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REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 10.10 (Task FC 601-4)

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR RADIATION SAFETY EVALUATION AND REGISTRATION OF DEVICES CONTAINING BYPRODUCT MATERIAL

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TABLE OF CONTENTS

<u>Section</u>	<u>Page</u>
1. INTRODUCTION	1
1.1 Purpose of Guide	1
1.2 Applicable Regulations	1
1.3 As Low As Is Reasonably Achievable (ALARA) Philosophy.	2
2. FILING AN APPLICATION	3
2.1 Style	3
2.2 Composition	3
2.3 Proprietary Information	4
2.4 Radiation Safety Evaluation Fees	4
2.5 Certification	5
2.6 Where To File	5
2.7 Medical Devices	5
2.8 Registration of a Foreign-Manufactured Device	6
2.9 Manufacturers/Distributors Located in Agreement States	6
2.10 Naturally Occurring and Accelerator-Produced Radioactive Materials	6
2.11 Transportation	7
3. CONTENTS OF AN APPLICATION	8
3.1 Summary Data	8
3.2 Summary Description	10
3.3 Details of Construction and Use	11
4. CERTIFICATE OF REGISTRATION	15
5. AMENDMENTS TO REGISTRATION CERTIFICATES FOR DEVICES	15
6. RESPONSIBILITY OF REGISTRANT	15
APPENDIX A Agreement States.	A-1
APPENDIX B Proprietary Information, Availability of Official Records.	B-1
APPENDIX C Principal Use Codes and Definitions for Sealed Sources and Devices	C-1
APPENDIX D Checklist for Radiation Safety Evaluation	D-1
VALUE/IMPACT STATEMENT	V/I-1

1. INTRODUCTION

1.1 PURPOSE OF GUIDE

The purpose of this regulatory guide is to provide assistance to device manufacturers and distributors on submitting requests for the U.S. Nuclear Regulatory Commission's (NRC's) radiation safety evaluation and registration of devices containing byproduct material.

For many uses of byproduct material¹ that are licensed by the NRC, the radioactive material is contained in a source that in turn is contained in a shielded source housing. As used in this guide, a "source" is radioactive material that is sealed in a protective envelope (capsule), contained in a foil, or plated on an inactive surface. The term "source" includes the radioactive material and its dispersion barrier, i.e., the capsule, foil, or plated surface. The source housing may have a shutter mechanism with which an operator can reduce the shielding in a particular direction so that a beam of radiation can exit the housing. The radiation beam is then available for such purposes as radiation treatment of people or examination of flaws in heavy metal castings. The source housing with its shutter mechanism and any other radiation control mechanisms is commonly called a "device." Examples of devices are teletherapy units, industrial radiographic equipment, industrial thickness gauges, and smoke detectors.

Before authorizing the distribution and use of byproduct material in a device, the NRC determines the adequacy of the radiation safety properties of the device. This determination is reached by reviewing the information submitted by the manufacturer or distributor of the device.

The NRC maintains a registry of radiation safety information on devices containing byproduct material that are intended for transfer by their manufacturers and distributors. Agreement States² also provide information on their radiation safety evaluations to the NRC for the registry. Both the NRC and the States use the information in the registry. Thus a manufacturer/distributor need provide detailed information about its device only to a single agency, and the results of the radiation safety evaluation will be available for use in granting licensing approval to users of the device throughout the United States.

1.2 APPLICABLE REGULATIONS

NRC regulations applicable to devices containing byproduct material and to NRC radiation safety evaluations are found in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings"; 10 CFR Part 19, "Notices, Instructions, and Reports to Workers; Inspections"; 10 CFR Part 20, "Standards for Protection

¹"Byproduct material" is defined in paragraph 30.4(d) of 10 CFR Part 30 and in paragraph 40.4(a-1) of 10 CFR Part 40. For the purposes of this guide, "byproduct material" means radioactive material that is produced in a nuclear reactor.

²"Agreement State" is defined in paragraph 30.4(c) of 10 CFR Part 30. Generally speaking, in an Agreement State, the State instead of the NRC regulates the use of byproduct material. A list of Agreement States is provided in Appendix A of this guide.

Against Radiation"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 31, "General Domestic Licenses for Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material"; 10 CFR Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations"; 10 CFR Part 35, "Human Uses of Byproduct Material"; 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"; and 10 CFR Part 170, "Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended."³

Before preparing your application you should be acquainted with the applicable regulations. Single copies of a specific NRC regulation may be obtained without cost from the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. A bound volume of NRC regulations may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Detailed requirements for certain devices are set out in the regulations (for example, a level gauge distributed under the provisions of § 32.51 of 10 CFR Part 32 for use under a general license). For many other devices (for example, a self-shielded gamma irradiator used under a specific license), the regulatory requirements are less detailed and NRC's radiation safety evaluation of the device is based principally on the comprehensive requirement in paragraph 30.33(a)(2) of 10 CFR Part 30 that the user's equipment and facilities must be adequate to protect health and minimize danger to life or property.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, and 71, which provide the regulatory basis for this guide. The information collection requirements in these parts have been cleared under OMB Clearance Nos. 3150-0044, 3150-0014, 3150-0017, 3150-0016, 3150-0001, 3150-0007, 3150-0010, and 3150-0008, respectively.

1.3 AS LOW AS IS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 20.1(c) of 10 CFR Part 20 states "...persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable." Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," provides the NRC staff position on this important subject. You should consider the ALARA philosophy as described in Regulatory Guide 8.10 when designing and constructing devices in order to avoid unnecessary exposures during installation, maintenance, repair, and use of the device.

³The NRC has issued a proposed 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well-Logging Operations" (50 FR 13797). When Part 39 becomes an effective regulation, its provisions will also be considered in the radiation safety evaluation of certain devices.

2. FILING AN APPLICATION

When applying for a radiation safety evaluation and registration of a device, you should submit an application containing the information outlined in Section 3. No special form is required, although applicants are encouraged to follow the format of Section 3. The application should indicate whether the device is intended for use under (1) an exemption from the regulations, e.g., a gas and aerosol detector (smoke detector) to be used under the provisions of § 30.20, (2) a general license, e.g., an industrial density-measuring gauge to be used under the provisions of § 31.5, (3) a specific license, e.g., a radiographic exposure device to be used under the provisions of 10 CFR Part 34, or (4) either a general license or a specific license, e.g., an industrial density-measuring gauge that may be used by some persons under the general license in § 31.5 and by other persons who elect not to comply with all the provisions of § 31.5 under a specific license issued under § 30.33.

Do not submit personal information about your employees unless it is necessary. For example, you should submit the title and telephone number of the individual to be contacted for additional information or clarification of your application. Employees' home telephone numbers should be submitted only if they are included in documentation that accompanies the device as part of an emergency assistance program you offer to users.

NRC's review of your application will be facilitated if you follow the guidelines in the following sections.

2.1 STYLE

All pages in an application should be numbered consecutively. If revisions are necessary after an application has been submitted, revised pages should be submitted; your revision should include clear and specific reference to those portions of the submission that are being revised. If revised pages are submitted, each revised page should show the date of revision. If supplemental pages are submitted for insertion, they should be indicated alphanumerically (e.g., 12a, 12b, etc.).

All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches. All drawings should have a drawing number, revision number, company name, title, scale, and date. If drawings have been reduced or enlarged, this should be clearly indicated so that the scale may be applied properly.

When drawings, operating manuals, descriptive sales literature, or similar documents are submitted as part of the application, they should be identified clearly as being part of the application. This might be done by marking the materials individually and listing them on a cover sheet for the application or listing them as enclosures to the letter that transmits the application.

2.2 COMPOSITION

You should strive for clear, concise presentation of the information provided in the application, avoiding ambiguous statements and wordy descriptions

that do not contribute to a technical review. The radiation safety adequacy of designs should be supported by technical data, i.e., by an appropriate engineering evaluation and descriptions of device tests and test results. Documented field experience with comparable devices may be included.

Terms should be used as they are defined in NRC regulations and national consensus standards. Abbreviations not in general use should be defined. References to tests, regulations, or standards in a foreign language should be supported by submitting an English translation of the cited document. The application, including notations on engineering drawings, must be in English. To facilitate preparing an application on a device manufactured outside the United States, the applicant may elect to write or otherwise affix the English translation directly on an engineering drawing.

Appendices may be used to include information not appropriate to the main text. Appendices may include, for example, photographs of physical tests and operating manuals.

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

2.3 PROPRIETARY INFORMATION

Proprietary (i.e., not to be disclosed to the public) data should not be submitted unless it is the only means to adequately describe the radiation safety properties of the device. If the application contains data you consider to be proprietary, the data should be clearly marked for appropriate handling by NRC. In addition, the letter transmitting the application should contain a request for withholding from public disclosure as discussed in paragraph 2.790(b) of NRC's regulations in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings." Pertinent portions of § 2.790 and a related § 9.5 of 10 CFR Part 9, "Public Records," are contained in Appendix B to this guide. It is essential that these procedures be followed so that NRC can recognize that a request for withholding is being made and then consider the request on its merits.

Standard blueprint blocks stating that drawings, sketches, etc., are "confidential," "restricted," or "are to be the express property of Company X" and similar notes in manuals and other documents should be removed from all submissions, or a statement should be made that the notes are to be disregarded, unless a formal request for withholding has been filed and properly supported with information required under § 2.790.

2.4 RADIATION SAFETY EVALUATION FEES

A radiation safety evaluation fee is required by paragraph 170.12(a) of 10 CFR Part 170. Refer to § 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services," to determine the amount of the fee that must accompany your application. An application received without the required fee

or with an inadequate fee may be returned to you. All application fees may be charged regardless of the NRC's disposition of the application or your withdrawal of it.

2.5 CERTIFICATION

If you are an individual applicant acting in a private capacity, you should sign the application for radiation safety evaluation. Otherwise, your application should be dated and signed by a representative of the corporation or other legal entity who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of your knowledge and belief. An unsigned application will be returned for proper signature.

2.6 WHERE TO FILE

You should prepare your application in triplicate. Retain one copy for yourself because you will be obligated to construct and distribute the device in accordance with the statements and representations in your application.

The original signed copy and one additional copy of your application for radiation safety evaluation and registration of your device, together with the fee payment (see Section 2.4 above), should be sent to:

U.S. Nuclear Regulatory Commission
Division of Fuel Cycle and Material Safety
Material Licensing Branch
Washington, DC 20555

Please note that the above address is different from that of the appropriate NRC Regional Office (identified in § 30.6 of 10 CFR Part 30) to which you would apply for authority to possess and use radioactive material under a manufacturing and distribution license.

When the NRC completes its radiation safety evaluation of your device, you will be sent a certificate of registration that acknowledges the registration of information about the device and the availability of that information for use in the issuance of specific licenses.

2.7 MEDICAL DEVICES

Please note that if a device is to be used for medical purposes and is subject to regulation by the Food and Drug Administration (FDA), an NRC registration certificate will not be issued unless the applicant has submitted to the NRC an FDA 510k Certificate or similar indication of marketing approval by FDA. Information on FDA requirements may be obtained by contacting:

Food and Drug Administration
Center for Devices and Radiological Health
HFZ-401
8757 Georgia Avenue
Silver Spring, MD 20910

2.8 REGISTRATION OF A FOREIGN-MANUFACTURED DEVICE

A device manufactured outside the United States may be registered by the NRC if the appropriate information is supplied and if NRC's administrative requirements are satisfied. The registrant must establish an address or representative in the United States where papers may be served, where records required by the NRC will be maintained, and where the NRC can inspect the registrant's activities as necessary to fulfill the requirements of NRC's regulations.

In addition, to facilitate the issuance of licenses to users of the device, it is preferable that the manufacturer establish a United States representative who is licensed to possess radioactive material and who will provide servicing, distribution, and disposal of devices when required. If a foreign manufacturer elects not to establish in the United States a representative who has technical expertise, facilities, and equipment, the applicant should explain how and by whom needed services will be performed. If arrangements for such servicing are not made, the applicant should recommend to NRC the minimum training and instructions for individuals who may perform servicing. For example, the applicant for registration of a self-shielded gamma irradiator may recommend and make available a training course in servicing at the manufacturer's facility or provide a comprehensive service manual.

2.9 MANUFACTURERS/DISTRIBUTORS LOCATED IN AGREEMENT STATES

A device manufacturer or distributor located in an Agreement State (see Appendix A) should contact that State's regulatory authority for guidance on preparing requests for evaluations of devices and applications for licenses to possess and use radioactive material. The one exception concerns devices such as smoke detectors that are intended for use by persons exempt from licensing and regulatory requirements. All requests for radiation safety evaluations of "exempt devices" should be prepared in accordance with NRC regulations and this guide and sent to NRC at the address in Section 2.6.

2.10 NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

Radioactive material includes "byproduct material" that is subject to regulation by the NRC and the Agreement States. Another class of radioactive material, called "NARM" (naturally occurring and accelerator-produced radioactive materials), is not subject to regulation by the NRC but is regulated by the States.

The Food and Drug Administration (FDA) assists the States in their review and regulatory approval for distribution of devices containing radium and other NARM. In their evaluations, they frequently apply the NARM guide⁴ published by the Department of Health and Human Services. Guidance provided in this regulatory guide for devices containing byproduct material is comparable to guidance provided in the NARM guide for devices containing NARM.

⁴Copies of the NARM guide (HHS Publication FDA 81-8025) may be purchased at current rates from the U.S. Government Printing Office, Washington, DC 20013-7082, or the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

As a general rule, the NRC does not accept applications for radiation safety evaluation and registration of devices that will contain NARM. An exception to this general rule occurs if the radionuclide used in the device is available from either a reactor (defined as byproduct material) or from an accelerator (defined as NARM). Cadmium-109 is an example of such a radionuclide. The NRC will accept applications concerning Cd-109, assuming for purposes of device evaluation and registration that the Cd-109 will be produced in a reactor. Another exception to the general rule is if the NARM is commingled with byproduct material.

2.11 TRANSPORTATION

This regulatory guide does not cover detailed requirements for the transportation of devices and sources. The NRC's transportation requirements are contained in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." Part 71 establishes (1) requirements for quality assurance, packaging, preparation for shipment, and transportation of licensed material and (2) procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of licensed material in excess of a "Type A quantity" (i.e., exceeding A_1 or A_2 as defined in § 71.4 of 10 CFR Part 71).

Although an application for radiation safety evaluation of a device or source is not expected to include a detailed description of packaging and transportation procedures to demonstrate full compliance with 10 CFR Part 71, the applicant is, however, expected to be familiar with the way those requirements apply to the device or source and the action needed to ensure that transportation of the device is performed in accordance with applicable requirements.

Two transportation requirements are particularly important with respect to devices that are frequently transported by the user (shipper), such as gamma radiography apparatus and well-logging devices. The manufacturer or distributor should be prepared to advise and supply the shipper (user) with the following:

- (1) A copy of the safety analysis, including documentation of the tests, demonstrating that the sealed source or device meets the "special form" requirements of NRC/DOT transport regulations (§§ 71.75 and 71.77 of 10 CFR Part 71; §§ 173.469 and 173.476 of 49 CFR Part 173). This is not required, however, in cases where A_1 equals A_2 and the source is not described on the shipping documents as "special form."
- (2) If an A_1 or A_2 quantity of radioactive material is involved, a copy of the documentation on the tests and engineering evaluation or comparative data showing that the package design meets the requirements of a DOT Specification 7A package (see paragraph 173.415(a) of 49 CFR Part 173).

Shippers of radioactive material are required to maintain the above documents on file for at least one year after any shipment. It is therefore important that the manufacturer or distributor supply the shipper (user) with this information.

Any manufacturer or distributor who has questions about the requirements for transportation may contact the appropriate NRC Regional Office (listed in § 30.6 of 10 CFR Part 30) to obtain assistance.

3. CONTENTS OF AN APPLICATION

An application for radiation safety evaluation and registration of a device is reviewed most readily by the NRC if the application is organized into three sections. The first section of the application should contain the information discussed in Section 3.1, "Summary Data." This information is used principally by the NRC to prepare the first page of the registration certificate. The first page identifies the device, radioactive source (radionuclide, quantity, and model), leak-test requirement, and the manufacturers and distributors who are involved.

The second section of the application should contain the information discussed in Section 3.2, "Summary Description." This information is used by the NRC for the descriptive portion of the registration certificate. This portion explains for interested persons, such as NRC field personnel and Agreement State regulatory personnel, what the device looks like and how it is used.

The third section of the application should contain the information discussed in Section 3.3, "Details of Construction and Use." This information is important to NRC's radiation safety evaluation of the device and determination of the conditions under which the device will be authorized for distribution and use.

Note that the format in this Section 3 is recommended, not required, but applicants are encouraged to use this format.

3.1 SUMMARY DATA

This section should be presented on one page and should contain key data under the following headings.

3.1.1 Date

Give the date of the application.

3.1.2 Applicant

Give the name and complete mailing address of the organization submitting the application; indicate whether the applicant is the manufacturer, distributor, or both. Also give the name, title, and telephone number of the individual to be contacted if additional information or clarification is needed by the NRC.

3.1.3 Device type

State the name used by the industry to identify the device (e.g., level gauge, radiography device, self-shielded irradiator, teletherapy unit).

3.1.4 Model

State the model number, series number, or drawing number used by the manufacturer or distributor to uniquely identify the device. This number will be used by regulatory groups to rapidly identify a registered device and to locate the information about the device. All devices should have a model number or other specific identifier.⁵

3.1.5 Other Companies Involved

Give the name and address of any other companies directly involved in the manufacture or distribution of this device. For example, if the applicant distributes a device manufactured by the XYZ Company, state that XYZ Company is the manufacturer and give the XYZ Company's mailing address.

3.1.6 Radioactive Source Model Designation

List the radioactive source or sources proposed for use in the device by manufacturer or distributor and model number.⁶

3.1.7 Radionuclides and Maximum Activity

List the radionuclides in any source proposed to be used in the device; include the maximum proposed activity level in curies or millicuries for each nuclide. If the application concerns a series of devices that are essentially identical except for the thickness of shielding, a maximum activity may be proposed for subgroups within the series. If depleted uranium will be used for shielding, indicate the number of kilograms to be used in each device.

3.1.8 Leak-Test Frequency

State the proposed frequency for testing the device for possible leakage of radioactive material. (Detailed leak-testing guidance is presented in Section 3.3.11.)

3.1.9 Principal Use Codes

From Appendix C to this guide, "Principal Use Codes and Definitions for Sealed Sources and Devices," select the code that most accurately describes the principal or predominant use for the device. State whether the device is proposed for use under (1) a specific license, (2) a general license, or (3) an

⁵For some devices, manufacturers routinely provide a variety of associated electronic controls, and for marketing purposes they may assign a model number on the basis of those controls even though the radiation safety features are the same on all the assembled units. For registration purposes, the applicant may appropriately assign a series number or similar identifier for devices with the same radiation safety features.

⁶If a source has not been registered with a licensing authority, the source manufacturer or distributor should contact the NRC for guidance on applying for safety review of the source. If the source manufacturer is located in an Agreement State, the licensing authorities in that State should be contacted (see Appendix A).

exemption from regulatory requirements. If the device is proposed for use under a general license or an exemption, indicate the primary section of NRC regulations applicable to its use.

3.1.10 Custom Device

Indicate whether the device is a custom device. A device specifically designed and constructed to the order of a single licensee may be considered a custom device that warrants the manufacturer's request for safety evaluation and an NRC review that are tailored to that licensee. The NRC reviewer can appropriately consider specific departures from accepted standards from the point of view of compensating qualifications or conditions of use for the particular licensee. Devices designed and constructed as off-the-shelf items or for use by more than a single licensee are not considered custom devices.

3.1.11 Custom User

If this is a custom device, give the name and address of the user.

3.2 SUMMARY DESCRIPTION

This section should include a short discussion of what the device is used for, how it operates, and its radiation safety features. This information frequently is found in a manufacturer's sales brochures and pamphlets. Such documents may be useful in presenting the summary description.

3.2.1 Written Description

Provide a brief written description of the nature and intended purpose of the device, i.e., what it is and how it is to be used. State whether the device is portable or installed in a fixed location. Indicate specifically if the source housing moves during use. Describe radiation safety features of the device, including dimensions,⁷ materials of construction, methods of assembly and attachment, and external radiation levels. Include a description of the shielding and the method for securing the source in the device. If applicable, describe the on-off mechanism, on-off indicators, and how the device is installed for use (e.g., bolted to a pipe). State the radioactive source classification according to the system in ANSI N542, "Sealed Radioactive Sources, Classification."⁸

3.2.2 Drawing

Provide an isometric projection drawing, sketch, or photograph showing components pertinent to radiation safety such as shielding material, shielding thickness, on-off mechanism, on-off indicator, label location, and approximate dimensions of the device. The drawing, sketch, or photograph should be no larger than about 4 in. by 6 in. and should be clear, legible, and suitable for photocopying.

⁷If the application covers a series of units, and within that series there are subgroups that differ only with respect to shielding thickness and quantity of radioactive material, the dimensions and quantity should be provided for each subgroup.

⁸Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

3.3 DETAILS OF CONSTRUCTION AND USE

This section should provide detailed information on the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device. The information presented should provide reasonable assurance that the device can be used without exceeding applicable radiation exposure standards. The following sections outline the type of detailed information that should be submitted.

3.3.1 Conditions of Use

Describe the planned use of the device and identify the extremes of environmental and operating conditions (e.g., temperature, humidity, corrosive atmosphere, vibration) expected during use. Include descriptions of the types of users, the locations of use, the occasions when persons will be near the device and the frequency of these occasions, and the possibility that the device may be used as a component in other products. State the expected useful life of the device.

3.3.2 Details of Construction

Submit engineering drawings or annotated drawings of the device that describe all materials of construction, dimensions, methods of fabrication, means for mounting the source and source holder in the device, and means of securing the device in its installed position. Describe in detail all special design features that protect the source from abuse, control the hazard from direct or scattered radiation, and discourage unauthorized access to the source. Indicate clearly the accessibility of the radiation beam during use. Specify the size of openings or gaps that could allow any part of a human body to enter the radiation beam. Include a description of the shutter or source-positioning mechanism used for exposing the radioactive source (if the device is so equipped) and the means used to indicate the source's position (exposed or shielded). If uranium shielding is used, describe how it is protected to prevent its causing low-level contamination.

3.3.3 Labeling

Submit samples or facsimiles of the labels or describe the labeling for the device. State how and where the label is attached to the device. The label or marking for a device usually includes the name, trademark, or logo of the manufacturer, assembler, or distributor; model number; serial number; type and amount of radioactive material and the date of measurement; the standard radiation symbol; and the words "Caution - Radioactive Material." The label or marking should be sufficiently durable to remain legible for the useful life of the device and should be located in a readily visible place on the device. For certain devices (for example, devices intended for distribution to persons generally licensed under § 31.5 of 10 CFR Part 31), specific labeling requirements are set out in NRC's regulations (see § 32.51 of 10 CFR Part 32). You should review any specific requirements for your device and ensure that your proposed label is consistent with those requirements.

3.3.4 Testing of Prototypes⁹

Describe the tests performed on each prototype device and submit the test results that establish the integrity of the radiation safety features of the device under the conditions of use to which the device is likely to be subjected.

In some instances, engineering analyses may be an acceptable alternative to testing of prototypes. For example, engineering analyses may be appropriate for custom devices, devices expected to have limited distribution, or devices with low potential hazard. If engineering analyses are used, consideration should be given to testing particular prototype components of the device and to close observation of performance during early use of the device. The applicant should also submit historical-use data or data from tests on prototypes of similar units to reinforce findings from engineering analyses.

3.3.5 Quality Control⁹

Describe the quality control program and procedures to be followed to ensure that each finished device meets specifications furnished to the NRC. Even for a custom device, you should provide a copy of the procedures to be followed or tests to be performed to ensure that the finished custom device meets your design specifications.

3.3.6 Radiation Profiles⁹

Submit radiation profiles of a prototype or working model of the device. Radiation levels should be determined using the maximum activity of each nuclide

⁹For many devices, guidance on design considerations, tests of prototypes, quality control programs, and determination and reporting of radiation profiles and levels is provided in industry or consensus standards. Applicants for safety reviews are encouraged to consider such guidance. Some standards that are particularly useful are (1) for teletherapy, NCRP Report No. 33, "Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MeV," (2) for radiography, ANSI N432, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (3) for gauges, ANSI N538, "Classification of Industrial Ionizing Radiation Gauging Devices," (4) for irradiators, ANSI N433.1, "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)," and N43.10, "Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)," (5) for smoke detectors, NEA "Recommendations for Ionization Chamber Smoke Detectors in Implementation of Radiation Protection Standards," 1977, (6) for self-luminous light sources, ANSI N540, "Classification of Radioactive Self-Luminous Light Sources," and (7) for sealed radioactive sources, ANSI N542, "Sealed Radioactive Sources, Classification." If there is no specific industry or consensus standard for your device, you may obtain useful general guidance from a standard for a comparable device. ANSI N538 may be particularly useful for general guidance on quality control and radiation profiles. ANSI standards are available by contacting the American National Standards Institute, 1430 Broadway, New York, NY 10018. NCRP reports are available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Ave., Bethesda, MD 20814. Nuclear Energy Agency (NEA) reports are available from the Organization for Economic Cooperation and Development (OECD), Publications and Information Center, 1750 Pennsylvania Ave. NW., Washington, DC 20006.

expected to be used in the device. In general, the isodistances for measuring in both the on (shutter open) and the off (shutter closed) conditions are 5 cm, 30 cm, and 100 cm from the nearest accessible surfaces of the device. A description of the method and instrumentation used to measure the radiation levels should be included.

3.3.7 Installation

If the device is to be mounted in a fixed position, describe the manner in which it is to be installed. Include a description of any extra shielding, barriers, or limited accessibility inherent in the type of installation and possible commitments on upper limits of radiation levels in accessible areas. If interlocks, locks, signs, etc., are used to restrict access to certain areas (e.g., to control access to the interior of a tank on which a gauge is mounted), these areas and control mechanisms should be described.

Indicate who will install the device if installation is required. For example, would you as the distributor install the device or would the user be expected to install the device? If the user will install the device, what instructions will you provide to the user?

3.3.8 Radiological Safety Instructions

Submit a copy of the radiological safety instructions to be furnished with the device, including any precautions or warnings on labels attached to the device but not described in Section 3.3.3 above. The radiological safety instructions should include:

- Specific instructions for safe operation and maintenance of the device (including testing for leakage of radioactive material and testing for proper operation of the on-off mechanism and indicator, if any). Identify service operations that usually should not be performed by the user.
- Recommended procedures to control radiation hazards in case of damage or malfunction of the device.
- A radiation profile of the device describing radiation levels external to the device, including those in any beam of radiation that may be accessible with the device in normal operation.
- If applicable, a caution against tampering with or modifying the device or unauthorized removal of the source contained in the device. If the user is expected to install or remove the source, specific instructions for these operations should be provided.
- Recommendations for disposal of the device (sources).

3.3.9 Documentation Accompanying the Device

In addition to the radiological safety instructions discussed in Section 3.3.8, you should submit samples or describe other radiation-safety-related documentation that you will supply with the device. Examples of such documentation are (1) a certificate providing date and results of the most recent leak test or contamination check and test of the on-off mechanism and indicator performed on the device, (2) reports of the radiation surveys performed at the time of manufacture or when the device was installed, (3) a copy of § 31.5 of

10 CFR Part 31 if the device is to be used under that general license and an explanatory note if the device is to be sent to a comparable general licensee in an Agreement State (paragraph 32.51a(b) of 10 CFR Part 32), (4) a copy of a "special form" certificate issued by a national competent authority or an evaluation by the source manufacturer indicating that the source is "special form" as defined in § 71.4 of 10 CFR Part 71, (5) a copy of the documentation of the tests on the package demonstrating that it meets the requirements of a DOT Specification 7A package (see paragraph 173.415(a) of 49 CFR Part 173), or (6) a copy of the applicable certificate of compliance which has been issued for any Type B package (see § 71.12 of 10 CFR Part 71 and paragraph 173.416(b) of 49 CFR Part 173).

3.3.10 Servicing

Describe the type and extent of the services that will be offered to the customer (e.g., radiation survey at the time of installation, repair, leak test, source replacement, relocation, training of operators).

3.3.11 Leak Testing

The NRC routinely requires, with certain exceptions, that devices be tested periodically for possible leakage of radioactive material at intervals not to exceed 6 months. However, an applicant may request a longer interval from the NRC. A request for an interval greater than 6 months (both for devices used under a specific license and for devices used under a general license) should address the subjects listed in paragraph 32.51(b) of 10 CFR Part 32 and the quality control measures that ensure an absence of leakage and contamination.

The NRC does not require periodic leak testing of a device during use if the device contains only (1) hydrogen-3, (2) radioactive material with a half-life less than 30 days, (3) radioactive material in the form of gas, (4) less than 100 microcuries of beta- or gamma-emitting material, or (5) less than 10 microcuries of alpha-emitting material. However, distributors of such devices must ensure that the devices are free of leakage and contamination when the devices are transferred.

3.3.12 Safety Analysis

The applicant should provide a paragraph that summarizes the important facts pertaining to safety and the results of a safety analysis performed by the manufacturer/distributor. Include references to appropriate industry or consensus standards (ANSI, NCRP, NEA, etc.) and to particular sections in NRC regulations, if applicable. For example, an application concerning a device to be used under a general license in § 31.5 should reference and include comments on the three specific points in paragraph 32.51(a)(2), or an application concerning a smoke detector to be used under § 30.20 should reference and include comments on the safety criteria in § 32.27.

Appendix D to this guide, "Checklist for Radiation Safety Evaluation," may be helpful to an applicant when compiling an application for a radiation safety evaluation of a device. This check list does not need to be submitted with the application.

4. CERTIFICATE OF REGISTRATION

Following a determination that you have submitted all the necessary information and after a satisfactory evaluation of your application, the NRC will issue you a numbered certificate of registration that specifically identifies the device by type and model or drawing number. This certificate will, among other things, summarize the information submitted in response to Section 3 of this guide and will specify any limitations on the use of the device such as to whom the device may be distributed (for example, persons exempt from licensing pursuant to § 30.20, persons generally licensed pursuant to § 31.5, or persons specifically licensed pursuant to § 30.33), leak-test and other periodic testing requirements, and restrictions on environmental conditions of use.

5. AMENDMENTS TO REGISTRATION CERTIFICATES FOR DEVICES

It is your obligation to keep your registration certificate current. If the information you provided in the application or set out in the certificate is modified or changed, you should submit an application for a certificate amendment. In the meantime, you are obliged to comply with the information in your certificate until the certificate is amended. You are encouraged to anticipate the need for certificate amendments insofar as possible.

An application to amend a certificate should be prepared in triplicate. You should retain one copy for your records and submit the original and one additional copy to the address specified in this guide in Section 2.6, "Where To File." Your application should identify your registration certificate by number and should clearly describe the changes and the effects of the changes on the safety properties of the device. For example, if you intend to change the radionuclide or increase the radioactivity limit, your application for an amendment should identify the new radionuclide or quantity limit and also state the new radiation levels and the expected effects on radiation exposures. References to previously submitted information should be clear and specific and should identify that information by date, document title, and page number.

You must send the appropriate fee for a certificate amendment with your application. Refer to § 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services," of 10 CFR Part 170 to determine the amount of the fee that must accompany your request for a certificate amendment. The NRC will not process an application for a certificate amendment before the proper fee is paid in accordance with § 170.12.

Please note that if the device is used for medical purposes and is subject to regulation by the Food and Drug Administration (FDA), the application for a certificate amendment should include an appropriate FDA 510k Certificate or similar indication of marketing approval by the FDA.

6. RESPONSIBILITY OF REGISTRANT

After you are issued a registration certificate, you are obligated to manufacture or distribute your device in accordance with (1) the statements and representations contained in your application for safety review and registration, (2) the provisions of the registration certificate, and (3) the NRC's regulations.

APPENDIX A

AGREEMENT STATES

<u>STATE</u>	<u>PHONE</u>	<u>ADDRESS</u>	<u>Became Agreement State On</u>
<u>Alabama</u>	205-261-5313	Mr. Aubrey Godwin, Chief Bureau of Radiological Health Environmental Health Adminis. Room 314, State Office Building Montgomery, Alabama 36130	10/1/66
<u>Arizona</u>	602-255-4845	Mr. Charles F. Tedford, Director Arizona Radiation Regulatory Agency 4815 South 40th Street Phoenix, Arizona 85040	5/15/67
<u>Arkansas</u>	501-661-2301	Mr. Frank Wilson, Director Div. of Radiation Control and Emergency Management Arkansas Dept. of Health 4815 West Markham Little Rock, Arkansas 72205	7/1/63
<u>California</u>	916-445-0931	Mr. Joe Ward, Chief (916-322-2073) Radiologic Health Section Department of Health 714 P Street, Room 498 Sacramento, California 95814	9/1/62
<u>Colorado</u>	303-320-8333 Ext. 6246	Mr. Albert J. Hazle, Director Radiation Control Division Office of Health Protection Department of Public Health 4210 East 11th Avenue Denver, Colorado 80220	2/1/68 Amended 4/20/82
<u>Florida</u>	904-487-1004	Lyle E. Jerrett, Ph.D., Director Office of Radiation Control Dept. of Health & Rehabilitative Service 1323 Winewood Blvd. Tallahassee, Florida 32301	7/1/64
<u>Georgia</u>	404-894-7610	Mr. Bobby G. Rutledge, Director Radiological Health Section Department of Human Resources 878 Peachtree Street Atlanta, Georgia 30309	12/15/69

<u>STATE</u>	<u>PHONE</u>	<u>ADDRESS</u>	<u>Became Agreement State On</u>
<u>Idaho</u>	208-334-4107	Mr. Robert Funderburg, Supervisor Radiation Control Section Idaho Department of Health and Welfare Statehouse Boise, Idaho 83720	10/1/68
<u>Iowa</u>	515-281-4928	Mr. John A. Eure, Director Environmental Health Section Iowa Department of Health Lucas State Office Building Des Moines, Iowa 50319	1/1/86
<u>Kansas</u>	913-862-9360 Ext. 284	Mr. David Ramono, Manager Bureau of Air Quality and Radiation Control Dept. of Health & Environment Building 740, Forbes Field Topeka, Kansas 66620	1/1/65
<u>Kentucky</u>	502-564-3700	Mr. Donald Hughes, Supvr. Radiation Control Section Dept. of Health Services 275 East Main Street Frankfort, Kentucky 40621	3/26/62
<u>Louisiana</u>	504-925-4518	Mr. William H. Spell, Administrator Nuclear Energy Division Office of Air Quality P.O. Box 14690 Baton Rouge, Louisiana 70898	5/1/67
<u>Maryland</u>	301-659-3130	Mr. Roland G. Fletcher, Chief Division of Radiation Control Dept. of Health and Mental Hygiene 201 W. Preston Street Baltimore, Maryland 21201	1/1/71
<u>Mississippi</u>	601-354- 6657/6670	Mr. Eddie S. Fuente, Director Division of Radiological Health 2423 North State Street P.O. Box 1700 Jackson, Mississippi 39205	7/1/62

<u>STATE</u>	<u>PHONE</u>	<u>ADDRESS</u>	<u>Became Agreement State On</u>
<u>Nebraska</u>	402-471-2168	Mr. Harold Borchert, Director Division of Radiological Health State Department of Health 301 Centennial Mall South P.O. Box 95007 Lincoln, Nebraska 68509	10/1/66
<u>Nevada</u>	702-885-5394	Mr. Stanley R. Marshall, Supervisor Radiological Health Section Consumer Health Protection Services Room 103 Kinkead Bldg. Capitol Complex Carson City, Nevada 89710	7/1/72
<u>New Hampshire</u>	603-271-4587	Ms. Diane Tefft, Program Manager Radiological Health Program Bureau of Environmental Health Health & Welfare Bldg., Hazen Drive Concord, New Hampshire 03301	5/16/66
<u>New Mexico</u>	505-827-2959	Mr. Michael Brown Radiation Protection Bureau Environmental Improvement Div. P.O. Box 968 Santa Fe, New Mexico 87504	5/1/74
<u>New York</u>	518-474-2178	Mr. Jay Dunkleberger, Director Bureau of Nuclear Operation New York State Energy Office Agency Building 2 2 Rockefeller Plaza Albany, New York 12223	10/15/62
<u>North Carolina</u>	919-733-4283	Mr. Dayne H. Brown, Chief Radiation Protection Section Division of Facility Service 701 Barbour Drive Raleigh, North Carolina 27603	8/1/64
<u>North Dakota</u>	701-224-2348	Mr. Dana Mount, Director Div. of Environmental Engineering Radiological Health Program 1200 Missouri Avenue Bismarck, North Dakota 58501	9/1/69
<u>Oregon</u>	503-229-5797	Mr. Ray Paris, Manager Radiation Control Section Dept. of Human Resources 1400 South West Fifth Avenue Portland, Oregon 97201	7/1/65

<u>STATE</u>	<u>PHONE</u>	<u>ADDRESS</u>	<u>Became Agreement State On</u>
<u>Rhode Island</u>	401-277-2438	Mr. James E. Hickey, Chief Div. of Occupational Health and Radiation Control Rhode Island Dept. of Health 75 Davis Street Providence, Rhode Island 02908	1/1/80
<u>South Carolina</u>	803-758-5548	Mr. Heyward Shealy, Chief Bureau of Radiological Health State Department of Health and Environmental Control 2600 Bull Street Columbia, South Carolina 29201	9/15/69
<u>Tennessee</u>	615-741-7812	Mr. Michael H. Mobley, Director Division of Radiological Health Department of Public Health Cordell Hull State Office Building Nashville, Tennessee 37219	9/1/65
<u>Texas</u>	512-835-7000	Mr. David K. Lacker, Chief Bureau of Radiation Control Texas Department of Health 1100 W. 49th Street (mail only) Austin, Texas 78756	3/1/63 Amended 3/24/82
<u>Utah</u>	801-538-6734	Mr. Larry Anderson, Director Bureau of Radiation Control State Department of Health 298 North, 1460 West P.O. Box 16700-0700 Salt Lake City, Utah 84116	4/1/84
<u>Washington</u>	206-753-3459	Mr. Terry R. Strong, Head Radiation Control Section Department of Social and Health Services Mail Stop LF-13 Airdustrial Park Olympia, Washington 98504	12/31/66 Amended 2/19/82

Note: This list is subject to change. The NRC's Office of Governmental and Public Affairs, Washington, DC 20555, maintains an up-to-date list and may be contacted for an agency's current phone number and address if you are unable to locate the regulatory authority in a particular State.

APPENDIX B

PROPRIETARY INFORMATION, AVAILABILITY OF OFFICIAL RECORDS

Certain portions of Part 2, "Rules of Practice for Domestic Licensing Proceedings," and Part 9, "Public Records," of Title 10 of the Code of Federal Regulations are reproduced here because they are particularly important to applicants for radiation safety evaluation or registration of devices containing byproduct material.

§ 2.790 Public Inspections, Exemptions, Requests for Withholding

(a) Subject to the provisions of paragraphs (b), (d), and (e) of this section, final NRC records and documents,* including but not limited to correspondence to and from the NRC regarding the issuance, denial, amendment, transfer, renewal, modification, suspension, revocation, or violation of a license, permit, or order, or regarding a rule making proceeding subject to this part shall not, in the absence of a compelling reason for nondisclosure after a balancing of the interests of the person or agency urging nondisclosure and the public interest in disclosure, be exempt from disclosure and will be made available for inspection and copying in the NRC Public Document Room, except for matters that are:

* * *

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

* * *

(b)(1) A person who proposes that a document or a part be withheld in whole or part from public disclosure on the ground that it contains trade secrets or privileged or confidential commercial or financial information shall submit an application for withholding accompanied by an affidavit which:

(i) Identifies the document or part sought to be withheld and the position of the person making the affidavit, and

(ii) Contains a full statement of the reasons on the basis of which it is claimed that the information should be withheld from public disclosure. Such statement shall address with specificity the considerations listed in paragraph (b)(4) of this section.

In the case of an affidavit submitted by a company, the affidavit shall be executed by an officer or upper-level management official who has been specifically delegated the function of reviewing the information sought to be withheld and authorized to apply for its withholding on behalf of the company. The affidavit shall be executed by the owner of the information, even though the information sought to be withheld is submitted to the

*Such records and documents do not include handwritten notes and drafts.

Commission by another person. The application and affidavit shall be submitted at the time of filing the information sought to be withheld. The information sought to be withheld shall be incorporated, as far as possible, into a separate paper.

The affiant may designate with appropriate markings information submitted in the affidavit as a trade secret or confidential or privileged commercial or financial information within the meaning of § 9.5(a)(4) of this chapter and such information shall be subject to disclosure only in accordance with the provisions of § 9.12 of this chapter.

(2) A person who submits commercial or financial information believed to be privileged or confidential or a trade secret shall be on notice that it is the policy of the Commission to achieve an effective balance between legitimate concerns for protection of competitive positions and the right of the public to be fully apprised as to the basis for and effects of licensing or rule making actions, and that it is within the discretion of the Commission to withhold such information from public disclosure.

(3) The Commission shall determine whether information sought to be withheld from public disclosure pursuant to this paragraph: (i) is a trade secret or confidential or privileged commercial or financial information; and (ii) if so, should be withheld from public disclosure.

(4) In making the determination required by paragraph (b)(3)(i) of this section, the Commission will consider:

(i) Whether the information has been held in confidence by its owner;

(ii) Whether the information is of a type customarily held in confidence by its owner and whether there is a rational basis therefor;

(iii) Whether the information was transmitted to and received by the Commission in confidence;

(iv) Whether the information is available in public sources;

(v) Whether public disclosure of the information sought to be withheld is likely to cause substantial harm to the competitive position of the owner of the information, taking into account the value of the information to the owner; the amount of effort or money, if any, expended by the owner in developing the information; and the ease or difficulty with which the information could be properly acquired or duplicated by others.

(5) If the Commission determines, pursuant to paragraph (b)(4) of this section, that the record or document contains trade secrets or privileged or confidential commercial or financial information, the Commission will then determine (i) whether the right of the public to be fully apprised as to the bases for and effects of the proposed action outweighs the demonstrated concern for protection of a competitive position and (ii) whether the information should be withheld from public disclosure pursuant to this paragraph. If the record or document for which withholding is sought is deemed by the Commission to be irrelevant or unnecessary to the performance of its functions, it shall be returned to the applicant.

(6) Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the document. The Commission may require information claimed to be a trade secret or privileged or confidential commercial or financial information to be subject to inspection: (i) Under a protective agreement, by contractor personnel or government officials other than NRC officials; (ii) by the presiding officer in a proceeding; and (iii) under protective order, by parties to a proceeding, pending a decision of the Commission on the matter of whether the information should be made publicly available or when a decision has been made that the information should be withheld from public disclosure. In camera sessions of hearings may be held when the information sought to be withheld is produced or offered in evidence. If the Commission subsequently determines that the information should be disclosed, the information and the transcript of such in camera session will be made publicly available.

(c) If a request for withholding pursuant to paragraph (b) of this section is denied, the Commission will notify an applicant for withholding of the denial with a statement of reasons. The notice of denial will specify a time, not less than thirty (30) days after the date of the notice, when the document will be placed in the Public Document Room. If, within the time specified in the notice, the applicant requests withdrawal of the document, the document will not be placed in the Public Document Room and will be returned to the applicant: Provided, that information submitted in a rule making proceeding which subsequently forms the basis for the final rule will not be withheld from public disclosure by the Commission and will not be returned to the applicant after denial of any application for withholding submitted in connection with that information. If a request for withholding pursuant to paragraph (b) of this section is granted, the Commission will notify the applicant of its determination to withhold the information from public disclosure.

* * * * *

§ 9.5 Exemptions

(a) The following types of records are exempt from public disclosure under § 9.4:

* * *

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential matter subject to this exemption is that which is customarily held in confidence by the originator. It includes, but is not limited to:

(i) Information received in confidence, such as trade secrets, inventions and discoveries, and proprietary data;

(ii) Technical reports and data, designs, drawings, specifications, formulae, or other types of proprietary information which are generated or developed by the NRC or for the NRC under contract;

(iii) Statistical data or information concerning contract performance, income, profits, losses, and expenditures, if received in confidence from a contractor or potential contractor.

APPENDIX C

PRINCIPAL USE CODES AND DEFINITIONS FOR SEALED SOURCES AND DEVICES

CODE

- A Industrial Radiography - The examination of the structure of materials by nondestructive methods that use sealed sources of radioactive material.
- B Medical Radiography - The process of producing x-ray or gamma ray images to assist in medical diagnoses.
- C Medical Teletherapy - The treatment of disease with gamma radiation from a controlled source of radiation located at a distance from the patient.
- D Gamma Gauges - The use of gamma radiation to measure or control thickness, density, levels, interface location, radiation leakage, or chemical composition.
- E Beta Gauges - The use of beta radiation to measure or control thickness, density, levels, interface location, radiation leakage, or chemical composition.
- F Well Logging - The lowering and raising of measuring devices or tools that may contain radioactive sources into well bases or cavities for the purpose of obtaining information about the well or adjacent formation.
- G Portable Moisture Density Gauges - Portable gauges that use a radioactive sealed source to determine or measure the content or density of material. Includes hand-held and dolly-transported devices with sources.
- H General Neutron Source Applications - All applications, except reactor startup and well logging, that use a neutron source.
- I Calibration Sources (Activity greater than 30 mCi) - Sources of a known purity and activity that are used to determine the variation in accuracy of a measuring instrument and to ascertain necessary correction factors.
- J Gamma Irradiator, Category I - An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volumes undergoing irradiation is not physically possible because of the design of the irradiator.

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

- X Medical Reference Sources - Includes flood sources, instrument check sources, spot markers.
- Y Calibrators - Devices containing calibration sources that are used to determine the variation in accuracy of a measuring instrument and to determine necessary correction factors.

APPENDIX D

CHECKLIST FOR RADIATION SAFETY EVALUATION

This checklist may be helpful to an applicant when compiling an application for a device safety evaluation. This checklist does not need to be submitted with the application. Certain items in this list are not appropriate for all devices, e.g., a smoke detector does not have a shutter or an on-off indicator. Accordingly, when using the checklist for the smoke detector, entries of "Not Applicable" would be made as appropriate under Description.

- _____ Registrant's Name and Address
- _____ Manufacturer's Name and Address
- _____ Device Model
- _____ Device Type
- _____ Users' Authority To Possess
(Specific license, general license, exemption)
- _____ Radionuclides, Amounts and Forms
(Source makes and models)

DESCRIPTION

- _____ Device design and dimensions
- _____ Materials
- _____ Assembly methods (welds, screws, etc.)
- _____ Source mounting and security
- _____ Shutter operation
- _____ On-off indicators
- _____ Interlocks, guards, etc.

RADIATION PROFILE

- _____ Instrumentation (type, window thickness, calibration)
- _____ Survey conditions
 - _____ Nuclide and activity
 - _____ Distance from source, surface
 - _____ Source exposed
 - _____ Source shielded
 - _____ Scatterer (product) in beam?
 - _____ Guards and shields in place?

INSTALLATION

- _____ Mobility
 - _____ Fixed
 - _____ Movable
 - _____ Portable
 - _____ Fixed installation, but movable
source housing

INSTALLATION (Continued)

- _____ Inherent shielding, inaccessibility
- _____ Interlocks, locks, barriers
- _____ Beam access: size of gaps and openings to beam

PROTOTYPE TESTS

- _____ Test methods and conditions
- _____ Test results

QUALITY CONTROL

- _____ Materials
- _____ Assembly methods (welds, screws, etc.)
- _____ Dimensional tolerances
- _____ Activity
- _____ Shielding, radiation levels
- _____ Leak/contamination check

LABELING

- _____ Copy or facsimile
 - _____ Content (wording, symbols, etc.)
 - _____ Materials
 - _____ Dimensions
 - _____ Colors
 - _____ Attachment method
 - _____ Location
 - _____ Durability

SAFETY INSTRUCTIONS

- _____ Operation and maintenance (including calibration)
- _____ Damage or malfunction procedures
- _____ Radiation profile
- _____ Specific warnings (if applicable)

DOCUMENTATION ACCOMPANYING THE DEVICE

- _____ Results of radiation safety checks
- _____ Transportation-related documents

SERVICING

By Manufacturer/Distributor

By User

Installation	_____	_____
Relocation	_____	_____
Maintenance	_____	_____
Repair	_____	_____
Source installation or replacement	_____	_____
Calibration	_____	_____
Leak testing	_____	_____
Radiation Survey	_____	_____
Training	_____	_____
Other	_____	_____

VALUE/IMPACT STATEMENT

A draft value/impact statement was published with the proposed version of this regulatory guide, Task FC 601-4, when the draft guide was published for public comment in August 1986. No changes were necessary, so a separate value/impact statement for the final guide has not been prepared. A copy of the draft value/impact statement is available for inspection and copying for a fee at the Commission's Public Document Room at 1717 H Street NW., Washington, DC 20555, under Task FC 601-4.

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