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OFFICE OF NUCLEAR REGULATORY RESEARCH

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DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-0007
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**GUIDE FOR THE PREPARATION OF APPLICATIONS FOR
LICENSES TO AUTHORIZE DISTRIBUTION OF VARIOUS
ITEMS TO COMMERCIAL NUCLEAR PHARMACIES
AND MEDICAL USE LICENSEES**

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules Review and Directives Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by **July 31, 1997.**

Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Office of Administration, Distribution and Mail Services Section.

1. INTRODUCTION

1.1 PURPOSE OF GUIDE

The purpose of this regulatory guide is to provide assistance to you, the applicant or licensee, in preparing applications for new licenses, license amendments, and renewals of medical distribution licenses under 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material" (i.e., licenses that authorize the distribution of radioactive drugs and sealed sources containing byproduct material to the Nuclear Regulatory Commission's (NRC's) and Agreement States' commercial nuclear pharmacy and medical use licensees). Medical distribution by applicants registered or licensed with the U.S. Food and Drug Administration or State agency as a drug or sealed source manufacturer is provided for in 10 CFR 32.72 and 32.74 or equivalent provisions of an Agreement State.

The medical distribution license only authorizes distribution; it does not authorize the possession of byproduct material. Therefore, an additional license is necessary, such as a specific license of either broad or limited scope that authorizes possession of byproduct material for research and development, manufacturing, and other activities.

Holders of licenses to manufacture and conduct broad scope research and development, who were authorized on January 1, 1995, to distribute radiolabeled drugs to medical use licensees by specific license conditions or under the authorized use item of the license but who did not have a 10 CFR Part 32 medical distribution license, may continue to distribute the radiolabeled drugs pursuant to the authorization without obtaining a medical distribution license. However, when the licensee wishes to amend or renew this authorization, a new 10 CFR Part 32 medical distribution license or authorization will be needed.

Separate draft guidance for those wishing to operate a commercial nuclear pharmacy has been issued as Draft Regulatory Guide DG-0006, "Guide for the Preparation of Applications for Commercial Nuclear Pharmacy Licenses." If as part of your business you operate as a commercial nuclear pharmacy, you must also follow the regulations applicable to commercial nuclear pharmacies in 10 CFR Part 32.

This guide is intended to provide you, the applicant or licensee, with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to authorizations to distribute various items to commercial nuclear pharmacies and medical use licensees.

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application and correspondence with the NRC, (2) the terms and conditions of the license, and (3) the NRC's regulations. The information you provide in your application should be clear, specific, and accurate.

Several words and phrases used in this guide should be explained. The phrase "byproduct material" means any radioisotope produced by a nuclear reactor. The term "distribution" has the same meaning as in 10 CFR Part 32, i.e., the routine transfer of licensed materials to others. For organizations licensed in accordance with 10 CFR 32.72 and 32.74, these transfers of licensed material are to specific licensees in accordance with the requirements of 10 CFR 30.41; these organizations' principal customers are commercial nuclear pharmacy and medical use licensees. The phrase "medical use licensee" means a physician, podiatrist, dentist, or medical institution licensed under 10 CFR Part 35 for "medical use," as defined in 10 CFR 35.2.

1.2 APPLICABLE REGULATIONS

NRC regulations applicable to medical distribution operations are found in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"; 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"; 10 CFR Part 20, "Standards for Protection Against Radiation"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material"; 10 CFR Part 35, "Medical Use of Byproduct Material"; 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"; 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"; and 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Material Licenses,

Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC." It is your responsibility as an applicant and as a licensee to have copies of, to read, and to abide by each regulation. As a license holder, you are subject to all applicable provisions of the regulations as they pertain to medical distribution operations.

(NOTE: On January 1, 1995, Section 32.73 of 10 CFR Part 32 was deleted from the regulations because radionuclide generators are included as a radioactive drug in 10 CFR 32.72, and the manufacture and distribution of reagent kits are no longer regulated by NRC.)

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required. Regulatory guides are issued in draft form for public comment to involve the public in the early stages of developing the regulatory positions. Draft regulatory guides have not received complete staff review and do not represent official NRC staff positions.

This guide identifies the information needed to complete NRC Form 313 for applications for a license to distribute various items to commercial nuclear pharmacy and medical use licensees. The information collection requirements in NRC Form 313 have been cleared under OMB Clearance No. 3150-0120.

1.3 MAINTAINING RADIATION DOSES AS LOW AS REASONABLY ACHIEVABLE (ALARA)

According to 10 CFR 20.1101(b), "The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)."

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. As an applicant, you should consider the ALARA philosophy as described in Regulatory Guide 8.10 in developing your plans for work with licensed radioactive materials.

2. FILING AN APPLICATION

You, as the applicant for a medical distribution license, should complete NRC Form 313 (see Appendix A to this guide). You should complete Items 1 through 4, 7 through 9, and 11 through 13 on the form itself. For Items 5, 6, and 10, you should submit the information on supplementary pages. Each separate sheet or document submitted with the application should be identified and keyed to the item number on the application to which it refers. 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, they should be folded to 8-1/2 x 11 inches. You should complete all items in the application in sufficient detail for the NRC to determine that your radiation safety program is adequate to protect health and minimize danger to life and property.

You may combine requests for authorization to distribute radioactive drugs to commercial nuclear pharmacy and to medical use licensees in one application. However, if you are also a manufacturer or initial distributor of sealed sources (or devices containing sealed sources), you should submit a separate application for authorization to distribute the sealed sources or devices. This is necessary because of the way distribution licenses are worded, reviewed, and issued. This separate application will facilitate NRC's review and evaluation of the radiation safety information for the sealed source or device and its certificate of registration.

Please note that license applications are available for review by the general public in the NRC Public Document Rooms. Do not submit proprietary information unless it is absolutely necessary. If submittal of such information is necessary, follow the procedure in 10 CFR 2.790. Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, home addresses and home telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, Social Security numbers, and radiation dose information should be submitted only if specifically requested by NRC.

You should file your application in duplicate. Also retain a copy for yourself, because the license will require that you distribute the authorized items in accordance with the statements and representations in your application and in any supplements to it.

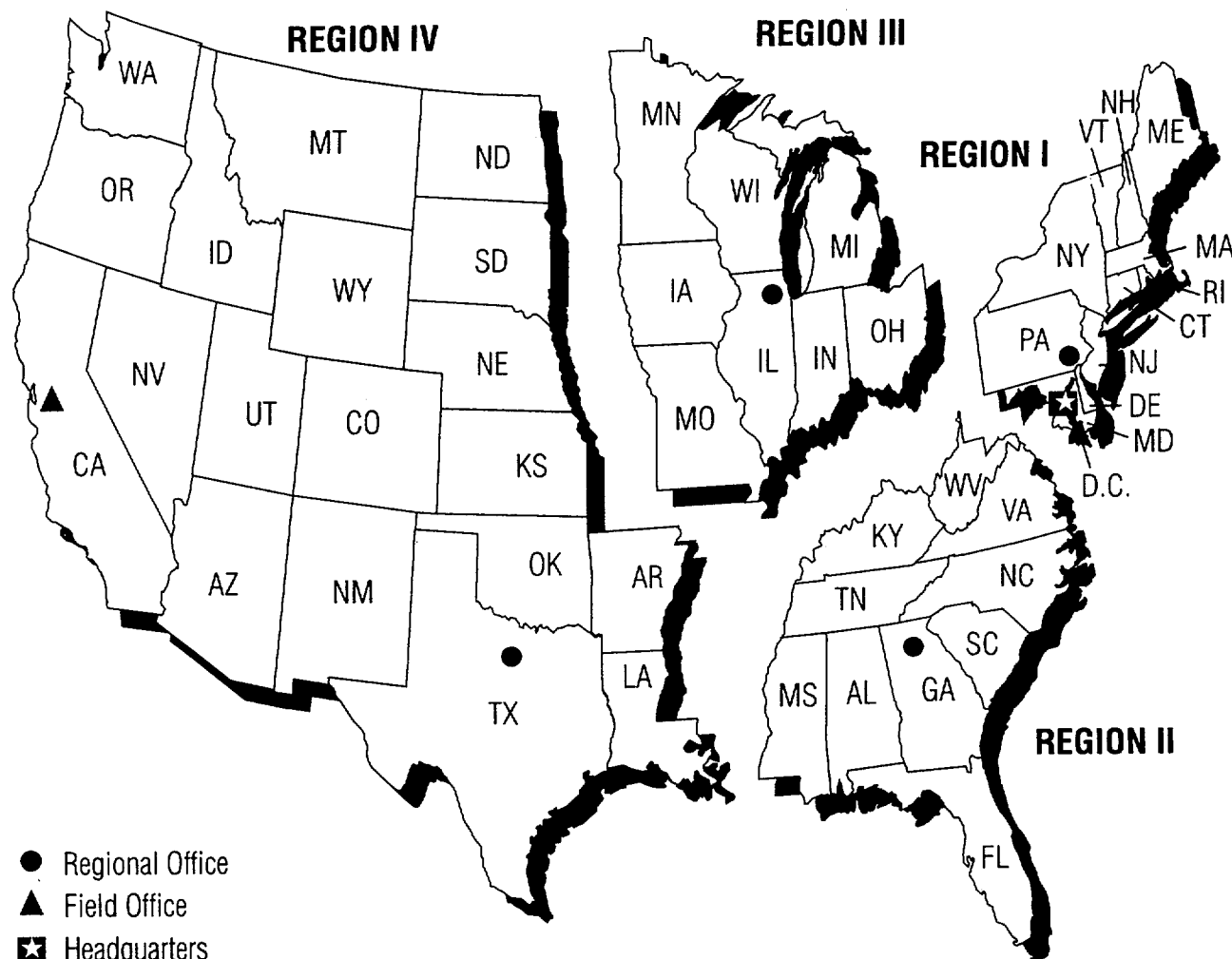
If you wish to distribute radioactive drugs or sealed sources from a site in a Federal facility or a State subject to NRC jurisdiction, you should file your application with the appropriate NRC Regional Office. The four Regional Offices and their respective areas for licensing purposes are given in Figure 1 of this guide and in 10 CFR 30.6.

All non-Federal organizations that wish to distribute, possess, or use licensed material in an Agreement State* should contact the responsible officials in that State for guidance on preparing an application; these applications should be filed with the State officials and not with the NRC. See Figure 2 of this guide for a map showing Agreement States.

The distribution license does not authorize you to either possess or use byproduct material. To possess or use licensed material on Federal property or in any State subject to NRC jurisdiction, an applicant must file an application with the appropriate NRC Regional Office with jurisdiction over the location where the material will be possessed or used. Otherwise, you must file an application with the appropriate Agreement State with jurisdiction over the location of use and possession.

*An "Agreement State" is any State with which the NRC or, previously, the Atomic Energy Commission, has entered into an effective agreement under Subsection 74b of the Atomic Energy Act of 1954, as amended. The current Agreement States are shown in Figure 2 of this guide or a current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from the Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or from NRC's Regional Offices, whose addresses are listed in Figure 1 and in 10 CFR 30.6.

NRC Regions



Note: Alaska and Hawaii are included in Region IV.

Headquarters

Washington, DC 20555
301-415-7000

Region I

475 Allendale Road
King of Prussia, PA 19406
601-337-5000

Region II

101 Marietta Street, Suite 2900
Atlanta, GA 30323
404-331-4503

Region III

801 Warrenville Road
Lisle, IL 60532
630-829-9500

Region IV

611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011
817-860-8100

Walnut Creek Field Office

1450 Maria Lane
Walnut Creek, CA 94596
510-975-0200

Figure 1 NRC Regions and Regional Offices

THE AGREEMENT STATES

As of March 21, 1997

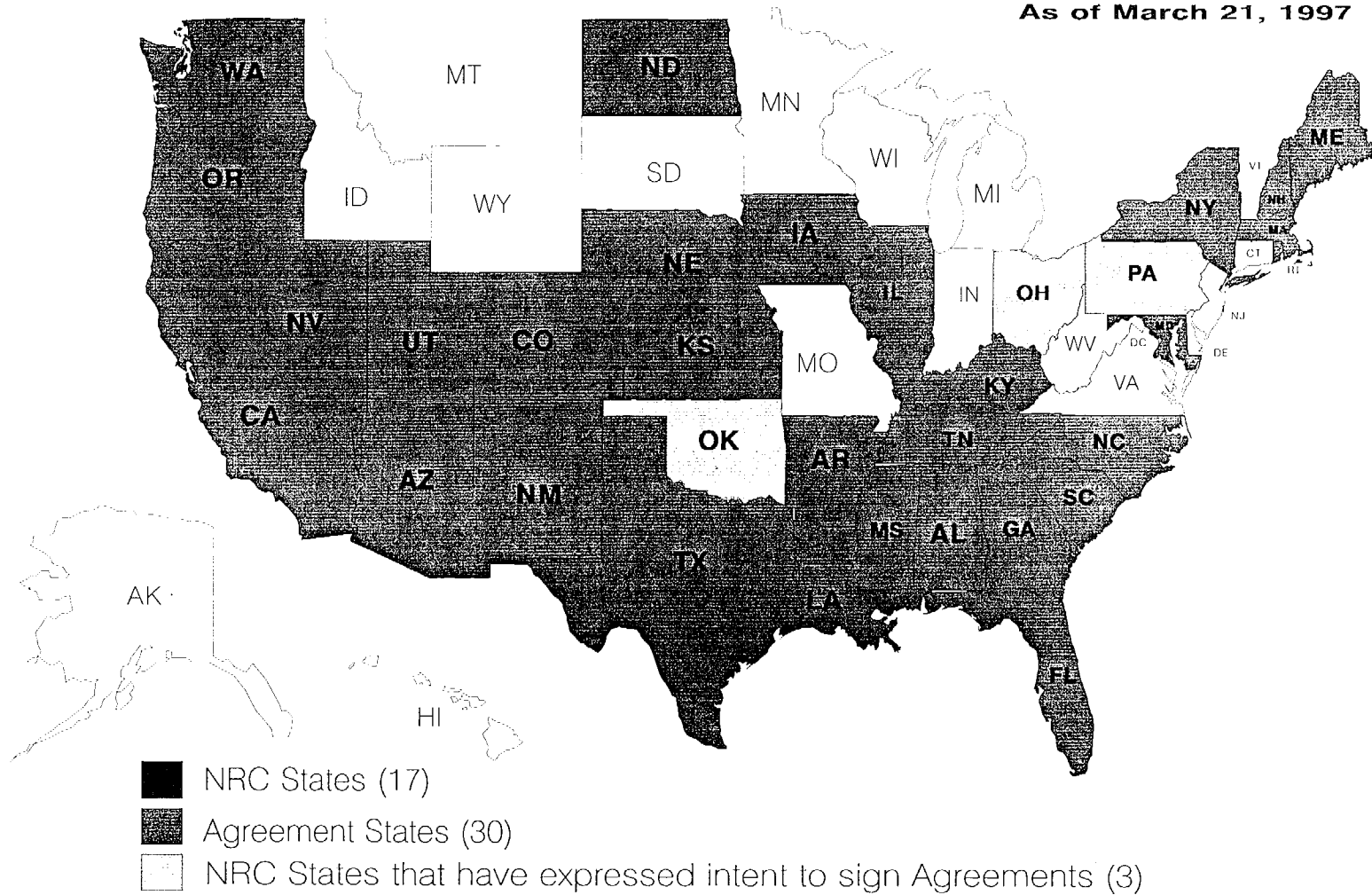


Figure 2 NRC Agreement States

3. CONTENTS OF AN APPLICATION

The following comments apply to the indicated items of NRC Form 313.

Item 1 - LICENSE INFORMATION

For a new license, check Subitem A. For an amendment to an existing license, check Subitem B. For a renewal of an existing license, check Subitem C. If you check Subitem B or C, be sure to enter your license number.

Item 2 - APPLICANT'S NAME AND MAILING ADDRESS

If you are an individual, you should be designated as the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment with a corporation or other legal entity. Otherwise, you, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address from which the material will be distributed as specified in Item 3.

Item 3 - LOCATIONS OF USE

You should specify by street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, State) of each location from which licensed material will be distributed. A Post Office Box address is not acceptable. If all licensed material will not be distributed from each location, identify each item with the address or addresses from which it will be distributed.

Item 4 - PERSON TO BE CONTACTED ABOUT APPLICATION

You should name the individual who knows your proposed program and can answer questions about your application. Also, please state the telephone number at which the individual may be contacted. If the contact person changes,

please notify the NRC. Notification of a contact change is for information only and would not be considered an application for a license amendment.

Items 5 and 6 – RADIOACTIVE MATERIALS AND USES

Identify the materials you wish to be authorized to distribute to NRC's and the Agreement States' commercial nuclear pharmacy and medical use licensees. The regulatory requirements and the subsequent information that is needed are different for radioactive drug and for sealed source licenses.

For radioactive drugs, specify the radionuclide and chemical form (for generators, specify the parent and daughter radionuclides and the name and model number, if appropriate, of the generator).

For sealed sources, specify the radionuclide, manufacturer's name and model number of each source, the maximum activity in each source, and the anticipated use of the sources. The NRC needs to know the anticipated use of the source to perform its safety evaluation. If the sealed sources are usually used in a device (e.g., bone mineral analyzer), specify the manufacturer's name and the model number of the device.

The following examples show appropriate responses to Items 5 and 6.

Radioactive Drugs:

Chromium-51 as Sodium Chromate

Molybdenum-99 as Molybdenum-99/Technetium-99m Generator (Model MTG-1)

Sealed Sources:

Cesium-137, XYZ Corp., Model 1234

Maximum activity per source: 100 microcuries

To be used by medical use licensees as dose calibrator reference sources as authorized in 10 CFR 35.57.

Strontium-90, ABC Corp., Model 567

Maximum activity per source: 150 millicuries

To be used as a strontium-90 beta eye applicator for treatment of superficial eye conditions.

Iodine-125, FGH Corp., Model 890

Maximum activity per source: 300 millicuries

To be used in an FGH Corp. Model BMA-1 device for bone mineral analysis.

Item 7 - INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR
TRAINING AND EXPERIENCE

Enter "Not applicable." No response is needed because the license, when issued, will authorize only distribution to commercial nuclear pharmacy and medical use licensees. Possession and use of licensed material is authorized in a separate license.

Item 8 - TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Enter "Not applicable." No response is needed because the license, when issued, will authorize only distribution to commercial nuclear pharmacy and medical use licensees. Possession and use of licensed material is authorized in a separate license.

Item 9 - FACILITIES AND EQUIPMENT

Enter "Not applicable." No response is needed because the license, when issued, will authorize only distribution to commercial nuclear pharmacy and medical use licensees. Possession and use of licensed material is authorized in a separate license.

Item 10 - RADIATION SAFETY PROGRAM

According to 10 CFR 32.72 and 32.74, certain radiation safety information must be submitted regarding licensed material to be distributed to commercial nuclear pharmacy and medical use licensees. The information needed for radioactive drugs is different from that needed for sealed sources. The information to be submitted for each type of licensed material to be distributed to commercial nuclear pharmacy and medical use licensees is identified in the following sections.

10.1 Radioactive Drugs

If you wish to distribute radioactive drugs to medical use licensees pursuant to 10 CFR 35.100, 35.200, or 35.300 and to commercial nuclear pharmacy licensees, you need to provide the information identified below.

10.1.1 Radioactive Drugs -- Commercial Distribution

According to 10 CFR 32.72(a)(2), you must provide evidence that you are registered or licensed with either the U.S. Food and Drug Administration (FDA) or a State agency as a drug manufacturer.

10.1.2 Radioactive Drugs -- Instrumentation

According to 10 CFR 32.72(c), you must possess and use instrumentation to measure the radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. Applicants should describe (1) the methods used to measure the radioactivity in dosages of radioactive drugs, (2) the instrumentation that will be used to measure this radioactivity, and (3) the instrumentation calibration procedures (e.g., accuracy, linearity, geometry dependency, constancy testing). Measurements may be made by direct measurement or a combination of direct measurement and calculation.

10.1.3 Radioactive Drugs -- Packaging and Shielding Licensing Criteria

According to 10 CFR 20.1101(b), you must use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable.

According to 10 CFR 32.72(a)(3), you must agree to provide shielding for the product that is adequate for safe handling and storage by medical use licensees.

For each radioactive drug you intend to distribute, you should:

1. Specify the radionuclide and its chemical and physical form;
2. State the maximum activity per type of container (vial, syringe, generator, or other container of the radioactive drug);

3. Describe the type and thickness of shielding that you will provide for each type of container; and
4. Indicate the maximum radiation dose rate to be expected at the surface of each transport radiation shield when the radioactive drug container is filled with the maximum activity.

The regulations in 10 CFR 32.72(a)(3) relate to information necessary for safe handling and storage of the final source container by medical use licensees, so it is not acceptable for you to say only that you will comply with Department of Transportation (DOT) regulations. DOT regulations apply to shipping. The dose rate limits of DOT regulations apply to the surface of the package, not the surface of the shielded syringe or vial.

10.1.4 Radioactive Drugs -- Licensing Criteria for Labeling

Your product labeling must fulfill the requirements of 10 CFR 20.1901 and 20.1904 and 10 CFR 32.72(a)(4) except for the exemptions in 10 CFR 20.1905.

Radioactive drug containers must be labeled in compliance with 10 CFR 20.1904 and 20.1905 and 10 CFR 32.72(a)(4).

In order to meet the requirements in 10 CFR 32.72(a)(4)(i), you must agree to label each transport radiation shield to show the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. The "transport radiation shield" could be constructed of lead glass, plastic, or other material, as appropriate for the isotope to be transferred for commercial distribution. The phrase "transport radiation shield" does not refer to the outer suitcase, package, packing, or other carrying device, even though that barrier may provide some radiation shielding. Also, the radiation symbol must be the same as described in 10 CFR 20.1901.

In order to meet the requirements in 10 CFR 32.72(a)(4)(ii), you must agree to label each syringe, vial, or other container (e.g., generators or ampules) used to hold radioactive drugs to be transferred for commercial distribution to show the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures the syringe, vial, or other container can be correlated with the information on the transport radiation shield label. The radiation symbol must be the same as described in

10 CFR 20.1901. Acceptable identifiers may include, but are not limited to, the lot number or the name of the radioactive drug or its abbreviation.

10.1.5 Generators -- Return Program

Some licensees offer a generator return program. In this program, customers may return used or spent generators to the licensee. Experience has shown that customers who do not ship radioactive materials frequently may not be familiar with the DOT regulations governing such shipments; the manufacturer's or distributor's instructions to customers have not been sufficiently detailed for these inexperienced shippers. As a result, when some spent generators were shipped back to the manufacturer or distributor, the shipment was not in accordance with applicable regulations.

10.1.5.1 Licensing Criteria. If you wish to offer a generator return program, the instructions (including instructions on labeling and shipping documents) you have developed and will supply to your customers should be sufficiently detailed to ensure that the shipper can comply with 10 CFR 71.5 and with DOT regulations. As a minimum, these instructions are to:

1. Establish the user's responsibility and liability as the shipper,
2. Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process, and
3. Discuss all the customer's responsibilities as a shipper under 49 CFR Parts 170 to 189.

10.1.5.2 Return Program Procedures. If you do not plan to offer a generator return program, so state and no additional information is necessary. However, if you plan to offer a generator return program, copies or facsimiles of all forms, labels, and instructions you will provide to customers for shipping the spent generators back to your facility should be provided. To avoid the problems experienced in the past by inexperienced shippers, you should ensure your instructions achieve the objectives outlined in items 1 through 3 above. The discussion of the customer's responsibilities mentioned in item 3 should include (but is not limited to):

- The requirements for surveying and wipe-testing the packages,

- The distance at which to survey packages,
- The action levels for the package wipe-test results,
- The dose rate limitations on the particular shipping label that you provide, and
- The need for sealing tape or another mechanism to fulfill the security seal requirement.

10.2 Sealed Sources

If you intend to distribute sealed sources to commercial nuclear pharmacy or medical use licensees, provide the information identified below.

10.2.1 Sealed Sources in Devices -- Licensing Criteria for Evaluation of Design and Construction

According to 10 CFR 32.74(a)(2)(i) to (vii), you must provide information that each sealed source (and device, if appropriate) to be distributed to commercial nuclear pharmacy or medical use licensees is designed and constructed to ensure containment of the radioactive material during normal use and likely accident situations. Both 10 CFR 32.74(a) and 32.210 require applicants to submit details of quality control procedures to ensure that production sources and devices meet the standards of the design and prototype test.

Applicants who request leak-test intervals of more than 6 months (as permitted by 10 CFR 32.74(b)) must justify the longer time interval based on (1) the performance of the sealed sources, devices, or similar sources or devices and (2) the design features that reduce the probability or consequences of leakage.

For each type of sealed source (and device, if appropriate) to be distributed to commercial nuclear pharmacy or medical use licensees, you should submit evidence that the source or device is either currently registered with NRC under 10 CFR 32.210 or an Agreement State, or it is currently under review by NRC or an Agreement State. (The information needed in support of a request for review of a sealed source or device may be submitted with the request for a medical distribution license. Include your request with your response to this item).

Regulatory Guides 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," and 10.11, "Guide for the Preparation of Applications for Radiation

Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material," may be used by applicants who wish to submit a source or device design for a safety evaluation and registration. This safety evaluation is required by 10 CFR 32.74 prior to the source or device being approved for distribution and use. These guides contain information on several areas:

- Applicable regulations.
- Information on filing an application, including where to file, how to determine the fees associated with the evaluation, how to handle proprietary information, other agencies that may be involved in the review process, and applicable transportation regulations.
- Information that should be included in the application and suggestions on the format in which the information should be arranged.
- Amendments to current registration certificates.
- The responsibility of the registrant once the safety evaluation has been performed and a registration certificate has been issued.

Both regulatory guides contain a checklist that may be used by applicants to ensure their submission is complete.

Applicants for registration of sources or devices may submit a quality assurance program instead of or in conjunction with quality control procedures. The quality assurance program should provide control over all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the source or device. Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," provides information necessary to establish and implement a quality assurance program that encompasses all the quality assurance and quality control provisions needed for the manufacture and distribution of a source or device.

10.2.2 Sealed Sources -- Labeling

10.2.2.1 Licensing Criteria. Your product labeling must fulfill the requirements of 10 CFR 20.1901, 20.1904, and 20.1905 and of 10 CFR 32.74(a)(2)(viii) and 32.74(a)(3).

A label, leaflet, or brochure accompanying the sealed source or device must contain appropriate instructions from a radiation safety standpoint for handling

and storing the source or device. For example, the instructions may specify the use of extremity monitors, the use of tongs or other devices (rather than bare hands) to pick up sources, storage within auxiliary shielding, and any special procedures needed in the handling and sterilizing of "fragile" sources (e.g., iodine-125 seeds).

A label, leaflet, or brochure must also contain the licensing statement required by 10 CFR 32.74(a)(3). For sources, the statement should read, "The (name of source or device) is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to [10 CFR 35.57, 35.400, or 35.500] or under equivalent licenses of Agreement States."

For each type of sealed source or device you intend to distribute, you should:

1. Submit copies or facsimiles of the labels that will accompany the product and specify where each label will be placed (e.g., on the device, on the source shield) and
2. Submit copies of all leaflets and brochures that will accompany the product.

For each type of source or device to be distributed, you should provide a copy of correspondence to and from the FDA that clearly shows that the FDA finds the source or device to be safe and effective or "substantially equivalent" to sources or devices offered for sale in the United States before May 1976.

(Note: An NRC registration will not be issued unless the applicant has submitted to the NRC a substantially equivalent letter pursuant to Section 510(K) of the Food, Drug, and Cosmetic Act, as amended, or a similar indication of premarketing approval by FDA.)

Devices and sources used in conjunction with medical applications involving computers and patient planning systems are within FDA jurisdiction and must also have a substantially equivalent letter pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act, as amended, or a similar indication of premarketing approval by FDA.

10.2.2.2 FDA and NRC Coordination. FDA and NRC signed a Memorandum of Understanding on August 26, 1993, to coordinate existing FDA and NRC regulatory programs for medical devices, drugs, and biological products that make use of byproduct, source, or special nuclear materials. The principal statute under which the FDA regulates devices is the Food, Drug and Cosmetic Act, as amended by the Safe Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices Act of 1992.

Under the Memorandum of Understanding, the agencies agree to promptly inform each other whenever they receive a report or otherwise become aware of potential public health problems involving products of mutual regulatory concern. Further, the agencies will share information to the extent practicable. For the NRC's Office of Nuclear Materials Safety and Safeguards (NMSS), this includes information on the design, manufacture, testing, quality assurance and control, etc., used by FDA and NRC for its product approval.

10.2.3 Sealed Sources -- Return Program and Device Service

10.2.3.1 Experience with Returns.

Some licensees offer a source return program or a device service or both. In this program, customers may return unused sources for credit or may return used sources or devices, for disposal, service, or replacement. Similar programs have been offered by manufacturers of other products. Experience with these other products indicates that customers who do not ship radioactive materials frequently are often not familiar with Department of Transportation (DOT) regulations governing such shipments. Unless the manufacturer's or distributor's instructions to customers were sufficiently detailed for these inexperienced shippers, some shipments were not in accordance with applicable regulations. Similar problems may arise with sealed sources or devices that are being returned.

10.2.3.2 Licensing Criteria. If you do not plan to offer a source return program or device service, so state and no additional information is necessary. However, if you offer a source return program or device service, you must have developed and must supply to your customers sufficiently detailed instructions (including instructions on labeling and shipping documents) to ensure that the shipper can comply with 10 CFR 71.5 and with DOT regulations. You must also submit to NRC copies or facsimilies of all forms, labels, and instructions that

you will provide to customers for shipping sources back to your facility. As a minimum, the instructions must:

1. Establish the user's responsibility and liability as the shipper,
2. Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process, and
3. Discuss all the customer's responsibilities as a shipper under 49 CFR Parts 170 to 189. This discussion of the customer's responsibilities should include (but is not limited to):
 - The requirements to survey and wipe-test packages,
 - The distance at which to survey packages,
 - The action levels for the package wipe-test results,
 - The dose rate limitations on the particular shipping label that you will provide, and
 - The need for sealing tape or another mechanism to fulfill the security seal requirement.

10.2.4 Calibration of Reference Sources -- Compatibility with 10 CFR 35.57 Licensing Criteria

You must request authorization to distribute calibration or reference sources that are described in 10 CFR 35.57. These calibration or reference sources must not exceed the activity limits of 10 CFR 35.57, and according to 10 CFR 32.74, you must confirm this in your license application.

If a source to be distributed contains byproduct material exceeding the activity limits of 10 CFR 35.57, source material, or special nuclear materials, it may not be distributed to medical licensees under the provisions of 10 CFR 35.57. In such cases, medical use licensees may purchase such sources only if their licenses specifically authorize possession and use of them. In these cases, you may not use a license issued under 10 CFR 32.74 to distribute the sources; rather, you need a license issued pursuant to 10 CFR Part 30, 40, or 70, as appropriate, that authorizes you to distribute such sources to your proposed customers. Contact the NRC licensing staff to explain your situation and to obtain further guidance.

Item 11 - WASTE MANAGEMENT

Enter "Not applicable." No response is needed because the license, when issued, will authorize only distribution to commercial nuclear pharmacy and medical use licensees. Possession and use of licensed material is authorized in a separate license that includes a description of your waste management program if you intend to accept waste from clients.

Item 12 - LICENSE FEES

An application fee paid in full is required by 10 CFR 170.12(a) for most distribution licenses, including applications for license amendments and renewals. Refer to 10 CFR 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services, Including Inspections, and Import and Export Licenses," to determine the amount of the fee that must accompany the application. The NRC will not issue the new license, amendment, or renewal before receipt of the appropriate fee. All application fees will be charged regardless of the NRC's disposition of your application or your withdrawal of the application.

Note that, in addition to the licensing fees described in 10 CFR 170.31, most NRC licensees are also subject to annual fees (see 10 CFR 171.16). Section 171.11 provides additional information on exemptions from annual fees. Paragraph 171.16(c) permits reduced annual fees for licensees qualifying as "small entities" under NRC size standards (10 CFR 2.810).

All questions about NRC's fees should be directed to the Office of the Controller (OC) at NRC's headquarters office in Rockville, Maryland. OC's telephone number is (301)415-7554.

Item 13 - CERTIFICATION

An application must be dated and signed by a representative of the corporation or legal entity who is authorized to sign official documents and to certify that it contains information that is true and correct to the best of his or her knowledge and belief. Unsigned applications will be returned for proper signature.

Correspondence to the NRC from the applicant should be signed by the certifying official named in Item 13. The NRC will send correspondence to that official. Commitments made by the applicant must be signed by the official listed in Item 13.

4. AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application and correspondence with the NRC, (2) the terms and conditions of the license, and (3) the NRC's regulations.

It is your obligation to keep your license current. You should anticipate the need for an amendment insofar as possible. If any of the information provided in your application or other correspondence is to be modified or changed, submit an application for an amendment. This includes making changes or modifications to the information submitted to obtain a sealed source and device registration certificate. In the meantime, you must comply with the terms and conditions of your license until it is actually amended; NRC regulations do not allow you to implement changes on the basis of a submission requesting an amendment to your license.

An application for an amendment to a license may be prepared either on the application form (NRC Form 313, see Appendix A) or in letter form and should be submitted in duplicate to the address specified in this guide in Figure 1 and in 10 CFR 30.6. Also retain a copy for yourself, because the license will require that you distribute the authorized items in accordance with the statements and representations in your application and in any supplements to it. Your application or letter should identify your license by number and clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph.

The most frequently requested amendments to medical distribution licenses are for either changes and modifications to an old product or the addition of a new product. In those cases, you should submit the information requested in Items 5, 6, and 10 for the changes or the new product.

You must send the appropriate fee for an amendment with your application or letter. As stated in 10 CFR 170.12, each application for which a fee is

required, including applications for license amendments and renewals, must be accompanied by the appropriate fee. Refer to 10 CFR 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services, Including Inspections, and Import and Export Licenses," to determine the amount of the fee that must accompany your application. The NRC will not issue the new license, amendment, or renewal before receipt of the appropriate fee. All application fees will be charged regardless of the NRC's disposition of your application or your withdrawal of the application.

All questions about NRC's fees should be directed to the Office of the Controller (OC) at NRC's headquarters office in Rockville, Maryland. OC's telephone number is (301)415-7554.

5. RENEWAL OF A LICENSE

The expiration date appears on your license. If you file an application for renewal of your license at least 30 days before the expiration date of your license and include the appropriate fee for renewal, your license will automatically remain in effect until the NRC takes final action on your application. However, if you file an application less than 30 days before the expiration date and the NRC cannot process it before that date, you could be without a valid license when it expires.

Send an application for renewal to the address specified in this guide in Figure 1 and in 10 CFR 30.6.

If your original application predates this guide, submit an entirely new application for renewal as if it were an application for a new license without referring to previously submitted information.

If your original application was prepared in accordance with this guide, you may use the following:

1. Review your current license to determine whether the information about distribution of various items to commercial nuclear pharmacy and medical use licensees accurately represents your current and anticipated program. Identify any necessary additions, deletions, or other changes and then prepare information appropriate for the required additions or changes.

2. Review the documents you submitted in the past to determine whether the information in them is up to date and accurately represents your packaging,

shielding, labeling, and other information pertinent to your program. Identify by date the documents you consider to represent your current program. Any out-of-date and superseded documents should also be identified, and changes should be made in the documents as necessary to reflect your current program.

3. Review NRC regulations to ensure that any changes in the regulations are appropriately covered in your program description.

4. After you have completed your review, submit a letter to the NRC in duplicate (also retain a copy for yourself), with the proper fee, requesting renewal of your license and providing the information specified in items 1, 2, and 3 above, as necessary.

5. Include the name and telephone number of the person to be contacted about your renewal application and include your current mailing address if it is not indicated correctly on your license.

It is important that the appropriate fee accompany your application for renewal of your license. The NRC will not issue the renewal before receipt of the appropriate fee.

6. TERMINATION OF A LICENSE

This license does not authorize the possession and use of byproduct material. Therefore, termination of your distribution license only requires a letter notifying NRC of the termination. If you are also terminating your possession license, 10 CFR 30.36(b) requires that a licensee notify the NRC promptly and request termination of the license. This notification normally requires (1) a completed form NRC-314, "Certificate of Disposition of Materials," certifying that all sources have been disposed of properly and (2) the results of a final radiation survey of the premises where the licensed activities were carried out.

(7-96)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this information collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Forward comments regarding burden estimate to the Information and Records Management Branch (T-8 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0189

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA,
OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH,
WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 78011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

☐
☐
☐

A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER _____

C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (include Zip code)

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL.

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY

AMOUNT
ENCLOSED \$

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

SIGNATURE

DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

DRAFT VALUE/IMPACT STATEMENT

1. BACKGROUND

Among the licenses issued by the Nuclear Regulatory Commission (NRC) are those authorizing distribution of byproduct material in the form of radioactive drugs and sealed sources to NRC's commercial nuclear pharmacy and medical use licensees. Medical use licensees are physicians, podiatrists, dentists, and medical institutions licensed pursuant to 10 CFR Part 35, for medical use, as defined in 10 CFR 35.2.

The NRC issued a draft regulatory guide, FC 406-4, in February 1985 that proposed guidance for preparing applications for medical distribution licenses that were filed on Form NRC-313. This guidance was never finalized and NRC significantly changed 10 CFR 32.72 and deleted Section 32.73 in 1995. Specifically, radionuclide generators are now included as a radioactive drug in 10 CFR 32.72 and the manufacture and distribution of reagent kits are no longer regulated because such kits do not contain byproduct material. Therefore, the NRC staff needed to issue valid, up-to-date guidance.

2. PROPOSED ACTION

2.1 Description

An applicant for a medical distribution license must develop a program that complies with NRC regulations and describe this program in the application. The proposed action is to issue a regulatory guide that provides guidance on establishing a program to meet NRC regulatory requirements for a medical distribution license. The proposed action would provide guidance for preparing license applications in conformance with the revised NRC Form 313.

2.2 Need

The regulatory changes to 10 CFR 32.72 and the deletion of Section 32.73 from 10 CFR Part 32 necessitate new guidance for NRC Form 313.

2.3 Value/Impact

2.3.1 NRC

The review and approval of applications would be facilitated by the instructions and guidance provided in the new regulatory guide. The proposed action would clearly list the regulations to be followed and the information required for licensing and implementing an acceptable program for distribution of various items to NRC's commercial nuclear pharmacy and medical use licensees. Staff review time would be shortened because less correspondence would be needed to compensate for a lack of sufficient detail in applications for licenses.

2.3.2 Other Government Agencies

Other government agencies will not be affected.

2.3.3 Industry

The proposed action would contribute to a reduction in time required for preparing medical distribution applications. Applicants would spend less time trying to interpret NRC regulations and requirements for information. More importantly, the proposed action would provide information for more effective product radiation safety design, thereby minimizing the exposure of workers to radiation.

2.3.4 Public

No impact on the public is foreseen.

2.3.5 Worker

The worker would benefit from the proposed action through reduced exposure to radiation as discussed in Item 2.3.3.

2.4 Decision on Proposed Action

A new regulatory guide should be prepared to provide guidance to applicants for the preparation of applications to distribute various items to commercial nuclear pharmacy and medical use licensees.

3. TECHNICAL APPROACH

Not applicable.

4. PROCEDURAL APPROACH

4.1 Alternatives

The alternative is to provide no specific guidance to applicants and to write individual letters to applicants.

4.2 Discussion

A regulatory guide is the most effective way to transmit information about regulations and licensing requirements. A regulatory guide ensures uniform transmission of information to applicants. Individual letters would be inefficient and, depending on the reviewing official, may not uniformly convey the same information to each applicant. Issuance of a regulatory guide is the most effective alternative.

5. STATUTORY CONSIDERATION

5.1 NRC Authority

Authority for the proposed action is derived from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended, and implemented through the Commission's regulations.

5.2 Need for NEPA Assessment

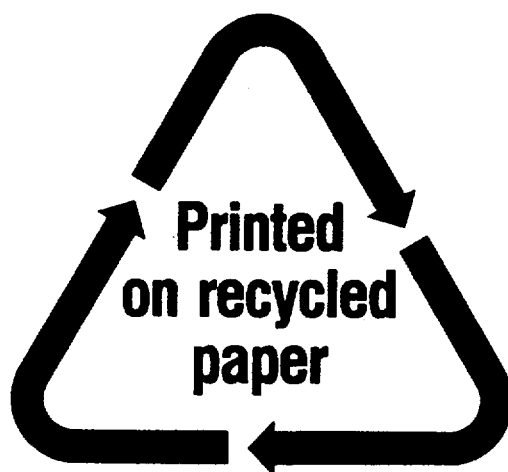
Issuance of guides for the implementation of regulations in Title 10, Chapter I, of the Code of Federal Regulations is a categorical exclusion under 10 CFR 51.22(c)(16). Thus, an environmental impact statement or assessment is not required for this action.

6. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

No conflicts or overlaps appear to exist.

7. SUMMARY AND CONCLUSIONS

The regulatory guide, when disseminated, will assist the NRC in its review of applications for medical distribution licenses and will provide applicants with guidance on submitting applications that conform to the new regulations. The proposed regulatory guide should be issued.



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NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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