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REGULATORY GUIDE

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

USNRC REGULATORY GUIDES

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1. INTRODUCTION

1.1 PURPOSE OF GUIDE

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

For many uses of byproduct material¹ that are licensed by the NRC, the radioactive material is contained in a sealed source. As used in this guide, a sealed source is radioactive material that is sealed in a protective envelope (capsule), contained in a foil, or plated on an inactive surface. The term "sealed source" or "source" includes the radioactive material and its confining barrier, i.e., the capsule, foil, or plated surface. The confining barrier is relied on to prevent dispersion of the radioactive material under normal conditions for use of the source and most accident conditions.

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

The NRC maintains a registry of radiation safety information on sealed sources 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 sealed source 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 sealed source throughout the United States.

1.2 APPLICABLE REGULATIONS

NRC regulations applicable to sealed sources 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 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";

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.

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 and Resources Management, 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, Post Office Box 37082, Washington, DC 20013-7082.

Detailed requirements for certain sources are set out in the regulations (for example, calibration or reference sources distributed under the provisions of § 32.57 of 10 CFR Part 32 for use under a general license). For many other sources, the regulatory requirements are less detailed and NRC's radiation safety evaluation of the source 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 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.

1.4 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 sources in order to avoid unnecessary exposures during the use of the source.

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 sources.

2. FILING AN APPLICATION

When applying for a radiation safety evaluation and registration of a sealed source, 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 sealed source is intended for use under (1) an exemption from the regulations, e.g., sources contained in ionization radiation measuring instruments for purposes of internal calibration or standardization to be used under the provisions of § 30.15, (2) a general license, e.g., an americium-241 calibration or reference source to be used under the provisions of § 31.8, (3) a specific license, e.g., a sealed source in 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., a sealed source in 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 work telephone number of the individual to be contacted for additional information or clarification of your application. An employee's home telephone number should be submitted only if it is the only means of contact about your application.

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., 2a, 2b, 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, 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 tests on sealed sources and the test results. Documented field experience with comparable sources 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 for a sealed source manufactured outside the United States, the applicant may elect to write or otherwise affix the English translation directly on the engineering drawing.

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

In a few instances, it may be advantageous to submit a dummy sealed source (i.e., without radioactive material) with an application. Sources containing radioactive material should not be submitted.

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 source. 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 of 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 submittals, 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 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.

2.5 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 sealed source 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 sealed source, together with the fee payment (see Section 1.3 above), should be sent to:

U.S. Nuclear Regulatory Commission
Division of Fuel Cycle, Medical, Academic,
and Commercial Use Safety
Medical, Academic, and Commercial Use Safety Branch
Washington, DC 20555

Please note that the above address is different from that of the appropriate NRC Regional Office or Washington, DC 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 sealed source, you will be sent a certificate of registration that acknowledges the registration of information about the source and the availability of that information for use in the issuance of specific licenses.

2.6 MEDICAL SEALED SOURCES

Please note that if a sealed source 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

2.7 REGISTRATION OF A FOREIGN-MANUFACTURED SEALED SOURCE

A sealed source manufactured outside the United States may be registered by the NRC if 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.

A person in the U.S. may elect to import a source that will be manufactured in a foreign country in accordance with specifications determined by that person. Under these conditions, the person (user) should register the appropriate radiation safety information with the NRC or with the Agreement State (see Section 2.8 of this guide) if located in an Agreement State.

2.8 MANUFACTURERS/DISTRIBUTORS LOCATED IN AGREEMENT STATES

A sealed source manufacturer or distributor located in an Agreement State (see Appendix A) should contact that State's regulatory authority for guidance on preparing requests for evaluation of sources and applications for licenses to possess and use radioactive material.

2.9 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 all 50 States.

The Food and Drug Administration (FDA) assists the States in their review and regulatory approval for distribution of sealed sources 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 sealed sources containing byproduct material is comparable to guidance provided in the NARM guide for sources containing NARM.

As a general rule, the NRC does not accept applications for radiation safety evaluation and registration of sealed sources that will contain NARM. There are two exceptions to this general rule. One exception is if the radionuclide used in the source 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 source evaluation and registration that the Cd-109 will be produced in a reactor. The other exception is if the NARM is commingled with byproduct material.

2.10 TRANSPORTATION

This regulatory guide does not cover detailed requirements for the transportation of 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 A₁ and A₂ as defined in § 71.4 of 10 CFR Part 71).

Although the application for radiation safety evaluation of a 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 expected to be familiar with the way those requirements apply to the source and the action needed to ensure that transportation of the source is performed in accordance with applicable requirements.

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.

Two requirements for transportation of sources are particularly important with respect to sources that are frequently transported by the user (shipper), such as gamma radiography sources and well-logging sources. 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 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 1 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 sealed source 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 here 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 of the certificate identifies the sealed source (model number), radioactive material (nuclides and quantity of each), leak-test requirement, and 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 sealed source looks like and how it is used.

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

Note that the format in this Section 3 is recommended, not required. However, applicants are encouraged to use this format to expedite the review process and minimize the number of follow-up letters and telephone calls.

3.1 SUMMARY DATA

This section should be presented on one page and should contain key information 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 Sealed Source Type

State the name used by the industry to identify the sealed source (e.g., radiography source, gamma irradiator source, teletherapy source, calibration source).

3.1.4 Model

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

3.1.5 Other Companies Involved

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

3.1.6 Radionuclide and Maximum Activity

List the radionuclides you propose to use in the sealed source and the maximum proposed activity level in curies, millicuries, or microcuries for each radionuclide.⁵ If the application concerns a series of sources that are

⁵If desired, the activity may be stated in both curies (or subunits thereof) and becquerels. In such case, please state the number of curies and then the number of becquerels with the number of becquerels enclosed in parentheses.

essentially identical, maximum activities may be stated for subgroups within the series. For example, the XYZ Company's Series 200 cobalt-60 teletherapy sources all have the same external dimensions, but within the series the Model 201 source has an active diameter of 1.5 cm and maximum activity of 1,500 Ci, the Model 202 source has an active diameter of 2.0 cm and maximum activity of 3,000 Ci, etc.

3.1.7 Leak-Test Frequency

State the proposed frequency for testing the sealed source for possible leakage of radioactive material. (Guidance on leak testing is presented in Section 3.3.7.)

3.1.8 Principal Use Codes

Select from Appendix C to this guide, "Principal Use Codes and Definitions for Sealed Sources and Devices," the code that most accurately describes the principal or predominant use for the sealed source. State whether the sealed source is proposed for use under (1) a specific license, (2) a general license, (3) an exemption from regulatory requirements, or (4) a combination of 1, 2, or 3. If the sealed source is proposed for use under a general license or an exemption, indicate the primary section of NRC regulations applicable to its use.

3.1.9 Custom Sealed Source

Indicate whether the sealed source is a custom source. A sealed source specifically designed and constructed according to the order of a single license applicant may be considered a custom sealed source that warrants an NRC review that is tailored to the particular applicant. Sealed sources designed and constructed as off-the-shelf items or for use by more than a single license applicant are not considered custom sealed sources.

3.1.10 Custom User

If this is a custom sealed source, give the name and address of the user and a contact (individual's name or title and telephone number) for the user.

3.2 SUMMARY DESCRIPTION

This section should include a short discussion of what the sealed source will be used for 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 sealed source, including information on the chemical and physical form of the radioactive material, materials of construction, dimensions (including wall and window thicknesses), and methods for fabricating and sealing the source. State the radioactive source

classification according to the system in ANSI N542, "Sealed Radioactive Sources, Classification."⁶

The application may concern a series of sources that are substantially the same. This series may be divided into subgroups that differ only with respect to identified properties. Each subgroup and its unique properties should be described.

3.2.2 Drawing

Provide an annotated sketch, photograph, or isometric projection or drawing showing components pertinent to radiation safety such as wall and window thicknesses, approximate dimensions, and label location (if any). 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. (The NRC may include a copy of the drawing, sketch, or photograph in the Certificate of Registration that is discussed in Section 4 of this guide.)

3.3 DETAILS ON CONSTRUCTION AND USE

This section should provide detailed information on the design, manufacture, prototype testing, quality control, leak testing, labels, proposed uses, and potential hazards of the sealed source. The information presented should provide reasonable assurance that the sealed source will maintain its containment integrity and 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 sealed source and identify the extremes of environment and operating conditions (e.g., temperature, corrosive atmosphere, vibration) expected during normal use. Include descriptions of the types of users and locations of use. List any stress limitations you have prescribed for use of the sealed source. Also describe the probable effects of severe conditions, including fires.

⁶In lieu of stating an ANSI N542 classification, an applicant may provide a classification under the International Standards Organization (ISO) standard ISO.2919, "Sealed Radioactive Sources--Classification." ANSI N542 and ISO.2919 are closely related. Each standard establishes a system of classification of sealed radioactive sources based on performance specifications related to radiation safety. Each provides a manufacturer of sealed sources with a series of tests for evaluating the safety of the product under specified conditions. Tests are prescribed for temperature, external pressure, impact, vibration, and puncture over a range of severity. Sealed source performance tests are identified for a variety of source applications; together with the degree of severity of each test. Both standards cover selecting a source for a particular application insofar as maintenance of source integrity is concerned. The ISO standard and ANSI N542 may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

3.3.2 Details of Construction

Submit engineering drawings or annotated sketches or drawings of the sealed source that describe all materials of construction, dimensions, methods of fabrication, and methods of sealing the source capsules. Describe in detail all special design features, such as recessing of the primary radiation beam window, that help prevent damage to vulnerable portions of the sealed source.

3.3.3 Labeling

Describe how (e.g., etched, engraved, or imprinted) and with what information the source will be labeled (e.g., the words "Caution - Radioactive Material," the manufacturer's name or trademark, model number or unique serial number, radionuclide, assay date, radiation symbol). If labeling the sealed source is impracticable, explain how safety-related information such as the above will be provided to the user (e.g., a tag attached to the source, a label on the storage container or other device containing the source).

3.3.4 Testing of Prototypes⁷

Describe the tests performed on each prototype sealed source and submit the test results that establish the integrity of the radiation safety features of the sealed source under the conditions of use to which the source is likely to be subjected. For example, describe the testing performed to establish the source classification stated in Section 3.2.1.

⁷For many sealed sources, guidance on design considerations, tests of prototypes, and quality control programs is provided in industry or consensus standards. Applicants for safety evaluations are encouraged to consider such guidance. Some particularly useful standards are (1) for sealed radioactive source classification, ANSI N542, "Sealed Radioactive Sources, Classification," and ISO.2919-1980, "Sealed Radioactive Sources--Classification," (2) for brachytherapy, ANSI N44.1-1973, "Integrity and Test Specifications for Selected Brachytherapy Sources," (3) for radiography, ANSI N432, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (4) for gauges, ANSI N538, "Classification of Industrial Ionizing Radiation Gauging Devices," (5) for irradiators, ANSI N433.1, "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category 1)," and ANSI N43.10, "Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)," (6) for self-luminous light sources, ANSI N540, "Classification of Radioactive Self-Luminous Light Sources," (7) for teletherapy, National Council on Radiation Protection and Measurements (NCRP) Report No. 33, "Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MeV," and (8) for smoke detectors, Nuclear Energy Agency (NEA) "Recommendations for Ionization Chamber Smoke Detectors in Implementation of Radiation Protection Standards" (1977). If there is no specific industry or consensus standard for your sealed source, you may obtain useful general guidance from a standard for a comparable source. ANSI N538 may be particularly useful for general guidance on quality control. ANSI and ISO standards are available from 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., Washington, DC 20014. NEA reports are available from the Organization for Economic Cooperation and Development (OECD) Publications and Information Center, Suite 1207, 1750 Pennsylvania Ave., NW., Washington, DC 20006.

In some instances, engineering analyses may be an acceptable alternative to testing of prototypes. For example, engineering analyses may be appropriate for custom sealed sources, sources expected to have limited distribution or low potential hazard, or sources that are quite similar to previously tested prototypes. Even in these instances, the applicant should submit historical use data or data from tests on prototypes of similar sources to reinforce findings resulting from engineering analyses.

Source manufacturers frequently evaluate their products to determine the effects of the tests for special form radioactive material (see § 71.77 of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"). If these tests are performed, the results of the tests should be submitted. If a national competent authority has issued a certificate stating that the sealed source satisfies the special form requirements for transportation purposes, a copy of that certificate should be included in the application for safety evaluation and registration.

3.3.5 Radiation Levels

Submit radiation profiles or other statement of radiation levels associated with the sealed source. Radiation levels should be determined using the maximum activity of each nuclide expected to be used in the source. In general, the distances for determining the radiation levels are 5 cm, 30 cm, and 100 cm from the source to the effective center of the radiation measuring chamber. A description of the method and instrumentation used to measure the radiation levels or the bases for calculations used to determine the levels should be included.

For a sealed source that emits more than one type of radiation, the contribution of each type should be provided as well as the total radiation level. For example, for an americium-241/beryllium neutron source used in well logging, both the gamma contribution and the neutron contribution should be provided. This information is important in determining radiation levels external to well logging tools and storage containers.

Occasionally a source may contain a radioactive contaminant, or the principal radionuclide may not be in equilibrium with its daughter products at the time of initial determination of radiation levels. Accordingly, subsequent determinations may show radiation levels that are significantly different from levels calculated by adjusting the initial determination for decay of the principal radionuclide. If this condition applies to your sealed source, you should describe the expected changes in the energy spectrum and radiation levels during the probable useful life of the source.

3.3.6 Quality Control⁷

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

You should include a description of the assay method used to determine the radioactive content of the sealed source. This method is expected to be traceable to a national standard.

A particularly important portion of the quality control program is ensuring that the sealed source is not leaking and is free of contamination at the time of transfer to the user. Generally, this means the absence of 0.005 microcurie or more of removable radioactive material.

3.3.7 Leak Testing During Use

The NRC requires, with certain exceptions, that sealed sources or devices containing sealed sources be tested periodically for possible leakage of radioactive material at intervals not to exceed 6 months.⁸ However, an applicant may request a longer interval for NRC consideration. A request for an interval greater than 6 months (both for sources and 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 sealed source or device during use if the sealed source or 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 sealed sources and devices must ensure that they are free of leakage and contamination when transferred.

3.3.8 Documentation Accompanying the Sealed Source

You should submit a sample of or describe radiation-safety-related documentation that you will supply with the sealed source. Examples of such documentation are (1) a certificate providing the date and results of the most recent leak test and contamination check, (2) a statement of the primary radionuclide and its quantity and the identity and quantity of other radionuclides (e.g., cesium-134 content of a nominal cesium-137 teletherapy source) in the sealed source, (3) a copy of a "special form" certificate issued by a national competent authority or an evaluation indicating that the source is "special form" as defined in § 71.4 of 10 CFR Part 71, (4) a statement of the ANSI or ISO source classification, (5) a statement of the radiation output of the source, and (6) any safety recommendations or warnings with respect to unpacking, handling, storing, etc., to be used to minimize exposure to user personnel.

⁸In most cases the user's test interval depends on the device (e.g., gauge, teletherapy unit) containing the sealed source and how that device is used. The NRC has issued Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," that discusses NRC's device evaluations. A registration certificate for a sealed source may specify a 6-month leak-test interval, but a particular device containing that source may specify a 3-year interval. When the source is used in that device, leak tests are required only at 3-year intervals.

Appendix D of this guide, "Check List for Sealed Source Radiation Safety Evaluation," may be helpful to you when preparing an application for a radiation safety evaluation of a sealed source. 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 sealed source by type and model, series, 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 and considerations on the use of the sealed source such as (1) to whom the sealed source may be distributed (for example, persons generally licensed pursuant to § 31.8 or persons specifically licensed pursuant to § 30.33), (2) leak-test requirements, and (3) restrictions on environmental conditions of use.

The NRC will provide copies of the registration certificate to regulatory authorities in the Agreement States for their use in granting licensing approval to users within their respective States.

A manufacturer or distributor of a sealed source may be asked by its customer to identify its product (by model number or serial number) so that this information can be referenced in the customer's application for a license. The customer should identify the sealed source exactly as it is identified in the manufacturer's or distributor's registration certificate. This will enable the licensing reviewer to relate the customer's application to the information in the registration certificate.

5. AMENDMENTS TO REGISTRATION CERTIFICATES FOR SEALED SOURCES

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 an amendment to your certificate. 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 2.5, "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 sealed source. For example, if you intend to change the radionuclide or increase the radioactivity limit and source dimensions, your application for an amendment should identify the new radionuclide or quantity limit, state the new radiation levels, and state the effects on the ANSI classification for the source. 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. You should 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 certificate amendment before the proper fee is paid in accordance with § 170.12.

Please note that if the sealed source is to be 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 sealed source 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.

7. IMPLEMENTATION

The purpose of this section is to provide information to applicants for radiation safety evaluation and registration of sealed sources containing by-product material and to registrants of such sources about the NRC staff's plans for using this regulatory guide.

This guide reflects current practices of the NRC staff for evaluating and registering radiation safety information about sealed sources. The information in this guide is guidance, not requirements. This guidance is intended to assist manufacturers and distributors in preparing and submitting information that describes and demonstrates the adequacy of radiation safety properties of a sealed source.

The NRC staff does not plan to use this guide to re-evaluate a presently registered sealed source unless the registrant requests an amendment of filed information. An applicant for amendment of information about a registered sealed source is encouraged by the staff to consider this guide when demonstrating the continued adequacy of radiation safety properties of the source.

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	Ms. Greta Dicus, 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>	303-331-4800	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. T. E. Hill, Acting 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>	208-334-5879	Mr. Mark Torf, Manager Compliance 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 and Nuclear Energy P.O. Box 14690 Baton Rouge, Louisiana 70898	5/1/67
<u>Maryland</u>	301-333-3130	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 Health Division Department of Human Resources 505 E. King Street 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>STATE</u>	<u>PHONE</u>	<u>ADDRESS</u>	<u>Became Agreement State On</u>
<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>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>	803-734-4700	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 the 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 sealed sources 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.

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

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 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 μCi) - 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 radioisotope 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

CHECK LIST FOR SEALED SOURCE RADIATION SAFETY EVALUATION

This check list may be helpful to an applicant when compiling an application for a sealed source safety evaluation. This check list does not need to be submitted with the application. Certain items in this list are not appropriate for all sealed sources, e.g., neither a 0.1-microcurie Am-241 source used in a smoke detector nor a 2-millicurie gaseous tritium self-luminous light source is required to be leak tested by the user. Accordingly, when using the check list for these sources, entries of "Not Applicable" would be made as appropriate under Leak-Test Frequency.

- _____ Registrant's name and address
- _____ Manufacturer's name and address
(May be same as registrant)
- _____ Sealed source type
- _____ Sealed source model
- _____ Radionuclide(s) and maximum activity (of each)
- _____ Leak-test frequency
- _____ Description
 - _____ Written description
 - _____ Small drawing
 - _____ ANSI N542 classification
- _____ Conditions of use
- _____ Details of construction
 - _____ Radioactive material
(Chemical and physical form: possible radioactive contaminants)
 - _____ Materials of construction
 - _____ Dimensions
 - _____ Fabrication and sealing methods
- _____ Labeling
- _____ Radiation levels and methods of determination
- _____ Quality control
(Including leak/contamination test limits)
- _____ Documentation accompanying source:

VALUE/IMPACT STATEMENT

A draft value/impact statement was published with the proposed version of this regulatory guide, Task FC 603-4, when the draft guide was published for public comment in December 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, under Task FC 603-4.

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