Revision 1
December 1988

U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 10.9
(Task FC 402-4)

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR THE USE OF SELF-CONTAINED DRY SOURCE-STORAGE GAMMA IRRADIATORS

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

Written comments may be submitted to the Regulatory Publications Branch, DFIPS, ARM, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The guides are issued in the following ten broad divisions:

1. Power Reactors
2. Research and Test Reactors
3. Fuels and Materials Facilities
4. Environmental and Siting
5. Materials and Plant Protection
6. Products
7. Transportation
8. Occupational Health
9. Antitrust and Financial Review
10. General

Copies of issued guides may be purchased from the Government Printing Office at the current GPO price. Information on current GPO prices may be obtained by contacting the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013-7082, telephone (202)275-2060 or (202)275-2171.

Issued guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161.

TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

1. INTRODUCTION

1.1 GENERAL

The Nuclear Regulatory Commission (NRC) issues specific licenses that authorize the use of byproduct material in gamma irradiators. Gamma irradiators are used for a variety of purposes in research, industry, and other fields. Typical uses are:

1. Sterilization or microbiological reduction of medical and pharmaceutical supplies
2. Preservation of foodstuffs
3. Radiation effects studies
4. Chemical and polymer synthesis and modifications
5. Insect eradication through sterile male release programs.

To obtain a specific license for a gamma irradiator, file an application on NRC Form 313, "Application for Material License." The application for a license will be approved if, among other things, (1) the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property and (2) the applicant is qualified by training and experience to use the radioactive material for the purpose requested in such a manner as to protect health and minimize danger to life or property.

For purposes of providing guidance to applicants for licenses, the NRC divides gamma irradiators into two groups. The first group includes self-contained dry source-storage gamma irradiators and is the subject of this Revision 1 to Regulatory Guide 10.9. The second group includes all other irradiators, and licensing guidance for this second group is being developed (see draft regulatory guide Task FC 403-4, "Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-Contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators").

The American National Standards Institute (ANSI) has developed and published safety standards for gamma irradiators. Under the ANSI system for considering basic safety requirements, all gamma irradiators are divided into four general categories of irradiators. ANSI Standard N433.1, "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I),"* deals with the same type of irradiator that is dealt with in this Regulatory Guide 10.9.

As defined in ANSI Standard N433.1, a Category I irradiator is an irradiator in which the sealed source (or sources) is completely contained in a dry container constructed of solid materials and is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is not physically possible in its designed configuration.

Depending on the particular design, the radiation source within the irradiator may be in a fixed position or the radiation source may be movable. In the latter case, interlocks are used to ensure that the source does not move into a

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

position that, during normal use of the irradiator, may cause a radiation hazard to any individual. Proper functioning of the interlocks ensures that shielding is in place. Bypassing or failure of an interlock could cause persons to be exposed to very high levels of radiation.

Category I gamma irradiators typically contain several hundred to several thousand curies of Cs-137 or Co-60 and range in weight from several hundred to several thousand pounds.

1.2 PURPOSE OF GUIDE

The purpose of this regulatory guide is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments, and license renewals for the use of self-contained, dry source-storage gamma irradiators (also known as Category I irradiators).

It has been NRC's practice to issue licenses that provide only for the use of one or more Category I irradiators. This administrative practice conveniently permits consideration of the few, but important, items essential to the safe use of Category I irradiators. An exception to this practice is the authorization for use of Category I irradiators under Type A specific licenses of broad scope. As provided in § 33.17 of 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," devices containing up to 100,000 curies of byproduct material in sealed sources used for irradiation of materials may be included on Type A licenses of broad scope.

Section 3 of this guide describes the information that is expected in an application for use of a Category I irradiator under a Type A license of broad scope.

1.3 APPLICABLE REGULATIONS

NRC regulations applicable to Category I Irradiators are in 10 CFR Part 19, "Notices, Instructions, and Reports to Workers; Inspections"; 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 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"; 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"; and 10 CFR Part 170, "Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended."

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 Freedom of Information and Publications Services, Office of Administration and Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or from your NRC Regional Office that is identified in Figure 1. 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.

This guide identifies the information needed to complete NRC Form 313 when applying for a license for the use of a self-contained, dry source-storage gamma

NRC REGIONAL OFFICES

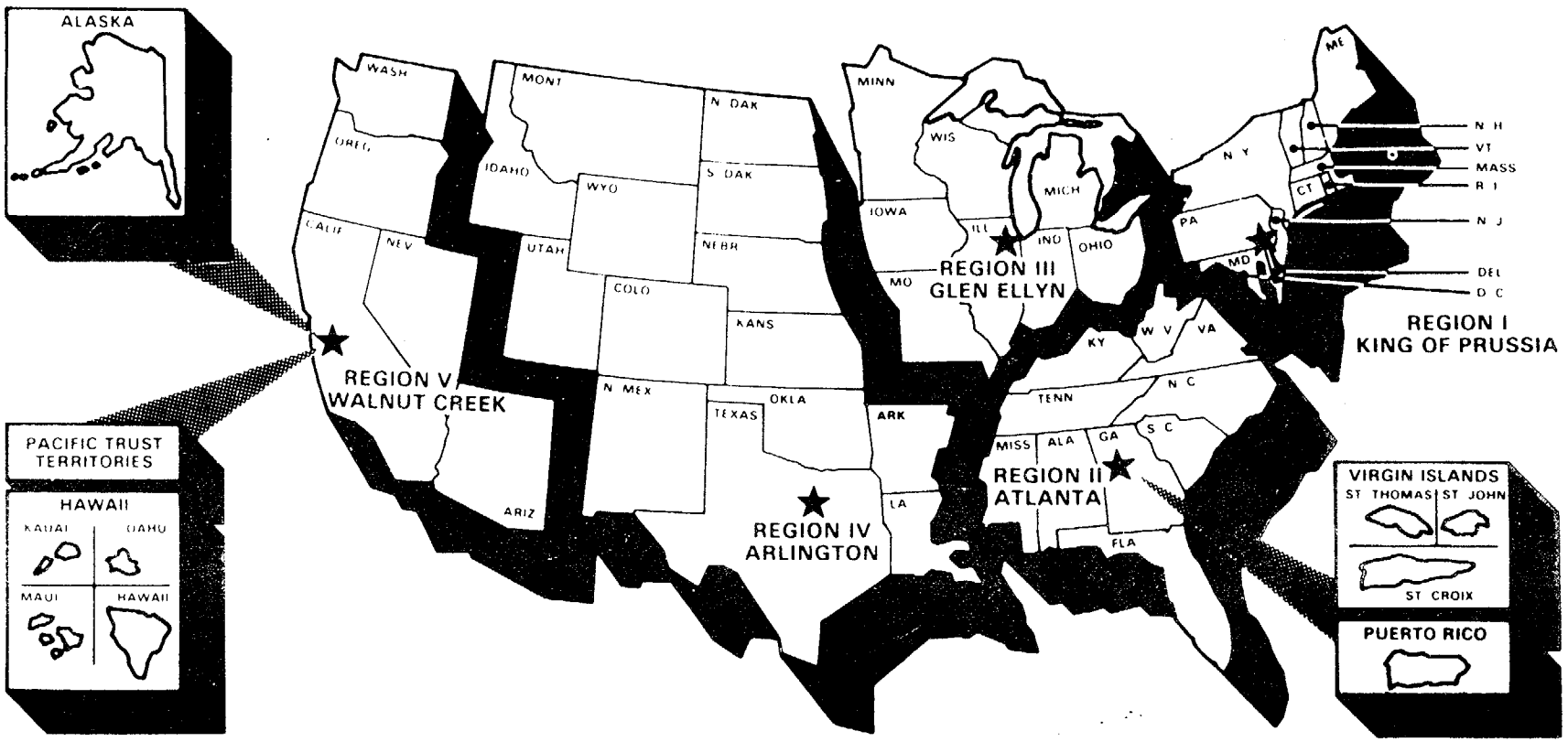

Figure 1

10.9-3

United States Nuclear Regulatory Commission

Region	Address	Telephone
I	475 Allendale Road, King of Prussia, Pennsylvania 19406	215-337-5000
II	101 Marietta St., Suite 3100, Atlanta, Georgia 30323	404-331-4503
III	799 Roosevelt Road, Glen Ellyn, Illinois 60137	312-790-5500
IV	611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011	817-860-8100
V	1450 Maria Lane, Suite 210, Walnut Creek, California 94596	415-943-3700

irradiator. The information collection requirements in NRC Form 313 have been cleared under OMB Clearance No. 3150-0120.

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

2. FILING AN APPLICATION

2.1 WHERE TO FILE

If you wish to possess or use licensed material on Federal property or in any State subject to NRC jurisdiction, you should file your application with the NRC Regional Office for the State in which the material will be possessed or used. The five Regional Offices and their respective areas for licensing purposes are given in Figure 1.

Twenty-nine States to date have entered into agreements with the NRC that give them the authority to license radioactive materials used or possessed within their borders. These States are called Agreement States and are shown in Figure 2. A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional Offices or from the Medical, Academic and Commercial Use Safety Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555. If you are a non-Federal organization that wishes to possess or use licensed material in one of these Agreement States, you should contact the responsible officials in that State for guidance on preparing your application and your application should be filed with the State officials and not with the NRC.

2.2 HOW TO FILE

You, as the applicant for a materials license issued by the NRC, should complete NRC Form 313 (see Appendix A to this guide). You should complete Items 1 through 4, 12 and 13, and Item 14 (if you so choose) on the form itself. For Items 5 through 11, submit the required information on supplementary pages. Each separate sheet or document submitted as part of the application should be identified and keyed to the item number on the form 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 equipment, facilities, training and experience,

AGREEMENT STATE PROGRAM

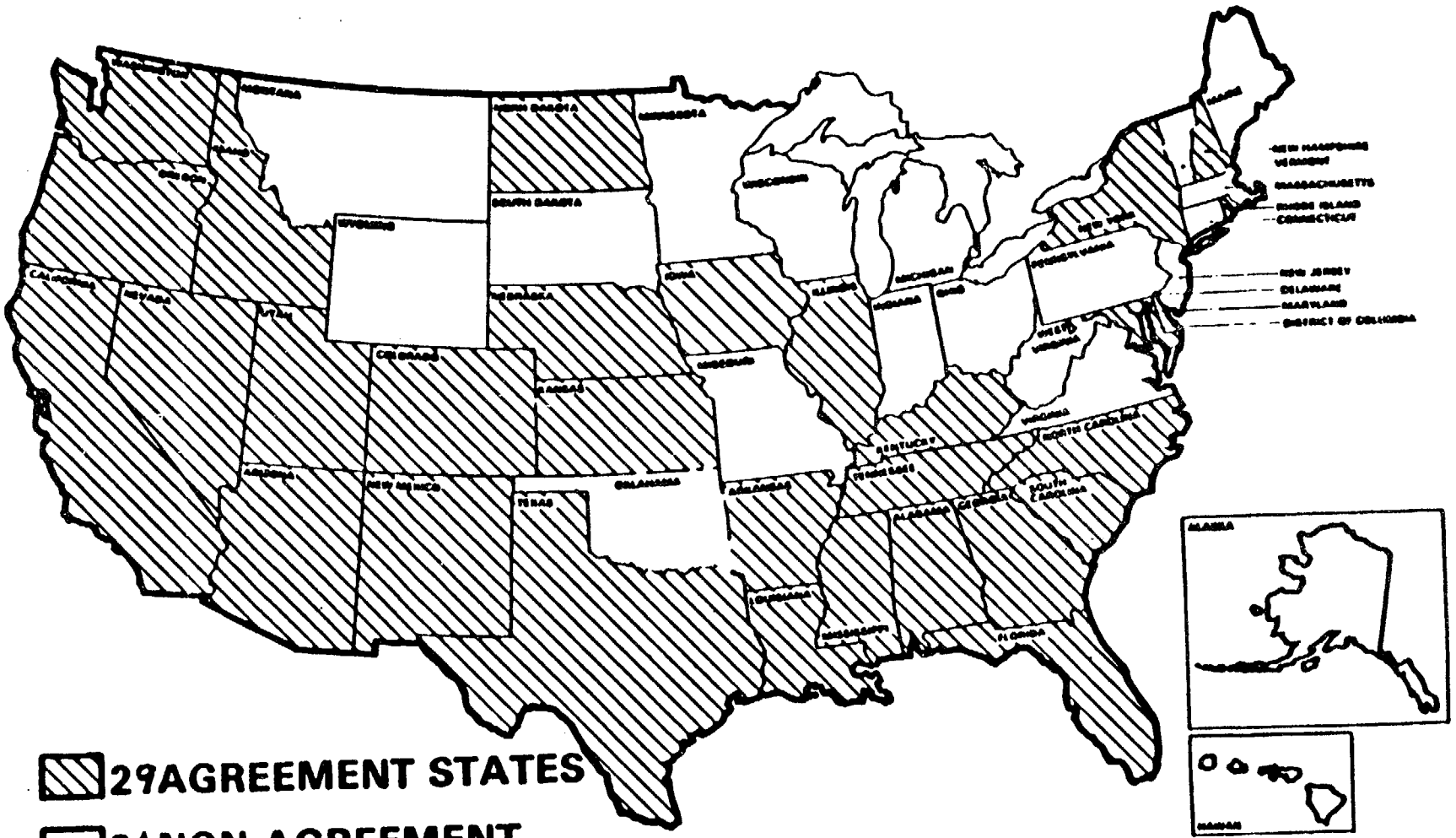

Figure 2

and radiation safety program are adequate to protect health and minimize danger to life or property.

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 § 2.790 of 10 CFR Part 2. 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, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should not be submitted. Dates of birth, Social Security numbers, and radiation dose information should be submitted only if specifically requested by NRC.

You should prepare your application in triplicate because you must file your application in duplicate. Retain one copy for yourself, because the license will require that you possess and use the licensed material in accordance with the statements and representations in your application and any supplements to it as well as with the requirements in the regulations.

3. CONTENTS OF AN APPLICATION

This portion of the guide comments, item by item, on the information requested on NRC Form 313 (Appendix A). If you have specific questions after reviewing this guide, contact the NRC material licensing staff at the appropriate Regional Office.

If you plan to use the irradiator under a Type A specific license of broad scope (defined in paragraph 33.11(a) of 10 CFR Part 33), subitems 10.1 about personnel monitoring, 10.2 about radiation survey instruments, 10.3 about leak testing, and Item 11 about waste management may be completed adequately by referring to the comprehensive radiation safety program for the broad scope license. This suggested action is particularly appropriate for a request for amendment of a Type A specific license to add a self-contained irradiator.

Item 1 - LICENSE INFORMATION

For a new license for an irradiator, check subitem A. For an amendment of an existing license for an irradiator or a Type A license of broad scope to add an irradiator, check subitem B. For a renewal of an existing license for an irradiator, check subitem C.

Item 2 - NAME AND MAILING ADDRESS OF APPLICANT

The applicant should be the corporation or other legal entity applying for the license. If you are an individual, you may be an applicant only if you are acting in a private capacity and the use of the irradiator is not connected with your employment by a corporation or other legal entity.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the irradiator will be used, as specified in Item 3.

Item 3 - LOCATION OF USE

You should specify each location of use by the street address, city, and State or other descriptive address (such as 5 miles east on Highway 10, Anytown, State) to allow us to easily locate your facilities. A Post Office box address is not acceptable. If irradiators are to be used at more than one location, you must give the specific address of each location. In Items 5 through 11 of the application, describe the intended use and the facilities and equipment at each location.

Item 4 - PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the person who knows your proposed program for the Category I gamma irradiator and can answer questions about your application. This person, usually the radiation safety officer (RSO) or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this person does not work for you full time, please specify his or her position and relationship to your firm. You should notify the NRC if the individual assigned to this function changes. Notification of a contact change is for information only and would not be considered an application for license amendment. A license amendment would be needed if the new contact person also is to be added to your program as an RSO or a principal user.

Item 5 - RADIOACTIVE MATERIAL TO BE POSSESSED

You should specify the radionuclide (e.g., Co-60), the number of curies per source (e.g., 750 curies), the name of the source manufacturer, the model number of the source (e.g., Able Company, Sealed Source Model Z-24), total number of sources in the irradiator (e.g., 8), and the maximum amount of Co-60 that will be possessed in the irradiator at any one time (e.g., 6,000 curies).

NOTE: You should be able to obtain the above information from the supplier of the irradiator. When contacting your supplier, you should determine whether safety information on the particular model source has been registered with the NRC or an Agreement State. Section 32.210 of 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material," allows a manufacturer to register safety information about a product. That registered information can then be used in NRC's consideration of license applications from the manufacturer's customers. If your manufacturer has not registered information about the source and does not intend to register, then you as the applicant for a license are required (by § 30.32 of 10 CFR Part 30) to submit detailed safety information on the source as identified in paragraph 32.210(c). If you need to prepare this detailed information, you are encouraged to follow the guidance in Regulatory Guide 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material."

Item 6 - PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

Specify the purpose for which the licensed material will be used (e.g., to be used in a Baker Company Model B-25 gamma irradiator for insect eradication through sterile male release programs.)

NOTE: As discussed above in Item 5 for the source, if your supplier has not registered safety information about the irradiator with NRC or an Agreement State, you must submit the detailed information identified in paragraph 32.210(c) of 10 CFR Part 32. If you need to prepare this detailed information, you are encouraged to follow the guidance in Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material."

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

Among the general requirements for issuance of specific licenses (see § 30.33 of 10 CFR Part 30) is the requirement that your staff (the users, supervisors of users, and radiation safety officer for an institutional applicant) must be qualified by training and experience to use the material for the purpose requested in such a manner as to protect health and minimize danger to life or property. The information you present in Items 7 and 8 of your application should show how you will satisfy this requirement.

In Item 7, you should state the name, training, and experience of each person responsible for the radiation safety program for the irradiator. The qualifications of each person (who may have a title such as radiation protection officer, radiological protection officer, supervisor, senior operator) should show that he or she will be familiar with:

1. The basic design, operation, and preventive maintenance of the irradiator.
2. The principles and practices of radiation protection.
3. The biological effects of radiation.
4. The written procedures for routine and emergency irradiator operations.
5. Your application for a license, your license, and regulations of NRC.

A person with a background in radiation protection (e.g., a person appointed as a radiological safety officer under paragraph 33.13(c)(2) or 33.14(b)(1), or as a user under paragraph 33.15(b), or an individual meeting the training and experience requirements of paragraph 35.900(a) or (b) for a radiation safety officer) and specific instruction on the particular model irradiator to be obtained (or a similar model) should have adequate training and experience. How the specific instruction was or will be obtained should be described for each person named in Item 7. Specific instruction on the irradiator should show that, under the supervision of a knowledgeable person, the named person has used the irradiator or a similar irradiator to perform several irradiations of samples. This knowledgeable person might be the irradiator manufacturer's representative or another experienced operator.

Although unlikely, an applicant may designate in Item 7 a person who has no previous training or experience in radiation protection or irradiator operation. In such case, the applicant should state where and from whom the individual will receive training in radiation protection (e.g., a basic radiation protection course of at least 3 days) and on-the-job training in operating an irradiator (e.g., a minimum of 2 days of supervised work at a licensed irradiator) prior to receipt of the irradiator by the applicant. Acceptable training and experience also may be obtained at an irradiator manufacturer's course consisting of a combination of radiation safety lectures, classroom exercises, written tests, and hands-on work on self-shielded irradiators.

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

According to § 19.12 of 10 CFR Part 19, all individuals who work in or frequent restricted areas must be instructed in the health protection problems associated with exposure to radioactive material. In addition, persons who actually work with radioactive material should receive training in the safe use of radioactive material.

You should submit a general description of the training you will provide to all persons working in or frequenting your restricted areas and provide more specific information about the training of irradiator operators.

Persons who will operate the irradiator under the supervision of a responsible individual (named in Item 7) do not need to be designated by name; however, the following should be submitted.

1. An outline of the training program for these persons, including the topics that will be covered. Topics expected to be included in the training program are (1) the principles and fundamentals of radiation safety and good safety practices related to the use of radioactive materials, (2) the use of radiation detection instruments, and (3) the design and operation of the irradiator. This training usually is several hours long and may be covered in part by instructions provided to workers to meet the requirements of § 19.12 of 10 CFR Part 19.

2. A means of evaluating the understanding of the individuals who have completed the training program. One acceptable technique is to use a written examination of about 25 multiple-choice questions with all aspects of the training program covered. You should describe in your application how you will determine the trainee's understanding of the subject.

3. A discussion of the on-the-job training that will be given to trainees. The training should consist of a minimum of several complete irradiation procedures by the trainee under close supervision by a responsible individual specified in Item 7.

4. The name of the training instructor. If this person is not a responsible individual specified in Item 7, submit this person's qualifications. The minimal qualifications for an instructor should be the same as those of an individual specified in Item 7.

5. A commitment that records documenting the training of each individual will be maintained.

Item 9 - FACILITIES AND EQUIPMENT

Paragraph 30.33(a)(2) of 10 CFR Part 30 states that an application will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and to minimize danger to life or property. As indicated above, information about the sealed source and irradiator should be presented in Items 5 and 6 of your application. Present information about the space where the irradiator will be located here in Item 9.

You should briefly describe the space where the irradiator will be located and comment on (a) control of access to the radioactive material by unauthorized persons and (b) fire protection considerations.

Regarding control of access to the radioactive material, if the irradiator will be located in a room that can be locked to prevent access by unauthorized persons, you need only repeat this statement in your application in a manner that constitutes a positive commitment. If the irradiator will not be located in a room that can be locked, you should explain how the requirements of § 20.207 of 10 CFR Part 20 will be met. Section 20.207 states that licensed materials in an unrestricted area must be secured from unauthorized removal from the place of storage and that licensed materials in an unrestricted area and not in storage must be under the constant surveillance and immediate control of the licensee.

Regarding fire protection, you should confirm that the room where the irradiator will be located will be equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) that is adequate to ensure the integrity of the irradiator and source in a fire. Alternatively, you should describe the conditions (e.g., ground floor location in fire-resistant building with little combustible material) and other controls (e.g., coordination with and training of fire-fighting personnel) that ensure a very low level of radiation risk attributable to fires.

Item 10 - RADIATION SAFETY PROGRAM

10.1 Personnel Monitoring Equipment

Section 20.202, "Personnel Monitoring," of 10 CFR Part 20 requires that personnel monitoring equipment be used by individuals (other than minors) entering restricted areas who receive, or are likely to receive, a dose in excess of 25% of the dose specified in paragraph 20.101(a). The specified doses per calendar quarter are 1-1/4 rems to the whole body, head and trunk, active blood-forming organs, or gonads; 18-3/4 rems to the hands and forearms or feet and ankles; and 7-1/2 rems to the skin of the whole body.

Individuals under 18 years of age need to use personnel monitoring equipment if they receive, or are likely to receive, a dose in excess of 5% of the specified doses in paragraph 20.101(a). The dose limits for minors are 10% of the specified doses in paragraph 20.101(a).

In determining the need for personnel monitoring equipment, you should consider both the doses related to the irradiator and the doses from other sources of radiation.

For various reasons, including the requirements in § 20.202, most licensees require their personnel to wear either a film badge or a thermoluminescence dosimeter (TLD) when they use the irradiator. Assuming that you propose to use such equipment, state the type of equipment (film badge or TLD) you will use and the frequency at which the film badges or TLDs will be changed. The frequency of change should be at least monthly for film badges and quarterly for TLDs.*

Some licensees elect to use direct-reading pocket dosimeters. If you propose to use this type of personnel monitoring equipment, you should state the range of the dosimeters and describe your program for their use. It is expected that the dosimeters have a range from zero to at least 200 milliroentgens, be worn by only one individual between readings, and be checked at periods not to exceed one year for correct response to radiation. Acceptable dosimeters should read within ± 30% of the true radiation exposure. If an individual's pocket dosimeter is discharged beyond its range, your program should prescribe action to evaluate the individual's dose.

10.2 Radiation Detection Instruments

Paragraph 20.201(b) of 10 CFR Part 20 requires the performance of such surveys as are necessary to evaluate the extent of radiation hazards that may be present and to comply with regulatory requirements. In order to perform appropriate surveys, you need to have operable, calibrated instrumentation.

State that you will have available for use a calibrated, operable survey meter that can measure up to several hundred milliroentgens per hour. You do not need to name the manufacturer or the model number of the survey meter. The reasons for the survey meter are the need to determine normal radiation levels near the irradiator, in the room housing the irradiator and in adjacent unrestricted areas, and the need to detect radiation levels that may indicate safety interlock and shielding failure, sealed source displacement, or sealed source failure with a resultant spread of contamination.

In order to perform adequate surveys, instruments must be operable and calibrated with an appropriate radiation source. State that the instrument will (1) be calibrated so that the readings are within ± 20% of the actual values over the range of the instrument and (2) be calibrated at least annually and after servicing (other than a simple battery exchange). Also state that calibration records will be kept for a minimum of 2 years after each calibration, and identify your selected means of calibration. There are three options for calibration:

1. If the instrument will be returned to the manufacturer for calibration, so state.

2. If a contractor will perform the calibration, state the name and address of the firm and its NRC or Agreement State license number.

*As of February 12, 1988, § 20.202 of 10 CFR Part 20 requires whole body personnel dosimetry devices such as film badges and TLDs to be processed by processors that have been accredited by the National Voluntary Laboratory Accreditation Program of the National Bureau of Standards.

3. If the instrument will be calibrated in-house, provide the experience and training in instrument calibration of each named person who will perform the calibrations and the methodology to be used.

10.3 Leak-Testing

As a licensee, you must perform such tests as the NRC deems appropriate or necessary pursuant to § 30.53, "Tests," of 10 CFR Part 30. Tests to determine if there is any leakage from the sealed sources in the irradiator are necessary and must be performed at intervals not to exceed 6 months. The measurement of the leak-test sample should be a quantitative measurement and must be sufficiently sensitive to detect 0.005 microcurie of activity.

The options for leak-testing are:

1. Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.

2. Use a commercial leak-test kit. You take the sample and send the sample to the kit supplier, which reports the results to you.

3. You perform the entire leak-test sequence, including taking the sample and measurement.

For option 1, specify the name, address, and license number of the consultant or commercial organization.

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier. State if the test samples will be taken by the individual specified in Item 7 who is responsible for the irradiator program. If another irradiator operator will take the test sample, instructions for taking the sample should be included in your operating and emergency procedures. Include in the instructions a requirement that any indication of possible source leakage should be reported to the individual responsible for the irradiator program for appropriate action.

For Option 3, state whether the test sample will be taken and measured by the individual specified in Item 7 who is responsible for the irradiation program. If another irradiator operator will take the test sample and make the measurement, instruction for those tasks should be included in your operating and emergency procedures. You should commit to use of an instrument capable of quantitatively measuring 0.005 microcurie or more activity; however, it is not necessary to identify the instrument in your application. If you also hold a specific license of broad scope issued pursuant to 10 CFR Part 33, state that the leak-test sequence will be performed by or under the supervision of the radiological safety officer (appointed pursuant to paragraph 33.13(c)(2) or 33.14(b)(1)) or by or under the supervision of individuals satisfying the requirements of paragraph 33.15(b).

10.4 Operating and Emergency Procedures

You should provide your personnel with written operating and emergency procedures and you should state in your application that the written procedures

will be provided to each person who uses the irradiator. The operating procedures should be maintained at the control station, and the emergency procedures should be conspicuously posted in the area. It is not necessary to submit the detailed operating and emergency procedures to the NRC. However, you should list the topics covered in your procedures, and you should state that these procedures include instructions in the following topics and will be available prior to use of the irradiator.

1. Step-by-step procedures for operation of the irradiator. Information may be extracted from the irradiator manufacturer's manual.

2. Determination and recording of radiation doses to persons operating the irradiator.

3. The methods to ensure that only authorized persons will use the irradiator.

4. Inspections, test procedures, and maintenance to ensure that all safety interlocks, devices, and components associated with the irradiator are functioning properly. Prohibited modifications (for example, changing the safety control system or removing the source) should be stated.

5. Emergency situations, e.g., when a survey reveals abnormal radiation levels around the irradiator, personnel should leave the irradiator room, lock the door, and contact the individual responsible for the irradiator program. Telephone numbers for the irradiator manufacturer's representative and the NRC should be included. In addition, your procedures should require that a survey be made with a radiation survey meter outside the irradiator room to determine whether further restriction of the area is necessary to ensure that no one can enter the area if the radiation level exceeds 2 milliroentgens per hour.

10.5 Plans for Installation and Certain Repairs

You should discuss your plans for irradiator installation, pre-operational check-out, and repairs or alterations involving removal of shielding or access to the licensed material. Normally these plans indicate that the tasks will be performed by the supplier or other persons who are specifically licensed by the NRC or an Agreement State for such work. If your plans depart from the normal, you should clearly explain how these tasks will be safely and adequately performed.

Note that under current licensing practice, your license contains a condition that requires you to file a report with the NRC in Washington, DC, if you incur a failure of a safety lock mechanism or a failure of the shielding of the irradiator. Reports submitted under this condition will be evaluated for indications of possible generic defects in your model irradiator and the need for NRC to alert other users of that model to take corrective action. Under this condition, you will be expected to report the failure of a door interlock on a moving source irradiator. You would not be expected to report routine maintenance, such as a burned out indicator bulb on the irradiator's control console (just replace the bulb).

Item 11 - WASTE MANAGEMENT

11.1 Authorized Disposal

Section 20.301 of 10 CFR Part 20 specifies the general requirements for disposal of licensed material. Because of the nature of the licensed material contained in irradiators, your only option for disposal is to transfer the radioactive source to an authorized recipient as specified in paragraph 20.301(a) of 10 CFR Part 20. You should state that disposal will be by transfer of the radioactive material to a licensee specifically authorized to accept it.

Authorized recipients are the original supplier of the irradiator source, a commercial firm licensed by the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of your licensed material.

11.2 Transportation

It should be noted that transportation of an irradiator for purposes of disposal or other reason must be done in accordance with 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." Prior to the adoption of 10 CFR Part 71 in 1966, irradiators could be transported without being evaluated under the accident damage test requirements that are now incorporated in Part 71. Accordingly, a licensee may have an irradiator that satisfied pre-1966 transportation regulations but now requires special attention to meet Part 71 requirements.

If the irradiator cannot practically be transported in packaging that meets the requirements of Part 71, the licensee may request a one-time shipment in accordance with §§ 71.7 and 71.41(c). In applying for a one-time shipment, the licensee must provide adequate controls so the shipment will not endanger life or property. Guidance on preparing a one-time shipment request may be obtained from the Division of Safeguards and Transportation, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Item 12 - LICENSE FEES

An application fee paid in full is required by paragraph 170.12(a) of 10 CFR Part 170 for most types of licenses, including applications for license amendments and renewals. You should 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 a 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 the application.

Item 13 - CERTIFICATION

Your application should be dated and signed by you if you are acting as an individual or by a representative of the corporation or 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 beliefs. Unsigned applications will be returned for proper signature.

Item 14 - VOLUNTARY ECONOMIC DATA

The Regulatory Flexibility Act of 1980 requires Federal agencies to consider the effects of their rules on small businesses and other small entities. In order for the NRC to maintain an up-to-date data base of its licensees, four categories of economic information are sought from applicants. These economic data will be used by the NRC in preparing regulatory analyses that contain, among other things, the anticipated economic burden a proposed rulemaking action will have on affected licensees. To the extent that it is possible and consistent with public health and safety, the NRC will consider the economic burden in light of the size of the entities affected by the rule in an attempt to mitigate the potential for significant economic impact on a substantial number of small entities.

14.a Annual Receipts

Guidance for determining the appropriate box in 14.a, Annual Receipts:*

1. Holders of One NRC License. If your organization (named on the license or application) holds one NRC license and operates from one address, check the box that most closely approximates your annual receipts; in the case of hospitals, academic institutions, or other entities that do not operate on the basis of receipts, check the box that most closely approximates the annual operating budget of your organization.

2. Holders of Multiple NRC Licenses Issued for One Address. If your organization (named on the license or application) holds multiple NRC licenses, all of which are issued to the same address, check the box that most closely approximates the annual receipts or annual operating budget for your entire organization, regardless of the number of NRC licenses possessed at that single address.

3. Holders of Multiple NRC Licenses at Multiple Addresses. If your organization (named on the license or application) holds multiple NRC licenses at multiple addresses, check the box that most closely approximates the annual receipts or annual operating budget for the operations conducted at the address on this license or application and not for the entire corporate entity.

14.b Number of Employees

The number of employees reported should reflect all employees for the organization at the address listed on the license or application, excluding outside contractors. The number of employees reported should not be that of a single department or division within the organization.

14.c Number of Beds (Hospitals Only)

Enter the total number of beds in the hospital excluding bassinets and nursing-home-type units.

---

*If the applicant is a university with a teaching hospital that operates under a separate annual budget and the applicant has been issued multiple licenses, the applicant should distinguish the figures that pertain solely to the university from those figures that pertain solely to the teaching hospital.

14.d Would You Be Willing To Furnish Cost Information on the Economic Impact of Current Regulations or any Future Proposed NRC Regulations that May Affect You?

Indicate if you would be willing to furnish additional economic data to the NRC that would help the NRC evaluate the economic impact of a rule on affected licensees.

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, (2) the terms and conditions of the license, and (3) the Nuclear Regulatory Commission's regulations.

It is your obligation to keep your license current. You should anticipate the need for a license amendment insofar as possible. If any of the information provided in the application is to be modified or changed, submit an application for a license amendment. 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 a license amendment may be prepared either on the application form (NRC Form 313) or in letter form and should be submitted in duplicate (see Section 2 of this guide for addresses). Your application should identify your license by number and should 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.

You must send the appropriate fee for a license amendment with your application. The NRC will not accept an application for filing or processing before the proper fee is paid in accordance with § 170.12 of 10 CFR Part 170.

5. RENEWAL OF A LICENSE

Licenses are issued for a period of up to 5 years. You must send an application for renewal in duplicate (see Section 2 of this guide for the address). You may submit an entirely new application for renewal as if it were an application for a new license without referring to previously submitted information.

As an alternative, you may:

1. Review your current license to determine whether the information accurately represents your current and anticipated program. Identify any necessary additions, deletions, or other changes and then prepare information appropriate for the needed additions or changes.

2. Review the documents you have submitted in the past to determine whether the information in them is up to date and accurately represents your management control program, facilities, equipment, personnel, radiation safety

procedures, locations of use, and any other information pertinent to your program. The documents you consider to represent your current program should be identified by date. Any out-of-date or superseded documents should also be identified, and changes should be made in these 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, in duplicate, with the proper fee, requesting renewal of your license and providing the information specified in items 1, 2, and 3 as necessary. If your current license and supporting documents accurately reflect your current program, state that operations will continue in accordance with those documents and applicable NRC regulations and license conditions.

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.

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

It is important that the appropriate fee accompany your application for license renewal. In accordance with § 170.12 of 10 CFR Part 170, the NRC will not accept an application for filing or processing before the proper fee is paid.

If you do not wish to renew your license, you must dispose of all licensed radioactive material you possess in a manner authorized by 10 CFR Part 20. Complete NRC Form 314, "Certificate of Disposition of Materials," and send it to the NRC before the expiration date of your license with a request that your license be terminated.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for continuation of your program or for storage only of the radioactive material. This renewal is necessary to avoid violating NRC's regulations that do not allow you to possess licensable material without a valid license. If you elect to request "storage only," you should describe plans, including a schedule, for safe storage and disposal of the radioactive material. A request for "storage only" would be particularly appropriate if you anticipate departure, without replacement, of all the authorized users named in the license. The amendment to authorize storage only will normally be issued for a period not to exceed 18 months.

Disposal of unused irradiators, in lieu of prolonged storage at your facility, is encouraged in order to avoid inadvertent transfer of radioactive material to scrap dealers or other unauthorized persons. Proper disposal of

sealed sources also minimizes the possibility of a ruptured source causing contamination problems at your facility.

6. IMPLEMENTATION

The purpose of this section is to provide information to you about the NRC's plans for using this regulatory guide and how these plans affect you.

This guide was distributed for comment to encourage public participation in its development (Task FC 402-4, October 1984). This final Revision 1 to Regulatory Guide 10.9 represents the staff position of the NRC after consideration of the public comments that were received on the draft guide.

The draft guide and final guide differ somewhat. If your license was issued or amended based on recommendations in the draft guide that are more restrictive than those in this final guide, you may choose to request an amendment to your license to reflect the less restrictive guidance.

In cases in which the final guide is more restrictive than the draft guide, licensing actions already completed will not be affected because all required regulatory findings have been made. However, the more restrictive recommendations in the final guide reflect items identified by the NRC staff as important to health and safety. Discrepancies may be addressed for effective licenses by license amendment or rule change. In unusual cases in which immediate action is required, you would be contacted directly by the NRC.

This regulatory guide provides guidance about requirements set out in the regulations. The NRC reviews each application to ensure that users of byproduct material are capable of complying with NRC's regulations. This guide provides one set of methods approved by the NRC for meeting the regulations.

NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-31-87

APPLICATION FOR MATERIAL LICENSE

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.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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 JURISDICTION.

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 8½ 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 AND 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, 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.

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- ☐ <$250K
- ☐ $250K–500K
- ☐ $500K–750K
- ☐ $750K–1M
- ☐ $1M–3.5M
- ☐ $3.5M–7M
- ☐ $7M–10M
- ☐ >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(Dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial–proprietary–information furnished to the agency in confidence)*
☐ YES ☐ NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY

AMOUNT RECEIVED	CHECK NUMBER		DATE

PRIVACY ACT STATEMENT ON THE REVERSE

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.

5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

APPENDIX B - J.L. Shepherd Irradiators

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUL 3 1984

URGENT NOTICE

TO ALL LICENSEES WHO POSSESS J. L. SHEPHERD IRRADIATORS

An NRC licensee recently identified a malfunction in the lock mechanism of its J. L. Shepherd self-shielded irradiator which could have resulted in a radiation overexposure. Although no overexposure appears to have occurred, the potential hazard warrants immediate preventive action. Therefore, we have prepared the enclosed Order which requires the use of radiation survey equipment when the irradiators are being used.

If you possess a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator, do not use it unless you provide appropriate radiation monitoring as specified in the Order. If you do not currently possess the appropriate equipment, you must obtain it before you resume use of your irradiator. Also, you should report any problems to your nearest NRC regional office immediately. Do not attempt to repair an irradiator, or allow anyone else to attempt repairs, unless specific authorization for repair of the irradiator which you possess is provided in an NRC license.

We suggest that you review who has access to your irradiator, and establish strict controls to assure that no untrained personnel have access. Trained persons who continue to use the irradiator should conduct careful radiation surveys as specified in the Order. Irradiator doors should be opened slowly, to minimize any accidental exposure and to avoid "blanking out" of instruments due to high exposure rates. Any unusual meter reading should be taken as evidence of a problem.

We are including in this mailing certain licensees about which we are uncertain whether they possess J. L. Shepherd irradiators. If you do not possess a J. L. Shepherd irradiator, please disregard this notice.

JUL 3 1984

Because this Order is effective immediately, it is important that you notify your radiation safety personnel immediately, and retain this Order with your license records. Questions and comments may be directed to your nearest NRC regional office.

Sincerely,

Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety

Enclosure: Order Modifying License

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D. C. 20555

ORDER MODIFYING CERTAIN LICENSES (EFFECTIVE IMMEDIATELY)

I

Recently, the Nuclear Regulatory Commission (NRC) staff was notified by a licensee of the failure of a locking mechanism on a self-shielded irradiator which could have resulted in a radiation overexposure. ("Self-shielded" irradiators are designed so that the radioactive source remains in a shielded position at all times, both during storage and during irradiations. Therefore, the irradiators need not be placed in a shielded room.)

The irradiator is a J. L. Shepherd Mark I, containing about 6,000 curies of cesium 137. The unit is operated as follows: (1) With the source in its shielded storage position, the shielded door is opened, (2) materials to be irradiated are placed inside the irradiator chamber, (3) the shielded door is closed, (4) the radioactive source is raised into the irradiation chamber, (5) after irradiation is complete, the source is lowered, and (6) the door is opened for removal of irradiated materials.

The shielded door is interlocked so that it should not open when the radioactive source is in the irradiation chamber. However, in the case reported to NRC, the lock mechanism failed. In such a situation, an operator who opens the shielded door with the source raised could be subjected to substantial radiation exposure. The J. L. Shepherd Model 81-22 irradiator employs an interlock similar to the Mark I.

The NRC staff has examined the irradiator in question and confirmed the defect. Furthermore, a New York City inspector checking a J. L. Shepherd Mark I irradiator in New York reported a malfunctioning interlock system. NRC and the Agreement States are studying the problem further to assess its generic implications.

Based on the foregoing, I have concluded that the possibility of failure of locking mechanisms and/or mechanical timers on J. L. Shepherd Mark I and Model 81-22 irradiators represents a potential radiation hazard warranting immediate preventive action pending further investigation. I have determined, therefore, that the public health, safety, and interest require that the restrictions on the use of such irradiators as prescribed in Section II of this Order should be made immediately effective.

II

Accordingly, pursuant to Sections 81, 116 i, 162 o, and 182 of the Atomic Energy Act of 1954, as amended, and 10 CFR Parts 2 and 30 of the Commission's regulations IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

Each license that authorizes possession of byproduct material in a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator is hereby amended to add the following conditions:

(1) The J. L. Shepherd irradiator shall not be used unless the licensee provides a calibrated and operable radiation survey meter or room monitor for use with the irradiator.

(2) The irradiator door shall not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.

(3) Each room monitor (a) shall be operable at all times when the irradiator is in use, (b) shall activate a visible and audible alarm when radiation levels exceed 2 millirems per hour, (c) shall be located to detect any radiation escaping from the irradiator door, and (d) shall be located so that it is visible to the irradiator user when he is next to the irradiator.

(4) If a room monitor is not installed, a survey meter shall be used (a) to determine the radiation level at the irradiator door when the door is closed, and (b) to check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators shall position themselves so as to minimize exposure to any radiation escaping from the open door.

(5) If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee shall stop use of the irradiator and immediately notify the appropriate NRC regional office by telephone.

(6) The licensee shall not attempt repair or authorize others to attempt repair of the irradiator except as specifically authorized in a license issued by NRC.

III

Any affected licensee may request a hearing on this Order. A request for a hearing shall be submitted within twenty (20) days of the date of this Order to Mr. R. E. Cunningham, Director, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the Executive Legal Director, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555. ANY REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

IV

If a hearing is requested, the Commission will issue an Order designating the time and place of any such hearing. If a hearing is held the issue to be considered at such a hearing will be: Whether, on the basis of the matters set forth in Section I and II of this Order, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety
Office of Nuclear Material Safety
and Safeguards

Dated at Bethesda, Maryland
this 3rd day of July, 1984

VALUE/IMPACT STATEMENT

A draft value/impact statement was published with the second proposed Revision 1 to Regulatory Guide 10.9 (Task FC 402-4) when the draft guide was published for public comment in October 1984. No substantive 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 or copying for a fee at the Commission's Public Document Room at 2120 L Street NW., Washington, DC, under Task FC 402-4.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

FIRST CLASS MAIL
POSTAGE AND FEES PAID
USNRC
PERMIT NO. G-67