Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees

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Abstract

This guide has been developed in parallel with the rulemaking on 10 CFR Parts 30, 31, and 32, "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material." This guidance document is consistent with the final rule.

As part of its redesign of the materials licensing process, NRC is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Vol. 16, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees," dated December 2000, is the sixteenth program-specific guidance document developed for the new process and is intended for use by applicants, specific and general licensees, and NRC staff. It also will be available to Agreement States.

The requirements for an NRC general license for persons who receive, possess, use, transfer, own, or acquire byproduct material in generally licensed products are provided in 10 CFR Part 31, "General Domestic Licenses for Byproduct Material." The requirements to obtain an NRC general distribution license for persons who distribute or initially transfer byproduct

material in generally licensed products are provided in 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material." Generally licensed products include static elimination devices, gauging devices, gas chromatograph detector cells, tritium signs, *in vitro* clinical or laboratory kits, and check sources. These devices/products are distributed to general licensees by companies who have a specific license from NRC or an Agreement State authorizing such distribution. This document combines and supersedes the guidance previously found in Information Notices and Policy and Guidance documents listed in Table A.1 of this NUREG.

This document provides assistance to applicants in preparing license applications for a specific license to distribute generally licensed devices. It also describes both the methods acceptable to NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the applications to determine if the proposed general distribution activity is acceptable for licensing purposes. This document was not intended for providing guidance to applicants requesting a specific license for possession and use of radioactive materials.

Appendices K and L are intended to assist specific licensees in providing their customers (general licensees) with information. They provide the general licensee with a concise listing of the regulatory requirements that apply to generally licensed devices. Appendix L does so specifically for users of self-luminous exit signs. Specific licensees may forward Appendices K or L to their customers. It is not intended, however, to take the place of the information requirements in 10 CFR 32.51a (a), (b), and (c).

Figures

Foreword

The United States Nuclear Regulatory Commission (NRC) is using Business Process Redesign (BPR) 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 list of volumes currently included in the NUREG-1556 series.

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Radiography Licenses	Final Report
3	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	Final Report
6	Program-Specific Guidance about 10 CFR Part 36 Irradiators	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	Draft
10	Program-Specific Guidance about Master Material Licenses	Draft
11	Program-Specific Guidance about Licenses of Broad Scope	Final Report
12	Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution	Draft
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	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
18	Program-Specific Guidance About Service Provider Licenses	Final Report

19	Guidance For Agreement State Licensees Proposing to Work in NRC Jurisdiction (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

The current document, NUREG-1556, Vol. 16, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees," dated December 2000, is the sixteenth program-specific guidance developed for the new process. It is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel.

A team composed of NRC staff from Headquarters and Regional Offices drafted this document, drawing on their collective experience in radiation safety in general and knowledge of general distribution of radioactive products. A representative of NRC's Office of the General Counsel provided a legal perspective.

This document represents a step in the transition from the current paper-based process to the new electronic process. It is available on the Internet at the following address:

<http://www.nrc.gov/NRC/NUREGS/SR1556/V16/index.html>

This document 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.

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Abbreviations

AEC	Atomic Energy Commission
ALARA	As Low as Is Reasonably Achievable
ANSI	American National Standards Institute
BPR	Business Process Re-engineering
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie

DOE	United States Department of Energy
DOT	United States Department of Transportation
FR	Federal Register
GBq	gigabecquerel
GL	general license, generally licensed
GPO	Government Printing Office
IL	Interpretive Letter
IMNS	Division of Industrial, Medical, and Nuclear Safety
IN	Information Notice
kBq	kilobecquerel
MBq	Megabecquerel
mCi	millicurie
MSIB	Materials Safety and Inspection Branch
NA	not applicable
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OGC	Office of the General Counsel
OMB	Office of Management and Budget
QA	quality assurance
QC	quality control
R	roentgen
RG	Regulatory Guide
RI	responsible individual
RSO	radiation safety officer
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSD	sealed source and device
std	standard
TAR	technical assistance request
USC	United States Code

 Ci	microcurie

1 Purpose of Report

This report provides both guidance to an applicant in preparing an application to distribute generally licensed products or devices and NRC criteria for evaluating a general distribution license application. It also provides guidance to general licensees covered in 10 CFR 31.5 on the use, possession, and registration requirements for general licensees.

General distribution licenses authorize the distribution (initial transfer) of byproduct material to persons generally licensed by 10 CFR 31.3, 31.5, 31.7, 31.8, 31.10 and 31.11.

This report identifies the information needed to complete NRC Form 313 (Appendix B), "Application for Material License," for the use of byproduct material contained in devices or products distributed to general licensees. The information collection requirements in 10 CFR Parts 30, 31, and 32, NRC Form 313, and NRC Form 483 have been approved under the Office of Management and Budget (OMB) Clearance Nos. 3150-0017, 3150-0016, 3150-0001, 3150-0120, and 3150-0038 respectively. NRC Form 653 is also included under OMB Clearance No. 3150-0001.

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

- Regulations - references the regulations applicable to the item.
- Criteria - outlines the criteria NRC uses to judge the adequacy of the applicant's response.
- Discussion - provides additional information on the topic sufficient to meet the needs of most readers.
- Response from Applicant - provides suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

Notes and references are self-explanatory and may not be found for each item on NRC Form 313.

2 NRC Regions And Agreement States

Certain states, called Agreement States (see Figure 2.1), have entered into agreements with NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials

used or possessed within their borders. Any applicant, other than a Federal Agency, who wishes to possess or use byproduct, source, or special nuclear material in one of these Agreement States needs to contact the responsible officials in that State for guidance on preparing an application. A current list of Agreement States, including the names, addresses, and telephone numbers of responsible officials, may be obtained upon request from NRC's Regional Offices. This information can also be found on the NRC Office of State and Tribal Programs' web site at <http://www.hsrd.ornl.gov/nrc/asframe.htm>.

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

Table 2.1 provides a quick way to determine which Agency has regulatory authority over the possession and use of byproduct, source, or special nuclear material.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal Agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, U.S. territory, or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site not subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC
Any entity in any State requesting authorization to distribute devices for use under 10 CFR 31.3	NRC

3 Management Responsibility

NRC recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. NRC believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely. NRC also believes that effective management will result in increased safety and compliance.

"Management" refers to the processes for conducting and controlling radiation safety programs and to the individuals who are responsible for those processes and who have the authority to provide necessary resources to achieve regulatory compliance.

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 all information provided to NRC (10 CFR 30.9);
- Knowledge about the contents of the license and application;
- Compliance with current NRC and Department of Transportation (DOT) regulations;
- Prohibition against discrimination of employees engaged in protected activities (10 CFR 30.7);
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 30.7 and 10 CFR 30.10, respectively;
- Obtaining NRC's prior written consent before transferring control of the license;
- Notifying the appropriate NRC Regional Administrator in writing, immediately following filing of a petition for voluntary or involuntary bankruptcy; and
- Ensuring that all generally licensed devices are distributed in accordance with NRC requirements.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600. NUREG-1600 is available electronically at <http://www.nrc.gov/OE>. For hard copies of NUREG-1600, see the Availability Notice (on the inside front cover of this report).

4 Applicable Regulations

The primary regulations applicable to persons who possess byproduct material in generally licensed products are located in 10 CFR Part 31, "General Domestic Licenses for Byproduct Material." Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items

Containing Byproduct Material," outlines, in part, the information required to initially transfer for sale or distribute products containing byproduct material. The following is a list of the regulations for general licensees in Part 31 and the corresponding requirements for distributors of generally licensed products in Part 32.

§ 31.3	**Certain devices and equipment**
	Licenses for distribution of general licensed devices authorized under 10 CFR 31.3 can be issued only by NRC. There are no corresponding regulations in 10 CFR Part 32. Each device is evaluated on a case-by-case basis.

§ 31.5	**Certain measuring, gauging, or controlling devices**
§ 32.51	Byproduct material contained in devices for use under 10 CFR 31.5; requirements for license to manufacture or initially transfer
§ 32.51a	Conditions of licenses
§ 32.52	Material transfer reports and records

§ 31.7	**Luminous safety devices for use in aircraft**
§ 32.53	Luminous safety devices for use in aircraft; requirements for license to manufacture, assemble, repair, or initially transfer
§ 32.54	Labeling of devices
§ 32.56	Material transfer reports

§ 31.8	**General license for use of byproduct material for certain *in vitro* clinical or laboratory testing General license for strontium-90 in Americium-241 in the form of calibration or reference sources**
§ 32.57	Calibration or reference sources containing americium-241; requirements for license to manufacture or initially transfer
§ 32.58	Labeling of devices

§ 31.10	**General license for use of byproduct material for certain *in vitro* clinical or laboratory testing General license for strontium-90 in ice detection devices**
§ 32.61	Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer

§ 31.11	**General license for use of byproduct material for certain *in vitro* clinical or laboratory testing**
§ 32.71	Manufacture and distribution of byproduct material for certain *in vitro* clinical or laboratory testing under general license.

Additional regulations applicable to holders of a general license and distributors of generally

licensed products are found in the following 10 CFR Parts:

- 10 CFR Part 19, "Notices, Instructions, and Reports to Workers: Inspection and Investigations"
- 10 CFR Part 20, "Standards for Protection Against Radiation"
- 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 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."

> It is the applicant's or licensee's responsibility to have up-to-date copies of applicable regulations, read them, and abide by each applicable regulation.

To request copies of the above documents, call GPO's order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of Title 10, Code of Federal Regulations, Parts 0-50 and 51-199 from the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. You may also contact the GPO electronically at <http://www.gpo.gov>. Request single copies of the above documents from NRC's Regional Offices (see Figure 2.1 for addresses and telephone numbers). Note that NRC publishes amendments to its regulations in the *Federal Register*.

5 General License Distribution

5.1 General

On February 12, 1959 (24 FR 1089) (*Federal Register*, Volume 24, page 1089), the Atomic Energy Commission (AEC) amended its regulations to provide a general license for the use of byproduct material contained in certain measuring, gauging, or controlling devices. Under current regulations (10 CFR 31.5), certain persons may receive and use a device containing byproduct material under this general license if the device has been manufactured and distributed according to the specifications contained in a specific license issued by NRC or by an Agreement State. A specific license authorizing distribution of generally licensed devices is issued if a regulatory authority determines that the safety features of the device and the instructions for safe operation of that device are adequate and meet regulatory requirements. The general licensee must comply with the requirements for labeling, instructions for use, and proper storage or disposition of the device.

A generally licensed device usually consists of radioactive material, contained in a sealed source, within a shielded device. The device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience; thus, the general license is meant to simplify the licensing process so that a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary.

The distributor of the generally licensed product/device is required to assure NRC or the Agreement State that all products are distributed in accordance with the specifications provided in its license application. These specific licenses are issued by NRC or the Agreement State and are referred to as "general distribution" licenses. See Appendix N for an example of a general distribution license.

General distribution licenses only authorize the distribution of products and device(s) to general licensees and do not authorize possession or use of radioactive material; therefore, applicants for general distribution licenses will need to file a separate application for a specific license authorizing possession and use of byproduct material, with the NRC Regional Office or the Agreement State for the State in which the material will be possessed and/or used. However, the determination of where to file the general distribution license application should be made based on the location from which the applicant wishes to distribute, not necessarily where the applicant possesses and/or uses the byproduct material (i.e., where the product is manufactured). The four Regions and the Regional Office addresses are provided on NRC Form 3, in 10 CFR Part 20, Appendices K and L, and in Section 2 of this document (Figure 2.1).

A license authorizing distribution to general licensees cannot be issued until the applicant
(1) obtains a registration certificate (see Section 5.2) for the device (if applicable); and
(2) obtains a possession and use license. To expedite the licensing process, the applicant should apply for the possession license and registration certificate concurrently, then apply for authorization to distribute once the registration certificate has been issued.

5.2 Licensing And Sealed Source/Device Registration

Applicants of a general distribution license are required to provide specific information about the

sources and products, as outlined in 10 CFR 32.51, 32.53, 32.57, 32.61, and 32.71, concerning the radionuclides and activities, containment and construction, labeling, quality control and assurance programs, etc. NRC will evaluate the information submitted in the application to ensure it meets all applicable standards and regulations and will contact the applicant, if necessary, to obtain additional clarification or information.

A sealed source and device (SSD) safety evaluation will be performed on the sealed sources and devices the applicant proposes to distribute to general licensees. Information about the review and approval process for SSDs is contained in NUREG-1556, Vol. 3. Upon completion of the SSD evaluation, a registration certificate will be issued. The registration certificate must be complete and available before the licensing reviewer may issue the license. An SSD evaluation and registration certificate is required for all devices authorized in 10 CFR 31.3, 31.5, 31.7, and 31.10. An SSD evaluation is *not* required for devices/products authorized in 10 CFR 31.8 and 31.11. An example of a registration certificate is provided in Appendix C of this document.

Note:

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

After the issuance of a license, licensees must conduct their programs for the distribution of generally licensed products/devices in accordance with the following:

- Statements, representations, and procedures contained in their application, and other correspondence with NRC;
- Terms and conditions of the license;
- Device registration, if applicable;
- Applicable NRC regulations.

Section 30.9 of 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," requires that the information provided in the application be complete and accurate in all material respects. Information is considered to be material if it is likely to change or affect an Agency decision on issuing the license; therefore, information should be clear,

specific, and accurate. Section 30.10, 10 CFR Part 30, "Deliberate misconduct," states that those providing information concerning a licensee's activities may not deliberately engage in misconduct or provide incomplete or inaccurate information to NRC.

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

5.3 Types of Generally Licensed Devices

General distribution licenses are based on the types of products/device(s) to be distributed according to the six categories of products/device(s) found in 10 CFR Part 31. The following provides the applicable regulation and some examples of products/device(s) that may be distributed under a general distribution license and possessed by a general licensee:

§ 31.3 and 31.5	**Certain measuring, gauging or controlling devices**

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

Figure 5.1 Gas Chromatograph Units. Certain gas chromatograph units (detector cells) used for analysis of chemical composition can be possessed under a general license (10 CFR 31.5).

Figure 5.2 Fixed Gauging Devices. Certain nuclear gauges can be possessed under a general license (10 CFR 31.5).

Figure 5.3 Static Eliminators. Certain static elimination devices can be possessed under 10 CFR 31.5.

Figure 5.4 Tritium Exit Signs. Certain tritium exit signs can be possessed under 10 CFR 31.5 (typical devices contain 25 Ci of tritium per sign).

§ 31.7	**Luminous safety devices for use in aircraft**

- Luminous safety devices containing only hydrogen-3 (tritium) or promethium-147;

- Tritium devices not to exceed 370 gigabequerels (GBq) (10 Ci) per device;

- Promethium-147 devices not to exceed 11 GBq (300 mCi) per device.

Figure 5.5 Luminous Exit Sign. Safety devices, such as luminous exit signs, containing tritium or promethium-147 that are used in aircraft may be used under the 10 CFR 31.7 general license.

§ 31.8 Americium-241 in the form of calibration or reference standards

- Single source not to exceed 185 kilobequerels (kBq) (5.0 Ci) at any one time and/or location of use or storage.

Figure 5.6 Calibration Standards. Certain calibration and reference sources containing americium-241 can be possessed under a general license authorized in 10 CFR 31.8.

§ 31.10 Strontium-90 in ice detection devices

- Single sources not to exceed 1,850 kBq (50 Ci) per source.

§ 31.11 Byproduct material for certain *in vitro* clinical or laboratory testing

- Iodine-125 not to exceed 370 kBq (10 Ci);

- Iodine-131 not to exceed 370 kBq (10 Ci);

- Carbon-14 not to exceed 370 kBq (10 Ci);

- Hydrogen-3 not to exceed 1,850 kBq (50 Ci);

- Iron-59 not to exceed 740 kBq (20 Ci);

- Selenium-75 not to exceed 370 kBq (10 Ci);

- Mock iodine-125 not to exceed 1.85 kBq (0.05 Ci) of iodine-129 and 0.18 kBq (0.005 

Ci) of americium-241.

Figure 5.7 In Vitro Kit. Certain in vitro kits used in medicine, veterinary medicine, hospitals, and clinical laboratories are authorized in 10 CFR 31.11.

5.4 Proprietary and Private Information

License applications are generally made available for review by the public. Private information, including employee personal information (i.e., home address, home telephone number, Social Security Number, date of birth, and radiation dose information), should not be submitted unless specifically requested by NRC. Also, proprietary information as described in 10 CFR 2.790 (i.e., information not to be disclosed to the public) should not be included in an application unless necessary.

Any proprietary or financial information submitted should be clearly marked by the applicant as "Proprietary Information." In addition, the applicant must support the request to withhold by submitting an affidavit following the procedure in 10 CFR 2.790, "Public inspection, exemption, requests for withholding." Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing the application.

Applications containing information marked as "Proprietary Information," will be reviewed to determine if this information is necessary to issue the license. If the information is determined unnecessary, it will be returned to the applicant. If the information is deemed necessary to issue the license, it will be reviewed by NRC to determine if it is indeed proprietary or confidential and should be withheld from public disclosure.

If NRC determines that the affidavit is deficient, i.e., does not contain the required information as outlined in 10 CFR 2.790(b)(4), the applicant will be notified that additional information is needed and that the review will continue when the required information is received. Applicants will be informed that NRC must review the information before determining whether to withhold it from public disclosure and that the review of their request for licensing may continue. If NRC determines that the information is not proprietary, but the applicant does not want the information released to the public, the information will be returned to the applicant. A license cannot be issued until the request to withhold information is resolved.

Once NRC has reviewed the application and affidavit and determined whether or not to withhold the information from public disclosure, NRC will notify the licensee by letter of its decision and the appropriateness of the 10 CFR 2.790 affidavit (see Appendix D). Appendix D also includes a checklist for requests for withholding the information.

Applicants should write "Proprietary Information" on the top and bottom of the front page of each document containing proprietary information. The license reviewer will place a Proprietary Information cover sheet (NRC Form 190) on the document.

Note: Additional procedures for the handling of proprietary information can be found in Directive 12.6 (formerly MC 2101), "NRC Sensitive Unclassified Information Security Program."

5.5 Foreign Vendors

Foreign vendors are unique in that NRC has no jurisdiction over the foreign entities. Pursuant to 10 CFR 110.53, "United States address, records, and inspections," foreign vendors or licensees involved in importing and exporting nuclear material and equipment are required to establish an address in the United States where papers may be served, where records can be maintained, and where NRC can inspect the applicant's activities and records as necessary to accomplish its mission. A general distribution license will, therefore, not be issued to a foreign vendor unless the requirements set forth in 10 CFR 110.53 have been satisfied.

6 How To File

6.1 Paper Application

Applicants wishing to distribute or initially transfer products containing byproduct material to persons generally licensed under 10 CFR Part 31 should complete NRC Form 313, "Application for Material License" (Appendix B). An application for a distribution license should contain information concerning the distribution of radioactive material only (not possession and use).

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance in preparing an application.
- Complete NRC Form 313 (Appendix B), Items 1 through 4, 12, and 13 on the form itself.
- Complete Items 5, 6 and 10, as applicable, and attach separately.
- Items 7, 8, 9 and 11 are not applicable to distribution licenses.
- Submit all typed pages, sketches, or drawings on 8-1/2 x 11-inch paper to facilitate handling and review. Larger drawings should be folded to 8-1/2 x 11 inches.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application and one copy.
- Retain one copy of the license application for future reference.

As required by 10 CFR 30.32(c), applications must be signed by a duly authorized representative; see Section 8.9, Certification of Application.

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

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

All license applications will be available for review by the public. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.790. Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Employee personal information (i.e., home address, home telephone number, Social Security Number, date of birth, and radiation dose information), should not be submitted unless specifically requested by NRC. See Section 5.4, Proprietary and Private Information, for guidance.

As explained in the Foreword, NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications at some future date. NRC will continue to accept paper applications. However, these will be scanned and put through an optical character reader (OCR) to convert them to electronic format. To ensure a smooth transition, applicants are asked to follow these suggestions:

- Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into the scanner.
- Choose 12-point or larger font size.
- Avoid stylized fonts (or type faces) such as script, italic, etc.
- 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).

6.2 Electronic Application

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via diskettes, CD-ROM, and through the Internet for those applicants/licensees who choose to file electronically. Additional filing instructions will be provided as these new mechanisms become available. The existing paper process will be solely

used until the electronic process is available.

6.3 Where to File

Applicants wishing to distribute or initially transfer products (containing byproduct material to persons generally licensed under 10 CFR Part 31 or equivalent Agreement State regulations) from any State or U.S. territory or possession subject to NRC jurisdiction, must file an application with the NRC Regional Office in the locale from which the material will be distributed or initially transferred. Figure 2.1 in Section 2 shows NRC's four Regional Offices and their respective areas for licensing purposes and identifies Agreement States.

In general, applicants wishing to distribute or initially transfer such products from a location in an Agreement State must file an application with the Agreement State, not NRC. See Section 2, NRC Regions and Agreement States, for additional information.

Requests for safety evaluations of sealed sources or devices are submitted directly by applicants to the Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 (address is also found at the top of NRC Form 313).

7 Application and Annual Fees

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to 10 CFR 170.31, "Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses," to determine the amount of the fee that must accompany your application. NRC will not issue the new license before receiving the fee. Once technical review 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.

For applicants wishing to distribute items containing byproduct material pursuant to 10 CFR 31.3, 31.5, 31.7, and 31.10 that require a source or device evaluation, the fee categories are 3B for possession and use license, 3J for distribution license, and 9A for the device evaluation or 9C for source evaluation. For applicants wishing to distribute items pursuant to 10 CFR 31.8 and 31.11 that do not require a source or device evaluation, the fee categories are 3B for possession and use and 3K for distribution.

Most NRC specific licensees are also subject to annual fees; refer to 10 CFR 171.16. The same fee categories that applied to the application, renewal, and registration fees also apply to the annual fees. Consult 10 CFR 171.11 for additional information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities."

Direct all questions about NRC's fees or completion of Item 12 of NRC Form 313 (Appendix B) to the Office of the Chief Financial Officer (OCFO) at NRC Headquarters in Rockville, Maryland, (301) 415-7554. Or call NRC toll free at (800) 368-5643, extension 415-7554.

NRC conducts rulemaking each year to establish the Part 171 annual fees and to make any necessary changes to the Part 170 licensing and inspection fees. The proposed changes to the fees are published in the *Federal Register* for public comment, and a copy of the proposed rule is mailed to all specific licensees. After consideration of the comments received, a final rule is published in the *Federal Register* and a copy is mailed to all licensees. At that time, invoices are issued for the annual fees. Although the invoices are issued for the full amount of the annual fee, the amount due may be reduced, as provided in 10 CFR 171.16(c), if the licensee qualifies as a small entity under NRC's size standards and so certifies by completing and returning NRC Form 526, "Small Entity Certification," which is enclosed with each annual fee invoice. A new certification must be submitted with the annual fee payment each year.

8 Contents of an Application

The following comments apply to the indicated items of NRC Form 313 (see Appendix B).

8.1 Item 1: License Action Type

THIS IS AN APPLICATION FOR (Check appropriate item)

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

Check box A for a new license request.

Check box B for an amendment[(1)] to an existing license, and provide license number.

Check box C for a renewal[1] of an existing license, and provide license number.

8.2 Item 2: Applicant's Name And Mailing Address

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

Note: While a U.S. address is required in order to issue a license, it is acceptable for the licensee's mailing address and the state code in the license number to be based on an address located in Puerto Rico, Canada, or the U.S. Virgin Islands.

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

Note: NRC must be notified before control of the license is transferred, and the licensee must receive written consent from NRC prior to the change of control. NRC must also be notified when bankruptcy proceedings have been initiated. See below for more details.

NRC Information Notice (IN) 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

NUREG-1556, Volume 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses," provides additional information about NRC requirements related to both changes of control and bankruptcy.

8.2.1 Timely Notification of Transfer Control

Regulations: 10 CFR 30.34(b).

Criteria: Licensees must provide full information and obtain NRC's prior written consent before transferring control of the license.

Discussion: Control over licensed activities can be construed as the authority to decide when and how that license (licensed material and/or activities) will be used. A change of ownership may be an example of a change of control, depending on whether the authority over the license has been transferred from one person to another. For example, a change may result from a merger or buyout. The transfer of stock or other assets is not a change of control, unless there is a change of authority over the license.

It is not NRC's intent to interfere with the business decisions of licensees. NRC will require

licensees to submit only such business information as is necessary to determine whether a change of control will take place. This information is required to ensure that all NRC requirements are followed.

Response from the Applicant:

- None from an applicant for a new license.

- For existing licensees undergoing change of control, refer to Appendix E, excerpted from IN 89-25 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, which identifies the information to be provided about changes of control.

Reference: See the Availability Notice on the inside front cover of this report to obtain copies of:

- Information Notice 89-25 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994;

- Information Notice 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997.

Information Notices are available on NRC's web site at <www.nrc.gov/NRC/reference.html>.

8.2.2 Notification of Bankruptcy Proceedings

Regulations: 10 CFR 30.34(h).

Criteria: Immediately following filing of a voluntary or involuntary petition for bankruptcy, specific licensees (as well as general licensee registrants) must notify the appropriate NRC Regional Administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. NRC needs to know when licensees are in bankruptcy proceedings in order to determine whether all NRC requirements are followed prior to the completion of the bankruptcy actions. NRC shares the results of its determinations with other involved entities (e.g., trustee) so that health and safety issues can be resolved before bankruptcy actions are completed.

Response from Applicant:

- No response is required at time of application for a new license.

- Licensees must notify NRC immediately following filing a bankruptcy petition.

References:

- Inspection Procedure 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing."

- Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," dated August 8, 1996.

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

An applicant for a general distribution license must be an organization with an address in the United States from which it will distribute the items. The applicant must specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each and every facility used as a location from which distribution will occur. A Post Office Box address is *not* acceptable. Each point of distribution will be listed on the general distribution license.

Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local requirements (e.g., local zoning requirements or local ordinances requiring registration of radioactive material).

8.4 Item 4: Person to Be Contacted About This Application

Identify the individual who can provide information and answer questions about the application and the product(s) to be distributed, and include his or her telephone number. This is typically the RSO for the license for possession and use of the material, unless the applicant has named a different person as the contact. NRC will contact this individual if there are questions about the application.

Notify NRC if the contact person or his or her telephone number changes so that NRC can contact the applicant or licensee in the future regarding questions, concerns, or information. Notification of a contact change is for information only and would not be considered an application for license amendment.

The individual named in Item 4 of the application may or may not be the same individual who signs the application as the "certifying official" on behalf of the licensee and has the authority to make commitments to NRC (see Item 13 on Form 313, Appendix B). Any commitments made by the applicant should be signed by the individual named in Item 13, since only that individual is considered by NRC to have the authority to make commitments on behalf of the applicant. NRC will not, therefore, accept license amendments or renewals signed by the individual identified in Item 4, if this person differs from the one named in Item 13.

NRC recognizes that licensees may use a consultant or consultant group to help prepare the

license application and provide support to the radiation protection program. Licensees are reminded that regardless of the role of the consultant in radiation protection program management, the licensee remains ultimately responsible for all aspects of the licensed program, including the services performed by the consultant. When selecting the person to be contacted, be aware that further important NRC communications will be directed to this person.

8.5 Items 5 and 6: Radioactive Material And Purpose(s) For Which Licensed Material Will Be Used

Regulations: 10 CFR 30.33; 10 CFR 32.51; 10 CFR 32.53; 10 CFR 32.57; 10 CFR 32.61; 10 CFR 32.71.

Criteria: An application for a general distribution license will be approved if the requirements of 10 CFR 30.33, and the applicable requirements of 10 CFR 32.51, 10 CFR 32.53, 10 CFR 32.57, 10 CFR 32.61, and/or 10 CFR 32.71 are met.

Discussion: Applicants should determine what devices or products are to be distributed and provide information about each type of product. Describe in general terms the purpose of each product. Activity should be specified in terms of "XX becquerels (YY curies)." For example, "the maximum activity per sealed source is 370 MBq (10 mCi) of cesium-137."

A safety evaluation of sealed sources and devices is required on certain generally licensed devices. An SSD evaluation is required for all devices authorized in 10 CFR 31.3, 31.5, 31.7, and 31.10. An SSD evaluation is *not* required for devices/products authorized in 10 CFR 31.8 and 31.11. This evaluation is performed by NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute the device to general licensees. The safety evaluation is documented in an SSD Registration Certificate. Information on SSD registration certificates is available on NRC's web site at <http://www.hsrd.ornl.gov/nrc/ssdrform.htm>. Information may also be obtained by contacting the Registration Assistant at NRC's toll free number, (800) 368-5642, extension 415-7231. For additional guidance relating to sealed sources and devices, also see NUREG-1556, Vol. 3, "Applications for Sealed Source and Device Evaluation and Registration."

You may not apply for a distribution license for devices that require an SSD evaluation and have not yet been through the above procedure. First obtain an SSD Registration Certificate, and then apply for a distribution license.

Response from Applicant: The applicant should provide the following information for each device to be distributed:

- Isotope;
- Manufacturer and model number;

- Maximum activity per device;

- Purpose of the device;

- SSD Registration Certificate Number for all devices authorized for use under 10 CFR 31.3, 31.5, 31.7, and 31.10.

References: See the Availability Notice (on the inside front cover of this report) to obtain a copy of NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration." Also, see the Sample Registration Certificates for Generally Licensed Products, in Appendix C of this document.

8.6 Items 7, 8, 9 and 11: Not Applicable

These items on Form 313 are not applicable for general distribution licenses.

8.7 Item 10: Radiation Safety Program (Requirements For a General Distribution License)

8.7.1 10 CFR 32.51: Requirements For Initial Transfer of Devices For Use Under 10 cfr 31.5 (Certain Measuring, Gauging, or Controlling Devices)

Regulations: 10 CFR 31.5; 10 CFR 32.51; 10 CFR 32.51a; 10 CFR 32.52.

Criteria: Applicants for a specific license to distribute generally licensed devices, as specified in 10 CFR 31.5, should provide information relative to the material transfer reports and records. Applicants should also provide a copy of the information packet to be sent to customers before transfer. An SSD review is required (See Section 5.2). All other requirements of 10 CFR 32.51 are handled in the SSD review.

Discussion: The following information must be submitted or addressed as part of the license application.

Quarterly Material Transfer Reports

Licensees are required to file a report with NRC within 30 days of the end of each calendar quarter in accordance with 10 CFR 32.52. Appendix Q contains NRC Form 653 entitled "Transfers of Industrial Devices Report." This form may be used to submit these quarterly reports. Alternatively, the licensee may use another report format as long as the report includes the following information:

1.	Name and license number of the specific licensee submitting the report.
2.	Name and address of *each* General Licensee to which a product was transferred.
	This address is to be the mailing address of the location of use of the device. For devices that are portable, this address shall be the mailing address of the primary place of storage of the device.
	When a customer has multiple locations of use, each location of use should be listed as a separate transfer, with the corresponding mailing address of each location of use (unless the multiple locations are contained within the same business campus or industrial complex). For example, suppose you transfer GL devices to Company A at two different locations (Plant 1 and Plant 2). Company A is considered two separate general licensees, one for each location of use. In other words, Company A-Plant 1 is considered a separate General Licensee from Company A-Plant 2. Both General Licensees, to which a product was transferred, should be reported.
	Different facilities at the same industrial complex or business campus are not considered separate locations.
	If there is no mailing address for the location of use, an alternative address for the general licensee should be submitted, along with information on the actual location of use.
	If there is no mailing address for the location of use, an alternative address for the general licensee should be submitted, along with information on the actual location of use.
	Reports to NRC should only include transfers of devices where the place of use is within NRC jurisdiction, or for portable devices, the primary place of storage of the device is within NRC jurisdiction.
3.	Name, title, and phone number of each General Licensee's responsible individual (RI).
	The RI is required to be an individual designated by the General Licensee to be responsible for having knowledge of and authority to take required actions to ensure the day-to-day compliance with the appropriate regulations and requirements. Each General Licensee must designate one RI per location and cannot designate more than one RI per location. An RI can, however, be assigned to more than one general licensee. This individual is not necessarily someone who works onsite at the place of use of the device and is not necessarily conducting all required actions, but is responsible for ensuring that required actions are taken.
4.	Date of transfer.
5.	Type, model number, and serial number of each product transferred.
6.	Quantity and type of byproduct material contained in the product.

Important Notes on Transfer Reports:

- If one or more "intermediate persons" will temporarily possess the device at the intended place of use before the intended user takes possession, the report must include the same information for each intermediate person, and clearly designate that person as an intermediate person. The term "intermediate persons" means a person, company, or corporation that will temporarily

possess the device at an intended place of use prior to its possession by the intended user. For example, if XYZ Building Company owns an office building during its construction and the building contains self-luminous tritium exit signs (GL devices), XYZ Building Company is the intermediate person. When XYZ Building Company sells the office building to Company 123, then Company 123 becomes the general licensee. Note that an intermediate person should not hold a device in storage for longer than two years (10 CFR 31.5(c)(15)).

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

- If you receive a device from a 10 CFR 31.5 General Licensee, the report must note this and identify the General Licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

- If no transfers or receipts were made during the reporting period, a report of no activity is required.

- If you make changes to a 10 CFR 31.5 device, such that the label must be changed to update required information, the report must identify the General Licensee, the device, and the change to information on the device label.

- Licensees must also submit a report containing the same information outlined above to the responsible Agreement State Agency for transfers to or from General Licensees in Agreement States. However, a report of no transfers is only required if an Agreement State requests it.

Recordkeeping

Information on all 10 CFR 31.5 transfers and receipts that supports the above reports, are required to be maintained for 3 years after the recorded event.

Licensees are required to make available, upon request, to the various regulatory agencies, records of final disposition of devices in the event the licensee files for bankruptcy or requests termination of the license.

Information to be Supplied to Customers

Licensees are required to provide information to their generally licensed customers before transfer of devices in accordance with 10 CFR 32.51a (a) and (b). The intent is for the customer to be aware of this information prior to making a commitment to purchase (e.g., so they can consider the requirements associated with the general license and the costs of disposal of the device in making a decision to purchase). The following information must be provided:

1.	A copy of 10 CFR 30.51, 31.2, 31.5, 20.2201, and 20.2202;
2.	A list of services that can only be performed by a specific licensee;
3.	Information on acceptable disposal options and estimated cost of disposal;
4.	An indication that NRC's policy is to issue high civil penalties for improper disposal.

If the customer is planning to use the device in an Agreement State, a copy of applicable state regulations and the name, address, and phone number of the contact at the Agreement State Regulatory Agency should be provided. A copy of the NRC regulations listed in Item 1 above can be substituted for the Agreement State regulations, with a note that the device is regulated by the Agreement State regulations. Item 4 is not applicable in this case.

Note that Appendices K and L can be supplied to customers for information as well. In the easy-to-read question and answer format, these Appendices contain useful information regarding generally licensed devices. Appendix K may be helpful to a wide range of generally licensees, and Appendix L may be helpful to general licensees who use Self-Luminous Exit signs.

Response from Applicant: Submit the following:

A statement that: "We will provide quarterly transfer reports in accordance with 10 CFR 32.52(a) and (b) and will maintain records in accordance with 10 CFR 32.52(c). We will provide information to customers prior to purchase in accordance with 10 CFR 32.51a (a) and (b)."

References: Appendix F contains a checklist for use in reviewing general distribution license applications for 10 CFR 31.5 devices. Appendix K contains guidance for General Licensees in the form of questions and answers. Appendix L contains guidance specific to Self-Luminous Exit Signs (tritium exit signs) in the form of questions and answers. Appendix Q contains a form for use in submitting quarterly material transfer reports.

8.7.2 10 CFR 32.53: Requirements For Initial Transfer of Luminous Safety Devices For Use in Aircraft

Regulations: 10 CFR 31.7; 10 CFR 32.53; 10 CFR 32.56.

Criteria: Applicants for a specific license to initially transfer luminous safety devices for use in aircraft containing tritium or promethium-147, for distribution to general licensees under 10 CFR 31.7, must provide sufficient information relative to annual material transfer reports. All devices distributed under 10 CFR 31.7 require an SSD review. All other requirements of 10 CFR 32.53 are handled in the SSD review (See Section 5.2).

For products distributed to general licensees pursuant to 10 CFR 31.7, the specific licensed distributor is required under 10 CFR 32.56 to file an annual report with NRC before July 30 of each year, covering the year ending June 30. The report must include the following information:

- Name of each general licensee to which a product was transferred (distributed);
- Types and numbers of each product transferred (distributed);
- Quantity of tritium or promethium-147 contained in each type of product; and
- Total quantity of tritium or promethium-147 transferred (distributed).

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

Response from Applicant: Submit the following:

A statement that: "We will provide annual material transfer reports in accordance with 10 CFR 32.56."

References: Appendix G contains a checklist for use in reviewing a general distribution license application for luminous safety devices for aircraft.

8.7.3 10 CFR 32.57: Requirements For Initial Transfer of Calibration or Reference Sources Containing Americium-241

Regulations: 10 CFR 31.8; 10 CFR 32.57; 10 CFR 32.58; 10 CFR 32.59.

Criteria: Applicants for a specific license to initially transfer calibration or reference sources containing americium-241, for distribution to persons generally licensed under 10 CFR 31.8, must provide sufficient information relative to 10 CFR 32.58.

Note that an SSD registration certificate is not required for americium-241 calibration sources that contain no more than 185 kBq (5.0 microcuries), and thus, the application process for a manufacturing license of such sources should include a review of 10 CFR 32.57 and 32.59. For information regarding applications for manufacturing, see NUREG-1556, Vol.12.

Discussion: This section outlines the requirements to obtain a license for an applicant wishing to distribute americium-241 reference and calibration sources.

The byproduct material must be prepared for distribution in calibration or reference sources consisting of americium-241 not exceeding 185 kBq (5.0 microcuries).

Each source or storage container for the source must bear a label that contains sufficient information relative to safe use and storage of the source and the following statement (or a substantially similar statement):

Figure 8.1 Label.

Response from Applicant: Submit an actual label for each americium-241 check or reference source to be distributed. These labels must contain the information described in the Discussion section above.

Reference: Appendix H contains a checklist for use in reviewing a general distribution license application for americium-241 calibration or reference sources under 10 CFR 31.8.

8.7.4 10 CFR 32.61: Requirements For Initial Transfer of Ice Detection Devices Containing Strontium-90

Regulations: 10 CFR 31.10, 10 CFR 32.61.

Criteria: Applicants for a specific license to initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under 10 CFR 31.10, must only provide sufficient information relative to Items 1 through 6 of NRC Form 313. An SSD review is required (See Section 5.2). All other requirements of 10 CFR 32.61 are handled in the SSD review.

Response from Applicant: No specific response required.

References: Appendix I contains a checklist for use in reviewing general distribution license applications for ice detection devices.

8.7.5 10 CFR 32.71: Requirements For Initial Transfer *in Vitro* Kits Under 10 CFR 31.11

Regulations: 10 CFR 20.1901(a); 10 CFR 20.2001; 10 CFR 30.42(d); 10 CFR 31.11; 10 CFR 32.71.

Criteria: Applicants for a specific license to initially transfer byproduct material for certain *in vitro* clinical or laboratory testing for distribution to persons generally licensed under 10 CFR 31.11, must provide sufficient information to satisfy 10 CFR 32.71(b)-(e).

Discussion: This section outlines the requirements to obtain a license for an applicant requesting authorization to distribute *in vitro* kits to persons who use them for a variety of clinical tests such as Schillings tests, red cell survival tests, hormone evaluations, and thyroid stimulating hormone tests (TSH). An SSD review is not required.

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

- Iodine-131, iodine-125, carbon-14, or selenium-75 not exceeding 370 kilobecquerels (kBq) 

  (10 microcuries (10 m Ci));

- Hydrogen-3 not exceeding 1,850 kBq (50 Ci);

- Iron-59 not exceeding 740 kBq (20 Ci);

- Mock iodine-125 not exceeding 1.85 kBq (0.05 Ci) of iodine-129 and 0.18 kBq (0.005 

  Ci) of americium-241.

Each prepackaged unit must bear a durable, clearly visible label including the following information:

- The radionuclide and chemical form;
- A statement that the radioactivity does not exceed the limit indicated above for each radionuclide;
- The radiation caution symbol described in 10 CFR 20.1901(a);
- The words, "Caution - Radioactive Material," and "Not for Internal or External Use in Humans or Animals."

Each package must also have a statement, or a substantially similar statement, that contains the following information on a label affixed to the prepackaged unit or in a leaflet or brochure accompanying the package.

Figure 8.2 Package Label.

This label or leaflet/brochure must contain adequate information about the precautions to be observed in handling and storing such byproduct material. Regarding Mock Iodine-125 reference/calibration sources, the information must also contain directions on disposing of waste in accordance with 10 CFR 20.2001. Usually, compliance with this requirement is achieved by transfer to an authorized recipient.

In accordance with 10 CFR 31.11(f), except for mock iodine-125 sources, these licensees are exempt from the requirements in 10 CFR Parts 19, 20, and 21, including the requirements on disposal of licensed material. The distribution licensees may wish to inform their customers of this exemption.

Note: The distributor of generally licensed *in vitro* kits must not transfer materials to a general licensee unless the general licensee has a properly completed NRC Form-483, "Registration Certificate - *In Vitro* Testing with Byproduct Material Under General License" on file with NRC. Distributors can verify this information by obtaining a copy of the general licensee's validated Form NRC-483. An NRC Form-483 has been validated if it has been assigned a registration number by NRC. Alternate methods for verification are listed in 10 CFR 30.41(d).

Response from Applicant: Submit an actual package label and/or leaflet/brochure for each type of prepackaged kit. These labels and/or leaflet/brochures must contain the information described in the Discussion section above.

References: Appendix J contains a checklist for reviewing general distribution license applications for certain *in vitro* kits under 10 CFR 31.11.

8.8 Item 12: Fees

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application. Applicants should be aware that they may be responsible for fees in each category applicable to their application or license. Refer to Section 7 for more information.

NRC may begin reviewing licensing requests without the proper fees; however, NRC will not issue a new license, amendment, renewal, or registration certificate before receiving the appropriate fee.

8.9 Item 13: Certification of Application

Individuals acting in a private capacity are required to date and sign NRC Form 313. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the form. ***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 "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. ***NRC will return all unsigned applications for proper signature.***

Note:

- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

- It is a violation of 10 CFR 30.9 and 10 CFR 30.10 to make a false statement on an application. Civil sanctions, including revocation of the license and/or orders removing individuals from licensed activity, may be taken.

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).

9 Deficiency in the Application

If, in the process of evaluating an application, it is determined that insufficient information has been submitted, the license reviewer will contact the applicant to obtain the necessary information. Depending on the type and complexity of the information needed, the reviewer may request the additional information through a formal written request or, especially for simple answers and clarifications, via telephone or electronic mail. Submittal of an inadequate or deficient application may delay the issuance of the license. The application could be rejected by NRC for failure to provide a prompt or timely response to a deficiency in the application.

Applicants may request an extension of time in order to respond to any correspondence or request for additional information about its application, provided NRC determines there is good cause and the additional time is reasonable. The request may be in writing or via telephone. Typically, the reviewer notifies the applicant by telephone that an extension has been granted and gives the applicant the new proposed date.

10 Issuance of a License

Licenses authorizing distribution of generally licensed products or devices under 10 CFR 32.51, 32.53, 32.57, 32.61, and/or 32.71 are prepared using NRC Form 374 (see Appendix M for a typical example). This is a separate license from the possession and use license, and it is commonly referred to as a "General Distribution" license. All general distribution licenses include the following information:

- Licensee's name and mailing address;
- License number, docket number and expiration date (all assigned by NRC);
- Byproduct material and its chemical and/or physical form;
- Authorized activity;
- Products, model number, and maximum activity per source or device;
- Location(s) from which generally licensed products may be distributed;
- Condition that "this license does not authorize possession or use of licensed material."

The general distribution license also contains a "tie-down" condition that commits the licensee to conducting its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, submitted by the applicant.

11 Amendments and Renewals to a License

It is the licensee's obligation to keep the license current and anticipate the need for a license amendment. If any of the information provided in the original application needs to be modified or changed, the licensee should consult the appropriate Regional Office to determine if an amendment to the license is required and if required, the licensee must submit an application for a license amendment before the change takes place. In general, you must submit an application

for an amended license whenever there is a substantive change to text or labels accompanying the product. Substantive changes include such items as a change in name and address of the licensed distributor, wording required by regulations, or a change in colors used on the hazard warning labels. An application for a license amendment is not needed for minor changes. Minor changes include changes in format, color intensity, typographical corrections, changes to distributor's logo, telephone number, e-mail address or web-site address.

Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a)).

For renewal and amendment requests, applicants must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request.
- Submit, in duplicate, either an NRC Form 313 and/or a letter requesting amendment or renewal.
- Provide the license number.

In requesting renewal of a license, licensees should do the following:

- Review the current license and associated documents submitted to NRC in the past to determine if the information is up-to-date and accurately represents the current licensed activities and products. Identify in the application, by date, those documents that are applicable and those that are out-of-date or superseded, and indicate any changes necessary to reflect the current program.

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

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

Licensees not wishing to renew their general distribution license should send a letter to NRC before the expiration date of the license, with a request that the license be terminated (see Section 13 for additional guidance).

Amending or changing the general distribution license may also require amendments to the possession and use license(s) and/or the device registration sheet(s) for additions, deletions, or modifications to models of sealed sources or devices to be distributed.

12 Applications for Exemptions

Regulations: 10 CFR 19.31; 10 CFR 20.2301; and 10 CFR 30.11.

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

Discussion: Various sections of NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, 20.2301, and 30.11(a)). These regulations state that NRC may grant an exemption, acting on its own initiative or on an application from an interested person. Key considerations are whether the exemption is authorized by law, will endanger life or property or the common defense and security, and is otherwise in the public interest.

Until NRC has granted an exemption in writing, NRC expects compliance with all applicable regulations.

Exemptions are not intended for large classes of licenses and are generally limited to a unique situation. Exemption requests must be accompanied by the following information:

- Request for the exemption and an explanation of why it is needed;
- Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested; and
- Alternative methods for complying with the regulation and why they are not feasible.

13 Termination of Activities

Regulations: 10 CFR 30.36.

Criteria: Termination of distribution activities.

Discussion: Pursuant to 10 CFR 30.36, general distribution licensees may request termination of their NRC license at any time. Licensees should notify NRC within 60 days of their decision to permanently cease licensed activities or the lack of licensed activities for 24 months.

General distribution licensees who intend to terminate their possession and use activities as well, are responsible for notifying and providing records to the appropriate NRC or Agreement State

authorities concerning the disposition of the possession license and all radioactive material, etc.

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

Response from Applicant: General distribution licensees who are required to submit material transfer reports under 10 CFR 32.52 or 10 CFR 32.56 are required to file material transfer reports when discontinuing activities authorized under the license. The report must include transfers since the period previously reported until the date of the last transfer. If no transfers of byproduct material have taken place, then the report should so indicate.

Appendix A: List of Documents Considered in Development of this NUREG

This report incorporates, updates, and supersedes previous guidance found in Information Notice, "Standard Review Plan for Use of Sealed Sources in Nonportable Gauging Devices," and Technical Assistance Requests as it applies to manufacturing and initial distribution of generally licensed devices/products for use under 10 CFR Part 31. All superseded documents have been marked by an asterisk (*).

Table A.1 List of Documents Considered in the Preparation of this Report

Document Identification	Title	Date
IL 81-2*	Interpretive Letter 81-2	5/4/81
IN 81-37*	Information Notice 81-37, "Unnecessary Radiation Exposure to the Public and Workers During Events Involving Thickness and Level Measuring Devices"	12/18/81
IN 87-37*	Information Notice 87-37, "Compliance with the General License Provisions of 10 CFR Part 31"	8/10/87
IN 88-02*	Information Notice 88-02, "Lost or Stolen Gauges"	2/2/88
IN 88-90*	Information Notice 88-90, "Unauthorized Removal of Industrial Nuclear Gauges"	11/22/88

IN 94-15*	Information Notice 94-15, "Radiation Exposures During an Event Involving a Fixed Nuclear Gauge"	3/2/94
FC 85-04*	Policy and Guidance Directive, "Standard Review Plan (SRP) for Applications for Use of Sealed Sources in Nonportable Gauging Devices"	2/6/85
FC 85-08*	Policy and Guidance Directive, "Licensing of Fixed Gauges and Similar Devices," Revision 1	6/29/88

Appendix B: United States Nuclear Regulatory Commission Form 313

United States Nuclear Regulatory Form 313	
Pages	**Title**
1	NRC Form 313 - Application for Material License (PDF Format)

Appendix C: An Example of a Sealed Source and Device (SSD) Registration Certificate for Generally Licensed Products

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

No.: NR-109-D-122-B	DATE: June 27, 1994	PAGE 1 OF 11

DEVICE TYPE: Transmission Gauge

MODEL:	TG-l (formerly registered as the Models 0-7, U-7, and U-7D)
MANUFACTURER/DISTRIBUTOR:	[Manufacturer’s name and address goes here]

SEALED SOURCE MODEL DESIGNATION:	ABB Models: Amersham Model:	S-11 S-16 S-18 S-20 CLC.Dl

ISOTOPE	MAXIMUM ACTIVITY	MODELS
Promethium-147	1000 millicuries (37 GBq)	S-20
Krypton-85	1000 millicuries (37 GBq)	S-11
Strontium-90	70 millicuries (2.6 GBq)	S-18
Curium-244	1000 millicuries (37 GBq)	CLC.Dl
Americium-241	5000 millicuries (185 GBq)	S-16

LEAK TEST FREQUENCY:	6 Months Not required for Krypton -85
PRINCIPAL USE:	(D) Gamma Gauge (containing Cm-244 or Am-241) (E) Beta Gauge (containing Pm-147, Kr-85 or Sr-90)
CUSTOM DEVICE:	_____YES __X__ NO

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

No.: NR-109-D-122-B	DATE: June 27, 1994	PAGE 2 OF 11

DEVICE TYPE: Transmission Gauge

DESCRIPTION:

The Manufacturer's Model TG-l device is designed for gauging physical characteristics of processed materials such as the thickness, density, weight per unit area or length, or composition of the measured material. The device is always mounted in a fixed geometry with a detector housing. The detector housing is mounted in front of the beam port of the device. The material to be measured is either passed between the device and detector or the device and detector are moved simultaneously, maintaining their geometrical relationship over the material to be measured. The air gap between source housing and detector ranges from 0.5 cm (0.20 inch) to 10 cm (3.93 inch) for beta-emitting sources and up to 50 cm (19.69 inch) for gamma-emitting sources.

The device is installed at fixed locations by the manufacturer or another specific licensee of NRC

or an Agreement State which is licensed to do so. The device may be installed into existing manufacturing equipment or onto a frame or scanner which is incorporated into the process. The device may be mounted in laboratory or similar locations.

The dimensions of the device range from 190 to 243 mm (7.48 to 9.57 inches) high by 419 mm (16.50 inches) long by 203 mm (7.99 inches) wide. The device consists of an outer shell, the sealed source, source holder, shutter mechanism, source holder adapter, and various electronic components. A drawing of the device is shown in Attachment 1.

The outer shell consists of four pieces: the source base plate, source head, and two side covers. The source head, three sides of the box shape, is either cast from aluminum or fabricated from steel. It has a minimum wall thickness of 6.4 mm (0.25 inch). The source base plate is fabricated from steel, 19.1 mm (0.75 inch) thick, and mechanically fastened to the enclosure with heavy-duty latches. The side covers are made of aluminum or steel and are 6.4 mm (0.25 inch) thick. The side covers are bolted in place and locked to prevent removal. When needed, insulating material is inserted between dissimilar material interfaces.

DEVICE TYPE: Transmission Gauge

DESCRIPTION (Cont.):

The source holder adapter is fabricated from steel and is bolted to the source base plate. It has a minimum thickness of 15.8 mm (0.62 inch).

The shutter mechanism is operated by an air or electric actuator. The actuator is equipped with a fail-safe spring mechanism which will automatically return the sintered tungsten or stainless steel shutter to the closed position if there is a power failure.

The source holder contains the sealed source and is fabricated from steel and/or sintered tungsten and lead shielding. The combination of materials and dimensions of the source holder depends on the isotope. The source contained in the device may be one of the sources listed on the first page of this document with the maximum activity listed.

The device is designed to withstand the environmental conditions listed in this document. If more extreme conditions are expected or realized, the manufacturer may substitute different materials for the source base plate, source head, and side covers and/or may plate, coat, or treat these components to achieve higher performance. Upon doing so, the manufacturer is required to submit details of the environmental conditions and design specifications of the device to the Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety, NRC.

The device is operated as part of a larger measurement and control system which is computer controlled. The computer control system may be located in a remote location. The system software and logic determines if the conditions are appropriate (material to be measured is present, line is moving, etc.) for the shutter to open. The operator cannot override the system logic and open the device shutter mechanism. However, the operator at the computer can close the shutter by executing a command such as "Off sheet" which will automatically close the shutter. The device may also be equipped with a mechanism which allows the shutter to be closed by executing a lock-out control at the operator's station or at the scanner.

The shutter position is indicated by lights in the immediate vicinity of the device. The lights are red (shutter open) and green (shutter closed). An illustration of the indicator lights for O-frame installations is shown in Attachment 2.

DEVICE TYPE: Transmission Gauge

DESCRIPTION (Cont.):

Large lantern lights are mounted to U- or C-frame applications. The lights are mounted so they are readily visible to anyone working in the area near the device. Additional indicator lights may be located throughout associated areas. This could include lights or video displays at the operators' monitoring and control stations.

The ABB source models listed on the first page of this document (and in attachment 4) are approved for use only in the Model TG-1. The sources may not be registered on separate certificates. The sources are manufactured to ABB specifications by Amersham Corporation or Du Pont Merck Pharmaceuticals.

The Model TG-l replaces the ABB Models 0-7, U-7, and U-7D. The primary change is that the Model TG-l is the source housing which was used in the Models 0-7, U-7, and U-7D, and this change allows the device to be mounted to various types of frames or existing process machinery.

LABELING:

The device is labeled in accordance with Section 20.203, 10 CFR Part 20. When distributed to persons generally licensed, the device is additionally labeled in accordance with the requirements of Section 32.51, 10 CFR Part 32. Copies of the labels are shown in Attachment 3.

Label A is self-adhesive and will be attached to the source holder. The label will include isotope, activity, and date assay of the source contained in the source holder. The label has a yellow background with black lettering and magenta trefoil symbols.

Label B is attached to the end of the device and to the outer shroud, carriage, frame, or mounting assembly containing the device so that it is clearly visible after the device is installed. Label B is either self-adhesive with the added information (isotope, activity, date of assay, serial number, model number, test interval, and distance specification) entered by typing and covered by a clear laminate, or is fabricated from anodized aluminum, attached with screws, and the information die stamped.

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

No.: NR-109-D-122-B	DATE: June 27, 1994	PAGE 5 OF 11

DEVICE TYPE: Transmission Gauge

LABELING (Cont.):

The manufacturer will choose a label sufficient to withstand the environment in which the device is installed. The label has a yellow background with black lettering and a magenta trefoil symbol.

Additionally, label C will be attached to the end of the devices distributed to general licensees. The label will be attached to the device and to the outer shroud, carriage, frame, or mounting assembly containing the device so that it is clearly visible after the device is installed. The label is either self-adhesive and covered by a clear laminate or is fabricated from anodized aluminum, attached with screws. ABB will choose a label sufficient to withstand the environment in which the device is installed. The label has a white background with black lettering.

The manufacturer's name is displayed on other labels and emblems attached to the supporting structures of the device.

The manufacturer's source models are engraved or stamped with the isotope, activity, serial number, and date of manufacture.

DIAGRAM:

See Attachments 1-4.

CONDITIONS OF NORMAL USE:

The device is intended for use in industrial gauging applications. Typical environments are those associated with measurement and control applications such as paper machines, metals rolling mills, plastics extrusions lines, fiberglass mat lines, or tire fabric calendars. Operating temperatures may vary from 0C to 200C (32F to 392F). The temperatures will typically not exceed 125C (257F). The device will withstand humidity up to 100% RH. Vibration, shock, and corrosion will be typical of those associated with applications listed above.

In operation in non-benign environments, the source housing is typically temperature controlled. It may be purged.

DEVICE TYPE: Transmission Gauge

CONDITIONS OF NORMAL USE (Cont.):

This controlled internal environment is designed to prevent condensation and corrosive conditions that might adversely affect shutter operation.

If the source housing is to be subjected to more extreme environments which would require different materials of constructions, or coatings or treatments of the materials, the manufacturer shall make the substitution and upon doing so, shall submit the environmental conditions and design specifications to the Source Containment and Devices Branch, NRC.

PROTOTYPE TESTING:

According to the manufacturer, the expected useful life of the shutter design is 200,000 cycles. This represents the typical number of shutter operations a device may encounter during 10 years of use.

A prototype of a shutter mechanism (source, source holder, and complete shutter mechanism), similar in design to the Model TG-l shutter mechanism, was subjected to the Underwriter's Laboratories four hour fire test. The test consisted of the device being subjected to a temperature of 2000 F (1093C) for four hours, followed by being dropped six feet while incandescent. The shutter mechanism was then immediately quenched in water at 68F (20C) and then dropped fifteen feet on each of its three major axes. After the test, the source remained in the device and leak tests indicated no leakage of byproduct material.

As stated, the Model TG-l has been manufactured and distributed as part of the Models 0-7, U-7, and U-7D. The device has demonstrated the capability to withstand the typical shock, vibration, and corrosion expected in typical operating environments.

The Models NER-584 and CLC.Dl have been tested and meet the ANSI N542-1977 classifications of 77C33232 and 77C64344 respectively. A13B has indicated that their source models meet the ANSI N542-1977 classifications listed in the table in Attachment 4.

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

DEVICE TYPE: Transmission Gauge

EXTERNAL RADIATION LEVELS:

The following is the maximum external radiation levels from the device when mounted with a detector unit. These levels were taken from isodistance radiation patterns submitted by the manufacturer. The manufacturer states the patterns were prepared using the procedures specified in ANSI N538-1979 and represent the worst-case situations, as determined from data of actual measurements of all of the geometric combinations envisioned.

Containing a 1000 mCi, promethium-147 source and having a 13 mm (0.51 inch) air gap between the source housing and detector:

		Max. Radiation Level			
Distance		Shutter open		Shutter closed	
(cm)	(in)	mR/hr	Image Not Available Sv/hr	mR/hr	Image Not Available Sv/hr
5	1.97	6.8	68	Background	
30	11.81	Background		Background	
100	39.37	Background		Background	

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

DEVICE TYPE: Transmission Gauge

EXTERNAL RADIATION LEVELS (Cont.):

As stated, the above levels represent the worst-case mounting configurations. However, once installed, the external radiation levels may be lower because of external shielding. In addition, because these housings are usually mounted within a frame or existing machinery, the workers will usually not be able to get within 30 cm of the device.

When installed at a general licensee's facilities, the radiation levels will be controlled with external shielding, barriers, and location such that dose rates at continuously occupied work

stations will not exceed 0.25 mR/hr (2.5 Sv/hr). In addition, maximum radiation levels on the surface of the application will not exceed 50 mR/hr (500 Sv/hr) when the shutter is in the closed position.

QUALITY ASSURANCE AND CONTROL:

The manufacturer 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 the Source Containment and Devices Branch.

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

No.: NR-109-D-122-B	DATE: June 27, 1994	PAGE 9 OF 11

DEVICE TYPE: Transmission Gauge

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

The device may be distributed to specific or general licensees of NRC or an Agreement State.

Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.

Source housings intended for use under a general license shall be initially tested for external radiation levels, required labels, and leakage/contamination of radioactive material by persons specifically licensed by NRC or an Agreement State.

The device, except when it contains Kr-85, shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.

When installed at a general licensee's facilities, the radiation levels shall be controlled such that dose rate levels at continuously occupied work stations will not exceed 0.25 mR/hr (2.5 

Sv/hr). Maximum radiation levels on the surface of the application shall not exceed 50 mR/hr

(500 Sv/hr) when the shutter is in the closed position.

When the source housing is to be subjected to extreme environments which require different materials of constructions, or coatings or treatments of the materials, the manufacturer shall make the substitution and upon doing so, shall submit the environmental conditions and design specifications to the Source Containment and Devices Branch, NRC.

When the device contains a beta-emitting source, the air gap between the source housing and the detector unit shall not exceed 10 cm (3.93 inches).

When the device contains a gamma-emitting source, the air gap between the source housing and the detector unit shall not exceed 50 cm (19.69 inches).

Servicing of the source housing, including installation and removal, and mechanisms essential to its inherent safety features (e.g. external shielding, automatic shutter closing mechanisms), shall be performed by persons specifically licensed by NRC or an Agreement State.

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

No.: NR-109-D-122-B	DATE: June 27, 1994	PAGE 10 OF 11

DEVICE TYPE: Transmission Gauge

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

The manufacturer's models S-11, S-16, S-18, and S-20 are approved for use in the Model TG-l as part of this registration.

This registration sheet and the information contained within the references shall not be changed without the written consent of NRC.

SAFETY ANALYSIS SUMMARY:

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

- The device can be safely operated by persons not having training in radiological protection.

- Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10% of the limits specified in Section 20.1201(a), 10 CFR Part 20.

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	15 rem (0.15 Sv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200 rem (2.0 Sv)
Other organs	50 rem (0.50 Sv)

DEVICE TYPE: Transmission Gauge

SAFETY ANALYSIS SUMMARY SECTION (Cont.):

Based on review of the Model TG-l device, the information and test data cited below, and the years of usage as part of the Models 0-7, U-7, and U-71), we conclude that this device is acceptable for licensing purposes.

Furthermore, we conclude that this device would be expected to maintain it's containment integrity for normal conditions of use and likely accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for the Model TG-l are hereby incorporated by reference and are made a part of this registry document:

- Manufacturer's application dated July 23, 1991.

- Manufacturer's letters dated April 21, 1993 (two letters), and August 13, 1993, with enclosures thereto.

- Manufacturer’s dated July 2, 1993, July 6, 1993, and October 18, 1993.

ISSUING AGENCY:

	U.S. Nuclear Regulatory Commission	
	Date: June 27, 1994	Reviewer: John Lubinski
	Date: June 27, 1994	Concurrence: Steven L. Baggett

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

No.: NR-109-D-122-B	DATE: June 27, 1994	ATTACHMENT 3

LABELS:

[example of the manufacturer’s proposed labeling of the device would go here]

Appendix D: 10 CFR 2.790: Withholding Letter

[Applicant Name]
[ATTN: Contact Name]
[City, State Zip Code]

Dear [:]

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED IN LICENSE APPLICATION

By NRC Form 313, "Application for Material License," or letter from (Licensee’s Name) dated _, and affidavit dated _, you submitted proprietary material consisting of client information and requested it be withheld from public disclosure pursuant to 10 CFR 2.790.

You stated that the submitted information should be considered exempt from public disclosure for the following reasons:

1.

2.

We have reviewed your application and the material in accordance with the requirements of 10 CFR 2.790 and, on the basis of your statements, have determined that the submitted information may/may not be withheld.

Therefore, we have determined that the information contained in Items _ of NRC Form 313 or the letter from (Licensee's name) dated , marked as proprietary, will be withheld from public disclosure pursuant to 10 CFR 2.790(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended. Your request for withholding will be maintained by this Office indefinitely or for as long as you continue to hold NRC License No. - - G.

Withholding from public inspection will not affect the right, if any, of persons properly and directly authorized to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, 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 be made available for public inspection, you should promptly notify NRC. You 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 your information. In all review situations, if NRC makes a determination adverse to the above, you will be notified in advance of any public disclosure.

	Sincerely, [Reviewing Official]

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 2.790. 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 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 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 E: Information Needed for Transfer of Control Application (Excerpted from Information Notice 89-25)

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license; some licensees refer to this as "transferring the license." Provide the following information, excerpted from IN 89-25, Rev. 1, "Unauthorized Transfer of Ownership or Control of Licensed Activities," concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1.	The new name of the licensed organization. If there is no change, the licensee should so state.
2.	The new licensee contact and telephone number(s) to facilitate communications.
3.	Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.