**NUREG-1556**
**Vol. 3, Rev. 1**

# Consolidated Guidance About Materials Licenses

## Applications for Sealed Source and Device Evaluation and Registration

Final Report

**U.S. Nuclear Regulatory Commission**

**Office of Nuclear Material Safety and Safeguards**

D.H. Tiktinsky, J. Jankovich, L. Psyk-Gersey, K. Traegde, G. Vinson

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Prepared by
D.H. Tiktinsky, J. Jankovich, L. Psyk-Gersey, K. Traegde, G. Vinson

**Division of Industrial and Medical Nuclear Safety**
**Office of Nuclear Material Safety and Safeguards**
**U.S. Nuclear Regulatory Commission**
**Washington, DC 20555-0001**

# ABSTRACT

NUREG-1556, Vol. 3, Rev. 1, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," is designed to provide guidance to applicants for requests for a sealed source or device safety evaluations and registrations. It also provides 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 concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

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# FOREWORD

NRC is using Business Process Redesign techniques to redesign its materials licensing process. This effort is described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996. A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. Below is a listing of volumes currently included in the NUREG-1556 series:

| Vol. No. | Volume Title | Status |
|---|---|---|
| 1, Rev. 1 | Program-Specific Guidance About Portable Gauge Licenses | Final Report |
| 2 | Program-Specific Guidance About Industrial Radiography Licenses | Final Report |
| 3, Rev. 1 | Applications for Sealed Source and Device Evaluation and Registration | Final Report |
| 4 | Program-Specific Guidance About Fixed Gauge Licenses | Final Report |
| 5 | Program-Specific Guidance About Self-Shielded Irradiators Licenses | Final Report |
| 6 | Program-Specific Guidance About 10 CFR Part 36 Irradiators Licenses | Final Report |
| 7 | Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope | Final Report |
| 8 | Program-Specific Guidance About Exempt Distribution Licenses | Final Report |
| 9 | Program-Specific Guidance About Medical Use Licenses | Final Report |
| 10 | Program-Specific Guidance About Master Materials Licenses | Final Report |
| 11 | Program-Specific Guidance About Licenses of Broad Scope | Final Report |
| 12 | Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution | Final Report |
| 13 | Program-Specific Guidance About Commercial Radiopharmacy Licenses | Final Report |
| 14 | Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses | Final Report |
| 15 | Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses | Final Report |
| 16 | Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees | Final Report |
| 17 | Program-Specific Guidance About Licenses for Special Nuclear Material of Less Than Critical Mass | Final Report |

| Vol. No. | Volume Title | Status |
|---|---|---|
| 18 | Program-Specific Guidance About Service Provider Licenses | Final Report |
| 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) | Final Report |
| 20 | Guidance About Administrative Licensing Procedures | Final Report |

NUREG-1556, Vol. 3, Rev. 1, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides applicants requesting a sealed source or device safety evaluation, and reviewers of such requests, with the information and materials necessary to make determinations that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

A team composed of NRC headquarters and Agreement State staff prepared NUREG-1556, Vol. 3, Rev. 1, drawing on its collective experience in radiation safety in general and as specifically applied to sealed source and devices designs, safety evaluations, and registrations.

NUREG-1556, Vol. 3, Rev. 1 is available on the Internet at the following address: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v3/r1>.

This report describes and makes available to the public information on methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations; techniques the staff uses in evaluating applications, including specific problems or postulated accidents; and data the NRC staff needs to review applications for source and device registration. NUREG-1556, Vol. 3, Rev. 1, is not a substitute for NRC regulations, and compliance is not required. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report will be acceptable if they provide enough information for the staff to make the determinations needed to issue or amend a certificate.

Charles L. Miller, Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

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## The Participants for this Revision

Bailey, Marissa G.
Bhachu, Ujagar S.
Brown, Carrie
Fogle, David B.
Schwartz, Maria

## The Participants for Previous Versions

Baggett, Steven L.
Broaddus, Douglas A.
Burgess, Michele L.
Camper, Larry W.
Compton, Eric B.
Cool, Donald A.
Lee, Sueng J.
Lubinski, John W.
Randall, Kimberly B.
Rich, Thomas W.
Schwartz, Maria E.
Smith, Brian W.
Vacca, Patricia C.

# ABBREVIATIONS

| | |
|---|---|
| ADAMS | Agency Document Access and Management System |
| ALARA | As Low As is Reasonably Achievable |
| ANSI | American National Standards Institute |
| Bq | bequerel |
| Ci | curie |
| CFR | Code of Federal Regulations |
| DCD | Document Control Desk |
| FDA | United States Food and Drug Administration |
| FR | *Federal Register* |
| GPO | Government Printing Office |
| IMNS | Division of Industrial and Medical Nuclear Safety |
| ISO | International Organization of Standardization |
| MML | Master Materials Licensee |
| MOU | Memorandum of Understanding |
| NARM | Naturally Accelerator-produced Radioactive Material |
| NORM | Naturally Occurring Radioactive Material |
| NRC | United States Nuclear Regulatory Commission |
| OC | Office of the Controller |
| OCFO | Office of the Chief Financial Officer |
| OGC | Office of the General Counsel |
| QA | Quality Assurance |
| QC | Quality Control |
| STP | [Office of] State and Tribal Programs |

# 1 PURPOSE OF REPORT

This NUREG provides assistance to applicants on submitting requests to NRC for radiation safety evaluation and registration of sealed sources and devices containing byproduct material. In addition, it is designed to provide the reviewer of such requests for sealed source and device safety evaluations with guidance, information, and materials necessary to make a determination that the product is acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

Radiation safety programs for the use of byproduct material as a sealed source or device 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.

NRC maintains the National Sealed Source and Device Registry (NSSDR) of radiation safety information on sealed sources and devices containing byproduct material. Agreement States also provide information on their radiation safety evaluations to NRC for the registry. Both NRC and the Agreement States use the information in the registry. Thus a vendor needs to provide detailed information about its sealed source or device 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 United States.

Any information collection activities mentioned in this document are contained as requirements in 10 CFR Parts 19, 20, 21, 30, 31, 32, 34, 35, 36, 39, 40, 70, and 71, which provide the regulatory basis for this document. The information collection requirements in these parts have been cleared under Office of Management and Budget Clearance Nos. 3150-0044, 3150-0014, 3150-0035, 3150-0017, 3150-0016, 3150-0001, 3150-0007, 3150-0010, 3150-0158, 3150-0130, 3150-0020, 3150-0009, and 3150-0008, respectively.

# 2 AGREEMENT STATES

Certain States, called Agreement States (see Figure 2.1), have entered into agreements with NRC that give them the authority for certain activities, including performing safety evaluations and registration of byproduct, source, or special nuclear materials used, possessed, or distributed by persons within their borders. A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from the NRC's Office of State and Tribal Programs (STP). Any applicant, other than a Federal agency or distributor of a product to persons exempt from licensing, that is located in an Agreement State and wishes to apply for safety evaluation and registration of a sealed source or device needs to contact the responsible officials in that State for guidance on preparing an application. Those entities should file these applications with State officials, not with NRC. Table 2.1 provides a quick way to check on which agency has regulatory authority.

Eight Agreement States (Arkansas, Iowa, Oklahoma, New Mexico, North Dakota, Oregon, Utah, and Wisconsin) have voluntarily relinquished their authority to perform sealed source and device safety evaluations. Applicants and registration certificate holders located in these States are regulated by NRC in the same manner, with respect to sealed source and device registration, as those not located in an Agreement State.

When an Agreement State issues a registration certificate, the State forwards a copy of the registration certificate to the Division of Industrial and Medical Nuclear Safety (IMNS). IMNS performs an administrative review of each certificate that includes looking for gross errors or omissions and ensures the inclusion of all necessary information on the first page of the certificate. The certificate is incorporated into the NSSDR, and copies are distributed to the NRC Regions, all Agreement States, and appropriate Federal and international agencies. If any administrative problems or errors are identified with an Agreement State registration certificate, they are resolved directly with the Agreement State.

Agreement State regulations may vary from NRC regulations. As such, sealed sources or devices registered by an Agreement State may have regulations that vary from NRC regulations, although the regulations are compatible.

**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, U.S. territory, or possession | NRC |
| Non-Federal entity in Agreement State at a non-Federally controlled site | Agreement State |
| Non-Federal entity in Agreement State at a Federally controlled site NOT subject to exclusive Federal jurisdiction | Agreement State |
| Non-Federal entity in Agreement State at a Federally controlled site subject to exclusive Federal jurisdiction | NRC |

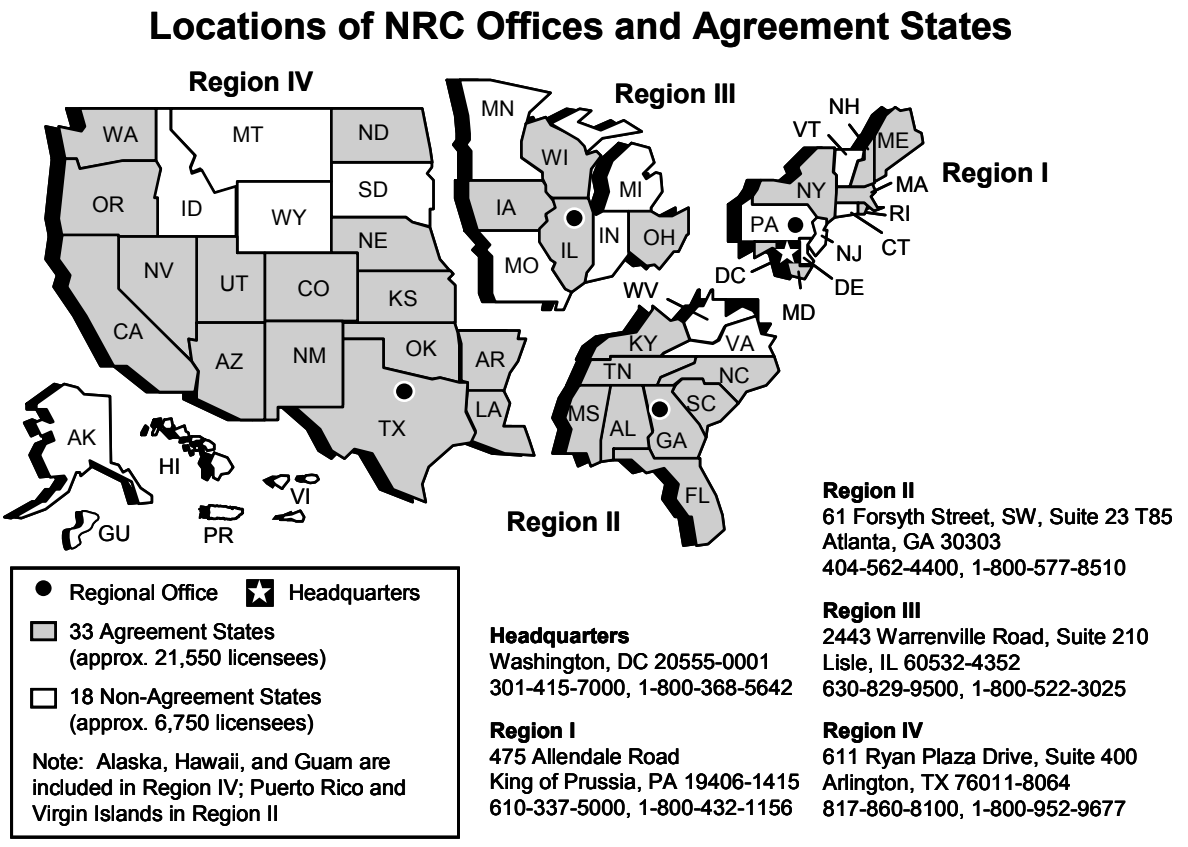



**Figure 2.1 U.S. Map.** *Location of NRC Offices and Agreement States.*

# 3 MANAGEMENT RESPONSIBILITY

NRC recognizes that effective applicant/registration certificate holder management is vital to achieving safety and compliance with regulatory requirements. NRC also believes that consistent compliance with its regulations provides reasonable assurance that regulated activities will be conducted accordingly. Based on the results of routine and special inspections of licensed activities, NRC has determined that ineffective management is frequently the underlying cause of compliance problems. Management refers to a senior-level manager who has responsibility for overseeing regulated activities.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Completeness and accuracy of records and all information provided to NRC (10 CFR 30.9).
- Knowledge about the contents of the application.
- Applying 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.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to ensure that the registration certificate holder meets its regulatory requirements. The registration certificate holder is required to manufacture or distribute the product in accordance with:
  - — the statements and representations contained in the application for safety review and registration;
  - — the provisions of the registration certificate; and
  - — NRC regulations.

Applicants and registration certificate holders may be subject to enforcement actions due to noncompliance with regulatory requirements. For information on the NRC enforcement program, see "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG-1600), which is available from NRC upon request. NUREG-1600 is also available on the Internet. Visit NRC's Home Page <http://www.nrc.gov>.

# 4 APPLICABLE REGULATIONS

It is the applicant's or registration certificate holder's responsibility to have up-to-date copies of applicable regulations, read them, and abide by each applicable regulation. The current versions can be found in the Electronic Reading Room section of NRC's Web site <http://www.nrc.gov>.

The following Parts of 10 CFR contain regulations applicable to sealed source and device evaluations:

- 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"
- 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigation"
- 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 Radiography and Radiation Safety Requirements for 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 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 Operating 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 NRC"

To request copies of the above documents, call the Government Printing Office (GPO) order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of Title 10, CFR, Parts 0 – 50 and 51 – 199 from the GPO, Superintendent of Documents,

Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. Single copies of the above documents may be requested from the NRC's Regional or Field Offices (see Figure 2.1 for addresses and telephone numbers).

The regulations embodied in 10 CFR 30.32(g) and 32.210 codify the current and long-standing practice whereby vendors of sealed sources of radioactive material and devices containing sealed sources submit radiation safety information necessary to perform an independent, technical safety evaluation, and to obtain registration of radiation safety information on certain sealed sources and devices. The practice has been used by NRC (and the United States Atomic Energy Agency) since the 1950s and by the Agreement States starting in 1962.

The specific provisions in 10 CFR 30.32(g) require a license applicant to either make reference to a registered sealed source or device or provide the information necessary to perform a safety evaluation of the sealed source or device. Section 32.210 outlines the NRC safety evaluation and registration criteria and clarifies the regulatory responsibility of registration certificate holders of products for which NRC evaluates and registers radiation safety information.

Current regulations require that products used under a general or specific license issued in accordance with 10 CFR Part 30 be registered with the Commission. However, if registration of a product design is deemed necessary by NRC, the applicant needs to provide the information contained in 10 CFR 32.210 and the application will be evaluated in the same manner as all registration applications.

The products listed in Sections 4.1 – 4.5 are used by persons exempt from licensing requirements or used in accordance with a general license and NRC has determined that registration of the product design is necessary. However, 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 the appropriate section (Sections 4.1 – 4.5) and need to be addressed during the product evaluation.

Some specific-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 4.6 – 4.9 and need to be addressed during the product evaluation.

If the sealed source or device contains NARM or NORM material, then the source or device is under the regulatory jurisdiction of the host State. Although NRC maintains the NSSDR that includes such materials, the applications for registration and amendments for sealed sources or devices containing NARM and NORM sources must be filed with the host State. The States should send a copy of the source and design registrations to NRC to be placed 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, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to 10 CFR 32.22. 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:

| **Area to be Addressed** | **Applicable 10 CFR Regulations** |
|---|---|
| Design | 30.19(a) & (c), and 32.22(a) |
| Maximum Radiation Levels | 32.22(a)(2)(vi) |
| Maximum Dose Commitments | 32.22(a)(2)(xiii) & (xiv) |
| Labeling | 32.25(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, or 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.

The design and prototype testing requirements for gunsights are delineated in Appendix O, "Standard Requirements for Gunsights Containing Tritium Gas Sealed in Glass Vials," in NRC Report NUREG-1556, Volume 8, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses." 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.

The regulation requires identification of the person licensed under 10 CFR 32.22. Identification can be the full name of the licensee, their registered trademark, or their exempt distribution license number.

The use of tritium, krypton-85, and promethium-85 in toys, novelties, adornments, or in 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 where the end use

of the product cannot be reasonably foreseen [10 CFR 30.19(c) and 10 CFR 32.22(b)]. Although the devices may be allowed in foreign countries to be commercially distributed, they cannot be distributed in the United States as delineated in the relevant NRC policy statement (*Federal Register* notice of March 16, 1965, 30 FR 3462).


**Figure 4.1** **Watches and Aiming Sights.** *Watches and aiming sights are products distributed to persons exempt from licensing under 10 CFR 30.19.*

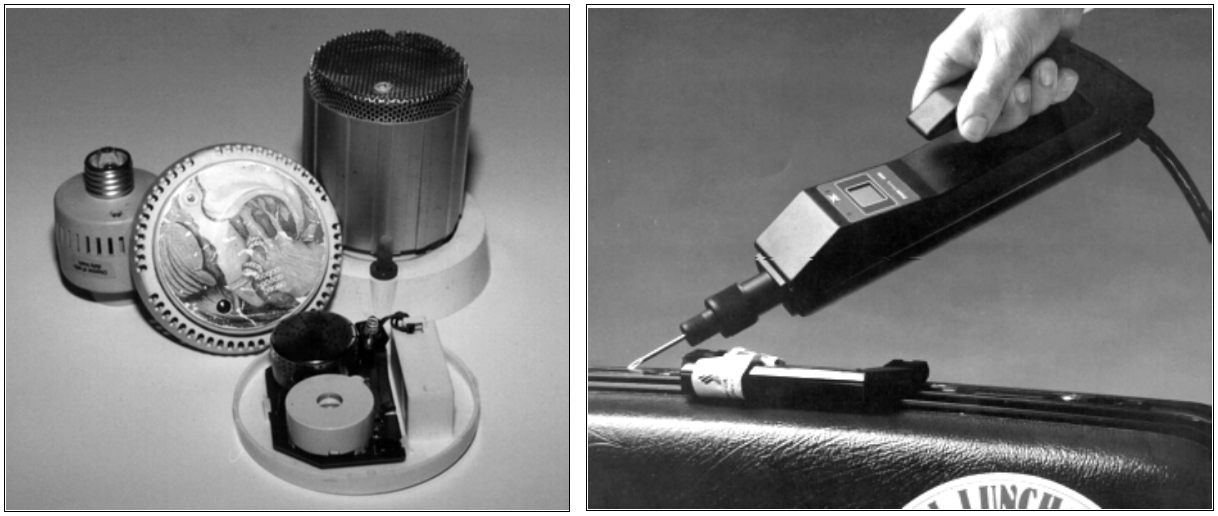


**Figure 4.2** **Smoke and Chemical Agent Detectors.** *Smoke and chemical agent detectors are products distributed to persons exempt from licensing under 10 CFR 30.20.*

## 4.2 GAS AND AEROSOL DETECTORS CONTAINING BYPRODUCT MATERIAL FOR USE BY PERSONS EXEMPT FROM LICENSING REQUIREMENTS

Under 10 CFR 30.20, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to 10 CFR 32.26. 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:

| Area to be Addressed | Applicable 10 CFR Regulations |
|---|---|
| Design | 30.20(a), 32.26[1] |
| Maximum Radiation Levels | 32.26(b)(6) |
| Maximum Dose Commitments | 32.26(b)(13) & (14) |
| Labeling | 32.29(b)[2] |

Regarding gas chromatographs, the electron capture detector (ECD) is usually evaluated instead of the entire device.

## 4.3 DEVICES USED UNDER THE GENERAL LICENSE IN 10 CFR 31.5

Under 10 CFR 31.5, persons may use certain devices in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.51 and 32.51(a). The devices used under the general license include devices designed for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. 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:

---

1 This regulation is applicable to devices designed to protect life or property from fires and airborne hazards. It has been determined that gas and aerosol detectors designed to detect explosives or chemical agents may be licensed for distribution in accordance with this regulation.

2 The regulation requires identification of the person licensed under 10 CFR 32.26. Identification can be the full name of the licensee, their registered trademark, or their NRC exempt distribution license number.

| 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) |
| Registration | 31.5 (c)(13) |

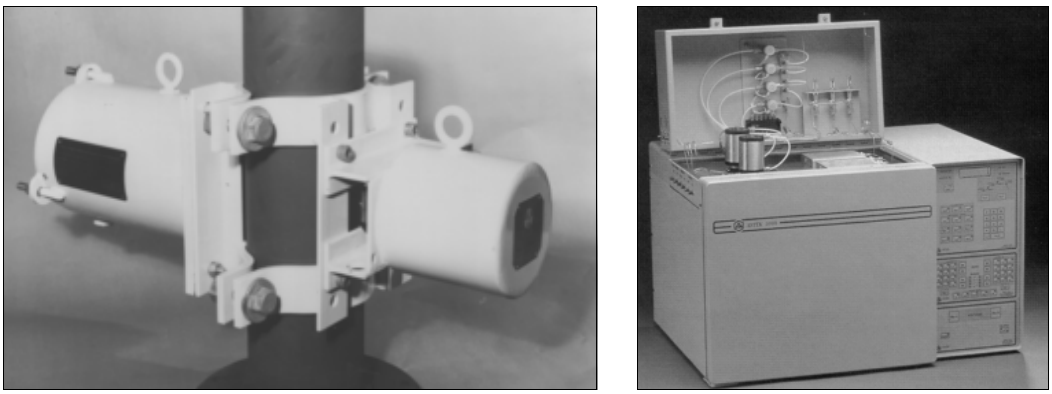


**Figure 4.3 10 CFR 31.5 General License.** *Gas chromatographs, density gauges, and static elimination devices are products used under 10 CFR 31.5 general license.*

## 4.4 LUMINOUS SAFETY DEVICES USED IN AIRCRAFT UNDER 10 CFR 31.7

Under 10 CFR 31.7, persons may use luminous safety devices containing tritium not more than 10 Ci or promethium-147 not more than 300 mCi, in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.53. 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:

| Area to be Addressed | Applicable 10 CFR Regulations |
|---|---|
| Design | 32.53(c) & (d) |
| Prototype Testing | 32.53(d)(4), 32.101 |
| Labeling | 32.54 |
| Quality Control | 32.55, 32.110 |
| Installation and Removal | 32.51(c) |
| Registration | 31.5(c)(13) |

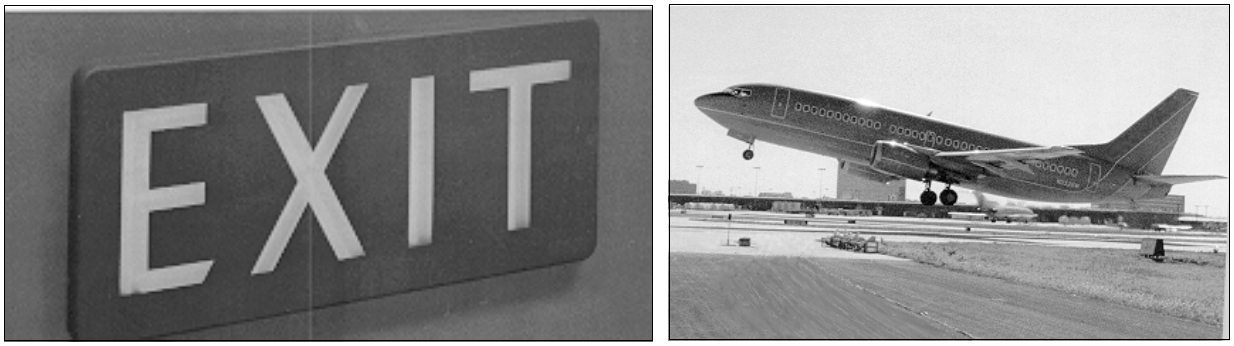



**Figure 4.4 10 CFR 31.7 General License.** *Safety devices, such as exit signs, containing tritium or promethium-147 and used in aircraft may be used under a 10 CFR 31.7 general license.*

## 4.5 ICE DETECTION DEVICES CONTAINING STRONTIUM-90

Under 10 CFR 31.10, persons may use ice detection devices containing strontium-90 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.61. Therefore, the requirements for product evaluation are imposed on the person licensed to 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 | 32.61(c) & (e) |
| Labeling | 32.61(d) |
| Prototype Testing | 32.61(e)(4), 32.103 |
| Quality Control | 32.61(e)(5), 32.62, 32.110 |

## 4.6 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 |

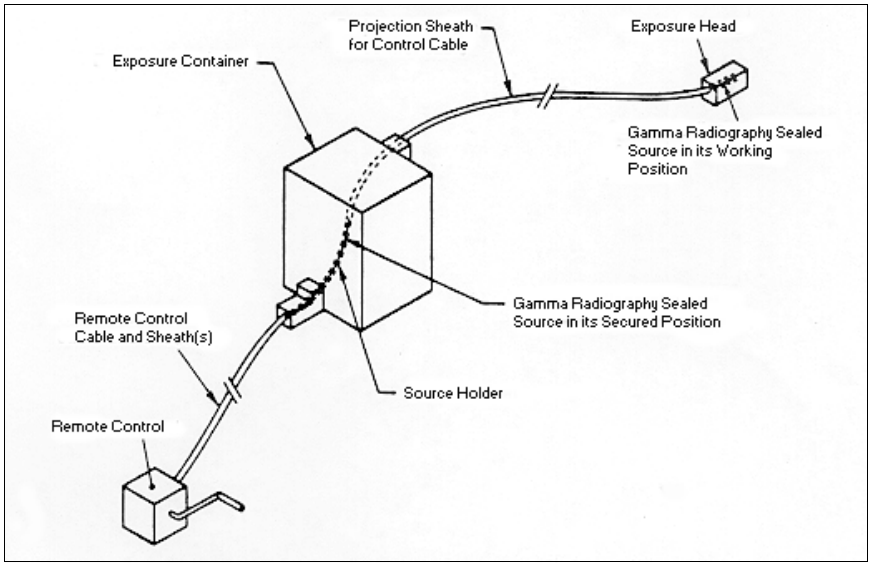



**Figure 4.5 Radiography Equipment.** *Radiography equipment, such as the equipment shown above, must meet the requirements of 10 CFR Part 34.*

NUREG-1556, Volume 2, "Program-Specific Guidance About Industrial Radiography Licenses," provides guidance to an applicant in 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. Only as a matter of convenience, an SSD applicant may include the description of associated equipment that is compatible with the radiographic source or device on the certificate. NRC has discontinued the practice of registering associated equipment because NRC determined that the Commission's regulations do not require associated equipment to be registered (see notice published in the *Federal Register*, July 15, 2003, ref. 68 FR 41757). The regulations (10 CFR 34.20) 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 (ANSI N432-1980). The life cycle test in ANSI N432-1980 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. This requirement is sufficient to maintain safety.

## 4.7 WELL-LOGGING EQUIPMENT

Persons specifically licensed to perform well-logging operations are only authorized to use equipment that meets the requirements of 10 CFR Part 39, Subpart C. 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. Therefore, 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) |

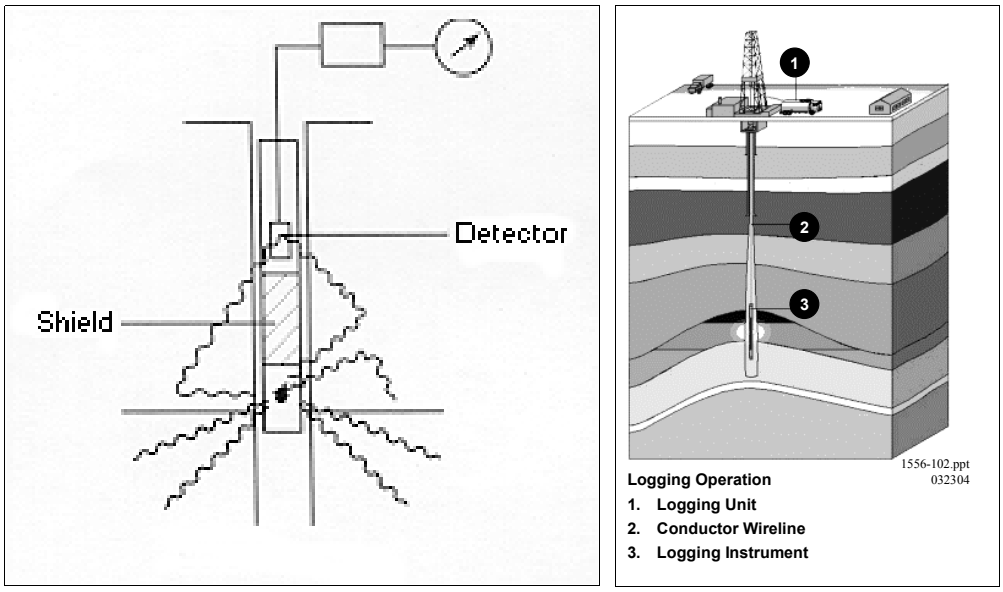
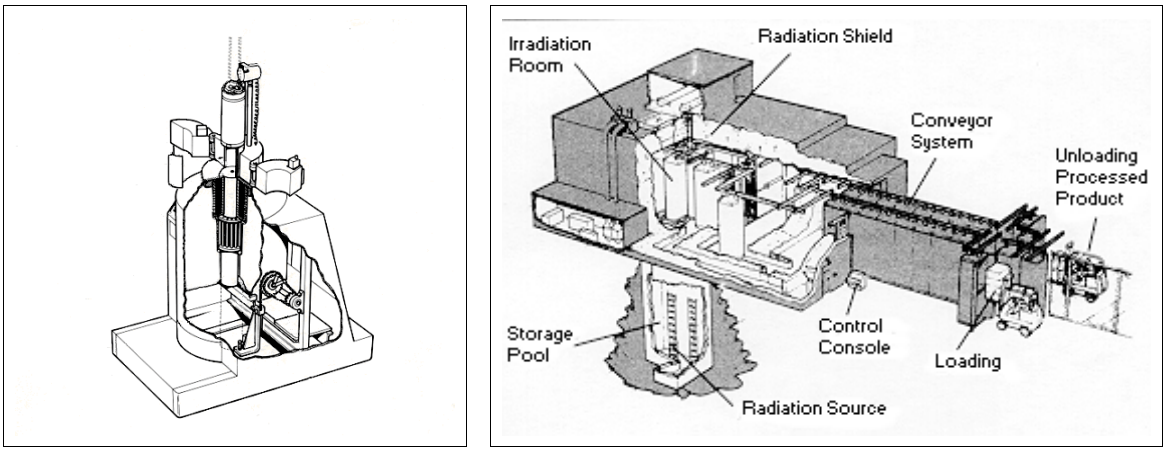



**Figure 4.6 Well-Logging Operations.** *Sealed sources used in well-logging operations must meet the requirements of 10 CFR Part 39.*

## 4.8 IRRADIATORS

Persons specifically licensed to use sealed sources in irradiators are only authorized to use sealed sources that meet the requirements of 10 CFR 36.21. 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) |




(a) (b)

**Figure 4.7 Irradiators.** *NRC evaluates both (a) category I (self-shielded) irradiators and (b) sealed sources used in category IV (Panoramic, wet source storage) irradiators.*

## 4.9 SEALED SOURCES AND DEVICES FOR MEDICAL USE

NRC has revised the requirements for the medical use of byproduct materials, in 10 CFR Part 35, to implement a risk-informed, performance-based approach to regulation. Revisions for medical licensees became effective October 24, 2002. In conjunction with the revised medical use regulations, NRC has published NUREG-1556, Vol. 9, "Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses." This guidance document provides information on applying for a medical use license.

Revised 10 CFR Part 35 states that, in accordance with 10 CFR 35.49, only sealed sources and devices that are manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74, or equivalent requirements of an Agreement State, may be used for medical purposes. Calibration, transmission, and reference sources in 10 CFR 35.65(a) and 35.65(b), used by medical licensees, must also meet the requirements in 10 CFR 32.74 or equivalent Agreement State requirements.

| **Area to be Addressed** | **Applicable 10 CFR Regulations** |
|---|---|
| Labeling | 32.74(a)(2)(viii) & (a)(3) |
| Leak Testing | 32.74(b) |

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

Prior to evaluation of a sealed source or device for medical use, the applicant must provide proof of Federal 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 FDA has several types of approvals for medical devices. One of the following four FDA approvals must be obtained before evaluation and registration of the device:

1. Premarket Notification (510(k))

   A 510(k) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is safe and effective, and 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 medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which 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 is exempt from the effectiveness requirements of a PMA. An 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 United States per year.

4. Investigational Device Exemption (IDE)

   An IDE allows the investigational device to be used in order to collect safety and effectiveness data required to support a premarket approval application or a 510(k) submission to the FDA. IDEs can be approved by only an Institutional Review Board (IRB) or by both an IRB and FDA.

   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 are required to perform their own safety analysis.

Applicants should provide as part of the application, proof that the information was reviewed by the FDA:

- type of FDA approval (510(k), IDE, PMA, or HDE, or IDE),
- sealed source activity for patient treatment approved by the FDA (if applicable), and
- any specific conditions or limitations imposed by the FDA that users should know.

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

Master Materials Licensees (MML) may not perform their own SSD review. A Broad Scope Permitee of an MML may perform their own safety analysis for sealed sources and devices as allowed under 10 CFR 33.13(c)(3)(iii).

For additional information on broad scope licenses, refer to Section 5.1.2 of this document.

# 5 GENERAL POLICIES AND PROCEDURES

## 5.1 SEALED SOURCE AND DEVICE DESIGNS THAT DO NOT REQUIRE EVALUATION AND REGISTRATION

The provisions of 10 CFR 30.32(g) apply to all sealed sources and devices used by NRC specific licensees and requires registration of the product by NRC. However, the possession and use of certain products do not require the evaluation and registration of the product by NRC or Agreement States. Specifically, evaluation and registration of the following products should be handled as indicated below by the license reviewer.

### 5.1.1 CALIBRATION AND REFERENCE STANDARDS

Calibration and reference sources may be licensed without registration by NRC or Agreement States if the sources do not exceed the following:

- For beta and/or gamma emitting material – 3.7 MBq (100 μCi) or ten times the quantity specified in Section 30.71, Schedule B, 10 CFR Part 30, whichever is greater.
- For alpha emitting material – 0.37 MBq (10 μCi).

The above values were chosen because they represent a minimal hazard to public health and safety. 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 possession and distribution to specific licensees may be authorized.

NRC does not authorize combining, also referred to as "bundling," exempt quantity sources in products for commercial distribution. NRC's position on bundling can be found in NRC Generic Letter 99-01: "Recent Nuclear Material Decision on Bundling Exempt Quantities," dated May 3, 1999. In some specific applications the use of multiple calibration sources is permitted as specified by the provisions of 10 CFR 30.15(a)(9). To manufacture and distribute a device with multiple calibration sources, the applicant must satisfy the applicable requirements for licensing (10 CFR 32.14).

**Figure 5.1 Calibration and Reference Sources.** *Calibration and reference sources may not need evaluation and registration by NRC or Agreement States.*

## 5.1.2 PRODUCTS USED IN RESEARCH AND DEVELOPMENT OR BY BROAD SCOPE LICENSEES

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

- 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.

NRC has granted broad scope licensees the authority to use sealed sources and/or devices 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 sealed source or device 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 review and approval of these safety evaluations by the radiation safety committee. This is especially important with the advent of emerging medical technologies used under 10 CFR Part 35. U.S. Food and Drug Administration reviews for medical efficacy of a product cannot be substituted for this evaluation. The review should determine if a source or device can be safely used from a radiological standpoint and provide adequate radiological protection for its intended use at the institution. This review 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. It is the licensee's responsibility to perform this review, obtain any necessary design and test information from the vendor and, if needed, conduct 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 sealed source or device 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 prior to transfer.

Licensing officials should utilize the following standard license condition for those recipients of the registered sealed source contained in unregistered devices:

> The licensee shall use only sealed sources for which a sealed source registration certificate has been issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210(e) or an Agreement State. Possession and use of the sealed sources used must adhere to the conditions and limitations of the registration certificate and the commitments made in the license application.

## 5.1.3 CUSTOM SEALED SOURCES OR DEVICES

Sealed sources or devices containing sealed sources built to the unique specifications of a given user (custom) need not be sent to NRC or the Agreement State for registration if: (a) they contain less than 7.4 GBq (200 mCi) of radioactive material or less than 740 GBq (20 Ci) of tritium, and (b) 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. Thus, the applicant would not have to rely on the intrinsic safety of the sealed source or device to demonstrate compliance with 10 CFR 30.33. Custom sealed sources and devices which contain an activity greater than that listed above must be submitted to NRC or the Agreement State for evaluation and registration.

To license these custom sealed sources and/or devices, 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 — examples include "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 described above, that have not been evaluated and registered by NRC or the Agreement State, apply to only to the custom user of the product. Licensees with custom sealed sources and devices should inactivate the custom registration in accordance with Section 13.4 of this guide when the sources/devices are permanently disposed

of, placed in permanent storage, or transferred to another licensee that has obtained their own custom registration or to a licensee with broad scope authorization.

A new custom evaluation must be performed when devices are transferred to new locations. These evaluations encompass specific safety features and operating procedures for each location of use.

## 5.2 CUSTOM USERS

A user of a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant is considered a custom user. Custom users are specifically identified on the first page of registration certificates. The request for the safety evaluation and registration of the product may be made by the custom user or vendor. Regardless of the applicant, the custom user is required to meet all commitments made in the application and registration certificate. Typically, 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 Commission's requirements to establish programs, procedures, and engineering controls for achieving doses that are as-low-as-is-reasonably-achievable (ALARA) are included in 10 CFR 20.1101. Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," explains 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 sealed sources or devices to avoid unnecessary exposures during installation, maintenance, repair, and use of the sealed source or device. Regulatory Guide 8.10 may be useful to applicants for establishing and following an ALARA philosophy during the design of a sealed source or device.

## 5.4 NATURALLY OCCURRING OR ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL

NRC does not have regulatory authority over sealed sources or devices containing NORM/NARM in either Agreement or Non-Agreement States. Although NRC does not regulate sealed sources or devices containing NORM/NARM, NRC maintains the NSSDR that contains registration certificates for some of these sealed sources and devices. This has been done to accommodate the fact that certain States require sealed sources or devices containing NORM/NARM to be registered. Therefore, Agreement and Non-Agreement States issuing registration certificates for these sealed sources or devices may send copies of the registration certificates to NRC. NRC will not perform a review of these certificates but will incorporate these certificates into the NSSDR. Copies are forwarded to the NRC Regions, all Agreement

States, and appropriate Federal and international agencies, as a service. Questions concerning NORM/NARM certificates should be directed to the State or STP.

As a general rule, NRC does not accept applications for radiation safety evaluation and registration of sealed sources or devices that contain NORM/NARM. Exceptions to this general rule include sealed sources or devices that contain material that can be reactor or accelerator produced (e.g., cadmium-109), or sealed sources or devices that contain NORM/NARM commingled with byproduct material, in either the same or separate encapsulations (e.g., moisture density gauges containing radium-226 and cesium-137).

## 5.5 FOREIGN VENDORS

Foreign vendors present a unique situation for NRC in that NRC has no jurisdiction over foreign entities. A foreign vendor is required by the provisions of 10 CFR 110.53(a) to establish an address in the United States to which NRC can correspond and serve papers as necessary to accomplish its mission. Accordingly, NRC accepts applications with a U.S. address of 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 designates the foreign vendor as the manufacturer. See Section 10.1 of this volume for further information on the designations. The U.S. distributor's responsibilities include the implementation of a quality assurance program to assure that the imported products are in accordance with the statements made in support of the registration certificates. In addition, NRC inspects the distributor of the product and may periodically audit foreign vendors to determine if the products distributed in the United States are in accordance with the statements made in support of the registration certificates.

**Figure 5.2** **Map of the World.** *Foreign vendors are required to establish an address in the United States to which the NRC can correspond and serve papers as necessary to accomplish its mission.*

## 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 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 American National Standards Institute (ANSI) N432-1980 for radiography equipment). 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 use, handling, storage, and transport of the product to determine if the standard is acceptable. The foreign or international standard may be compared with an applicable United States standard in determining the acceptance of the standard. This may include professional judgment on the parts of the applicant and reviewer.

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 — FDA–NRC MEMORANDUM OF UNDERSTANDING

The FDA and NRC signed a Memorandum of Understanding (MOU)[3] 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 NRC, this includes information used for product evaluations and approvals, and any incidents involving product failures. The FDA should be notified in writing when NRC begins an evaluation of a medical product, whether it is for a new 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 premarketing approval issued by FDA (FDA form 510(k)). If the premarketing approval is not submitted with the application, the applicant will be instructed to contact the FDA and obtain the appropriate approval.

3 The MOU was published in the *Federal Register* on December 23, 2002.

Applicants needing information on FDA requirements may contact:

Food and Drug Administration
Office of Compliance
HFZ-300
2098 Gaither Road
Rockville, MD 20850
(301) 594-4692

## 5.8 COMPUTER SOFTWARE

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 reviewer will determine that if such systems fail (e.g., a power failure), the sealed source or shielding would return to, or remain in, the fully shielded position. Medical applications involving computer software and patient planning systems are, in general, within FDA jurisdiction and FDA is responsible for any necessary review of the software.

**Figure 5.3** **Computer Software.** *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.*

## 5.9 REGISTRATION CERTIFICATE REVOCATION

If it is determined that a sealed source or device evaluated by NRC or the Agreement State may pose an undue hazard when used in accordance with the conditions of the registration certificate, and corrective actions cannot be implemented or agreed upon between the registration certificate

holder and NRC or the Agreement State, then NRC or the Agreement State may modify or remove the registration certificate from the NSSDR and may issue orders modifying licenses to all persons licensed to use the sealed source or device. NRC will also notify STP so that the Agreement States are made aware of the NRC actions concerning the sealed source or device.

## 5.10 INCIDENTS

Incidents involving products evaluated and registered by NRC are assessed to determine whether the integrity or adequacy of the product was compromised. The assessment involves a reevaluation of the product to determine its integrity and adequacy, taking into account the causes of the incident. If it is determined that a generic product fault exists, the registration certificate holder will be notified and appropriate actions, affecting both products currently in use and newly manufactured products, will be taken. In addition, NRC will re-evaluate similar products to ensure 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 reevaluation of the product.

Some information concerning incidents involving products evaluated by NRC is kept on file for use in performing future evaluations of the products involved and products similar to those involved. However, the Office of Nuclear Security and Incident Response (NSIR) is the NRC office responsible for compiling, tracking, and analyzing incidents and reports.

## 5.11 PROPRIETARY INFORMATION

Registration certificates and information contained in the background files for the registration certificates, such as applications, may be made available to the public. Persons may request access to this information in accordance with 10 CFR 9.23.

Proprietary information (i.e., information not to be disclosed to the public) should not be included in an application 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, in accordance with 10 CFR 2.390, for withholding the information. The applicant must request withholding at the time the document is submitted 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 B includes a checklist for requests for withholding information from public disclosure). If the request is denied, in whole or in part, the reviewer needs to give the applicant

the option of withdrawing 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 denied 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, for example, if the scope of a Freedom of Information Act request includes the information. In all review situations, if 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.

## 5.12 TRANSPORTATION

This document does not cover detailed requirements for the transportation of devices and sealed sources. NRC's transportation requirements are contained in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." The provisions in 10 CFR Part 71 establish the following:

- procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of licensed material in excess of a "Type A quantity" (i.e., exceeding $A_1$ or $A_2$ as defined in 10 CFR 71.4); and
- requirements for quality assurance, packaging, preparation for shipment, and transportation of licensed material.

An application for radiation safety evaluation and registration of a sealed source or device as discussed in this document does not include a detailed description of packaging and transportation procedures to demonstrate compliance with 10 CFR Part 71. The applicant is expected to be familiar with the way those requirements apply to the sealed source or device and the action needed to ensure that transportation of the device is performed in accordance with applicable requirements.

Any vendor who has questions about the requirements for transportation should contact the appropriate NRC Region or NRC's Transportation Safety and Inspection Branch, Spent Fuel Project Office, at (301) 415-7000 to obtain assistance. Certificates of Compliance for Type B Transportation packages can be found at the Web site <http://www.rampac.com>.

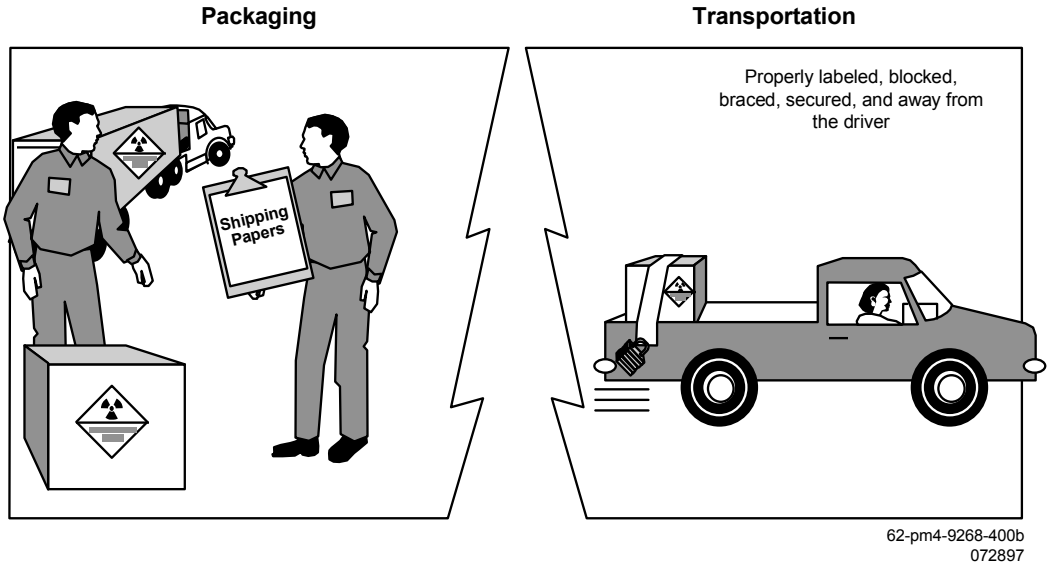



**Figure 5.4 Packaging and Transportation.** *Registration certificate holders must meet all NRC and DOT requirements for packaging and transporting sealed sources and devices.*

Although NRC or the Agreement State does not evaluate packaging or transportation requirements during sealed source or device evaluations, the effects of the packaging or transportation on normal use and operation of the product are part of the evaluation. Specifically, NRC or the Agreement State evaluates the effects of normal conditions experienced during transport (e.g., extreme temperatures, vibration) on the sealed source or device. Applicants should consider these effects during the design of 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 173 Subpart I. Having a manufacturer demonstrate and certify that a device meets the Type A packaging requirements clarifies for the shipper if additional packaging and certification are necessary. This information may be included in the device registration. Type B packages are evaluated separately by NRC.

# 6 HOW TO FILE

No special form is required for applications for sealed source or device evaluations. However, to facilitate the review process, applicants for a sealed source or device evaluation are encouraged to perform the following.

## General/Format

To standardize the format of an application for a sealed source or device, 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.
- Review the online NSSDR for (a) the potential existence of a product evaluation for the device/source the applicant is about to submit for evaluation and (b) specific examples of the type of information, based on accepted evaluation of similar devices/sources, necessary to be submitted to NRC for product evaluation.
- Submit all documents, including all drawings if practicable, printed, on standard 8-1/2 inch × 11 inch paper. If submission of larger documents is necessary, they should be folded to 8-1/2 inch × 11 inch.
- Number all pages in an application, consecutively. If revisions are necessary after an application has been submitted, revised or replacement pages should be submitted and should show the date of revision or revision number. Supplemental pages submitted for insertion should be indicated alphanumerically (e.g., 12a, 12b).
- Submit an original, signed application and one additional copy. Retain a copy of the registration application for future reference.

## Content

To standardize the contents of an application for a sealed source or device, applicants are encouraged to perform the following steps:

- Complete the "Summary Data" section of Appendix A, "Application and Review Checklist."
- Attach the balance of the application to the "Summary Data" information. The order of the information in the application should correspond to the appropriate subsection in Chapter 10.
- Use the "Checklist" included in Appendix A as a guide to determine whether all necessary information has been provided.
- Include drawing(s), no larger than about 4 inch × 6 inch, that are suitable to be included in the registration certificate and that provide an overall representation of the product and its safety features.

- 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, operating manuals, descriptive sales literature, or similar documents when they are submitted as part of an application. This might be done 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.
- Avoid submitting proprietary information unless it is absolutely necessary.
- 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. All abbreviations and acronyms should be defined.

## Engineering Drawings

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

- A drawing number, revision number, company name, title, scale, and date should be included. References to parts or other drawings should be clearly indicated. If drawings have been reduced or enlarged, this should be clearly indicated.
- 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; assembly methods; source mounting and security; and dimensions, tolerances, and materials of construction suitable for insertion in a source or device registration should be included.
- The drawings should include overall details of the safety related components (e.g., outer housing, secondary shielding, C-frames, and environmental control systems).
- The drawings should include complete details for safety critical 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 should be included.
- Function/operation.
- 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).
- Accessibility of the radiation beam during use (including air gaps that could allow radiation exposures and barriers/guards).
- Tamper resistant construction/hardware.

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

It may be advantageous to submit a product (without radioactive material) or a part of a product with an 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.

All license applications will be available for review by the general public in NRC's public document room and on NRC's ADAMS document control system which can be found at <http://www.nrc.gov>. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.390. See Section 5.11 of this NUREG for additional details.

Applications may be scanned or put through an optical character reader to convert them to electronic format. To assist with the conversion of the application to electronic media, applicants are requested to follow these suggestions:

- Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into a scanner.
- Be sure the print is clear and sharp.
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

NRC has amended its rules to clarify when and how licensees may use electronic means such as CD-ROM and e-mail to communicate with the agency. The agency has a guidance document on electronic submittals. The Electronic Maintenance and Submission of Information rule (ADAMS ML032580290), 10 CFR Chapter I, became effective on January 1, 2004.

# 7 WHERE TO FILE

Applicants located in States or territories subject to NRC jurisdiction wishing to register a sealed source or device may file an application with NRC by submitting the application to:

United States Nuclear Regulatory Commission
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
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:

United States Nuclear Regulatory Commission
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Two White Flint North
11545 Rockville Pike
North Bethesda, MD 20852-2738

Applicants in locations subject to Agreement State jurisdiction wishing to apply for safety evaluation and registration of a sealed source or device should file the application with the appropriate Agreement State agency, not NRC. See Chapter 2 for additional information concerning filing applications with Agreement States.

# 8 REGISTRATION FEES

Each application for which a fee is specified must be accompanied by the appropriate fee, including applications for new registration certificates and registration certificate amendments. Refer to 10 CFR 170.31 to determine the fee amount. For applicants for sealed source and device evaluations, the appropriate fee categories are 9A, 9B, 9C, and 9D. The registration certificate or amendment will not be issued until full payment of the fee has been received. Once the technical review process has begun, no fees will be refunded; application fees will be charged regardless of NRC's disposition of an application or the withdrawal of an application.

Most NRC registration certificate holders are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for additional information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for registration certificate holders that may qualify as "small entities."

Direct all questions about NRC's fees to the Office of the Chief Financial Officer (OCFO) at the NRC headquarters in Rockville, Maryland, (301) 415-7000.

# 9 DOCUMENT FLOW

## 9.1 APPLICATION RECEIPT AND ASSIGNMENT TO A REVIEWER

Requests for safety evaluations of sealed sources or devices usually are submitted by the applicant directly to NRC or the Agreement State. However, applications may be submitted to other NRC Divisions or Offices (e.g., as part of a licensing action) and forwarded to IMNS 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 OCFO may receive a request to make a registration certificate inactive. The processing of the application is the same in all cases.

NRC staff submitting technical assistance requests for sealed source and device evaluations to IMNS should use NRC Form 567, "Request for a Sealed Source Device Evaluation." The requester needs to follow the instruction block at the top of the form for specific detail on how and what to submit.

When NRC or the Agreement State receives an application, an acceptance review may be performed to determine whether there is sufficient information to initiate a review. If there is insufficient information, the entire package may be returned to the applicant for resubmission of a complete application.

As specified by the NRC or Agreement State internal procedures, applications are logged into the sealed source and device action tracking system where they await assignment to a reviewer. Each action is assigned 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 dire need for the product to protect public health and safety, the product providing a currently unavailable benefit to society, or commercial hardship that is likely to be experienced by the applicant if the evaluation process is delayed. Requests for higher priority should include adequate justification.

While an application is awaiting assignment to a reviewer, a copy of the cover letter to the application and of NRC Form 567 is sent to the OCFO for verification that the appropriate application fees have been received. The OCFO will return NRC Form 567 to IMNS indicating whether the appropriate fees have been collected. IMNS may start an evaluation of a sealed source or device before fees are collected, however, a final approval of the product will not be issued until the application fees are paid in full.

## 9.2 EXPEDITED REVIEWS

### NRC–Expedited Reviews on the Basis of National Security

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

1. A request for expedited review is made directly to NRC by the U.S. Military or a Federal Agency (e.g., U.S. Customs, Federal law enforcement agencies).
2. A request is made in writing (e-mail is acceptable) by the appropriate agency official to the appropriate Section Chief or higher-level management.
3. The requesting agency should state that national security is at stake and briefly, and in general terms, describe what the product will be used for. A detailed description that could disclose sensitive information is not necessary. 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 that:
   a. the application is of sufficient quality and provides the necessary information to support an expedited review, and
   b. the applicant is responsive to NRC requests for information.

In conducting the 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 judgement.

## NRC–Expedited Reviews for Reasons Other than National Security

An application may be assigned a higher priority upon request. Requests for higher priority must include adequate justification as indicated. Any request must be made by the Company President or CEO, in writing to the appropriate NRC manager, and include the following information:

1. On the dire need for the product to protect public health and safety, the product provides a currently unavailable benefit to society. The applicant must provide details of the need, including (a) who directly benefits from the use of the product, (b) how they benefit, (c) how existing products fail to provide that benefit, (d) why the review must be accomplished in less that the normal review time, and (e) when is it needed.
2. A description of the commercial hardship that is likely to be experienced by the applicant if the evaluation process is delayed. The applicant must provide details of the hardship, including (a) who is affected by the hardship; (b) how they are affected (e.g., bankruptcy, layoffs); and why completion of the action is the only way to avoid that effect; (c) why the review must be accomplished in less than the normal review time; and (d) when it is needed.

## 9.3 RESPONSIBILITIES OF THE REVIEWER

The reviewer is responsible for performing the technical evaluation of the product, ensuring the product meets all applicable standards and regulations, corresponding with the applicant to obtain additional information, if necessary, generating the registration certificate, and ensuring the application is reviewed and signed by two persons having signature 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, it may be necessary for the reviewer to exercise professional judgment regarding the adequacy and safety of the product design. Such judgment should be discussed with the applicant and included in a note from the reviewer to the registration file. A copy of the note to the registration file should be provided to the applicant.

Once the evaluation and registration are complete, 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.

See Chapter 2 for NRC's role in the review of Agreement State registration certificates.

## 9.4 DISTRIBUTION OF COMPLETED CERTIFICATES

The registration assistant processes distribution of all registration certificates issued by NRC and the Agreement States.

After the registration certificate is completed and the package is forwarded to the registration assistant, all correspondence between NRC and the applicant is sent to the Document Control Desk (DCD). Copies of Agreement State certificates in their entirety should be forwarded to DCD. DCD ensures that the information is included in the Public Document Room and NRC's file management system, called the Agency Document Access and Management System (ADAMS), which can be accessed through the NRC Web site <http://www.nrc.gov>.

The registration assistant distributes copies of all registration certificates to the NRC Regions, all Agreement States, other Federal agencies, and international agencies. The NRC Document Control Desk ensures that original NRC registration certificates are maintained in the registration folders and that a master set of copies of the certificates is maintained and easily accessible.

## 9.5 INCLUSION IN THE SEALED SOURCE AND DEVICE COMPUTERIZED REGISTRATION SYSTEM

Once issued, the registration certificate is added to the sealed source and device computerized registration system. The registration certificate is included in the system and certificate information can be located by searching on any item that is included in the certificate (see Section 12.2). The registrations can be found in NRC's Office of State and Tribal Programs (STP) Web site <http://www.hsrd.ornl.gov/nrc/asframe.htm>.

# 10 APPLICATION AND REVIEW PROCESS

Applicants requesting safety evaluations and persons who evaluate the adequacy of products should address the following items to verify sufficient information is submitted and determine whether the design of the product is adequate for its proposed uses.

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

It should be noted that certain regulations include specific requirements applicable to evaluation and registration of products. Chapter 4 lists these regulations and each regulation also is listed at the end of the applicable topic of this section. The regulatory requirements take precedence over the general guidance provided in this section. Applicants must ensure, and reviewers verify, that all regulatory requirements are met.

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

## 10.1 SUMMARY INFORMATION

### 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 distributor. However, if different, the distributor should be the person applying 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 instances, 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 United States. In such cases, NRC issues a separate vendor code and registration certificate to each of the distributors in order to maintain distinction and traceability of the product(s). See Appendix C for 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 initially manufactured and/or transferred

pursuant to 10 CFR 30.41 or 32.74 or under equivalent Agreement State requirements, by the manufacturer for use or resale and requires evaluation/registration of the product with the guidance provided 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 as 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, specific approval from NRC, in the form of a `specific license and separate evaluation/registration of the sealed source or device must be obtained.

For redistribution of sealed sources or devices, the reviewer should confirm the following:

- Sealed sources or devices to be redistributed will be obtained from a person licensed pursuant to 10 CFR 30.41 or 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.

## Custom User

Applications must indicate whether the product is intended for use by a custom user. The custom user must be identified by name and complete address. See Section 5.2 for additional information concerning custom users.

A product specifically designed and constructed to the order of a single licensee may be considered a custom product. Since there is a single user of the product, 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.

## Other Companies Involved

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

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

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 model number is used by NRC and Agreement States 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, there should be similarities in the design and construction of the products. Applicants should provide detailed engineering drawings of each basic source or device series containing overall dimensions, maximum and minimum dimensions, tolerances, materials of construction, and differences between models in the series.

The application needs to identify the sealed source or device 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. A listing of principal use codes is included in Appendix C. This information assists applicants and reviewers in determining the applicable regulations, codes, and standards that affect registration of the product.

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. Information needed to make this determination must be provided by the applicant. This is discussed further under Section 10.2, which addresses the conditions of use of the product.

## 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. It is not necessary for applicants to 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 model number designation and the manufacturer or distributor of the sealed source, as listed on the registration certificate for the sealed source, must be identified.

## 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 only approved for use in the device.

## Leak Test Frequency

The applicant must provide the maximum time interval between leak tests to be performed on the product. Typically, products are required to be leak tested at intervals not to exceed 6 months. Leak test procedures must be capable of detecting the presence of 185 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 kBq (10 μCi) are exempt from periodic leak testing requirements. However, prior to initial distribution of the product, a leak test should be performed.

Devices may be approved with leak test intervals greater than 6 months if sufficient information is submitted to justify such a request. Current policy requires, for specific- or general-licensed products, the applicant to supply the information listed in 10 CFR 32.51(b) or 32.74(b)(1) for a safety and risk analysis if a longer leak test interval is requested.

The following regulations should be referenced for additional information concerning leak testing:

| Regulations | Applicability |
|---|---|
| 10 CFR 32.51(b) | Devices used under the 10 CFR 31.5 general license |
| 10 CFR 34.27 | Sources and devices designed for use in radiography operations |
| 10 CFR 39.35 | Sources used in well-logging operations |
| 10 CFR 36.59 | Irradiator operations |
| 10 CFR 35.67(f)(4) | Seeds of Iridium-192 encased in nylon ribbon |
| 10 CFR 32.74(b) | Sources or devices for medical use |

### 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, signing the application acknowledges management's commitment and responsibilities for the regulatory requirements. **NRC will return all unsigned applications for a proper signature.**

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

## 10.2 CONDITIONS OF USE

The applicant must identify, and the reviewer must evaluate, 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, QC and quality assurance (QA), or leak testing requirements.

The intended use of the product should include descriptions of 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 regarding the product's estimated working life to determine whether it is justified based on the information submitted. Inclusion of the working life of the product is important since registration certificates do not have expiration dates. Therefore, the working life provides an indication of when servicing or reevaluation of product integrity may be necessary.

## 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. This 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 the 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 means of relocation if portable, the primary construction materials used for the product's structure and integrity and for its safety features, accessibility of the radiation beam during use, the means of providing containment, security, and shielding of the radiation source including shutters or other movable shielding, location and operation of on/off or shielded/exposed indicators, and identification of other design features that protect the product from abuse or tampering. In addition, the identification of the components of the product 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 complete annotated engineering design and/or construction drawings of all safety critical components, specification sheets, materials lists, and/or detailed written descriptions. In particular, mounting and integrity of the radioactive material or sealed source in the product must be described in detail. Drawings of safety critical parts and components should be fully dimensioned with tolerances, include identification of the safety critical parts, indicate the materials of construction or refer to a materials specification sheet or list, indicate fabrication and assembly methods, and include a drawing number and revision date or number. Parts critical to safety include those parts or components that provide primary containment, safety, and shielding of the radioactive material or sealed source. In addition, drawings and descriptions of non-safety critical components and parts that contribute to safety and/or integrity of the product should be provided. 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 determine if the non-safety critical components could degrade the effectiveness or usefulness of safety critical components.

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 need to be adequately described. In addition, 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 need to be addressed.

The reviewer must evaluate how the product is constructed and evaluate its integrity. The reviewer should 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, and drastic changes in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.
- If construction includes use of dissimilar materials, the materials are compatible and corrosion is not likely to occur because of 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).
- The materials of construction (e.g., adhesives, lubricants, and gaskets) will not be detrimentally affected by exposure to radiation or expected conditions of use.
- The assembly methods would have no detrimental effects on the product during its fabrication (e.g., heat from welding a holder directly to the sealed source, secure 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 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 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, 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 would cause the shutter to return to, or remain in, the fully shielded position.
- If applicable, tamper-resistant hardware or assembly methods are used in the design of the device. Typically, this is required for devices used by general licensees and persons exempt from licensing.
- If applicable, 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.

Integrity of the product does not necessarily mean the product will perform its intended uses after being subjected to an accident or unlikely use conditions. However, the product should still ensure 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% constitutes a compromise of the shielding integrity.

The following regulations should be referenced for additional information concerning product designs:

| Regulations | Applicability |
|---|---|
| 10 CFR 30.19(a) and (c)<br>10 CFR 32.22(a) | Devices used under the 10 CFR 30.19 exemption |
| 10 CFR 30.20(a),<br>10 CFR 32.26 | Devices used under the 10 CFR 30.20 exemption |
| 10 CFR 31.5(a),<br>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 34.20 and 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 |

## 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. It is recommended that applicants provide samples or copies of the labels as part of the application.

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

### Devices

Label devices with the following, as suggested:

- Include the Model Number, Serial Number, Isotope, Activity, Distributor's Name, Date of Assay, Trefoil Symbol, and the words "CAUTION – RADIOACTIVE MATERIAL."[4]
- If applicable, the label should include a statement that it contains depleted uranium as shielding and include the total weight of the uranium.
- The label should also include limiting conditions of use or other information necessary for safe use of the product, such as servicing instructions, if applicable.

### Sealed Sources

Label sealed sources with the following, as suggested:

- Include the same information as included on a device. However, because of its size, all of the information may not fit. Therefore, it should contain as much of the information as possible with inclusion based on the importance of the information. The applicant should provide a justification for which information will be included. Final approval of the information is left to the discretion of the reviewer. Below is a listing of the information, in order of importance, with a description of why the information should be displayed:
  - — Trefoil Symbol and/or the Words "CAUTION – RADIOACTIVE MATERIAL" – This information is important if a source is found by a member of the public since it alerts the person finding the source that it contains radioactive material. The trefoil system is fairly

4 The word "danger" may be used in lieu of the word "caution."

well recognized. Therefore, for small sources where all the information may not fit, it is probably 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 back to this information, either the vendor or the last person possessing the source must be known and be 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 Logo – This is important in trying to locate additional information concerning the source. Information about the distributor resides in the NSSDR. Alternate distributors may also be identified in the registration certificate.
- Model Number – NRC includes the sealed source model numbers in its sealed source and device computerized registration system. Therefore, NRC could identify the distributor, possible isotopes, and maximum allowable activities, given the model number.
- 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 information included on the source, as indicated above, or by analysis and from 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 through the working life of the product.

The preferred method of labeling sealed sources is engraving or laser etching the information. 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 and will remain attached to the part of the device that contains the radioactive material, that is, they are not 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 following regulations should be reviewed for additional information concerning product labeling:

| Regulations | Applicability |
|---|---|
| 10 CFR 32.25(b) | Devices used under the 10 CFR 30.19 exemption |
| 10 CFR 32.29(b) | Devices used under the 10 CFR 30.20 exemption |
| 10 CFR 32.51(a)(3) | 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(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)(viii) and (a)(3) | Sources and devices for medical use |

## 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 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 to the test results the change would be expected to cause (see engineering analysis below).
- Performing an engineering analysis. An engineering analysis consists of a detailed, systematic analysis of the design and materials of construction of the product and the processes used in the manufacturing of the product to 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 includes 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 United States 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 its 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 concerning 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 the 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 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 where 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 which may not be able to be used after testing. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

## Sources

Typically, for sealed sources, 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 ANSI N43.6-1997, "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 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 information prior to testing.

## Devices

When evaluating a device, the reviewer must verify that the sealed source incorporated in the device has achieved the appropriate ANSI N43.6-1997 or ISO 2919-1999 classification for its intended use and be 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. A listing of applicable standards is included in Appendix F.[5] If there is no applicable standard for a product, the applicant and reviewer, using professional judgment, need to 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 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.

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5 For copies of standards, contact the Health Physics Society, 1313 Dolley Madison Blvd., Suite 402, McLean, VA 22101, Telephone: (703) 790-1745, Web site: <http://www.hps.org>.

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 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% 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 Laboratory 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 71.4 and 10 CFR 71.75 are not sufficient by themselves.

The following regulations should be referenced for additional information concerning prototype testing:

| Regulations | Applicability |
|---|---|
| 10 CFR 32.53(d)(4),<br>10 CFR 32.101 | Devices used under the 10 CFR 31.7 general license |
| 10 CFR 32.61(e)(4),<br>10 CFR 32.103 | 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 39.41(a)(3) | Sources used in well logging operations |
| 10 CFR 36.21(a)(5) | Sources used in irradiator operations |

## 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, 30 cm, and 100 cm (2.0 in., 11.8 in., and 39.4 in.) from the product, and levels in the radiation beam (if the beam is accessible). If applicable, radiation levels should include when the device is in the open and closed conditions and when material is present in the measuring area. 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.

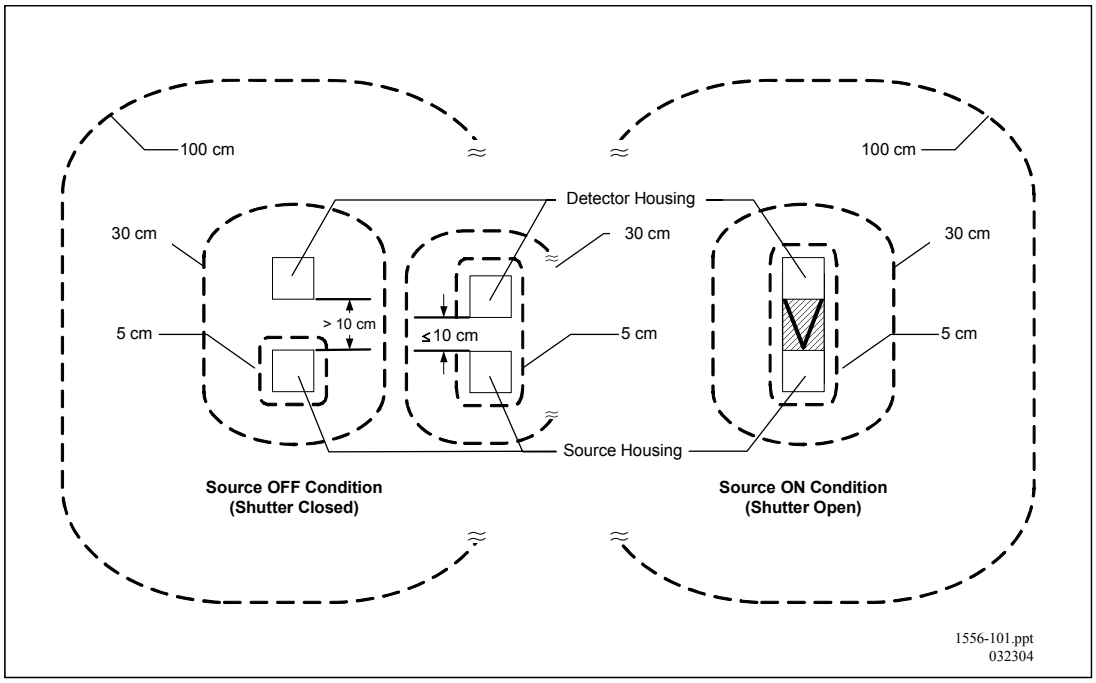


**Figure 10.1 Radiation Profiles.** *ANSI-N43.8-1979 (Reaffirmed 1988) suggests radiation profiles be provided as indicated above.*

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

If the applicant is taking 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 non-gamma 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 μSv/hr (5 mrem/hr) 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, it is the responsibility of the user to ensure 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 ALARA).

If a device is intended for use on a patient, the dose to the patient for a typical application should be provided. This will serve as a reference point in approving and licensing the product.

The following regulations should be referenced for additional information concerning radiation profiles and maximum dose commitments:

| 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 32.51(a)(2)(ii) and (iii) | Devices used under the 10 CFR 31.5 general license |
| 10 CFR 34.20 and 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 the statements contained in the registration certificate for the product. At a minimum, the QA program needs to ensure that: (a) the materials of construction and the final assembly meet the design specifications; (b) the final product is leak tested; (c) a final radiation profile is performed; (d) a test that verifies the product operates as intended, including all safety functions, is performed; and (e) a visual and mechanical inspection of components that are considered critical to safety or are expected to be susceptible to failure under extreme or unusual conditions must be performed. 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 sealed sources or devices. 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 or other generally accepted guidance.

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

International Organization of Standardization, the American National Standards Institute (ANSI) QA program standards, military QA standards, or requirements or regulations established by other U.S. Government agencies (such as FDA).

Sealed source and device vendors frequently use and are accredited in accordance with international/U.S. quality assurance standard ANSI/ISO/ASQ 9001-2000, "Quality Management Systems – Requirements" (the earlier version of the standard, ANSI/ISO/ASQ 9001-1994, is no longer used and accreditations to the 1994 version became invalid in December 2003). The NRC position on the international quality standards is documented in the policy paper entitled "Approaches for Adopting More Widely Accepted International Quality Standards" (SECY-03-0117, 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 sealed sources and devices.

In cases when the vendor of sealed sources and devices 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 which address the specific issues involved in the fabrication of sealed sources and devices such as:

- There is full design conformity in accordance with the statements and commitments submitted in support of the application (including materials, dimensions within stated tolerances, manufacturing methods, assembly methods, labeling), using sampling methods that meet the provisions of 10 CFR 32.110 or equivalent.
- 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. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

If a vendor is a foreign manufacturer with an affiliate distributor in the United States, then it is the responsibility of the distributor to assess 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 assure quality assurance 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, (a) the leak test results and (b) copies of documents certifying that the QA/QC commitments made in the application have been met. The records must be reviewed and approved by the U.S. distributor 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 preformed and from being responsible for ensuring that the product is distributed 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.

It is not the responsibility of the reviewer to establish a frequency for audits of the QA program by the regulatory agency issuing the registry. Audits of the QA program by regulatory agencies do not need to occur on a routine basis but may occur if trends indicate generic failures of a product. Third-party audits by an unbiased entity should be included by the licensee as an integral part of the QA program.

Devices for medical use are approved by the FDA prior to device evaluation and registration. FDA requires domestic or foreign manufacturers to have a quality system for design and production of medical devices intended for commercial distribution in the United States. Manufacturers must comply with the Good Manufacturing Practices (GMP) requirements in 21 CFR Part 820, which covers all aspects of quality management. FDA's GMP requirements are extensive and similar to those of NRC, and therefore, QA programs do not need to be submitted or reviewed for FDA-approved sealed sources or devices. Applicants should provide documented proof that the sealed source or device has been approved by the FDA and that they maintain an FDA-approved QA program. See Section 4.9 for types of FDA product approvals.

The following regulations should be referenced for additional information concerning quality assurance and control:

| Regulations | Applicability |
|---|---|
| 10 CFR 32.55 and 32.110 | Devices used under the 10 CFR 31.7 general license |
| 10 CFR 32.61(e)(5), 32.62, and 32.110 | Devices used under the 10 CFR 31.10 general license |
| 10 CFR 32.14(5) | Exempt products |

| Regulations | Applicability |
|---|---|
| 10 CFR 32.22(a)(2)(xv) | Self-luminous products |
| 10 CFR 32.26(b)(15) | Gas and aerosol detectors |
| 10 CFR 32.51(a)(2) | Generally licensed items |
| 10 CFR 32.53(b)(5)) | Luminous devices for aircraft |
| 10 CFR 32.57(b)(5) | Am-241 calibration sources |
| 10 CFR 32.61(b)(5) | Sr-90 ice detectors |
| 10 CFR 32.74(a)(2)(v) | Medical equipment |
| 10 CFR 32.110 | Sampling procedures |
| 10 CFR 32.210(c) | Specifically licensed sources and devices |

## 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 mounting, installing interlocks, guards or barriers, and determining whether the installation needs to be performed by a specific licensee. General licensees may be permitted to mount products, depending on their design.

An applicant may request that general and specific licensees, without specific authorization under that license, be permitted to mount products. In order for 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 that the source must be otherwise fully shielded.
- The product must be received in good condition (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 any mounting after moving.

In addition, the applicant needs to indicate whether other services necessary to support safe use of the products need to be performed by a specific licensee or may be performed by a general licensee. These include calibration, relocation, leak test, routine maintenance, radiation surveys, necessary 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 general-licensed users, the device should not be registered. Reviewers should recognize that vendors or service companies may discontinue providing services. NRC is typically notified when a vendor decides to 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.

The reviewer must verify that the distributor provides the user of the product with the information necessary to safely operate and maintain the product. These include instructions for operation, maintenance, calibration, damage/failure, specific warnings, leak tests, and radiation surveys. The distributor also should provide information to the user concerning who may provide services for the product. For devices distributed to general licensees, the distributor needs to provide copies of regulations governing use and transportation of the product and a listing of regulatory authorities who license possession and use of the product.

To assist the reviewer in determining whether certain activities may be performed by general licensees, the applicant must provide an estimate of the dose to a worker for each activity to be performed.

The reviewer needs to verify that the documentation provided to users of the products does not misinterpret, misrepresent, or lead the user into violating any applicable regulations.

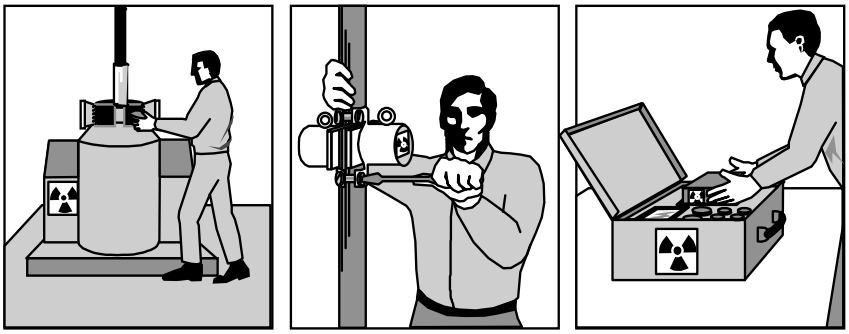


**Figure 10.2 Installation and Servicing of Devices.** *Applicants must specify the qualifications needed by individuals to perform installation and servicing of devices.*

The following regulations should be referenced for additional information concerning servicing:

| 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 afterloaders, teletherapy units, or gamma stereotactic radiosurgery units |
| 10 CFR 35.655 | Five-year inspection for teletherapy and gamma stereotactic radiosurgery units |

## 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 to the same level of detail as the initial review. The concurrence review should be focused on ensuring that the product meets all applicable regulations, that the product would not pose any health of 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 implication resulting from the widespread distribution of sealed sources and devices.

# 11 DEFICIENCIES IN THE APPLICATIONS

In the process of evaluating an application, a reviewer may determine that insufficient information has been submitted. If this is the case, the reviewer must contact the applicant to obtain the information. Depending on the type of information needed, the reviewer may obtain the information by sending a formal written request to the applicant, requesting a meeting with the applicant, notifying the applicant of the need for information via telephone or electronic mail, or obtaining 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 following actions described in Sections 11.1 – 11.4 when addressing deficiencies in applications.

## 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 should request that the response be provided in duplicate. 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 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 a written response[6] to the deficiency letter is not received within the number of days specified in the letter, the reviewer will consider the application as "abandoned"[7] for failure to provide the requested information "without prejudice" to the resubmission of a complete application.

Prompt action (taken within 5 working days) should be taken to "close" the application after the application has been considered as "abandoned." The reviewer should notify the applicant, in writing, that the application has been considered abandoned and the reviewer will "close" the review. The closed files should be placed in DCD in the manner described in Section 9.4.

If a response to the deficiency letter is received after the application has been voided and the response is received not more 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

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6 A written response may be either a letter or a fax from the applicant.

7 "Abandoned" is not meant to have legal connotations. It means simply that the applicants for a new license or for an amendment to an existing license has given up their pursuit of the license or amendment. "Without prejudice" is not meant to be understood in a legal sense. This means that the applicants can resurrect their application within some reasonable time without having to pay another fee, having their application redocketed, and so forth. "Close" should not be thought of in a legal sense. It means here that the application is, in practical effect, nullified.

may be necessary if it is a continuation of the evaluation. Higher priority will not be assigned solely based on the fact the application is a resubmission.

## 11.2 MEETING WITH APPLICANTS

NRC or applicants may request meetings to discuss sealed source and device applications. The meetings may be prior to submission of an application or to discuss items included in a deficiency letter. Meetings between NRC and applicants may be at an NRC office, or at the applicant's facility if it is determined that it would enhance NRC's understanding of the product.

## 11.3 USING THE TELEPHONE OR ELECTRONIC MAIL TO OBTAIN ADDITIONAL INFORMATION

There is no prohibition against using the telephone or electronic mail to obtain clarifying information from an applicant. These mechanisms may be used to notify an applicant of simple deficiencies, to accelerate the review process.

Use of the telephone or electronic mail for notifying an applicant of deficiencies must be limited to items that are simple and such that they can be specified simply. Simple items include a model number for a sealed source, need for an applicant commitment to perform a procedure, or clarification of a material type or a dimension.

If the deficiency is 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, either via the telephone or electronic mail, must be documented and included as part of the application.

In all cases, the telephone conversation or electronic mail transmitting deficiencies to an applicant must be documented by the person initiating the telephone call. If the applicant does not respond within 15 calendar days, a confirmatory letter must be sent to the applicant. The confirmatory letter must clearly specify the deficiencies and 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 time frame or the application will be voided.

## 11.4 REQUESTING RESPONSE TIME EXTENSIONS

A request from an applicant for an extension of time to respond to any correspondence about its application may be granted if it is determined that there is good cause to grant an extension. The request may be in writing or via the telephone. Typically, the reviewer responds by telephone to notify the applicant that an extension has been granted. All requests for extensions must be approved by 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 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 includes standard formats for registration certificates for a sealed source, for a device, and for an exempt device. Further clarification of the information that is included in a registration certificate is listed below.

## 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 type. If the certificate is amended or corrected, this is indicated in the title; the page number of each corrected page(s) needs to be listed or the header notes that the certificate is amended in its entirety. The registration number is assigned by the reviewer, 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 name and complete address of the manufacturer and distributor, the model number of the sealed source or device, the manufacturer or distributor and model number for the sealed source incorporated in the device, 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 NRC–maintained**,** computerized NSSDR.

The following subsections are included in the order listed below starting on the second page of the certificate.

## 12.3 DESCRIPTION

This section provides a narrative description of the construction of the product, the safety features of the product, and ON/OFF and safety indicators. The description should include the materials of construction and fabrication techniques for critical safety components of the product. These typically include source encapsulation materials, source holder materials, shutter mechanisms, welding process, and device security features, such as tamper resistant fasteners, locks. Overall dimensions of the sealed source and the device are also included.

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, fire-proof, corrosion-resistant).

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

## 12.4 LABELING

This section describes how the labeling requirements are fulfilled. It lists the information that can be found 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 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. The normal intended uses of the product and any limitations that define these uses are included in this section. 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, the corresponding classification, as defined by the standard, should be stated in this section. 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 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, a conservatively calculated maximum radiation profile is listed. 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. Ideally, the radiation levels listed in this section will include the levels on contact with the product, at 5 cm, 30 cm, and 100 cm (2.0 in., 11.8 in., and 39.4 in.) from the product, and in the beam.

Should there be a device containing a number of isotopes and 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 include limitations concerning the installation of the device.

## 12.9 QUALITY ASSURANCE AND QUALITY CONTROL

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

## 12.10 LIMITATIONS AND OTHER CONSIDERATIONS OF USE

This section establishes the limiting conditions imposed on the sealed source or device. These include leak testing, handling, storage, use, transfer, disposal, 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, state that sources or devices should not be subjected to environments that exceed their ANSI or ISO classifications, and state that if subjected to such environments, the licensee must discontinue use of the source or device until a demonstration that no affect to the source or device integrity has occurred as a result of operation outside the specified range. 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 NRC.

Limitations on sealed sources and devices can be divided into two categories, the first being limitations placed on the manufacturer or distributor of the sealed source or device and the second being limitations placed on the user of the sealed source or device. Limitations of the first category are derived from regulations. In addition to regulations, the second category of limitations is also derived from conditions imposed by the manufacturer, by particular conditions of use that would reduce the radiation safety of the device, and by circumstances unique to the sealed source or device, which require that the sealed source or device 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 services will be provided by the vendor.

## 12.11 FDA APPROVAL SUMMARY

This section contains FDA information for sealed sources and devices used for medical use. Reviewers do not evaluate the data provided by the applicant. The references provided by the applicant is for information only. Applicants provide proof of FDA approval type and specific use limitations that are not evaluated by NRC or Agreement States but 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. Also, typically listed in this section are 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

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 retain the references in accordance with applicable records retention requirements.

## 12.14 ISSUING AGENCY

This section identifies 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 quality control measures.

## 12.15 ATTACHMENTS

This section typically contains diagrams, drawings, sketches, or pictures of the product, as discussed previously in Section 12.5. These provide inspectors a tool by which they can 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.

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 sealed source or device type.

## 12.16 DIMENSIONS AND USE OF DUAL UNITS

NRC's Metrication Policy (SECY-96-098) requires that documents specific to a registration certificate holder, such as the registration certificate, include dimensions in the units employed by the registration certificate holder.

# 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 obliged 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.

An application to amend a certificate should be prepared in triplicate. The registration certificate holder should retain one copy for their records and submit the original to the address specified in Chapter 7. 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 CFR 170.31 for current requirements and Chapter 8 for specific guidance). For medical products, the registration certificate holder must have obtained FDA approval prior to 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 if 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 if 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 may have detrimental effects on how the device will react to accident conditions. This type of detrimental effect may have been overlooked by the manufacturer.

## 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)

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 type face to highlight the changes that

have been made to the certificate. In addition, if there are still products in use that meet the previous design specifications, reviewers must ensure that previous design information remains in the registration certificate and delete sections that are no longer applicable. The registration certificate also must identify, by date or serial number, when the design change is implemented.

## 13.2 CORRECTIONS

If the change only involves corrections to the certificate (i.e., does not require a safety evaluation to be performed such as change in address or error identified in the certificate), then only the affected pages of the certificate need to be updated and issued. The reviewer should use bold type face 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. An example of this format is shown below:

(CORRECTED PAGES 1, 2, & 4 – JULY 5, 0000)

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 in the reference section of the certificate.

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 hold off making corrections to the signature page until the registration certificate holder requests an amendment, requiring a safety evaluation, to the certificate.

## 13.3 COMBINING REGISTRATION CERTIFICATES

Registration certificate holders may request that NRC combine two or more certificates into a single certificate. However, it is NRC policy that only products which are essentially identical in design, function, construction, and which vary only in a dimensional capacity, in the sources used or in their application, may be grouped together on a single registration certificate.

Combining registration certificates does not require a safety evaluation. However, the reviewer must determine whether the request meets the IMNS policy and whether the registration certificates can be administratively combined.

## 13.4 TRANSFERS TO INACTIVE STATUS

If a registration certificate holder requests that a registration certificate be transferred to inactive status,[8] the registration certificate holder should provide:

- the total number of the products sold; the number of products still in use;[9]
- 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;
- a commitment that the registration certificate holder will no longer commercially distribute the product; and
- 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 reviewer should verify that the above information is included 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 required. 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 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.

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8 NRC also will transfer a registration certificate to inactive status if it knows the registration certificate holder is out of business.

9 The actual number of products sold and still in use may not be known by the registration certificate holder. However, the registration certificate holder should still provide a best estimate.

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

Licensees with custom sealed sources and devices should inactivate the custom registration when sources/devices are permanently disposed of, placed in permanent storage, or transferred to another licensee that has obtained their own custom registration or a licensee with broad scope authorization. The licensee should verify the number of sealed sources/devices 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. Requests to reactivate inactive registration certificates are handled in one of the three methods:

1. If the background information on file with NRC for the inactive registration certificate is complete, up-to-date, and the vendor does not request any changes to the information, the vendor may simply submit a letter to NRC requesting reactivation of the registration certificate. The letter must include commitments that the information on file with NRC is complete and accurate and that the vendor commits to abide by all information on file with NRC. The reviewer must verify the information is complete prior to assigning a new registration certificate number and reissuing the certificate
2. If the background information on file with NRC for the inactive registration certificate is incomplete, 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 must submit a complete application for evaluation and registration in accordance with this document. The reviewer must review and evaluate the application in the same manner as a new application.
3. 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 holder request that a registration certificate be transferred due to ownership changes and corporate relocations, the registration certificate holder should perform the following:

1. Delineate the facility's name and location where the products are manufactured.
2. Specify the serial number of the last unit that was distributed by the old company prior to the name/address change, and the number of completed units that were transferred to be distributed by the old company to the new company.
3. Change of ownership information discussing transfer of products, records custody, and servicing arrangements for products previously distributed.
4. Provide a new label for the devices indicating the new company name and the effective date of the label change.
5. Confirm that no changes were made to the product since its initial registration or last amendment.
6. Verify that there are no changes to previous commitments that have been made by the old company.
7. Provide details regarding the quality assurance program at the new location.
8. Assign a new vendor code when ownership changes.
9. Change the registration number to the new vendor and its next sequential unit number when a product registration is taken over by another vendor (see Appendix B).

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

Registration certificate holders are required to 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 Part 21 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 Parts 30, 40, 50, 60, 61, 70, 71, or 72. However, NRC Information Notice 91-39, "Compliance with 10 CFR Part 21, Reporting of Defects and Noncompliance" (available from NRC at <http://www.nrc.gov>), 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 a 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 a year or less.
- Guidelines for determining 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 NRC pursuant to 10 CFR 21.21. In addition, registration certificate holders are required to meet the posting requirements specified in 10 CFR 21.6.

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

***Active Vendor*** means a vendor, listed on a registration certificate, who 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 NRC allowing the State to regulate the use of byproduct material within the State. A complete listing of the current Agreement States, including addresses and points of contacts, can be obtained from STP.

***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 NRC or an Agreement State. The applicant is responsible for ensuring the information provided in the application is complete and accurate.

***Associated Equipment*** is equipment that is used in conjunction with a device and directly effects the safe use of the device or ensures 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). Associated equipment supplied by the vendor of the device should be evaluated and registered as part of a device. If the associated equipment is supplied by another vendor, the evaluation and registration should be handled the same as a device evaluation and a separate registration certificate should be issued for the equipment.

***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 and/or use more than one product.

***Inactive Registration Certificate*** means a registration certificate for a sealed source or device that may have been authorized for distribution at one time but no longer may be authorized for initial distribution. Unless otherwise stated in 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.

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 who no longer may be authorized to initially distribute the sealed source or device listed on a registration certificate but may be authorized to provide services for the sealed source or device.

***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.

***NARM/NORM*** stands for Naturally-occurring (NORM) or Accelerator-produced Radioactive Material (NARM). This material is not subject to regulation by NRC but is regulated by the States. The FDA Center for Devices and Radiological Health assists States in their review and regulatory approval for distribution of devices containing NARM.

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

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

***Registration Certificate Holder*** means a vendor or custom user of a product that holds a certificate of registration with NRC or an Agreement State. The registration certificate holder is responsible for ensuring the information in the registration certificate is current and correct and for ensuring 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 when the product is expected to maintain its integrity. The working life should be based on the 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

**SUMMARY DATA**

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

**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 IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, 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.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

| | |
|---|---|
| **Certifying Officer — Typed Name and Title** | |
| **Signature:** | **Date:** |

**CHECKLIST**

**Registration Certificate Holder:**

**Model:**

| DESCRIPTION | OK/DEF | | COMMENTS |
|---|---|---|---|
| | 1st Reviewer | 2nd Reviewer | |
| DESCRIPTION/CONSTRUCTION | | | |
| If 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):**<br>Radiography - Unprotected . . . . . 43515<br>Radiography - In Device . . . . . 43313<br>Medical - Radiography . . . . . 32312<br>Medical - γ Teletherapy . . . . . 53524<br>Medical - Brachytherapy . . . . . 53211<br>Medical - Source Applicators . . . . . 43312<br>γ Gauges - Unprotected . . . . . 43333<br>γ Gauges - In Device . . . . . 43232<br>β Gauges, Low Energy γ Gauges, or X-ray fluorescence . . . . . 33222<br>Oil Well Logging . . . . . 56522<br>Portable Moist/Density . . . . . 43333<br>Neutron Applications . . . . . 43323<br>Calibration source activity > 30$\mu$Ci (1 MBq) . . . . . 22212<br>γ Irradiators (I) . . . . . 43323<br>γ Irradiators (II, III) . . . . . 43424<br>γ Irradiators (IV) . . . . . 53424<br>Chromatography . . . . . 32211<br>Static Eliminators . . . . . 22222<br>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, qty., location) | | | |
| Safety interlocks, guards, and so forth to prevent access to beam or high radiation levels | | | |
| Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium & steel, and so forth) | | | |
| Shielding efficiency and integrity | | | |

**CHECKLIST**

**Registration Certificate Holder:**

**Model:**

| DESCRIPTION | OK/DEF | | COMMENTS |
|---|---|---|---|
| | 1st Reviewer | 2nd Reviewer | |
| **For medical devices:**<br><br>**Type of FDA approval:**<br>• **Premarket notification (501(k))**<br>• **Premarket approval (PMA)**<br>• **Investigational Device Exemption (IDE)**<br>• **Humanitarian Device Exemption (HDE)**<br><br>**Type of Medical Use:**<br>• **manual brachytherapy, 35.400**<br>• **medical diagnosis, 35.500**<br>• **photon-emitting remote afterloader, 35.600**<br>• **photon-emitting teletherapy unit, 35.600**<br>• **gamma stereotactic radiosurgery unit, 35.600**<br>• **other medical, 35.1000 (intervascular brachytherapy, beta-emitting remote afterloaders, etc)**<br><br>**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 (e.g. radiography, Brachytherapy, etc.) | | | |

**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#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "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 Part 32 for distribution general licensees or persons exempt from licensing | | | |
| PROTOTYPE TESTING/HISTORICAL USE | | | |
| Tests methods and conditions (for source and device) | | | |
| Tests results | | | |
| Years of use (incidents, failures, etc.) | | | |
| Similarities to other sources/devices if they are used as basis. | | | |
| RADIATION PROFILES | | | |
| Survey instrument used (type, window thickness, sensitivity, **calibration dates**, etc.) | | | |
| 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 radiation surveys for γ radiation meet $inv^2$ law. | | | |
| Verify radiation surveys for non-γ radiation have not been calculated using $inv^2$ 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 SSDs 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:<br>Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations | | | |

**CHECKLIST**

**Registration Certificate Holder:**

**Model:**

<table>
<tr><th colspan="4" rowspan="2">DESCRIPTION</th><th colspan="2">OK/DEF</th><th rowspan="2">COMMENTS</th></tr>
<tr><th>1st Reviewer</th><th>2nd Reviewer</th></tr>
<tr><td colspan="4">SERVICING</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">The following activities may be performed by the persons indicated:</td><td rowspan="11"></td><td rowspan="11"></td><td rowspan="11"></td></tr>
<tr><td>Activity</td><td>by a General Licensee</td><td>Only by a Specific Licensee</td><td>Will be Offered by the Applicant</td></tr>
<tr><td>Installation</td><td></td><td></td><td></td></tr>
<tr><td>Relocation</td><td></td><td></td><td></td></tr>
<tr><td>Maintenance</td><td></td><td></td><td></td></tr>
<tr><td>Repair</td><td></td><td></td><td></td></tr>
<tr><td>Source Exchange</td><td></td><td></td><td></td></tr>
<tr><td>Calibration</td><td></td><td></td><td></td></tr>
<tr><td>Leak Testing</td><td></td><td></td><td></td></tr>
<tr><td>Radiation Survey</td><td></td><td></td><td></td></tr>
<tr><td>Training</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">FOREIGN VENDORS</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Drop ship</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Who and where is source installed</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Leak test and radiation surveys</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">QA in the U.S.</td><td></td><td></td><td></td></tr>
</table>

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

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

# Appendix B

# Assigning
# Registration Certificate Numbers

## Assigning Registration Certificate Numbers

Each registration certificate has a unique registration number. The registration number consists of either 10 or 11 characters as described below:

NR-XXXX-D-YYY-S

Agency Code (NR): A two-letter abbreviation of the agency issuing the certificate. All certificates issued by NRC have NR as the Agency Code.

Vendor Code (XXXX): Each vendor (manufacturer or distributor) is assigned a unique three-digit number (the number may be four-digits) on a nationwide basis. The vendor code used for the registration certificate number will be the vendor code for the distributor. If the company is out of business or no longer has an active registration certificate, the vendor code will 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): A one-letter code which indicates whether a registration certificate is for a sealed source (S), a device (D), or (A) associated equipment.

Unit Number (YYY): 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 issuance of unit numbers is typically controlled by the agency that regulates the vendor.

License Code (S): This is a one-letter code which indicates how the source or device has been registered. "S" indicates it may only be used by specific licensees, "G" indicates it may only be used by general licensees, "B" indicates it may be used by both specific and general licensees, and "E" indicates 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, 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, that use a neutron source. |
| **I** | ***Calibration Sources (Activity greater than 30 mCi)*** | 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. Includes flood sources, instrument check sources, 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, or equivalent Agreement State regulations. |
| **AB** | ***Medical Diagnosis Sources*** | For use in medical diagnosis in accordance with 10 CFR 35.500, or equivalent Agreement State regulations. |
| **AC** | ***Photon-emitting Remote Afterloaders*** | For use in Photon-emitting Remote Afterloaders in accordance with 10 CFR 35.600, 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 or equivalent Agreement State regulations, Includes intervascular brachytherapy and beta-emitting remote afterloaders. |

# Appendix D

# Standard
# Registration Certificate Formats

# Standard Registration Certificate Formats

## Table of Contents for Standard Registration Certificate Formats

APPENDIX D

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 manufacturer and distributor are the same.)*

| ISOTOPE: | MAXIMUM ACTIVITY: |
|---|---|
| *List Isotopes* | *XX Gbq (XX mCi)*<br>*units should be such that the amount is in the 1 to 999 range* |

LEAK TEST FREQUENCY:
Not Required
6 Months

PRINCIPAL USE:
*(A) Industrial Radiography from listing in Appendix C*

CUSTOM SOURCE: ___ Yes X 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 were reported by the manufacturer 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/hr)*** | ***(mR/hr)*** | ***(µSv/hr)*** | ***(mR/hr)*** |
| *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 NRC. A copy of the program is on file with NRC. [For medical sources that have been manufactured under FDA good manufacturing practices, the QA/QC program may not be on file with 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.]*

DEVICE TYPE: *Provide a short description of the device 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 manufacturer and distributor are the same.)*

SEALED SOURCE MODEL DESIGNATION: *ACME MODEL 123*

| ISOTOPE: | MAXIMUM ACTIVITY: |
|---|---|
| *List Isotopes* | *XX GBq (XX mCi)*<br>*units should be such that the amount is in the 1 to 999 range* |

LEAK TEST FREQUENCY: Not Required
6 Months

PRINCIPAL USE: *(A) Industrial Radiography from listing in Appendix C*

CUSTOM SOURCE: ___ Yes X 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)

NO.: NR-***-D-***-X DATE: PAGE 2 OF 8

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 32.51 and 32.51a.*

*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.*

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.*

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.*

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

NO.: NR-***-D-***-X DATE: PAGE 4 OF 8

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 9320 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/hr (5 mR/hr) 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/hr)*** | ***(mR/hr)*** | ***(mSv/hr)*** | ***(mR/hr)*** |
| *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/hr)*** | ***(mR/hr)*** | ***(mSv/hr)*** | ***(mR/hr)*** |
| *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 NRC. A copy of the program is on file with 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 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: *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" and "B", generally and 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 NRC for use in the Model ABC. The source is not registered on a separate certificate.*
- *[For "G" and "B", generally and 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: *Short description of the device type.*

SAFETY ANALYSIS SUMMARY (Cont.):

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

- *[For "G" and "B", generally and both specifically and generally licensed device] The device can be safely operated by persons not having training in radiological protection.*
- *[For "G" and "B", generally and 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 Section 20.1201(a), 10 CFR Part 20.*
- *[For "G" and "B", generally and 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: *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: *Smoke Detector/Gun Sight*

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.)*

SEALED SOURCE MODEL DESIGNATION: *ACME MODEL 123*

| ISOTOPE: | MAXIMUM ACTIVITY: |
|---|---|
| | *37 kBq (1.0 mCi)* |
| *Americium-241* | *2.2 GBq (60 mCi)* |
| *Hydrogen-3* | |

LEAK TEST FREQUENCY: Not Required

PRINCIPAL USE: *(P) Ion Generator, Smoke Detectors*

*(W) Self-Luminous Light Sources*

CUSTOM SOURCE: ___ Yes X No

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

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

DEVICE TYPE: *Smoke Detector/Gun Sight*

DESCRIPTION:

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

REFERENCES:

*The following supporting documents for the Model ABC smoke detectors/gun sights 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 Information from Public Disclosure

# Checklist for Requests to Withhold 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, NRC may send copies of this information to NRC consultants working in that area. NRC will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, the applicant should promptly notify NRC. The applicant also should understand that NRC may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes the information in question. In all review situations, if NRC makes a determination that the information should be made publicly available, the applicant will be notified in advance of any public disclosure.

## Checklist for Requests to Withhold Information from Public Disclosure

In order to request that 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. The applicant should submit all of the following:

[ ] A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.

[ ] A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should **not** be marked as proprietary.

[ ] An affidavit that:

- [ ] Is notarized.
- [ ] Clearly identifies (such as by name or title and date) the document to be withheld.
- [ ] Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information 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 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 of others 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 N43.8-1979 | "Classification of Industrial Ionizing Radiation Gauging Devices" (Reaffirmed 1988) |
| **Irradiators:** | |
| ANSI N433.1-1977 | "Safe Design and Use of Self-Contained Dry Source Storage Gamma Irradiators (Category I)" (withdrawn) |
| 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)" |
| **Light Sources:** | |
| ANSI N43.4-2000 | "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 9001-2001 | "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 3999-1977(E) | "Apparatus for Gamma Radiography – Specification" |
| **Smoke Detectors:** | |
| OECD/NEA 1977<br>(Nuclear Energy Agency) | "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 N43.6-1997 | "Sealed Radiation Sources, Classification" – (Revision of ANSI N5.10-1968) |
| ANSI N5.10-1968 | "Sealed Radiation Sources, Classification" |
| IAEA-TECDOC-1344 | "Characterization of Radioactive Sources" – July 2003 |
| **Teletherapy:** | |
| ANSI N449.1-1984 | "Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment" |
| **X-Ray Fluorescence:** | |
| ANSI N43.2-1977 | "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 N43.3-1993 | "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 QA Programs

The checklist in this appendix is designed as an aid in reviewing quality assurance (QA) programs for completeness either by the licensee or the license reviewer. 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? | | | |

**Table G.1 Checklist for Reviewing QA Programs (continued)**

| Questions | Program/Implementation | | Comments |
|---|---|---|---|
| | Yes | No | |
| **PERSONNEL** | | | |
| 10. Does the applicant have procedures to ensure up-to-date records of all employees' qualifications? | | | |
| **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 released? | | | |
| 17. Do the procedures include notifying regulatory agencies of any changes? | | | |
| 18. Do the procedures ensure alternative approaches in the absence of specifications? | | | |

**Table G.1 Checklist for Reviewing QA Programs (continued)**

| Questions | Program/Implementation | | Comments |
|---|---|---|---|
| | Yes | No | |
| 19. Is there a history file, for each document, that includes previous versions, document changes, and reasons for the changes? | | | |
| 20. Are the copies on file of all up-to-date documents for each job? | | | |
| 21. Are there procedures for verification of 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? | | | |
| 24. Are there procedures for receipt inspection? | | | |
| 25. Do receipt inspection procedures verify:<br>• correct sizes?<br>• quantity?<br>• document and specification conformance?<br>• paperwork? | | | |
| 26. Are there procedures for receipt of nonconforming material? | | | |
| 27. Are there records of receipt inspections, including nonconforming material? | | | |

**Table G.1 Checklist for Reviewing QA Programs (continued)**

| Questions | Program/Implementation | | Comments |
|---|---|---|---|
| | Yes | No | |
| 28. Do all purchase orders contain:<br>• scope of work?<br>• technical requirements?<br>• identification of the documents that must accompany the order?<br>• identification of the records that the applicant must keep?<br>• signature of the appropriate individual? | | | |
| 29. Are there records of all purchases? | | | |
| 30. Are there inventory procedures? | | | |
| 31. Do inventory procedures include:<br>• special handling?<br>• marking?<br>• tagging?<br>• labeling?<br>• segregating?<br>• paperwork procedures?<br>• handling of nonconforming material? | | | |
| 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? | | | |

**Table G.1 Checklist for Reviewing QA Programs (continued)**

| Questions | Program/Implementation | | Comments |
|---|---|---|---|
| | Yes | No | |
| 34. Are periodic physical inventories performed? | | | |
| 35. Does the system ensure that products that are marked or segregated as complete have 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:<br>• acceptance criteria?<br>• receipt criteria?<br>• at what points to perform in-process inspections and tests?<br>• procedures for determining sample sizes?<br>• procedures for final inspection and testing?<br>• provisions for nonconforming material? | | | |
| 40. Are there records for inspections of production procedures? | | | |

**Table G.1 Checklist for Reviewing QA Programs (continued)**

| Questions | Program/Implementation | | Comments |
|---|---|---|---|
| | Yes | No | |
| 41. Are there records of all inspections and testing, including date and person performing inspection or test? | | | |
| 42. Is there a system for marking or segregating items that have been inspected or tested? | | | |
| 43. Does final inspection include 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 disposition of nonconforming materials and for introducing 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? | | | |

**Table G.1 Checklist for Reviewing QA Programs (continued)**

| Questions | Program/Implementation | | Comments |
|---|---|---|---|
| | Yes | No | |
| 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? | | | |
| **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:<br>• name of complainant?<br>• nature and date of complaint?<br>• corrective action taken?<br>• cause of failure?<br>• model and serial number of the device? | | | |

**Table G.1 Checklist for Reviewing QA Programs (continued)**

| Questions | Program/Implementation | | Comments |
|---|---|---|---|
| | Yes | No | |
| 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? | | | |
| 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

# Conversion Tables

# GUIDE TO SI UNITS

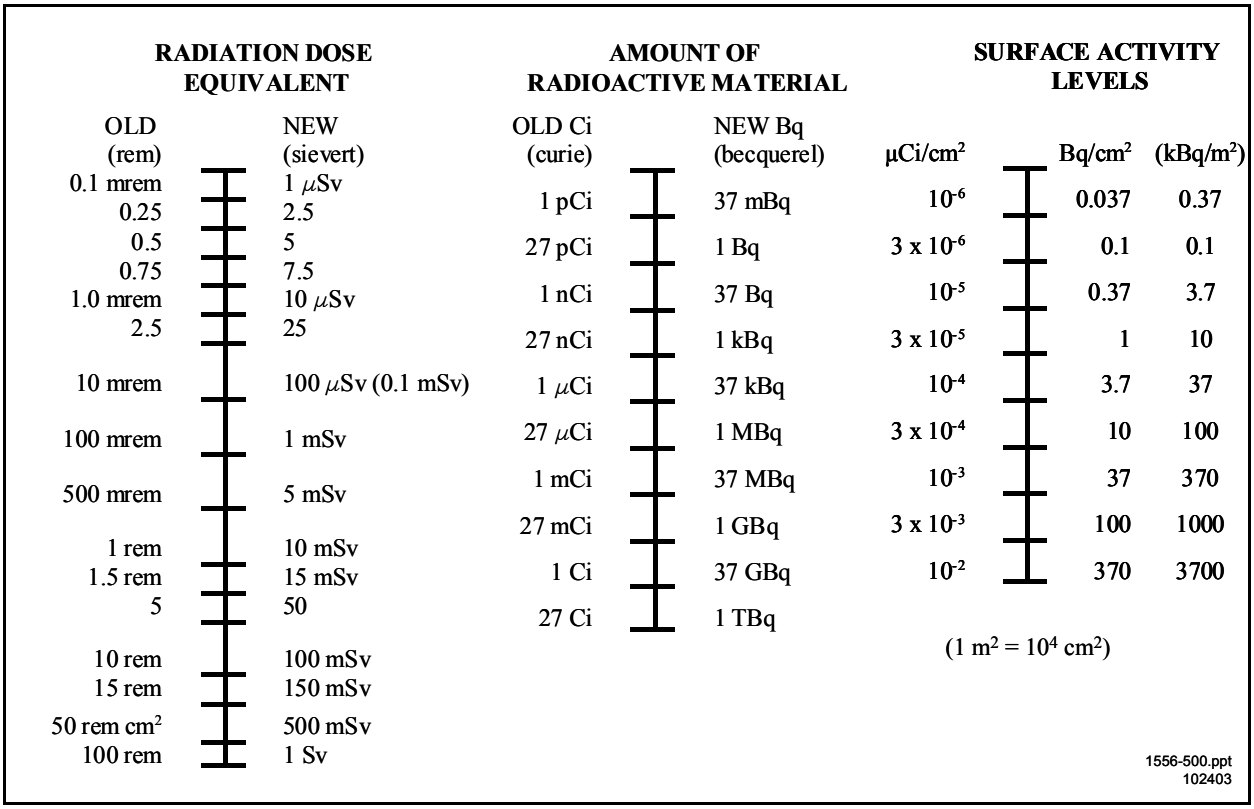


**Figure H.1 Equivalent SI and English Units.**

## Table H.1 English to SI Unit Conversions

| CONVERSIONS | RADIATION DOSE RATES | DERIVED AIR CONCENTRATION (DAC) | CONCENTRATION IN SOLUTION |
|---|---|---|---|
| 100 rem = 1 Sv | | Units: Bq $m^{-3}$ | $\mu$Ci kBq/$dm^3$ (kBq/l) |
| 100 rad = 1 Gy (gray) | $\mu$Sv/h, mSv/h | | 1 37 |
| 1 ton = 1 Mg | e.g., | Conversion: | 10 370 |
| 1 ton = 1000 kg | 7.5 $\mu$Sv/h | $\mu$Ci $cm^{-3} \times 3.7 \times 10^{10}$ = Bq $m^{-3}$ | 100 3700 |
| 1 kg = 1000 g | 25 $\mu$Sv/h | $\frac{\text{dpm}^{-3}}{60}$ = Bq $m^{-3}$ | 1 $m^3$ = $10^3$ $dm^3$ = $10^3$ l or $10^3$ L |
| 1 MBq/ton = 1 Bq/g | | | 1 mBq/$m^3$ = 1 kBq/$dm^3$ |

## Table H.2 Prefixes for SI Units

| PREFIXES FOR UNITS: | | | | | | | |
|---|---|---|---|---|---|---|---|
| a | atto | $10^{-18}$ | | k | kilo | $10^{3}$ | thousand |
| f | femto | $10^{-15}$ | | M | mega | $10^{6}$ | million |
| p | pico | $10^{-12}$ | trillionth | G | giga | $10^{9}$ | billion |
| n | nano | $10^{-9}$ | billionth | T | tera | $10^{12}$ | trillion |
| μ | micro | $10^{-6}$ | millionth | P | peta | $10^{15}$ | |
| m | milli | $10^{-3}$ | thousandth | E | exa | $10^{18}$ | |