration certificate. These differences can include, for example, description of tamper proofing, labeling, and other applicable features.*

DEVICE TYPE: *Provide a short description of the device type.*

MODEL: *ABC*

MANUFACTURER/DISTRIBUTOR:	*NameStreetCity, State, Zip (If manufacturer and distributor are the same, keep subheading as shown. If different, delete the word "manufacturer" from the subheading.)*
MANUFACTURER:	*NameStreetCity, State, Zip (This subheading and information is not necessary, if the manufacturer and distributor are the same.)*
SEALED SOURCE MODEL DESIGNATION:	ACME MODEL 123
ISOTOPE: *List Isotopes*	MAXIMUM ACTIVITY: *XX* GBq (*XX* mCi) *(Units should be such that the amount is in the 1 to 999 range.)*
LEAK TEST FREQUENCY:	Not Required/6 Months
PRINCIPAL USE:	(…) See Appendix C
CUSTOM SOURCE:	___ Yes ___ No

CUSTOM USER:

Name
Street
City, State Zip
(Delete entire subsection if not applicable.)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

DEVICE TYPE: *Provide a short description of the device type.*

DESCRIPTION:

Provide the complete description of the device and include, if not registered separately, the source(s) used in the device.

LABELING:

The device is labeled in accordance with 10 CFR 20.1901. The labels contain the radiation symbol, isotope, activity, model number, serial number, name of the distributor, and the words "CAUTION—RADIOACTIVE MATERIAL."

(For "G," generally licensed device) When distributed to persons generally licensed under 10 CFR 31.5, the device is additionally labeled in accordance with 10 CFR 31.5(c)(1) and 32.51.

The labels are made of stainless steel or aluminum, rectangular in shape, *XX* cm × *XX* cm (*XX* inches × *XX* inches), and are permanently attached by rivets or screws to the device. A copy of the label is shown in Attachment *X*.

DIAGRAM:

Reference all attachments to the document, including the total number of attachments.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for measuring....

The devices are expected to be subjected to environments typically found in laboratories occupied by humans. Since the device is portable, it may experience vibration and shock typical during normal transportation.

(For "C," custom device) The device will only be used by ABC Corporation at their Anytown, Any State, facility.

DEVICE TYPE: *Provide a short description of the device type.*

CONDITIONS OF NORMAL USE (Cont.):

The devices are intended for use in industrial gauging applications. The devices are typically used in industrial process control environments for the measurement of properties of materials in a tank or vessel. The devices are designed for the following environments:

Temperature	-40° C to 60° C (-40° F to 140° F)
Pressure	Atmospheric
Vibration	Ranges from zero to mild
Corrosion	Ranges from zero to highly corrosive vapors
Fire	NEC Division 2, hazardous area possible
Explosion	NEC Division 2, hazardous area possible

The estimated working life of the device is XX years or XX operational cycles.

PROTOTYPE TESTING:

(The reviewers should list either the standard classification and/or the actual test results.)

A prototype of the device has been tested in accordance with ANSI/ISO standard... and has achieved a classification of.... The device passed the tests in accordance with the acceptance criteria included in the standard.

The sealed sources used in the device have been tested by their manufacturers and have achieved the following ANSI *(ANSI N-43.6-1997 or ISO 2919-1999)* classifications:

Manufacturer	Model	ANSI Classification
ABC	AMCL	77C64344
DEF	NER-465	C33232
HIJ	PH-55	C33232

The sealed source contained in the device has achieved an ANSI N43.6-1997 or ISO 2919-1999 classification of 96C00000.

DEVICE TYPE: *Provide a short description of the device type.*

PROTOTYPE TESTING (Cont.):

The sealed source contained in the device has achieved an ISO 2919-1999 classification of C00000.

A prototype of the Model *XXXX* was constructed and subjected to the tests listed below. No malfunction occurred, nor was there any loss of shielding or containment integrity.

Temperature	110° C (230° F) for a period of 7 hours.
Vibration	Approximately 30 cps at an amplitude of 0.76 mm (0.03 in.) for 90 minutes.
OFF/ON Mechanism	Operated by a pneumatic cylinder for a total of 9,320 OFF/ON cycles.
Impact	Dropped three times from a height of 122 cm (4 ft).
Penetration	Dropped a 5.9 kg (13 lb), 3.2 cm (1.25 in.)diameter steel rod from a height of 102 cm (40 in.).

EXTERNAL RADIATION LEVELS:

XXXX Corporation reports that the radiation levels from the device are not discernable from background.

XXXX Corporation reports that the radiation levels from the device do not exceed 50 μSv/h (5 mR/h) at 30.5 cm (12 in.) from the surface of the device.

The following dose rates *were reported by the manufacturer* for the Model ABC transmission gauge containing a 37 GBq (1.0 Ci) of Am-241 sealed source:

Table 1

Distance		***Maximum Radiation Level with Shutter***			
		Closed From Window		***From Sidewall/Back***	
(cm)	***(inches)***	***(mSv/h)***	***(mrem/h)***	***(mSv/h)***	***(mrem/h)***
5	*1.97*				
30	*11.81*				
100	*39.37*				

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE:

DEVICE TYPE: *Provide a short description of the device type.*

EXTERNAL RADIATION LEVELS (Cont.):

Table 2

Distance		***Maximum Radiation Level with Shutter***			
		Open From Window		***From Sidewall/Back***	
(cm)	***(inches)***	***(mSv/h)***	***(mrem/h)***	***(mSv/h)***	***(mrem/h)***
30	*11.81*				
100	*39.37*				
100	39.37				

The dose rates were taken with no material present in the measuring area. XXXX Corporation indicates this represents the highest radiation levels of any possible configuration.

QUALITY ASSURANCE AND CONTROL:

XXXX Corporation maintains a quality assurance and control program, *which has been* deemed acceptable for licensing purposes *by the NRC*. A copy of the program is on file with the NRC. *(For medical devices that have been manufactured under FDA's Good Manufacturing Practices, the QA/QC program may not be on file with the NRC.)*

(For medical applications) All manufacturing of the Model XXXX sources/devices and related operations are to be carried out in manufacturing processes consistent with the current Good Manufacturing Practices Final Rule, Quality System Regulation, 21 CFR Part 820, under the supervision of the Quality Assurance group at XXXX Corporation.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- *(For "S," specifically licensed device)* The device shall be distributed to persons specifically licensed by the NRC or an Agreement State.
- *(For "B," both specifically and generally licensed device)* The device may be distributed to specific or general licensees of the NRC or an Agreement State.
- *(For "G," generally licensed device) The device shall be distributed to persons generally licensed by the NRC or an Agreement State.*
- *(For custom device) The device shall only be distributed to the custom user, ABC Corporation.*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 6 OF 8

DEVICE TYPE: *Provide a short description of the device type.*

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont.):

- *(For "S," specifically licensed device) Handling*, storage, use, transfer, and disposal*: To be determined by the licensing authority*.
- *(For "G" generally licensed device as well as for "B" both specifically and generally licensed device) Handling*, storage, use, transfer, and disposal*: To* be determined by the licensing authority or as required by 10 CFR 31.5 or Agreement State equivalent.
- The device shall be leak tested at intervals not to exceed X months using techniques capable of detecting 185 Bq (0.005 μCi) of removable contamination.
- The Model XXXX sealed source is approved by the NRC for use in the Model ABC. The source is not registered on a separate certificate.
- *(For "G" generally licensed device as well as for "B" both specifically and generally licensed device)* The generally licensed user is authorized to perform certain maintenance on the device (see the device operation manual). These services include....
- REVIEWER NOTE: Neither the distributor nor manufacturer of the device will provide servicing for the device.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

FDA APPROVAL SUMMARY *(For sources in use in accordance with 10 CFR Part 35 or equivalent Agreement State regulations):*

This source was approved by the U.S. Food and Drug Administration, Approval No. *XXXX*, Form 510(k), dated *MM/DD/YYYY*.

SAFETY ANALYSIS SUMMARY:

- *(For "S," specifically licensed device)* Based on *our* review of the information and test data cited below and the past history of similar designs, *we continue to conclude)* that the Model XXXX devices are acceptable for licensing purposes.
- *(For "S," specifically licensed device)* Furthermore, *we continue to conclude* that these devices would be expected to maintain their integrity for normal and accidental conditions of use *which* might occur during the uses specified in this registration sheet.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 7 OF 8

DEVICE TYPE: *Provide a short description of the device type.*

SAFETY ANALYSIS SUMMARY (Cont.):

The distributor has submitted sufficient information to provide reasonable assurance *that*:

- *(For "G" generally licensed device as well as for "B" both specifically and generally licensed device)* The device can be safely operated by persons not having training in radiological protection.
- *(For "G" generally licensed device, as well, as for "B" both specifically and generally licensed device)* 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 source housing, and it is unlikely that any person will receive in any period of *one* year a dose in excess of 10 percent of the limits specified in 10 CFR 20.1201(a).
- *(For "G" generally licensed device as well as for "B" both specifically and generally licensed device)* Under accident conditions associated with handling, storage, and use of the source housing, 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 the following chart:

PART OF BODY	DOSE
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.15 Sv (15 rem)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 cm^2 (0.15 in^2)	2.0 Sv (200 rem)
Other organs	0.50 Sv (50 rem)

Based on review of the Model XXXX, and the information and test data cited below, *we {continue to} conclude* that the device is acceptable for licensing purposes.

Furthermore, *we {continue to} conclude* that the device would be expected to maintain its containment integrity for normal conditions of use and accidental conditions *which* might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 8 OF 8

DEVICE TYPE: *Provide a short description of the device type.*

REFERENCES:

The following supporting documents for the Model ABC are hereby incorporated by reference and are made a part of this registry document.

- XXXX Corporation's application dated December 25, 0000, with enclosures thereto.
- XXXX Corporation's letters dated July 4, 0000, and December 25, 0000, with enclosures thereto.
- XXXX Corporation's facsimiles dated July 4, 0000, and December 25, 0000.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: Reviewer: _____
Name of 1st Reviewer

Date: Concurrence: _____
Name of 2nd Reviewer

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: ATTACHMENT 1 OF X

(Insert Drawings)

(Insert Captions)

Example 3

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-E DATE: PAGE 1 OF 2

DEVICE TYPE: *Short description of the device type*

MODEL: ABC

MANUFACTURER/DISTRIBUTOR:	*NameStreetCity, State, Zip (If manufacturer and distributor are the same, keep subheading as shown. If different, delete the word "manufacturer" from the subheading.)*
MANUFACTURER:	*NameStreetCity, State, Zip (This subheading and information is not necessary if the manufacturer and distributor are the same.)*
SEALED SOURCE MODEL DESIGNATION:	ACME MODEL 123
ISOTOPE: *List Isotopes*	MAXIMUM ACTIVITY: *XX* GBq (*XX* mCi) *(Units should be such that the amount is in the 1 to 999 range.)*
LEAK TEST FREQUENCY:	Not Required
PRINCIPAL USE:	(…) See Appendix C
CUSTOM SOURCE:	___ Yes ___ No

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-E DATE:

DEVICE TYPE: *Short description of the device*

DESCRIPTION:

Provide a concise, basic description of the device; if more than one model is registered, provide the differences between models.

REFERENCES:

The following supporting documents for the Model ABC *(Short description of the device)* are hereby incorporated by reference and are made a part of this registry document.

- XXXX Corporation's application dated December 25, 0000, with enclosures thereto.
- XXXX Corporation's letters dated July 4, 0000, and December 25, 0000, with enclosures thereto.
- XXXX Corporation's facsimiles dated July 4, 0000, and December 25, 0000.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: Reviewer: _____
Name of 1st Reviewer

Date: Concurrence: _____
Name of 2nd Reviewer

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE: ATTACHMENT 1 OF X

(Insert Drawings)

(Insert Captions)

APPENDIX E

CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE

Checklist for Requests to Withhold Proprietary Information From Public Disclosure

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, the U.S. Nuclear Regulatory Commission (NRC) may send copies of this information to NRC consultants working in that subject area. The 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 applicant should promptly notify the NRC. The applicant also should understand that the NRC may have cause to review this determination in the future if, for example, the scope of a Freedom of Information Act request includes the information in question. In all review situations, if the NRC makes a determination that the information should be made publicly available, the agency will notify the applicant in advance of any public disclosure.

Checklist for Requests to Withhold Proprietary Information from Public Disclosure

In order to request that the NRC withhold information contained in an application from public disclosure, the applicant must submit the information and application, including an affidavit, in accordance with 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 nonproprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the nonproprietary 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 sought to be withheld and who has been authorized to apply for withholding on behalf of the company.
- [ ] States that the company 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 company, the amount of effort or money expended in developing the information, and the ease or difficulty with which others might be able to acquire the information.

APPENDIX F

INDUSTRY AND CONSENSUS STANDARDS

Industry and Consensus Standards

Brachytherapy:

ANSI N44.2-1984	"For Leak-Testing Radioactive Brachytherapy Sources"
ANSI N44.1-1984	"Integrity and Test Specifications for Selected Brachytherapy Sources"

Gauges:

ISO 7205-1986(E)	"Radionuclide Gauges—Gauges Designed for Permanent Installation"
ANSI N43.8-2008	"Classification of Industrial Ionizing Radiation Gauging Devices"

Irradiators:

ANSI N433.1-1977	"Safe Design and Use of Self-Contained Dry Source Storage Gamma Irradiators (Category I)" (withdrawn)
ANSI N43.7-2007	"Self Contained, Dry Source Storage Irradiators (Category I)"
ANSI N43.10-2001	"Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV) and Dry Source Storage Gamma Irradiators (Category II)"
ANSI N43.15-2001	"Self Contained, Wet Source Storage Irradiators (Category III)"

Light Sources:

ANSI N43.4-2005	"Classification of Radioactive Self-Luminous Light Sources"

Power Generators:

IAEA No. 33	"Guide to the Safe Design, Construction, and Use of Radioisotopic Power Generators for Certain Land and Sea Applications"

Quality Assurance:

ANSI/ISO/ASQ 9001-2008	"Quality Management Systems—Requirements"

Radiography:

ANSI N43.5-1993	"General Safety Standard for Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up to 10 MeV"
ANSI N43.9-1991	"For Gamma Radiography—Specifications for Design and Testing of Apparatus"

ANSI N432-1980	"Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography"
ISO 3999-2004	"Apparatus for Gamma Radiography—Specification"
Smoke Detectors:	
OECD/NEA 1977	"Recommendations for Ionization Chamber Smoke Detectors in Implementation of Radiation Protection Standards"
Sources (General):	
ISO 2919-1999	"Radiation Protection—Sealed Radioactive Sources—General Requirements and Classification"
ISO 9978-1992	"Radiation Protection—Sealed Sources—Leakage Test Methods"
ANSI N43.6-2007	"Sealed Radiation Sources, Classification" (Revision of ANSI N5.10-1968)
ANSI N5.10-1968	"Sealed Radiation Sources, Classification"
IAEA-TECDOC-1344, July 2003	"Characterization of Radioactive Sources"
Teletherapy:	
ANSI N449.1-1984	"Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment"
X-Ray Fluorescence:	
ANSI N43.2-2001	"Radiation Safety for X-Ray Diffraction and Fluorescence Analysis Equipment"
ANSI N537-1976	"Radiological Safety Standard for the Design of Radiographic and Fluoroscopic Industrial X-Ray Equipment"
Miscellaneous:	
ANSI N43.3-2008	"Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up to 10 MeV"
NCRP Report No.49	"Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV"
BS EN 46001-1997	"Application of EN ISO-9001 to the Manufacture of Medical Devices"

APPENDIX G

CHECKLIST FOR REVIEWING QUALITY ASSURANCE PROGRAMS

The checklist in this appendix is designed to help the applicant or the Sealed Source and Device license reviewer in reviewing quality assurance (QA) programs for completeness. The checklist is designed as an aid and may not be all-inclusive. In addition, certain items may not be applicable to all applicants.

Table G–1. Checklist for Reviewing QA Programs

Questions	Program/Implementation		Comments
	Yes	No	
1. Does the vendor have a QA manual or set of instructions defining the QA program?			
2. Is the manual up to date?			
3. Is the manual approved and signed by a designated official from each department?			
ORGANIZATION			
4. Is the organizational structure of the applicant documented in the QA manual?			
5. Are all the QA personnel listed, along with all their responsibilities?			
6. Is the QA Director someone in upper management not directly responsible for manufacturing or production?			
7. Does the QA Director have continual involvement in the QA program?			
8. Is the NRC contact listed and up to date?			
9. Do the QA Manager and QA Director have the authority to halt production?			
PERSONNEL			
10. Does the applicant have procedures to ensure up-to-date records of all employees' qualifications?			

Table G–1. Checklist for Reviewing QA Programs (continued)			
Questions	Program/Implementation		Comments
	Yes	No	
DESIGN AND DOCUMENT CONTROL			
11. Are there procedures for ensuring that all documents contain all pertinent information and conform to all pertinent regulations and specifications?			
12. Are there procedures for handling document and design changes?			
13. Do the procedures ensure that all appropriate departments are notified of the changes?			
14. Do the procedures ensure that documents under revision are not used?			
15. Are all changes documented?			
16. Do the procedures ensure the documents and changes are checked and approved before release?			
17. Do the procedures include notifying regulatory agencies of any changes?			
18. Do the procedures ensure alternative approaches in the absence of specifications?			
19. Is there a history file, for each document, that includes previous versions, document changes, and reasons for the changes?			
20. Are copies on file of all up-to-date documents for each job?			
21. Are there procedures for verifying the adequacy of suppliers?			
22. Are there records of all audits of suppliers?			
23. Are audits of suppliers performed at intervals less than 3 years?			

Table G–1. Checklist for Reviewing QA Programs (continued)			
Questions	Program/Implementation		Comments
	Yes	No	
24. Are there procedures for receipt inspection?			
25. Do receipt inspection procedures verify:			
• correct sizes? • quantity? • document and specification conformance? • paperwork?			
26. Are there procedures for receipt of nonconforming material?			
27. Are there records of receipt inspections, including nonconforming material?			
28. Do all purchase orders contain:			
• scope of work? • technical requirements? • identification of the documents that must accompany the order? • identification of the records that the applicant must keep? • signature of the appropriate individual?			
29. Are there records of all purchases?			
30. Are there inventory procedures?			
31. Do inventory procedures include:			
• special handling? • marking? • tagging? • labeling? • segregating? • paperwork procedures? • handling of nonconforming material?			

Table G–1. Checklist for Reviewing QA Programs (continued)			
Questions	Program/Implementation		Comments
	Yes	No	
32. Does the inventory system have provisions for material with shelf life?			
33. Does the inventory system have provisions to ensure that the correct material is used in production?			
34. Are periodic physical inventories performed?			
35. Does the system ensure that products that are marked or segregated as complete have also passed their final inspections and testing?			
PRODUCTION PROCEDURES AND PROCESSES			
36. Are there procedures that describe production processes?			
37. Is there a flowchart describing the flow of material and inspection hold points?			
38. Are there procedures for in-process and final inspection and testing of the device?			
39. Do inspection procedures include:			
• acceptance criteria? • receipt criteria? • at what points to perform in-process inspections and tests? • procedures for determining sample sizes? • procedures for final inspection and testing? • provisions for nonconforming material?			

Table G–1. Checklist for Reviewing QA Programs (continued)			
Questions	**Program/Implementation**		**Comments**
	Yes	**No**	
40. Are there records for inspections of production procedures?			
41. Are there records of all inspections and testing, including date and person performing the inspection or test?			
42. Is there a system for marking or segregating items that have been inspected or tested?			
43. Does final inspection include an operational check and removal contamination test of 100% of the devices?			
NONCONFORMING MATERIALS			
44. Are there procedures for handling nonconforming items received from a supplier or customer or found during production?			
45. Are nonconforming materials tagged or segregated from production?			
46. Are there procedures for the disposition of nonconforming materials and for the introduction of materials back into production?			
47. Are there records of nonconforming material?			
PACKAGING AND TRANSPORTATION			
48. Are there procedures for inspecting packaging and the form of transportation?			
49. Do these procedures ensure that all paperwork and manuals are included with the shipment or are being shipped separately to the customer?			
50. Are there records of all packaging and shipping reports and inspections?			

Table G–1. Checklist for Reviewing QA Programs (continued)			
Questions	Program/Implementation		Comments
	Yes	No	
DEVIATIONS AND CUSTOMER COMPLAINTS			
51. Are there procedures for evaluating deviations and customer complaints?			
52. Are there procedures for informing the appropriate members of the organization and the NRC of deviations?			
53. Are there procedures for informing customers of devices that may contain a deviation?			
54. Are there records of all deviations and customer complaints?			
55. Do customer complaint records contain:			
• name of complainant? • nature and date of complaint? • corrective action taken? • cause of failure? • model and serial number of the device?			
56. Are there procedures for trend analysis of deviations and complaints?			
57. Is trend analysis performed at intervals that do not exceed 1 year?			
AUDITS			
58. Does the applicant have procedures for auditing its QA program?			
59. Do the procedures include acceptance criteria?			
60. Do the procedures ensure that all records and procedures are up to date?			

Table G–1. Checklist for Reviewing QA Programs (continued)			
Questions	Program/Implementation		Comments
	Yes	No	
61. Do audits include verification of audits of suppliers?			
62. Is the auditor responsible for any of the matters being audited?			
63. Do records include deficient areas in the program and corrective action taken?			
64. Are all deficiencies found during audits corrected in a timely manner?			
65. Are all records signed and dated by the appropriate member of the organization?			

APPENDIX H

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 NRC's Agencywide Documents Access and Management System (ADAMS) Accession Number ML11146A047.

Safety Culture Policy Statement

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

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

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

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

The following are traits of a positive safety culture:

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

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

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

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

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

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

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

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

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

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

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

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This technical report contains information intended to provide guidance to applicants for requests for sealed source or device safety evaluations and registrations. It also provides the U.S. Nuclear Regulatory Commission (NRC) reviewers of such requests with the information and materials necessary to determine that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information on applicable regulations and industry standards, general policies and procedures affecting evaluation and registration, how and where to file a request, the application review process, and how to draft and modify a registration certificate.

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