Revision 2*
August 1987

U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 10.8
(Task FC 415-4)

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL USE PROGRAMS

*The substantial number of changes in this revision has made it impractical to indicate the changes with lines in the margin.

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 Rules and Procedures Branch, DRR, ADM, 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

LIST OF APPENDICES

PART 1 - MODEL PROCEDURES THAT APPLICANTS MAY USE TO PLAN RADIATION SAFETY PROGRAMS

TABLE OF CONTENTS

LIST OF APPENDICES (Continued)

LIST OF EXHIBITS

1. INTRODUCTION

1.1 GENERAL

The Nuclear Regulatory Commission (NRC) regulates the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in 10 CFR Part 35, "Medical Use of Byproduct Material."

The NRC usually issues a single byproduct material license to cover an entire radioisotope program except teletherapy, nuclear-powered pacemakers, and irradiators. Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. A license applicant should carefully study this guide and all the regulations identified in Section 1.2 and should then complete the application form, NRC Form 313. The NRC may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program.

1.1.1 Purpose of Guide

This guide is designed to describe the type and extent of information needed by the NRC to evaluate an application for a medical use license and to describe the medical use byproduct material regulations. (Separate guidance is being developed to meet the specific needs of a teletherapy applicant. Draft Regulatory Guide FC 414-4, "Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs," has been issued for public comment.) This guide does not apply to academic programs that do not use byproduct material for medical use.

1.1.2 Purpose of Appendices to Guide

The regulations require that the licensee develop and implement procedures that will ensure compliance with the regulations. Appendices A through R to this guide describe model radiation safety procedures. Each applicant should carefully read the applicable regulations and model procedures and then decide if the model procedures are appropriate for its specific radiation safety needs. In the application, applicants may certify that they will follow model procedure (appropriate certification language is given at the beginning of each appendix) or may say that they have developed a procedure that is enclosed for review (appropriate reference language is given at the beginning of each appendix).

1.2 APPLICABLE REGULATIONS

In addition to 10 CFR Part 35, other regulations pertaining to the medical use of byproduct material are found 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 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."

This regulatory guide identifies the information needed to complete NRC Form 313 when applying for a license for a medical use program. The information collection requirements in NRC Form 313 have been cleared under OBM Clearance No. 3150-0120.

1.3 AS LOW AS 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 Guides 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," and 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable," provide the NRC staff position on this important subject. Applicants should consider the ALARA philosophy as described in Regulatory Guides 8.10 and 8.18 in developing plans for work with licensed radioactive materials.

1.3.1 General ALARA Considerations

Each individual who is authorized to use byproduct material should provide appropriate instruction to all individuals who work with or in the vicinity of byproduct material and should ensure that the facility and equipment are adequate for safe use. NUREG-1134, "Radiation Protection Training for Personnel Employed in Medical Facilities," provides information on training programs for use by medical use licensees. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or Radiation Safety Office (RSO).

1.3.2 ALARA in Medical Institutions

Each medical licensee must have a formal ALARA program (see § 35.20 of 10 CFR Part 35). The success of an ALARA program depends on the cooperation of each person who works at the licensee's facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources. A Radiation Safety Committee composed of individuals who have special expertise in the safe use of byproduct material is required by § 35.22 to review uses for safety and ALARA considerations. (See Section 1.4.2 of this guide).

The Committee, the RSO, and management should audit the byproduct material program to ensure the continued safe use of byproduct material. In addition to being a member of the Committee, the RSO serves as a technical consultant to the Committee and is also responsible for the day-to-day operation of the radiation safety program.

A model ALARA management program is contained in Appendix G to this guide. Several other NRC publications contain background information on the ALARA philosophy and its application in the medical environment. For example, Regulatory Guide 8.18 and NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably

Achievable," contain information, methods, and references useful in establishing radiation safety programs to maintain exposures ALARA is medical institutions. Applicants should consider the ALARA philosophy in the development of plans for work with radioactive materials.

1.4 TYPES OF LICENSES

The NRC issues three types of licenses for the use of byproduct material in the practice of medicine. They are described below. This guide is only for persons who want to apply for a specific medical use license. However, persons who are applying for other types of licenses may find the information in this guide useful in designing their radiation safety program.

1.4.1 General License

Section 31.11 of 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use certain small quantities of byproduct material for in vitro clinical or laboratory tests not involving medical use (that is, not involving administration to humans). Section 31.11 explains the requirements for using materials listed in that section. If the general license alone meets the applicant's needs, only Form NRC-483, "Registration Certificate--In Vitro Testing with Byproduct Material under General License," need to be filed. Medical use licensees do not need to file the form (see paragraph 31.11(b)).

If you need more than 200 microcuries of photon-emitting § 31.11 materials, you may request an increased inventory limit as a separate line item on your NRC Form 313 application. Licensees generally request 3 millicuries. The use of materials listed in § 31.11 within the inventory limits of that section will only be subject to the requirements of that section and not subject to the requirements of Parts 19, 20, 21, and 35 except as provided in § 31.11. If you request an increased inventory limit, you will be subject to the requirements of those parts, including the requirements regarding waste disposal.

1.4.2 Specific License

Specific licenses for physicians in private practice are generally limited to physicians who are located in private offices and not on hospital premises. A Radiation Safety Committee is not required. Methods of use that require hospitalization of the patient are not permitted.

Specific licenses are also issued to medical institutions. A medical institution is an organization in which several medical disciplines are practiced. These licenses authorize byproduct material for medical uses by physicians named on the institution's license. The regulations in § 35.22 of 10 CFR Part 35 require an institutional licensee to have a Radiation Safety Committee to oversee the use of licensed material throughout the institution and to review the institution's radiation safety program. The physicians named on the institution's license conduct their programs with the approval of the Radiation Safety Committee.

A specific license may also be issued for a mobile nuclear medicine service (see § 35.29 of Part 35). Both private practitioners and institutions may apply for authorization to use byproduct material in a mobile service.

1.4.3 Specific License of Broad Scope

Some medical institutions provide patient care and conduct research programs that use radioisotopes for in vitro, animal, and medical procedures. In these cases, the NRC may issue a specific license of broad scope as discussed in 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material." Specific licenses of broad scope for medical use, i.e., licenses authorizing multiple quantities and types of byproduct material for unspecified uses, are issued to institutions that (1) have had previous experience operating under a specific institutional license of limited scope and (2) are engaged in medical research as well as routine diagnosis and therapy using radioisotopes.

Such programs operate under the supervision of the Radiation Safety Committee. A broad scope license allows the Radiation Safety Committee to review proposed methods of use and to permit individuals to use material under the provisions of the broad scope license. An applicant for a broad scope license must show that appropriate personnel, equipment, and facilities are available. Individual users are not named on the license nor are radioisotopes limited to specified uses. Individual users and methods of use are authorized by the institution's Radiation Safety Committee. This type of license is not appropriate for most institutions performing routine procedures with byproduct material.

Institutions may also apply for a broad scope license that combines features of the specific license and the specific license of broad scope discussed above. It authorizes medical uses as described in Part 35 and authorizes the Committee to review and approve in vitro animal research uses. This type of license is not appropriate for most institutions performing routine medical procedures with byproduct material.

2. FILING AN APPLICATION

You should apply for a license by completing NRC Form 313 (see Exhibit 1). You should complete Items 1 through 2, 12, 13, and 14 on the form itself. For Items 5 through 11, submit the required information on supplementary pages. You should identify and key each separate sheet or document submitted with the application to the items number of 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, fold them to 8-1/2 x 11 inches.

You should complete all items in the application in enough detail for the NRC to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and 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 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 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. Retain one copy for yourself because the license will be issued based on the statements and representations in your application and any supplements to it as well as the requirements in the regulations.

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 exceptions to the above are the United States Air Force and Navy and persons wishing to distribute exempt material under 10 CFR Part 32, Subpart A, who should file their applications directly with the U.S. Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, Washington, DC 20555.

Many States 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. A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from the Material Licensing Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or from NRC's Regional Offices, whose addresses are listed below. If you are a non-Federal organization that wishes to possess or use licensed material in one of these Agreement States, your application should be filed with the State's radiation control program and not with the NRC.

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 your applications to the U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 631 Park Avenue, King of Prussia, PA 19406.

If you are located in Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, or West Virginia, send your applications to the 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 your applications to the U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 799 Roosevelt Road, Glen Ellyn, IL 60137.

If you are located in Arkansas, Colorado, Idaho, Kansas, Louisiana, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, Utah, or

Wyoming, send your applications to the U.S. Nuclear Regulatory Commission, Region IV, Material Radiation Protection Section, 611 Ryan Plaza Drive, Suite 1000, Arlington, TX 76011.

If you are located in Alaska, Arizona, California, Hawaii, Nevada, Oregon, Washington, or U.S. territories and possession in the Pacific, send your applications to the U.S. Nuclear Regulatory Commission, Region V, Material Radiation Protection Section, 1450 Maria Lane, Suite 210, Walnut Creek, CA 94596.

3. CONTENTS OF APPLICATION

This portion of the guide explains, item by item, the information requested on NRC Form 313 (Exhibit 1). The appendices to this guide serve several different purposes, i.e., to provide additional information on certain subject areas, to provide a model procedure the licensee may adopt in response to an item on the application form, or to provide an outline the applicant may use to develop a procedure for review by the NRC staff. The exhibits following the appendices include copies of the application form (NRC Form 313, Exhibit 1); Supplements A and B (Exhibits 2 and 3) that may be used to document training and experience; and two logs to document training, the Resident's Support Technology Training Task Log (Exhibit 4) and Resident's Clinical Procedures Training Log (Exhibit 5). Exhibits 4 and 5 may be used as worksheets when preparing Supplements A and B.

If you have specific questions after careful review of this guide, contact the NRC material licensing staff at the appropriate address as specified in Section 2 of this guide.

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.

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 at which the material will be used as specified in Item 3.

Item 3 - LOCATIONS 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 byproduct material is 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.

If you are applying for a license for a mobile nuclear medicine service, specify so and list the name and location of each client.

Item 4 - PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer questions about the application. This individual, usually the 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 individual is not your full-time paid employee, specify your relationship with this individual. 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 a license amendment.

Item 5 - RADIOACTIVE MATERIAL and Item 6 - PURPOSE

Part 35 divides byproduct material for medical use into six types of use. Using the table format of Table 1 as a guide, you may indicate only the types of use you want and the maximum amount. You may say "As needed" in the "Amount" column as shown. For § 35.400 implant material, express the total amount in millicuries (mCi). If you plant to have an eye applicator, list it as a separate line item and note its total activity in mCi.

Table 1

	Byproduct Material	Amount		Purpose
5.a	Material in § 35.100	As needed	6.a	Medical use
5.b	Material in § 35.200	As needed	6.b	Medical use
5.c	Material in § 35.300	As needed	6.c	Medical use
5.d	Implant Material in § 35.400	____ mCi	6.d	Medical use
5.e	Eye applicator in § 35.400	____ mCi	6.e	Medical use
5.f	Material in § 35.500	As needed	6.f	Medical use

(Note: Broad scope medical use applicants may request "Any byproduct material with atomic numbers 3 through 83 for medical use.")

If you need other items (for example, more byproduct material for in vitro testing than is allowed under § 31.11, depleted uranium for linear accelerator shielding, a survey meter calibration source, a teletherapy dosimetry system constancy check source, or material for in vitro, animal, or human studies, or authorization to participate in a protocol approved by a Radioactive Drug Research Committee that has been approved by the Food and Drug Administration), make a separate line entry for each item. (Do not list sources that are authorized in § 35.58.) Number each line entry consecutively following the Part 35 material. Each line entry must identify the radionuclide, the physical form, maximum amount of hand expressed in mCi, and the purpose for which the material will be used. If you do not want all the material listed in a Part 35 section, you must identify, line by line, the material that you do want from the section.

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

Responsible individuals are the authorized users, the RSO, and for teletherapy the teletherapy physicist. Paragraph 30.33(a)(3) of 10 CFR Part 30 requires that an applicant be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Subpart J of Part 35 provides specific criteria for acceptable training and experience for authorized users for medical use, for the RSO, and for the teletherapy physicist. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience.

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate,

2. Prescription of the radiation dosage or dose and how it is to be administered,

3. Actual use of, or direction of technologists or other paramedical personnel in the use of, byproduct material, and

4. Interpretation of results of diagnostic procedures and evaluation of results of therapy procedures.

Numbers 1 through 4 may be delegated to a physician who is under the supervision of an authorized user. Technologists or other personnel may use byproduct material under an authorized user's supervision when permitted under applicable Federal, State, or local laws. Supervision is defined in § 35.25.

For in vitro and animal research or other uses that do not involve the intentional exposure of humans, the list of proposed authorized users should include those individuals who will actually be responsible for the safe use of the byproduct material for the requested use. Note which user will be involved with which use by reference to Items 5 and 6 of the application. Those authorized users may direct the use of the byproduct material by technologists or other individuals for the requested use.

7.1 Authorized Users for Medical Use

1. Make a separate attachment for the RSO and each authorized user. Number the attachments "ATT 7.1.1," "ATT 7.1.2," etc. Type the full name of the individual and note, by reference to Items 5.a, 5.b, etc., which proposed uses are requested for the individual.

2. If a physician has been previously authorized for medical use and only wants to use material permitted by the previous license, you only need to submit the previous license number (if issued by AEC or NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an authorized user.

3. If a physician is certified by an organization listed in the appropriate section of Subpart J of 10 CFR Part 35, submit Supplement A (see Exhibit 2) with Items 1, 2, and 3 completed. A physician certified as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR) should submit a copy of the certificate and evidence of specialization in radiation therapy.

4. Physicians not previously authorized by AEC or NRC or an Agreement State and not certified by an appropriate organization must submit a complete description of their training and experience using Supplements A and B (see Exhibits 2 and 3). This documentation will be reviewed on a case-by-case basis. If the training and experience does not appear to meet the Subpart J standards, the NRC will request the assistance of its Advisory Committee on the Medical Uses of Isotopes.

5. Broad scope medical use applicants should submit the criteria they will use to evaluate the training and experience of authorized users. Subpart J may be used as a guide. The criteria may include a provision that allows the applicant's Radiation Safety Committee to grant case-by-case exceptions.

7.2 Authorized Users for Nonmedical Use

List the full name of each individual proposed as an authorized user for nonmedical use. Submit a complete description of the person's training and experience using Supplement A (Exhibit 2). If the individual was already identified in Item 7.1, no additional attachment is needed here.

7.3 Radiation Safety Officer

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience using Supplement A (see Exhibit 2). The RSO should be a full-time employee of the licensee. Even if the licensee employs a consultant to assist the RSO, the licensee is still responsible for the radiation safety program as required by the license.

Items 8 through 11

Your responses to these items should consist of one sentence that says that you will follow the model procedure in Appendix __ in Regulatory Guide 10.8, or that you have enclosed your procedure for review, or simply the notation "NA" for "not applicable." Follow the instructions on the Applicability Table, Table 2, to determine whether you must provide information or may simply respond "NA" to each item that follows. Before you respond to an item, read the introductory paragraphs of the referenced appendix. Your short sentence or NA responses to Items 8 through 11 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments.

If you edit a model procedure solely to identify responsible individuals, equipment by name or model, room numbers, or other site-specific information, there is no need to submit that procedure for review.

Table 2

APPLICABILITY TABLE

To determine those items to which you must respond, "highlight" the columns under the categories of material you requested in Item 5. If any "√" beside an item is highlighted, you must provide information in response to the item. If only the letters "NA" (not applicable) are highlighted, you may respond "NA" in your application.

Item	Topic	Material in 10 CFR Sections 35.100	35.200	35.300	35.400	35.500	Other	App.
8.1	Training program	√	√	√	√	√	NA	A
8.2	Other training program	NA	NA	NA	NA	NA	√	-
9.1	Annotated drawing	√	√	√	√	√	√	Exh.
9.2	Survey instrument calibration	√	√	√	√	√	√	B
9.3	Dose calibrator calibration	√	√	√	NA	NA	NA	C
9.4	Personnel monitor program	√	√	√	√	NA	√	D
9.5	Imaging equipment QA	(See special instruction 9.5 in the text)						E
9.6	Other equipment and facilities	NA	NA	NA	NA	NA	√	-
10.1	Radiation Safety Committee/Radiation Safety Officer	(See special instruction 10.1 in the text)						F
10.2	ALARA program	(See special instruction 10.2 in the text)						G
10.3	Leak test	√	√	√	√	√	NA	H
10.4	Safe use of radio-pharmaceuticals	√	√	√	NA	NA	NA	I
10.5	Spill procedures	√	√	√	NA	NA	NA	J
10.6	Ordering and receiving	√	√	√	√	√	√	K
10.7	Opening packages	√	√	√	√	√	√	L
10.8	Unit dosage records	√	√	√	NA	NA	NA	M
10.9	Multidose vial records	√	√	√	NA	NA	NA	M
10.10	Mo-99 concentration records	NA	√	NA	NA	NA	NA	M
10.11	Implant source use records	NA	NA	NA	√	NA	NA	M
10.12	Area survey procedures	√	√	√	√	NA	√	N
10.13	Air concentration control	NA	√	NA	NA	NA	NA	O
10.14	Radiopharmaceutical therapy	NA	NA	√	NA	NA	NA	P
10.15	Implant therapy	NA	NA	NA	√	NA	NA	Q
10.16	Other safety procedures	NA	NA	NA	NA	NA	√	-
11.1	Waste disposal	√	√	√	√	√	NA	R
11.2	Other waste disposal	NA	NA	NA	NA	NA	√	-

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

8.1 Training Program

Describe your training program for individuals who work with or in the vicinity of radioactive material described in Part 35. See Appendix A of this guide.

8.2 Other Training Program

Describe your training program for individuals who handle radioactive material other than the Part 35 material that you listed in Item 5 of this application. Append it as ATT 8.2.

Item 9 - FACILITIES AND EQUIPMENT

9.1 Annotated Drawing

Submit an annotated drawing of the room or rooms and adjacent areas where byproduct material will be used. Append it as ATT 9.1. Note the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.

2. The direction of north.

3. Room numbers and principal use of each room or area (for example, in vitro, hot lab, waiting, examining, imaging, reading, office, file, fresh materials storage, radioactive waste storage, film processor, toilet, closet, hallway).

4. Any shielding available.

5. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors).

See Exhibit 6 for an example.

9.2 Survey Instrument Calibration

Submit your procedure for calibrating survey instruments. See Appendix B.

9.3 Dose Calibrator Calibration

Submit your procedure for calibrating the dose calibrator. See Appendix C.

9.4 Personnel Monitor Program

Describe your personnel occupational exposure monitor program. See Appendix D of this guide.

9.5 Imaging Equipment

If you are transporting imaging equipment as part of a mobile nuclear medicine service, describe your procedure for checking the equipment to ensure it has not been damaged in transit. See Appendix E. If you are not going to provide mobile nuclear medicine service, say "NA."

9.6 Other Equipment and Facilities

Describe other equipment and facilities available for the use and storage of material described in Item 5 of this application other than material described in Part 35. Append it as ATT 9.6.

Item 10 - RADIATION SAFETY PROGRAM

10.1 Radiation Safety Committee/Radiation Safety Officer

Describe your Radiation Safety Committee Charter and Radiation Safety Officer delegation of authority. A Radiation Safety Committee must be established by each medical institution licensee (see § 35.22) unless the application is only for devices listed in § 35.500 (such institutions will be exempted by license condition). If you are not an institution, you only need to submit the Radiation Safety Officer delegation of authority. See Appendix F.

10.2 ALARA Program

Submit your ALARA program. Each medical licensee must have an ALARA program (see § 35.20) unless the application is only for devices listed in §35.500 (such institutions will be exempt by license condition). If you are only applying for devices in § 35.500, say "NA." Otherwise, see Appendix G.

10.3 Leak Test

Submit your procedure for leak-testing sealed sources. See Appendix H.

10.4 Safe Use of Radiopharmaceuticals

Submit a copy of your rules for the safe use of radiopharmaceuticals. See Appendix I.

10.5 Spill Procedures

Submit a copy of your spill procedures. See Appendix J.

10.6 Ordering and Receiving

Submit a copy of your procedure for ordering and receiving radioactive material. See Appendix K.

10.7 Opening Packages

Submit your procedure for opening packages that contain radioactive material. See Appendix L.

10.8 Unit Dosage Records

Submit your procedure for keeping records of unit dosage use. See Appendix M.1.

10.9 Multidose Vial Records

Submit your procedure for keeping records of multidose vial use. See Appendix M.2.

10.10 Molybdenum Concentration Records

Submit your procedure for measuring and recording molybdenum concentration. See Appendix M.3.

10.11 Implant Source Use Records

Submit your procedure for keeping an inventory of implant sources. See Appendix M.4.

10.12 Area Survey Procedures

Submit your area survey procedures. See Appendix N.

10.13 Air Concentration Control

1. Submit your procedure for estimating worker dose from submersion in noble gases. See Appendix O.

2. Submit your procedure for estimating worker dose from aerosol concentrations. See Appendix O.

3. Submit your procedure for estimating aerosol and gas concentration in effluents. See Appendix O.

4. Submit your procedure for calculating spilled gas clearance times. See Appendix O.

10.14 Radiopharmaceutical Therapy

Submit your procedure for radiation safety during radiopharmaceutical therapy. See Appendix P.

10.15 Implant Therapy

Submit your procedure for radiation safety during implant therapy. See Appendix Q.

10.16 Other Safety Procedures

Submit safety procedures that will be followed by individuals who handle radioactive material described in Item 5 of this application other than material described in Part 35. Append them as ATT 10.16.

Item 11 - WASTE MANAGEMENT

11.1 Waste Disposal

Submit your procedures for waste disposal. See Appendix R.

11.2 Other Waste Disposal

Submit waste disposal procedures that will be followed for radioactive materials described in Item 5 of this application other than material described in Part 35. Append them as ATT 11.2. (If they are the same as the procedures submitted in Item 11.1, say "See Item 11.1.")

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," of 10 CFR Part 170 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 irrespective of the NRC's disposition of the application or your withdrawal of the application.

Item 13 - CERTIFICATION

If the application is for a private practice, it should be signed by a senior partner or the president. If the application is for an institution, hospital, or medical center, it must be signed by its director or chief executive officer. Identify the title of the office held by the individual who signs the application.

BEFORE SUBMITTING IT, REVIEW YOUR APPLICATION TO BE SURE YOU HAVE RESPONDED TO EACH ITEM AND TO BE SURE THAT EACH PAGE THAT YOU HAVE ATTACHED HAS AN ATTACHMENT NUMBER AND IS DATED.

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. This 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 a significant economic impact on a substantial number of small entities.

Item 14.a Annual Receipts

Guidance for determining the approximate 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.

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.

---

*If the applicant is a university with a teaching hospital that operates under a separate annual budget and has been issued multiple licenses, the applicant should check the box that most closely approximates the annual operating budget of the entity that is the applicant, either the university or the teaching hospital.

4. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program, changing the Radiation Safety Officer or teletherapy physicist, or adding to the staff of authorized users. See § 35.13 for the specific requirements. An application for an amendment must be filed in duplicate either on NRC Form 313 or as a letter and must be signed as described in Item 13. If the amendment application is the first one submitted after the effective date of the revision of 10 CFR Part 35 (April 1, 1987), the NRC will use this opportunity to list the Radiation Safety Officer and teletherapy physicist on the license. The teletherapy physicist's credentials must be submitted as part of the amendment application.

5. RENEWAL OF LICENSE

An application for the renewal of a license should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before final action on the application has been taken by the NRC as provided for in paragraph 30.37(b) of 10 CFR Part 30. The application for renewal must be filed in duplicate on NRC Form 313. The application for renewal may reference attachments that were previously submitted. For example, "See ATT 10.7 dated November 14, 1985."

6. IMPLEMENTATION

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

The guide was distributed for comment to encourage public participation in its development (Task FC 415-4, August 1985). This final Revision 2 represents the staff position of the NRC, which incorporates the public comments that were received on the draft guide.

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

In cases where 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.

The information in this regulatory guide is guidance, not requirements. 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.

APPENDICES

Part 1 - MODEL PROCEDURES THAT APPLICANTS MAY USE TO PLAN RADIATION SAFETY PROGRAMS

APPENDIX A

Model Training Program
(See §§ 19.12 and 35.21)

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2, and have appended a table ATT 8.1 that identifies the groups of workers who will receive training and the method and frequency of training." You may use lectures, video-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of § 19.12. Say on your application, "We have developed a training program for your review that is appended as ATT 8.1." Be sure to include the table that identifies groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instruction has been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. All training should be tailored to meet the needs of the individuals in attendance. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. Licensee's in-house work rules.

6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.

7. Appropriate response to emergencies or unsafe conditions.

8. Worker's right to be informed of occupational radiation exposure and bioassay results.

9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

10. Question and answer period.

APPENDIX B

Model Procedure for Calibrating Survey Instruments
(See § 35.51.)

You or your contractor may use the following guidance to calibrate survey instruments. If you, or the contractor, follow all the guidance, you may say on your application, "We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2."

If your procedure does not follow the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.51. Say on your application, "We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2," and append your survey instrument calibration procedure.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

MODEL PROCEDURE

1. The source must be approximately a point source.

2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cs-137 or 21 millicuries of Co-60.

5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.

6. A record must be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

8. Three kinds of scales are frequently used on survey meters:

   a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.

   b. Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

   c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.

10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.

11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:

   a. The owner or user of the instrument;

   b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;

   c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;

   d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;

   e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);

   f. The angle between the radiation flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument);

   g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

h. The apparent exposure rate from the check source; and

i. The name of the person who performed the calibration and the date on which the calibration was performed.

12. The following information will be attached to the instrument as a calibration sticker or tag:

a. The source that was used to calibrate the instrument;

b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);

c. For each scale or decade, one of the following as appropriate:

(1) The average correction factor,

(2) A graph or graphs from which the correction factor for each scale or decade may be deduced, or

(3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;

d. The angle between the radiation flux and the detector during the calibration; and

e. The apparent exposure rate from the check source.

Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

See Exhibit 7 for a form you may want to use.

APPENDIX C

Model Procedure for Calibrating Dose Calibrator
(See § 35.50.)

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may say on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2."

If you develop your own dose calibrator calibration procedure for review, you should carefully review § 35.50 and all the features in the model procedure. Say on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as ATT 9.3," and append your dose calibrator calibration procedure.

MODEL PROCEDURE

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)

    a. Constancy at least once each day prior to assay of patient dosages (±5 percent).

    b. Linearity at installation and at least quarterly thereafter (±5 percent).

    c. Geometry dependence at installation (±5 percent).

    d. Accuracy at installation and at least annually thereafter (±5 percent).

2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57,* or Ra-226* using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

    a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).

    b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

*Co-57 and Ra-226 are not subject to NRC licensing; the appropriate State agency should be consulted to determine its requirements for possessing this material.

c. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.

d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form (see Exhibit 8). This first assay should be done in the morning at a regular time, for example, 8 a.m.

b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.

e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-line) = deviation.

f. If the worst deviation is more than ± 0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary

to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them.

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.

b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

d. Continue for all sleeves.

e. Complete the decay method linearity test steps b through g above.

f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.

g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.

h. Continue for all sleeves.

i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

b. Steps c through e below must be completed within 6 minutes.

c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

e. Continue for all sleeves.

f. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

g. Plot the data using the equivalent decay time associated with each sleeve.

h. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/A-line = deviation.

i. If the worst deviation is more than ±0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

j. Put a sticker on the dose calibrator that says when the next linearity test is due.

6. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.

b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form (see Exhibit 9).

c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

d. Repeat the process until you have assayed a 2.0-cc volume.

e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the

data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

f. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that, if a Ra-226 source is used, it must be at least 10 microcuries; other sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on the

Dose Calibrator Geometry and Accuracy Form (see Exhibit 9). Repeat for a total of three determinations.

b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.

c. Repeat the procedure for other calibrated reference sources.

d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.

e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

f. Put a sticker on the dose calibrator that says when the next accuracy test is due.

8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

See Exhibits 8 and 9 for some forms you may want to use.

APPENDIX D

Model Personnel External Exposure Monitoring Program
(See § 20.101.)

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application, "We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of § 20.101. Say on your application, "We have developed an external exposure monitoring program for your review that is appended as ATT 9.4," and append your monitoring program.

MODEL PROGRAM

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for such patients.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

APPENDIX E

Model Procedure for Checking Equipment
Used in Mobile Nuclear Medicine Service
(See §§ 35.29 and 35.80.)

The NRC normally limits its review of equipment quality assurance programs to those programs developed for radiation safety equipment. However, when delicate imaging equipment is transported from one location of use to another, e.g., by a mobile nuclear medicine service, it is reasonable to assume that it may suffer damage in transit. Therefore, the NRC requires that mobile nuclear medicine services have an imaging equipment quality assurance program to ensure that the use of byproduct material will not be inimical to the public health and safety. Mobile nuclear medicine services should also check ventilation equipment if gases or aerosols will be used.

You may use the following procedure to ensure the proper operation of imaging equipment that has been transported. If you follow the procedure, you may say on your application, "We will establish and implement the model procedure for ensuring equipment performance that was published in Appendix E to Regulatory Guide 10.8, Revision 2."

If you want to develop your own procedure for review, you should consider for inclusion all the features in the model procedure and the procedure recommended by the manufacturer and carefully review the requirements of §§ 35.29 and 35.80. Say on your application, "We have developed a procedure for ensuring equipment performance for your review that is appended as ATT. 9.5," and append your imaging equipment quality assurance procedure.

MODEL PROCEDURE

Survey Meter

Check the survey meter with the dedicated check source at each location of use. Material may not be used if the survey meter is not working. There is no need to keep a record of these checks.

Camera

1. Perform the following checks daily at each location of use before administering byproduct material:

   a. Peak each camera according to the manufacturer's instructions.

   b. Using either Tc-99m or Co-57, perform an extrinsic flood field with a frequently used collimator in place, or perform an intrinsic flood field test. Accumulate at least 1,000,000 counts for small-field-of-view cameras and 3,000,000 counts for large-field-of-view cameras. Process the image as if it were an image of a patient.

   c. Do not administer material until an authorized user or a designated technologist approves the camera for use.

d. You do not have to make a permanent record of these daily checks.

2. Perform the following checks weekly:

   a. With the same frequently used collimator in place, image a flood source and either a parallel-line-equal-space (PLES), bar, orthogonal-hole (OH) or resolution-quadrant phantom with the flood field as a source.

   b. If a PLES or bar phantom is used, rotate it 90° so that the camera is tested for both vertical and horizontal geometric linearity.

   c. If a resolution-quadrant phantom is used, rotate it so that each quadrant is imaged in each quadrant of the crystal. Then turn it over and again image it four more times. This procedure will check both resolution and horizontal and vertical geometric linearity in each quadrant of the crystal.

   d. Process the images as if they were images of a patient. Mark them clearly to indicate image orientation, source activity, and date.

   e. Retain the images for 2 years.

3. Perform the following safety checks after repairs and quarterly:

   a. Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 3.b.

   b. Check the motion switches. Put the camera in motion and first release just the direction switch to stop the motion. Then put the camera back in motion and release just the dead-man switch. Test all motion switches and all directions in this manner. Release of either the motion switch or the dead-man switch alone should disable the camera motion. If this is not the case, repair the camera before clinical use.

4. Set the equipment in the same manner each time checks are run. Make a record of all these checks. Keep a separate file or ring binder for each camera. Retain the record for 2 years.

Ventilation

If gases or aerosols will be used, check the ventilation supply, exhaust vents, and collection devices for operation with tissue paper or a velometer. There is no need to keep a record of these checks.

APPENDIX F

Model Radiation Safety Committee Charter
and Radiation Safety Officer Delegation of Authority
(See §§ 35.21, 35.22, and 35.23.)

You may use the following text as it appears here, saying on your application, "We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix F to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own statement of authority, duties, administrative procedures, and delegation of authority. If you do so, you should consider for inclusion all the features in the model text and carefully review the requirements of §§ 35.22. Say on your application, "We will issue the Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that are appended as ATT 10.1," and append your charter and delegation.

MODEL CHARTER

Charge. The Committee shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;

2. Ensure that licensed material is used in compliance with NRC regulations and the institutional license;

3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;

4. Establish a table of investigational levels for individual occupational radiation exposures; and

5. Identify program problems and solutions.

Responsibilities. The Committee shall:

1. Be familiar with all pertinent NRC regulations, the license application, the license, and amendments;

2. Review the training and experience of the proposed authorized users, the Radiation Safety Officer (RSO), and the teletherapy physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;

5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required in § 19.12 of 10 CFR Part 19;

7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system;

8. Recommend remedial action to correct any deficiencies identified in the radiation safety program;

9. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and

10. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

1. The Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)

3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

MODEL DELEGATION OF AUTHORITY

Memo To: All Employees
From: Chief Executive Officer
Subject: Delegation of Authority

_____ has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

The Radiation Safety Officer is also responsible for assisting the Radiation Safety Committee in the performance of its duties and serving as its secretary.

APPENDIX G

Model Program for Maintaining Occupational Radiation Exposure
at Medical Institutions ALARA
(See § 35.20.)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own ALARA program for NRC review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.20. Say on your application, "We have developed an ALARA program for your review that is appended as ATT 10.2," and append your program.

ALARA PROGRAM

_____
(Licensee's Name)

_____
(Date)

1. Management Commitment

   a. We, the management of this (medical facility, hospital, etc.), are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable

level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (see Section 6 below for a discussion of investigational levels).*

---

*The NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

Table 1

Investigational Levels

	Investigational Levels (mrems per calendar quarter)	
	Level I	Level II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes.

(3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by § 20.401 of 10 CFR Part 20. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

   The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Personnel dose equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Reestablishment of investigational levels to levels above those listed in Table 1.

   In cases where a worker's or a group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

7. Signature of Certifying Official*

I hereby certify that this institution has implemented the ALARA Program set forth above.

_____
Signature

_____
Name (print or type)

_____
Title

*The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

APPENDIX H

Model Procedure for Leak-Testing Sealed Sources
(See § 35.59.)

You or your contractor may use the following model procedure to leak-test sealed sources. If you, or the contractor, follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of §.35.59. Say on your application, "We have developed a leak-test procedure for your review that is appended as ATT 10.3," and append your leak-test procedure.

MODEL PROCEDURE

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

   a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

   b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.

   c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor crosshairs. Also wipe the primary and secondary collimators and trimmers.

   d. If you are testing radium sources at the same time you are testing NRC-licensed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

4. The samples will be analyzed as follows:

   a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

   b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.

   c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

   d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.

   e. Continue the same analysis procedure for all wipe samples.

   f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC must be notified. (See paragraph 21.21(b) of 10 CFR Part 21 and paragraph 35.59(e)(2) of 10 CFR Part 35.)

   g. Sign and date the list of sources, data, and calculations.

APPENDIX I

Model Rules for Safe Use of Radiopharmaceuticals
(See § 35.21.)

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of Part 35. Say on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4," and append your model rules for the safe use of radiopharmaceuticals.

MODEL RULES

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a crystal probe or camera.

4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

12. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed dosages of less than 10 microcuries. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.

15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

APPENDIX J

Model Spill Procedures
(See § 35.21.)

You may use the following model spill procedures as they appear here, saying on your application, "We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed spill procedures for your review that are appended as ATT 10.5," and append your spill procedures.

MODEL PROCEDURES

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

4. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.

5. Report the incident to the Radiation Safety Officer (RSO).

6. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 10) and the Radioactive Spill Contamination Survey (see Exhibit 11).

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.

2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. Close the room and lock or otherwise secure the area to prevent entry.

5. Notify the RSO immediately.

6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 10) and the Radioactive Spill Contamination Survey (see Exhibit 11).

The following is not part of the model spill procedure:

Major Spills and Minor Spills

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill procedure may be restricted access pending complete decay.

Table J-1, which may be used as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented, was developed based on a comparision of information from the following sources:

1. "Standards for Protection Against Radiation," Proposed Rule, Part 20, published January 9, 1986, Appendix B, Table 1, Column 3 (Derived Air Concentration Values), 51 FR 1092.

2. "Gamma Radiation Levels for One Curie of Some Radionuclides," Radiological Health Handbook, January 1970 edition, Department of Health, Education, and Welfare, Washington, DC, p. 131.

3. National Council on Radiation Protection and Measurements, "Safe Handling of Radioactive Materials," NCRP Report No. 30, paragraph 2.3 and Table 2, 1964.

4. "Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees," Advance Notice of Proposed Rulemaking on Parts 30, 40, and 70, 46 FR 29712, Table 1, June 3, 1981.

Table J-1 may need to be modified before being used for guidance in a specific area of use.

TABLE J-1

Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	Tc-99m	100
Cr-51	100	In-111	10
Co-57	100	I-123	10
Co-58	10	I-125	1
Fe-59	10	I-131	1
Co-60	1	Yb-169	10
Ga-67	100	Hg-197	100
Se-75	10	Au-198	10
Sr-85	10	Tl-201	100

Spill Kit

You may also want to consider assembling a spill kit that contains:

6 pairs disposable gloves, 1 pair housekeeping gloves
2 disposable lab coats
2 paper hats
2 pairs shoe covers
1 roll absorbent paper with plastic backing
6 plastic trash bags with twist ties
"Radioactive Material" labeling tape
1 china pencil or marking pen
3 prestrung "Radioactive Material" labeling tags
Supplies for 10 contamination wipe samples
Instructions for "Emergency Procedures"
Clipboard with one copy of Radioactive Spill Report Form
Pencil

Forms

You may want to use Exhibit 10, Radioactive Spill Report, and Exhibit 11, Radioactive Spill Contamination Survey Forms.

APPENDIX K

Model Guidance for Ordering and Receiving Radioactive Material (See §§ 30.51 and 20.205.)

You may use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of §§ 30.51 and 20.205. Say on your application, "We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 10.6," and append your procedure for ordering and receiving radioactive material.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. For routinely used materials

      (1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

      (2) The above records will be checked to confirm that material received was ordered through proper channels.

   b. For occasionally used materials (e.g., therapeutic dosages)

      (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

      (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.

4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room ____. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, _____, at extension ___.

	Name	Home Telephone
Radiation Safety Officer:	_____	
Chief of Nuclear Medicine:	_____	
Chief Nuclear Medicine Technologist:	_____	
Nuclear Medicine Technologist on call (call page operator at extension ___)		
Nuclear Medicine Physician on call (call page operator at extension ___)		

APPENDIX L

Model Procedure for Safely Opening Packages Containing Radioactive Material
(See §§ 35.23, 30.51, 20.203(f)(4), and 20.205.)

You may use the following model procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2."

If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Say on your application, "We have developed a package opening procedure for your review that is appended as ATT 10.7," and append your package opening procedure.

MODEL PROCEDURE

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm^2.

2. For packages received under the specific license, the following procedure for opening each package will be followed:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

   c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see § 71.4 of 10 CFR Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See § 172.403 of 49 CFR Part 172.))

   d. Open the package with the following precautionary steps:

      (1) Remove the packing slip.

(2) Open the outer package following the supplier's instructions, if provided.

(3) Open the inner package and verify that the contents agree with the packing slip.

(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

(5) If anything is other than expected, stop and notify the RSO.

e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. [The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.] Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.

h. Make a record of the receipt.

3. For packages received under the general license in § 31.11, the following procedure for opening each package will be followed:

a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.

b. Check to ensure that the material received is the material that was ordered.

See Exhibit 12 for a sample record form you may want to use.

APPENDIX M

Records of Byproduct Material Use

General

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures. Also, you do not have to replicate entries. For example, if you prepare a multidose vial for use one day, you do not have to record the date each time you draw a dosage from it; if you take 30 Ir-192 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

M.1 Records of Unit Dosage Use (§§ 30.51, 35.21, 35.53)

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of §§ 30.51, 35.21, and 35.53. Say on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as ATT 10.8," and append your unit dosage record procedure.

MODEL PROCEDURE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
    a. Prescribed dosage (unless already recorded in clinical procedure manual),

b. Measured activity in millicuries or microcuries and date and time of measurement,
c. Patient name and identification number if one has been assigned;

9. If discarded, the date and method of disposal; and

10. Initials of the individual who made the record.

See Exhibit 13 for a Unit Dosage Receipt and Use Log Form you may want to use.

M.2 Records of Multidose Vial Use (§§ 30.51, 35.21, 35.53)

You may use the following model procedure to keep a record of multidose vial use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own multidose vial record system for review. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of §§ 30.51, 35.21, and 35.53. Say on your application, "We have developed a procedure for a multidose vial record system for your review that is appended as ATT 10.9," and append your multidose vial record procedure.

MODEL PROCEDURE

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;

2. Generic name or its abbreviation or trade name;

3. Date of receipt or preparation;

4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);

5. Supplier or kit manufacturer;

6. If administered,

   a. Prescribed dosage (unless already recorded in clinical procedure manual),
   b. Date and time dosage was drawn and measured,
   c. Calculated volume that is needed for the prescribed dosage,
   d. Measured activity in millicuries or microcuries,
   e. Patient name and identification number if one has been assigned;

7. If discarded, the method of disposal and date; and

8. Initials of the individual who made the record.

See Exhibit 14 for a Multidose Vial Preparation and Use Log Form you may want to use.

M.3 Measuring and Recording Molybdenum Concentration (§ 35.204)

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect that should be reported under paragraph 21.21(b) of 10 CFR Part 21.

The model procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig." Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99m generator elution. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix M.3 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of § 35.204. Say on your application, "We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as ATT 10.10," and append your procedure for measuring and recording molybdenum concentration.

MODEL PROCEDURE

Each time a generator is eluted, make a record of the:

1. Date the generator was received;

2. Date and time of elution;

3. Measured Mo-99 activity in microcuries;

4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;

5. Measured Tc-99m activity in millicuries;

6. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. (If it isn't, stop and notify the RSO. In conformance with paragraph 21.21(b) of 10 CFR Part 21, the licensee must notify the NRC if

a leaking generator is detected.) [The 0.07 action level allows for the quicker decay of the Tc through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.]

7. Initials of the person who made the record.

M.4 Keeping an Inventory of Implant Sources (§§ 30.51, 35.21, 35.406)

You may use the following model procedure to keep an inventory and use record for implant sources. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for keeping an inventory and use record for implant sources. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of §§ 30.51, 35.21, and 35.406. Say on your application, "We have developed a procedure for keeping an inventory of implant sources for your review that is appended as ATT 10.11," and append your procedure for keeping an inventory and use record for implant sources.

MODEL PROCEDURE

1. Use a locking installed cabinet or safe to store all implant sources.

2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.

3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.

4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.

5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name, and the time and date they were removed from storage; initial the record.

6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.

7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

See Exhibit 15 for a sample form you may want to use.

APPENDIX N

Model Procedure for Area Surveys
(See § 35.70.)

You may use the following model procedure to perform area surveys. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of § 35.70. Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

MODEL PROCEDURE

Ambient Dose Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.

   d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:

   a. The date, area surveyed, and equipment used.

   b. The name or initials of the person who made the survey.

   c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions." See Regulatory Guide 8.23 or Table N-1 below for guidance in establishing your action levels.)

   d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm^2, as appropriate.

   e. Actions taken in the case of excessive dose rates or contamination and followup survey information.

2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

The following information is not part of the model procedure.

See Exhibit 16 for a sample record form.

Table N-1

Recommended Action Levels in dpm/100 cm^2 for Surface Contamination by Radiopharmaceuticals

		P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1.	Unrestricted areas, personal clothing	200	2,000
2.	Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX O

Model Procedure for Monitoring, Calculating, and Controlling Air Concentrations
(See §§ 20.103, 20.106, 20.201, 35.90, and 35.205.)

WORKER DOSE FROM NOBLE GASES (Item 10.13.1)

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

If you will collect spent gas in a shielded trap with an effluent air contamination monitor and will follow the monitor manufacturer's instructions for checking its accuracy and constancy, you may respond to Item 10.13.1 by saying, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you will collect spent gas in a shielded trap and will follow the model procedure for checking trap effluent, you may respond to Item 10.13.1 by saying, "We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix 0.3 to Regulatory Guide 10.8, Revision 2.

If you are not monitoring trap effluent or if you exhaust spent gas to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for NRC review during inspections.) If you will follow the model procedure below for calculating worker dose from noble gases, you may respond to Item 10.13.1 by saying, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix 0.1 to Regulatory Guide 10.8, Revision 2."

If none of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of §§ 20.103, 20.201, 35.90, and 35.205. Say on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as ATT 10.13.1," and append your procedure for monitoring worker dose from noble gases.

WORKER DOSE FROM AEROSOLS (Item 10.13.2)

If you will collect spent aerosol in a shielded trap, will use an air contamination monitor for reusable traps, and will follow the monitor manufacturer's instructions for checking for accuracy and constancy, you may respond to Item 10.13.2 by saying, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for NRC

review during inspections.) If you will follow the model procedure below for calculating worker dose from aerosols, you may respond to Item 10.13.2 by saying, "We will follow the model procedure for calculating worker dose from aerosols that was published in Appendix 0.1 to Regulatory Guide 10.8, Revision 2."

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of §§ 20.103, 20.106, 20.201, 35.90, and 35.205. Say on your application, "We have developed a procedure for monitoring worker dose due to aerosol concentrations that is appended as ATT 10.13.2," and append your procedure for monitoring worker dose from aerosols.

0.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS

1. Collect the following data:

   a. Estimated number of studies per week;

   b. Activity to be administered per study;

   c. Estimated activity lost to the work areas per study (you may assume 20 percent loss);

   d. Measured airflow supplied by each vent in the imaging room (if different during heating and cooling seasons, use the lesser value);

   e. Measured airflow exhausted by each vent in the imaging room (the exhaust should be vented and not recirculated within the facility);

   f. Measured airflow exhaust at the storage site (e.g., a fume hood); and

   g. Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-5} µCi/ml in restricted areas and 3×10^{-7} µCi/ml in unrestricted areas. For soluble Tc-99m, the maximum permissible values are 4×10^{-5} µCi/ml in restricted areas and 1×10^{-6} µCi/ml in unrestricted areas. For other gases or aerosols, see Appendix B to 10 CFR Part 20.

2. The following calculations must be made:

   a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.

   b. The estimated average concentration in restricted areas.

      (1) The total activity released to the restricted area (activity used each week multiplied by estimated fractional loss per study) divided by the total air exhausted (sum of all exhaust rates multiplied by the length of the work week) must be less than the applicable maximum permissible value for a restricted area.

(2) If this is not the case, plan for fewer studies. (An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.)

0.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable maximum permissible value for an unrestricted area.

2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

0.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions and keep a record of the checks.

2. If you do not monitor the trap effluent, check it on receipt and once each month. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.

3. The RSO will establish an action level based on cpm or a multiple of background cpm. If you measure a significant increase in the bag cpm, the trap is breaking down and must be replaced.

4. Follow the trap manufacturer's instructions for replacing the trap.

PUBLIC DOSE FROM AIRBORNE EFFLUENT (ITEM 10.13.3)

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value of Table II of Appendix B to 10 CFR Part 20.

If you are not directly venting aerosols and gases to the atmosphere, you may respond to Item 10.13.3 by saying, "We will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary."

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. (You do not have to submit

the calculations with your application, but you should keep them for NRC review during inspections.) If you will follow the model procedure below for calculating release concentrations, you may respond to Item 10.13.3 by saying, "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix 0.2 to Regulatory Guide 10.8, Revision 2."

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of §§ 20.106, 20.201, 35.90, and 35.205. Say on your application, "We have developed a procedure for monitoring airborne effluent concentration that is appended as ATT 10.13.3," and append your procedure for monitoring airborne effluent concentration.

SPILLED GAS CLEARANCE TIME (Item 10.13.4)

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described in Appendix 0.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

If you will calculate spilled gas clearance times according to the following procedure, you may respond to Item 10.13.4 by saying, "We will calculate spilled gas clearance times according to the procedure that was published in Appendix 0.4 to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of § 35.205. Say on your application, "We have developed a procedure for calculating spilled gas clearance times that is appended as ATT 10.13.4," and append your procedure.

0.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

1. Collect the following data:

   a. A, the highest activity of gas in a single container, in microcuries;

   b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;

   c. Q, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;

   d. C, the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-5} µCi/ml in restricted areas and 3×10^{-7} µCi/ml in unrestricted areas. For other gases, see Appendix B to 10 CFR Part 20; and

   e. V, the volume of the room in milliliters.

2. For each room make the following calculations:

   a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.

   b. The evacuation time $t = \frac{-V}{Q} \times \ln (C \times V/A)$.

APPENDIX P

Model Procedure for Radiation Safety During Iodine Therapy Over 30 Millicuries
(See §§ 35.300, 35.75, and 20.105.)

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix P to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of §§ 19.12, 20.105, 35.75, and 35.300. Say on your application, "We have developed a procedure for radiation safety during therapeutic use of radiopharmaceuticals for your review that is appended as ATT 10.14," and append your procedure.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.

2. Prepare the room for the procedure as follows:

   a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, door knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.

   b. Prepare separate boxes for linen, disposable waste, and nondisposable contaminated items. Place a single large reclosable plastic bag in each box, or supply several small plastic bags.

   c. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.

      (1) Containers should be unbreakable and closable.

      (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.

      (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.

      (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)

      (5) Supply a wide-mouth antisplash funnel.

d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

4. Supply the nurses with film badges, TLDs, or pocket ionization chambers.

5. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Iodine-131, Phosphorus-32, or Gold-198" (Exhibit 17), or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

7. Only those persons needed for medical, safety, or training purposes should be present during the administration.

8. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in paragraph 20.105(b)). Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.

10. For patients treated with liquid or gelatin-capsuled I-131, 1 day after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also consider a thyroid burden assay for patient care personnel 2 days after the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.

11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.

12. Do not release any patient until either the exposure rate from the patient is less than 5 millirem per hour at 1 meter or the retained radioactivity is less than 30 millicuries (see § 35.75). If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.

    a. Remove all absorbent paper, and place it in the appropriate container.

    b. Transfer all containers to a decay-in-storage or decontamination area.

    c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm^2.

    d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

Exhibit 18, "Radiation Safety Checklist for Iodine Therapy over 30 Millicuries," may also be helpful to you.

APPENDIX Q

Model Procedure for Radiation Safety During Implant Therapy
(See §§ 35.75, 35.404, and 35.406.)

You may use the following procedure to reduce worker and public dose during implant therapy. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for radiation safety during implant therapy that was published in Appendix Q to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of §§ 19.12, 20.105, 35.75, 35.404, and 35.406. Say on your application, "We have developed a procedure for radiation safety during implant therapy for your review that is appended as ATT 10.15," and append your procedure.

You may find a checklist to be helpful, such as Exhibit 19, "Radiation Safety Checklist for Temporary Implant Therapy."

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room unless the dose at one meter from the implant meets the requirements in paragraph 20.105(b) of 10 CFR Part 20.

2. Supply the nurses with film badges, TLDs, or pocket ionization chambers.

3. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated With Temporary Implant Sources," Exhibit 20, or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing.

4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.

5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.

6. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

7. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in paragraph 20.105(b)). Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.

8. Do not release any patient who has received a temporary implant from the hospital until both a radiation survey of the patient and a count of

implant sources, trains, or ribbons confirms that all sources have been removed from the patient and are accounted for. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form. For low-activity seeds (less than 1 millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.

9. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than 5 mR/hr at 1 meter. Measure this exposure rate with a radiation measurement survey meter at a distance of 1 meter from the umbilicus with the patient standing.

You may want to use the sample forms in Exhibit 19, "Radiation Safety Checklist for Temporary Implant Therapy," Exhibit 20, "Nursing Instructions for Patients Treated with Temporary Implant Sources," and Exhibit 21, "Sample Cesium Implant Source Log."

APPENDIX R

Model Procedure for Waste Disposal
(See §§ 20.301, 20.303, 20.306, and 35.92.)

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review the requirements of §§ 20.301, 20.303, 20.306, and 35.92. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 11.1," and attach your procedure.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (see paragraph 20.303(d)) and generally licensed in vitro kit exemptions (see paragraph 31.11(f)), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See paragraphs 30.51(a) and 20.401(c)(3).)

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in § 20.303. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.303(d).) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 millicurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (§ 20.306). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your radiation detection survey meter for proper operation;

   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container;

e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to § 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

Part 2 - ADDITIONAL INFORMATION FOR MANAGING RADIATION SAFETY PROGRAMS FOR MEDICAL USE LICENSEES

APPENDIX S

Regulatory Requirements

The following documents provide licensees with a summary of the information considered by the Commission when preparing the revision of 10 CFR Part 35.

COMMISSION NOTICES

POLICY STATEMENTS

Medical Uses

44 FR 8242
Published 2/9/79
Effective 2/9/79

Regulation of the Medical Uses of Radioisotopes; Statement of General Policy

AGENCY: Nuclear Regulatory Commission.

ACTION: Final Policy Statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) has the following policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes. It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

EFFECTIVE DATE: February 9, 1979.

FOR FURTHER INFORMATION CONTACT

Mr. Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone: 301-443-5860).

SUPPLEMENTAL INFORMATION: The NRC has developed the following three part policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. On March 17, 1978, the three part policy statement was published in the FEDERAL REGISTER (43 FR 11208) for public comment. Copies of the policy statement were sent to all NRC medical licensees, the States and 25 professional societies, Federal agencies, and individuals. The comment period expired May 16, 1978. Twenty-two comments were received. Nine commenters favored all three parts of the policy statement, four commenters opposed one part of the policy statement and nine commenters addressed specific issues discussed in the March 17, 1978 FEDERAL REGISTER notice. The comments are discussed in Section II. Copies of the comments may be examined in the NRC Public Document Room at 1717 H Street, N.W., Washington, D.C.

I. STATEMENT OF GENERAL POLICY

This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes.

It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

Based on past experience and the comments and advice of the public, other Federal agencies, the States, and NRC's Advisory Committee on the Medical Uses of Isotopes, the Commission has developed the following statement of general policy to guide its regulation of the medical uses of radioisotopes:[1]

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

[1] NRC licenses radioisotopes in three categories: byproduct, source and special nuclear material. The NRC does not regulate naturally occurring or accelerator produced radioisotopes. The term *byproduct material* means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material. The term *source material* means (1) uranium, thorium or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of (i) uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material. *Special nuclear material* means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235 or (2) any material artificially enriched by any of the foregoing, but does not include source material.

II. RATIONALE

The NRC and its predecessor the Atomic Energy Commission have regulated the medical uses of radioisotopes since 1946. AEC recognized that physicians have the primary responsibility for the protection of their patients and designed its regulations accordingly. The physicians were required to be licensed by the State, and their applicable training and experience were evaluated in consultation with the Advisory Committee on the Medical Uses of Isotopes. This regulation has been generally oriented toward assisting qualified physicians in discharging their responsibilities to patients. However, regulation by AEC/NRC has at one time or another encompassed nearly every aspect of the delivery of radioisotope medical services to patients. The broadest regulation occurred between 1962 and 1975, when the Food and Drug Administration (FDA) exempted from its requirements for new drugs all radiopharmaceuticals regulated by AEC. During this period AEC regulated the radiation safety of workers and the general public *and* the safety and efficacy of radioactive drugs and devices with respect to patients. AEC regulation included production of the radioisotope, manufacture of the final radioactive drug product or device, distribution, use and disposal of the products. In 1975, the FDA terminated the exemption for radiopharmaceuticals, stating that it would now regulate the safety and efficacy of radioactive drugs with respect to patients. (As noted later in this statement, FDA does not regulate the physician's routine use of radiopharmaceuticals.) At the same time, NRC withdrew from regulating radioactive drug safety and efficacy, stating that it would regulate the radiation safety of the workers and the public. The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act extended FDA's authority over medical devices (including devices containing radioactive materials) in a way similar to its authority over drugs.

NRC's authority to regulate domestically the medical uses of byproduct material is found in the Atomic Energy Act of 1954, as amended. For example, section 81 of that Act authorizes NRC "to issue general or specific licenses to applicants seeking to use byproduct material for * * * medical therapy * * *." Section 81 directs NRC

to regulate the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import and export of byproduct material. Finally, Section 81 also directs that:

> The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.

Commission regulations, for the most part set forth in 10 CFR Parts 30 through 35, were promulgated to carry out the broad regulatory scheme envisaged by section 81. For example, Part 35 establishes regulations specific to human uses of byproduct material. FDA's statutory authority (Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*) does not diminish NRC's authority. Where NRC's and FDA's authorities overlap, the respective authorities can be harmonized by interagency agreement.

The central question is a question of *policy* not *authority*, namely:

To what extent should the protection of the patient be considered in NRC's regulation of the medical use of byproduct material?

From the standpoint of *authority*, it is clear that NRC can regulate the medical uses of byproduct material to protect the health and safety of users of this material, for instance, patients. In licensing the possession and use of byproduct material, NRC establishes limits within which physicians exercise professional discretion. From the standpoint of *policy*, these limits depend upon how NRC views the potential hazard to the patient's health and safety in the uses of the byproduct material. The greater the potential hazard to a patient from the byproduct material or its use by a physician, the more NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.

The first part of NRC's policy statement indicates that NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.[2] This is the traditional regulatory function of NRC for all uses of byproduct, source and special nuclear material. It is a regulatory role that was not questioned by any of the commenters but, rather, it was consistently recognized as a necessary role in the medical uses of radioisotopes.

NRC's regulation of the radiation safety of workers and the general public in the medical uses of radioisotopes is relinquished by NRC to Agreement States; does not overlap with FDA's activities; is in harmony with regulation by the Department of Transportation, Social Security Administration and the Joint Commission on Accreditation of Hospitals; and dovetails with Occupational Safety and Health Administration regulation of the work-place for the use of naturally-occurring and accelerator-produced radioactive materials.

The second part of NRC's policy statement indicates that NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate. As noted before, NRC has the authority to regulate the radiation safety of patients.

The NAS-BEIR [3] report discusses limiting the exposure of the population to medical applications of ionizing radiation. That report, which includes all medical uses of ionizing radiation, shows an average dose rate from radiopharmaceuticals of 1 mrem/year and an average dose rate from diagnostic radiology of 72 mrem/year in 1970.

The following quotation is from the NAS-BEIR report:

> In the foreseeable future, the major contributors to radiation exposure of the population will continue to be natural background with an average whole body dose of about 100 mrem/year, and medical applications which now contribute comparable exposures to various tissues of the body. Medical exposures are not under control or guidance by regulation or law at present. The use of ionizing radiation in medicine is of tremendous value but it is essential to reduce exposures since this can be accomplished without loss of benefit and at relatively low cost. The aim is not only to reduce the radiation exposure to the individual but also to have procedures carried out with maximum efficiency so that there can be a continuing increase in medical benefits accompanied by a minimum radiation exposure.

NRC will act to help ensure that radiation exposure to patients is as low as is reasonably achievable, consistent with competent medical care and with minimal intrusion into medical judgments. NRC will not exercise regulatory control in those areas where, upon careful examination, it determines that there are adequate regulations by other Federal or State agencies or well administered professional standards. Wherever possible, NRC will work closely with Federal and State agencies and professional groups in designing new voluntary guidance for practitioners to limit unnecessary patient radiation exposure.

The third part of NRC's policy statement indicates that NRC will minimize its intrusion into medical judgments affecting the patient and into other areas traditionally considered to be a part of the practice of medicine. The Commission recognizes that physicians have the primary responsibility for the protection of their patients. The Commission believes that basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient relationship and are traditionally considered to be a part of the practice of medicine. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

The regulations try to find a balance between adequate controls and avoidance of undue interference in medical judgments. A consequence of too much regulation could be poorer health care delivery to patients. A consequence of leaving to physicians the majority of the decisions concerning their patients is that the physicians will make mistakes. The tightest regulation of physicians' decisions by Federal, State and professional groups will not be able to prevent future incidents in the medical uses of radioisotopes.

The Commission recognizes that FDA regulates the manufacture and interstate distribution of drugs, including those that are radioactive. FDA also regulates the investigational and research uses of drugs as well as the specific guidance on doses and procedures found in the product labeling. However, FDA does not have the authority to restrict the routine use of drugs to procedures (described in the product labeling) FDA has approved as safe and effective. Indeed, NRC is the only Federal Agency that is currently authorized to regulate the routine use of radioactive drugs from the standpoint of reducing unnecessary radiation exposure to patients.

The Commission believes that the diagnostic use of radioactive drugs is, in most cases, clearly an area of low radiation risk to patients. Therefore, NRC will not control physician's prerogatives on patient selection, instrument selection, procedure selection, drug selection and dose level for most diagnostic uses of radioisotopes. For all therapeutic uses of radioactive drugs, and in certain diagnostic uses – for example, the use of phosphorus-32 for localization of eye tumors—the risk to patients is not low. The risk of tissue or organ damage (or even death) is inherent in the use of therapeutic levels of radioactive drugs. NRC will continue to restrict the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by FDA. The NRC will not control the physicians' prerogatives on patient selection and instrument selection for therapy procedures, because these procedures are so specialized and patient specific.

Congress recently gave FDA authority to regulate medical devices, similar to FDA's authority to regulate drugs, but with additional authority to restrict the routine use of medical de-

---

[2] The term general public in this statement specifically excludes patients.

[3] National Academy of Sciences Advisory Committee on the Biological Effects of Ionizing Radiations (NAS-BEIR) report. *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation, National Academy of Sciences—National Research Council*, Washington, D.C. (1972).

vices as may be necessary to provide reasonable assurance of their safety and effectiveness. FDA has not yet had sufficient time to implement its full authority to regulate medical devices containing byproduct, source or special nuclear material. Therefore, NRC will continue to restrict physician's uses of these medical devices, both for diagnosis and therapy, to those procedures that NRC has determined (in consultation with its Advisory Committee on the Medical Uses of Isotopes) to be safe and effective.

The Commission does not consider equipment calibration, qualifications of paramedical personnel or reporting to NRC misadministrations of radioactive material to be exclusively the practice of medicine or a part of physician-patient relationships. The Commission intends to regulate these areas of patient radiation safety where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

III. Discussion of Public Comments

A. Comments on the Policy Statement

One commenter opposed the use of the general term "radioisotopes" in the first part of the policy statement. This commenter was concerned that, if taken out of the context of the footnote, it could be interpreted to include naturally occurring and accelerator produced radioisotopes.

The Commission believes that the general term "radioisotopes" is plain English and easily recognized by the public. It was properly footnoted in the policy statement to include the more cumbersome but specific terms: byproduct, source and special nuclear material and to exclude naturally occurring and accelerator produced radioactive material.

One commenter, in opposition to NRC's regulation of patient radiation safety, suggested that NRC limit its role to the radiation safety of the hospital staff and the general patient population. He believes that patient dosimetry is a responsibility of the individual institution and not NRC. This commenter feels that NRC should first require adequate staffing, including a board certified physician or radiopharmacist and a radiation safety officer, and then essentially leave the institution alone regarding dosimetry, instrumentation, calibration, drug procurement or any other function considered to be the practice of medicine.

NRC does require the licensee to staff its operation with a radiation safety officer and a physician (not necessarily board certified) trained to administer radioactive material or radiation to patients. However, the Commission cannot limit its regulatory role to protecting the hospital staff and the general patient population and at the same time fulfill its congressional mandate to protect the health and safety of the public as regards source, byproduct and special nuclear material. The patient being treated or diagnosed with radioactive material, as well as the general public who may be exposed to radiation as a result of that treatment, are all members of the public to be protected by NRC.

Two commenters objected to NRC's regulation of patient radiation safety because they believe that NRC does not have the authority to regulate patient safety. They note that NRC's enabling legislation does not specifically mention the radiation safety of patients. They believe that patient safety is the responsibility of the physician, a responsibility that cannot be shared. They believe that the Commission is in error to equate patients with the public and to consider patients as users rather than recipients of radioactive material.

As noted in the analysis of the similar comment above, the NRC's overriding congressional mandate is to protect the health and safety of the public. The patient is a member of the public, notwithstanding the Commission's recognition of physicians' primary responsibility for protection of their patients. The policy statement and, indeed, all of the Commission's actions in regulating the medical uses of radioisotopes, acknowledge the secondary but necessary role of NRC in regulating the radiation safety of patients. The Commission also considers patients to be both users and recipients of radioactive material. However, the distinction between receipt and use of radioactive materials is not meaningful in this case because NRC regulates, among other things, receipt, possession, use and transfer of byproduct, source and special nuclear material in protecting the health and safety of the public.

B. Comments on Specific Issues

There were six comments on the question of reporting misadministrations of radioactive material. Three commenters opposed any misadministration reporting and three commenters offered suggestions on how they should be reported. All of the comments will be considered in dealing with NRC's newly proposed misadministration reporting requirement that was published in the Federal Register for public comment on July 7, 1978 (43 FR 29297).

There were six comments on the specific issue of paramedical training. Three commenters believe that it is unnecessary for NRC to become involved in paramedical training because several organizations are already providing or developing minimum standards, guidelines or certification. One commenter believed that NRC should be involved in this area because the technologist, not the physician, does most of the work with radioisotopes. Two commenters believe that radiological physicists should be separated out from other paramedical personnel and one of these commenters offered a definition of radiological physicist.

As noted in the proposed policy statement, NRC is studying the various allied health certification programs currently in effect or being drafted by other Federal, State and professional groups. If the coverage provided by these programs is not adequate to protect the patient from unnecessary radiation exposure, NRC will work with these groups to develop a new NRC proposed rule for the training of allied health personnel.

There were five comments on the specific subject of nuclear pharmacies (radiopharmacies).

One commenter urged NRC to distinguish between radiopharmacists working in a hospital setting and those working in a retail environment (commercial nuclear pharmacy). This commenter also noted the complexity of the problem of definition when the hospital based radiopharmacy provides radiopharmaceuticals to other hospitals and practitioners in its area.

As noted in the proposed policy statement, the NRC will defer to the Food and Drug Administration (FDA) regarding a determination of those activities of nuclear pharmacies that will be considered manufacture and those activities that will be considered the ordinary practice of pharmacy (compounding and dispensing).

Four commenters objected to NRC's licensing nuclear pharmacies to distribute only those products that they have prepared from FDA-approved radiopharmaceuticals or reagent kits. One commenter cited the practice of nuclear pharmacies supplying radiochemicals to researchers who use them on humans under their own FDA "Notice of Claimed Investigational Exemption for a New Drug" (IND). One commenter noted that FDA permits nuclear pharmacies to operate in the absence of a final determination of their status, providing they meet all State and local pharmaceutical regulations. The two other commenters characterized the NRC's restrictions on the distribution of radiopharmaceuticals by nuclear pharmacies as an unwarranted intrusion into the practice of pharmacy which is regulated by the States.

NRC licenses nuclear pharmacies to distribute radioactive drugs that have been approved by FDA. This includes radioactive drugs subject to an FDA-approved "New Drug Application" (NDA), or "Notice of Claimed Investigational Exemption for a New Drug" (IND). NRC relies on FDA approval of radioactive drugs because NRC has not regulated the safety and effectiveness of radioactive drugs since 1975. Also, there are not many States that are equipped to regulate radioactive drug safety and effectiveness.

Dated at Washington, D.C. this 1st day of February 1979.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, 35, and 40

Medical Use of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is revising its regulations to modify the process for licensing and regulating the medical use of radioactive byproduct material. The revision will primarily affect hospitals, clinics, and individual physicians.

By clarifying and consolidating all the essential radiation safety requirements that are now contained in the regulations, license conditions, regulatory guides, and staff positions, the regulation provides a single source of requirements related specifically to the medical use of byproduct materials. The regulation also provides flexibility for licensees by allowing them to update their day-to-day radiation safety procedures without applying for and receiving a license amendment. The revised regulations provide for a more efficient method of regulating the medical use of byproduct material.

EFFECTIVE DATE: April 1, 1987. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 1, 1987.

ADDRESSES: Copies of the regulatory analysis, analysis of major issues, environmental impact assessment, and the comments received on the proposed rule may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. Single copies of the regulatory analysis, analysis of major issues, and environmental impact assessment are available from Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427–4108.

FOR FURTHER INFORMATION CONTACT: Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427–4108.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Byproduct Material in Medicine

Use for Patient Care

Radioactive materials are used in drugs in the field of nuclear medicine. Drugs labeled with radioisotopes are known as radiopharmaceuticals. In diagnostic nuclear medicine, patients receive these materials by injection, inhalation, or oral administration. Physicians use radiation detection equipment to visualize the distribution of a radioactive drug within the patient. Using this technology, it is possible to locate tumors, assess organ function, or monitor the effectiveness of a treatment. In therapeutic nuclear medicine, larger quantities of radiopharmaceuticals are administered to treat hyperactive thyroid conditions and certain forms of cancer. An estimated 10 million nuclear medicine procedures are performed in this country annually.

Sealed radioactive sources that produce high radiation fields are used in radiation therapy to treat cancer. A radioactive source in a teletherapy machine can be adjusted to direct a radiation beam to the part of the patient's body to be treated. An estimated 100,000 patients receive cobalt-60 teletherapy treatments from NRC licensees each year. Smaller, less radioactive sealed sources are designed to be implanted directly into a tumor area or applied on the surface of an area to be treated. This procedure is known as brachytherapy. NRC licensees perform approximately 10,000 brachytherapy treatments annually.

Sealed radioactive sources can also be used in machines that are used for diagnostic purposes. The source provides a beam of radiation that is projected through the patient. A device on the other side of the patient detects the amount or spatial distribution of radiation that goes through the patient. This can provide information about tissues within the patient. This is a relatively new development in the field of medicine and the NRC has no estimate of the number of these diagnostic procedures performed annually.

State and Federal Regulation

Twenty-eight States, known as Agreement States, have assumed responsibility for regulating certain radioactive materials within their respective borders by agreement with the NRC. (This kind of agreement is authorized by the Atomic Energy Act.) They issue licenses for the medical use of byproduct material, and currently regulate about 5,000 licensees. In non-Agreement States, the NRC issues licenses to medical institutions (mostly hospitals and clinics) and to individual physicians. These licenses authorize certain diagnostic and therapeutic uses of radioactive materials.

II. NRC's Regulatory Program

Policy Regarding the Medical Use of Byproduct Material

In a policy statement published February 9, 1979 (44 FR 8242), the NRC noted that it regulates the medical use of byproduct material as necessary to provide for the radiation safety of workers and the general public, regulates the radiation safety of patients where justified by the risk to patients, and minimizes its intrusion into medical judgments affecting patients and into other areas traditionally considered to be the practice of medicine. The NRC does have the authority to regulate the medical use of byproduct material to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

This revision retains NRC's current balance between adequate controls and undue interference in medical judgments. Too much regulation could result in poorer health care delivery to patients. Insufficient regulation could

result in the unwarranted or unsafe use of radiation.

Current Licensing Practice

The current regulations in 10 CFR Part 35, "Human Uses of Byproduct Material," provide for licensing medical institutions and physicians for medical use. A license may be issued for one or more of six types of medical use. The types of use are defined in Groups I–VI in the current § 35.100. Each group is comprised of a number of diagnostic or therapeutic procedures that have been grouped together because they require similar physician training and radiation safety precautions for safe use. A separate specific license may also be issued for use of a teletherapy unit. Applications for a specific license are very detailed and contain the applicant's step-by-step radiation safety procedures, which are reviewed and approved individually by NRC.

NRC currently has about 2500 specific medical licensees (2200 hospitals and 300 physicians in private practice). Each year the NRC receives about 100 new applications, 500 license renewal applications, and 2,000 license amendment requests.

To help licensees design their radiation safety programs, the NRC has published many NUREG reports and regulatory guides that contain radiation safety guidance. These publications address three general areas: radiological health and safety, personnel training and experience, and facilities and equipment. Experience has shown that if licensees follow the guidance in the publications, the medical use of byproduct material generally poses no hazard to workers and the public.

Because of the potential radiation hazard to workers and the public, the specific license program that NRC uses to regulate medical use incorporates three regulatory features: case-by-case review of applications, on-site inspections, and periodic license renewals.

A major problem with the current licensing program is that radiation protection requirements are not located in one document. Requirements are scattered in the regulations, Inspection and Enforcement (IE) orders that modify a license or group of licenses, and in conditions attached to individual licenses. Suggestions for good practice are contained in NRC regulatory guides and technical reports (NUREG's). For example, Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," [1] and NUREG–0267, "Principles and Practices for Keeping Occupational Radiation Exposure at Medical Institutions As Low As Reasonably Achievable," [2] contain many recommendations that the NRC believes are important for the safe use of byproduct material. The revision of Part 35 incorporates those recommendations, and also corrects the piecemeal fashion in which the regulations have been amended over the years to address specific problems.

When preparing a specific license application for review under the current licensing program, the applicant must include sufficient information to assure NRC reviewers that byproduct material will be used safely. Applicants include, as an integral part of the application package, copies of their proposed step-by-step radiation safety procedures. In many cases, the procedures are edited versions of procedures described in Regulatory Guide 10.8.

When NRC receives the application, a licensing reviewer evaluates the applicant's training and experience, facility, equipment, and radiation safety procedures in detail. If the application is found to be incomplete or inadequate, a "deficiency letter" is sent to the applicant explaining what additional information is needed. Review of the application is not resumed until a written response from the applicant has been received. Staff studies indicate that about 40 percent of all applicants receive either a deficiency letter or a phone call for additional information. The need for deficiency letters stems from two sources. Guidance on what submissions are required to get a license is unclear and scattered in various documents. Application review practice must be conservative because the application and license comprise the basis for regulatory control. Deficiency letters are costly for the NRC and the applicant and greatly increase the time needed to complete licensing actions.

When the application, including any additional submitted information, is approved, the NRC issues a specific license that grants the authority for medical use of byproduct material in accordance with the program described in the application. Requirements in addition to those contained in the regulations are frequently incorporated in the license as conditions of use. Since the licensee must comply with conditions specified in the license, the license, rather than the regulations, is frequently used to regulate radiation safety in the day-to-day use of byproduct material.

The specific license is valid for five years. The license must be amended before methods of use or procedures may be added or changed, or before permitting additional physicians to use materials. Amendments to a specific license involve an application, review, and approval process similar to that for new licenses. Renewals are treated in the same manner as new license applications.

This regulatory process was appropriate during the evolution of the use of byproduct material in medicine. Radiation safety problems were not well defined, regulatory requirements had not caught up with developing technology, physician training curricula had not been established, and there were no formal training programs for nuclear medicine technologists. Therefore, it was necessary to regulate by reviewing each individual radiation safety program to ensure that the applicant had adequate personnel, facilities, and equipment.

III. Revision of the Regulatory Program

Overview

NRC is modifying its regulation of the medical use of byproduct material. The Commission has revised the regulations to provide a single source of requirements specifically related to medical use of byproduct materials. Within the boundaries set by the regulations, NRC will allow medical licensees to make minor changes in their radiation safety procedures that are not potentially important to safety. Such changes are sometimes needed so licensees can make prompt use of new safety methods and also meet new needs caused by changes in the demand for various patient care services or changes in the number of patients served by the licensee. The revision of 10 CFR Part 35 is consistent with the Commission's general policy on medical use of byproduct material issued February 9, 1979 (44 FR 8242). As stated

[1] Regulatory guides are available for inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, DC. Copies of active guides may be purchased at the current Government Printing Office price. A subscription service for future guides in specific divisions is available through the Government Printing Office. Information on the subscription service and current prices may be obtained by writing to the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013–7082.

[2] Copies of NUREGs may be purchased through the U.S. Government Printing Office by calling (202) 275–2060 or by writing to the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013–7082. Copies may also be purchased from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. A copy is available for inspection and copying for a fee in the NRC Public Document Room, 1717 H Street NW., Washington, DC 20555.

in the policy statement, "NRC will continue to regulate the medical uses of radioisotopes, as necessary, to provide for the radiation safety of workers and the general public."

Codification of Requirements in the Regulations

The proposed revision was published for public comment on July 26, 1985 (50 FR 30616). In the proposal, the NRC said it would simplify regulation of medical licensees by incorporating all medical use requirements into 10 CFR Part 35. These regulations would become the primary means of regulating the medical use of byproduct material. General safety requirements for worker instruction, worker safety, noncompliance reports, and materials licensing that are in Parts 19, 20, 21, and 30 will also continue to apply to Part 35 licensees.

The current license application process will be unchanged. The applicant still will complete Form NRC-313, which asks for the following information: the name and mailing address of the applicant; the location of use; a person who can be contacted about the application; what materials are requested; the purpose (in this case, "medical use"); the training and experience of the authorized users and Radiation Safety Officer; the worker radiation safety training program; facilities and equipment; the radiation safety program; and waste management.

Licensees will not face significant new regulatory burdens in their radiation safety programs because, in most cases, the information submitted on Form 313 is transformed into license conditions. Under the revised regulations the license authorizes medical use of byproduct materials for specified types of use. A licensee's use of byproduct material is controlled by the regulations and by license conditions for sitespecific circumstances that can not be generically covered by regulations. This simplifies inspections for NRC because inspectors need only be familiar with one set of regulations rather than a different set of license conditions and radiation safety procedures at each facility.

License Application, Issuance, and Authority and Responsibility Radiation Safety Programs.

New revisions of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," and Draft Regulatory Guide TM 608-4,[3] "Guide for the Preparation of Licenses in Medical Teletherapy Programs," which were distributed to licensees for comment, contain instructions on the type and extent of information that must be submitted based on the byproduct materials for which the applicant has requested a license. The regulatory guides also contain model procedures that the applicant can use to develop site-specific procedures. (Consistent with current practice, applicants will alternatively be allowed to simply certify that they will follow a model radiation safety procedure developed by NRC staff with public comment and published in a regulatory guide. This method significantly reduces the amount of time NRC must spend reviewing radiation safety procedures.) The applicant mails the completed license application, with application fee, to the NRC office identified on the form.

The NRC staff will continue to review the application to determine whether the applicant's radiation safety program is sufficient to comply with the regulations. After completing the review, if the applicant's program appears incomplete or inadequate, NRC will issue a deficiency letter that describes the apparent shortcomings in the applicant's program and requests clarification or correction. If the applicant's response to the deficiency letter is satisfactory, or if no deficiency letter was needed, the license will be issued.

In most cases license conditions will only be used to identify authorized users for each type of use, the Radiation Safety Officer, a teletherapy physicist if required, types of material authorized, possession limits for teletherapy units and brachytherapy sources, and areas set aside for byproduct material use. This regulatory scheme will not incorporate the current license condition requirement that licensees use byproduct material in accordance with the statements made in the application.

Major radiation safety program changes that are clearly potentially important to safety are listed in §§ 35.13 and 35.605 of the final rule; they will require a license amendment. This is required because such changes could significantly affect the public health and safety. Licensees will be free to make minor changes in their radiation safety programs that are not potentially important to safety after conducting an internal review and approval process. This will allow each licensee to make prompt use of new safety methods and to adjust radiation safety procedures to meet new needs caused by changes in demand for patient care services or patient load. A list of radiation safety topics that should be considered when reviewing proposed changes appears in the new revision of Regulatory Guide 10.8. The right to make minor changes does not relieve the licensee from the requirement to comply with the regulations. For example, requirements to have certain equipment on hand and to conduct certain surveys at a certain frequency are required by regulation and cannot be changed. See the analysis of comments on § 35.31 for further discussion of this matter.

The regulations require specific training and experience for each type of use. Proposed authorized user physicians, teletherapy physicists, and Radiation Safety Officers will have to submit summaries of their training and experience. The NRC will review those individuals' training and experience against the standards in the regulation before authorizing them to work under the license. Consistent with current practice, any individual who does not meet the standards may ask for an exemption from the training and experience requirements. The NRC staff will review the individual's training and experience with the assistance of its Advisory Committee on the Medical Uses of Isotopes, and may issue the exemption as a license condition.

Training and Experience Criteria

The NRC notes that, as a separate project, it is reviewing its physician training and experience criteria. If it decides that changes might be in order, the proposed changes will be published for public comment as a separate rulemaking action.

Enforcement

Licensees will be cited for failure to meet the requirements of the regulations or license conditions (which will list, for example, authorized users, address of use, types of use, byproduct material and inventory limits, and site-specific limitations), failure to have on hand the written procedures required by the regulations, failure to follow the procedures on hand, failure to have the records required by the regulations, or failure to follow technically valid radiation safety procedures (examples: using an instrument that doesn't work, not determining instrument detection efficiency, not allowing an instrument enough time to respond, or making

[3] Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Technical Information and Document Control. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

unsubstantiated assumptions in calculations). Use of material can be authorized either by license or by virtue of working under the supervision of an authorized user. Use without authorization would be a violation of the regulations and the Act, which would subject the licensee and individual to enforcement action.

Amendments

Under current regulatory policy, the application coupled with the licensee condition requirement to use material in accordance with the statements made in the application usually provides the basis for inspection citations. Now the regulations will contain sufficient prescriptive and performance criteria on which to base enforcement actions. Therefore, the NRC will allow a licensee to make minor changes in its radiation safety procedures that are not potentially important to safety after making an internal review to assure that the change complies with the regulations in Part 35 and in other parts of 10 CFR Chapter I.

However, amendments still will be required for some changes. The NRC will review the training and experience of each proposed authorized user, Radiation Safety Officer, and teletherapy physicist before the individual is listed on a license. A licensee's request to add a type of use (for example, adding radiopharmaceutical therapy to a license that authorizes radiopharmaceuticals for imaging) to an existing license will be handled as a new application. The authorized user's training and experience and the procedures needed in support of the request will be reviewed for completeness and adequacy with respect to the new type of use before the amendment is issued.

A request to leave one location of use and begin working in a new location, for example when moving a private practice to a new office or when moving into a new hospital building, will have to be supported by a complete new license application package.

Licensees that are already allowed to receive packages, prepare radiopharmaceuticals, and package waste at a central facility, but use the byproduct material at satellite locations, will only have to identify the new location. (Due to the training, space, and equipment commitments needed for safety during therapy procedures, the NRC will generally not authorize licensees to perform therapies, except low-level iodine therapies, outside medical institutions. This type of request will be handled on a case-by-case basis.)

Renewals

The NRC license is valid for five years. If a person wants to continue using byproduct material after the five-year license period the license must be renewed. The renewal application must completely describe the entire radiation safety program just as a new application does. If a radiation safety procedure, facility description, or equipment list that was submitted in the application or an approved amendment still accurately reflects that part of the licensee's program, the renewal applicant may simply make a clear reference to the previous submission. If the licensee has changed a procedure, or is using different equipment, a complete new description of the particular procedure or equipment must be submitted. The licensee may also take this opportunity to identify new authorized users or request wider authorization.

Summary of Changes in the Regulatory Program

In summary, the new regulation will require that licensees meet standards that are currently imposed by license conditions. The NRC will continue to review user training and experience. The NRC will review applicants' radiation safety programs, including the site-specific radiation safety procedures, for completeness and adequacy and issue deficiency letters if necessary, but will allow licensees to make minor changes in their radiation safety procedures that are not potentially important to safety after conducting an internal radiation safety review of each change. However, the right to change procedures does not relieve the licensee from the requirement to comply with the regulations. Amendment requests will generally be reviewed just as new applications are reviewed, but they may include by reference material contained in the original application and any previous amendments.

Transition Policy For General Licensees

The General License for Medical Use. The general license program is based on the fact that the quantities and forms of material that are authorized by a general license present a very low health risk. The NRC believes it is no longer efficient to issue medical general licenses that allow the administration of byproduct material to humans. The tests authorized under § 35.31 have been superseded by newer procedures with greater diagnostic accuracy. These developments have been reflected by a significant decrease in applications for general licenses.

To determine the status of general license use, the staff performed a telephone survey of 10 percent of the current registrants. The survey results indicated that less than 9 percent of all the current registrants still use material for medical use under a general license. Many general licensees are now using byproduct material under a specific license. Because of the low level of use of the general license, the NRC has concluded that it no longer serves a useful role in licensing the medical use of byproduct material.

The in vivo general license contained in current § 35.31 has been eliminated from the regulations. In the future, all medical use will be authorized by a specific license. Current general licensees, all of whom are physicians, will receive a specific license that will be incorporated into NRC's filing system for keeping track of specific licensees. However, these licensees will be limited to the clinical procedures described in the current § 35.31, and relieved, by license condition on a pre-printed license, from the requirements that are more burdensome than current requirements under the general licensee. The only action they will need to take is to respond affirmatively to an NRC notice that asks if they want to continue to have an NRC license that is limited to the clinical procedures authorized by the current general license.

The Commission will, under § 170.11(b), exempt these licensees from application and renewal fees as long as their programs are limited to the material uses described in current § 35.31. Under the new specific licensing system, former general licensees that want to make any changes in their programs, amend their licenses, or transfer them to other physicians, will have to apply for a specific license and will be subject to all the fees that apply to other specific licensees.

The Commission has decided to waive fees to former general licensees for the following reasons. General licensees do not now pay fees. About 90% of the 1,100 or so general licensees are inactive. Each year NRC receives only a very few requests for general licenses under § 35.31. There would be no NRC review time needed and only a minor NRC administrative cost to process these licenses. It would be unfair to charge these licensees the fees listed in 10 CFR Part 170, and it would be more costly for NRC to alter that fee structure than to grant the exemption.

The General License for in vitro use. The current Part 35 also grants a general

license for in vitro work described in § 31.11 to group licensees without requiring that they submit an in vitro registration form. The NRC will continue this program unchanged.

Transition Policy for Specific Licensees

Under the current regulatory program, the license document with the appended application is used to regulate each individual licensee. Because the requirements in the revision were taken from commonly used topical license conditions and from regulatory guidance that most licensees have incorporated into their applications, the Commission does not expect any significant inconsistencies between current licensee radiation safety programs and radiation safety programs of applicants that apply after the effective date of the regulations. Therefore, current licensees will normally be cited if they do not comply with the new regulations. However, because each current licensee's radiation safety program was reviewed individually and license conditions were tailored to meet the licensee's individual needs, there may be an occasional inconsistency between a license condition and the regulation (for example, a license may require survey instrument calibration biennially, but the proposed regulation would require calibration annually). There is no health and safety reason to undo these licenses to effect compliance with the regulation. To impose the regulation in addition to or in lieu of the license conditions would not provide for significant additional protection for the public health and safety. The Commission has decided to resolve possible temporary inconsistencies between license conditions and the regulation by providing in the regulation a transition period between the effective date of the rule and the expiration date of each license. During this transition period, if there is an inconsistency between a provision in a license (issued prior to the regulation) and the regulation, the license condition takes precedence over the regulation. Because the license conditions were reviewed from the perspective of overall safety and approved by the NRC, the inconsistency would not result in an increased risk to workers or the public.

In addition to the topical license conditions mentioned above (for example, sealed source leak test requirements, special bioassay requirements, radioactive patient surveys and release limits, or waste disposal restrictions), each specific license has an encompassing license condition that requires each licensee to possess and use licensed material in accordance with the statements, representations, and procedures contained in the license application and in letters of clarification. Despite this encompassing condition, licensees would be allowed to make minor changes in their radiation safety procedures that are not potentially important to safety; permissible changes would be restricted to those identified in § 35.31, and the licensee would have to conduct the internal review required by that section.

In the case of record retention, the regulation will take precedence because, in the past, the Commission has not offered much guidance on this topic. If a record is substantively the same as a record described in the proposed regulation and the licensee has not stated a retention period for that specific record, licensees may adopt the retention period stated in the final rule. However, during the transition period, licensees still will have to comply with any record retention period required by a license condition that deals with a specific topic, or by another Part of 10 CFR Chapter I (for example Part 20). For example, surveys that provide the basis for occupational dose records or measurements of effluent release are governed by Part 20. A license condition that requires retention of a particular record would only have been imposed for a specific public health and safety reason.

NRC does not currently review teletherapy physicist credentials, and does not identify the Radiation Safety Officer on the license. NRC will begin to review the credentials of the Radiation Safety Officer and Teletherapy Physicist and identify both of them just as it does now for authorized users. To add current licensees to this new scheme, licensees must submit the credentials for review and approval when the next amendment or renewal request is required. These individuals will be identified on the next license amendment.

IV. Analysis of Comments

Overview

The NRC analyzed all 113 comment letters that were received prior to drafting the final rule. Comments came from many different sources. A tally is provided in Table 1.

TABLE 1

Source [1]	PP	H	A	C	I	S	O	M
Comments submitted	18	42	8	10	6	22	2	5
ALARA	1	6	0	2	0	1	1	0
Minor changes	0	6	0	-	0	20	2	0
Misadministration reports	1	10	2	1	1	0	2	0
Technical comments	2	31	5	10	6	16	3	4

[1] PP-private practioner; H-hospital; A-professional association; C-radiation safety consultant; I-individual; S-state regulatory program; O-Scientific organization; M-manufacturer

Twenty-nine of the letters addressed training and experience criteria for diagnostic radiopharmaceuticals, an issue which the NRC stated in the Notice of Proposed Rulemaking was being handled as a separate project that will be published for public comment separately. Thirty-three complimented the agency on the completeness and clarity of the rule.

Many commenters addressed the three major issues raised by the proposed rule: the requirement to have an ALARA program, misadministration reporting requirements, and the provision that allows licensees to make minor changes in their radiation safety programs. Nine of the 11 comments received on the ALARA program requirement recommended that the requirement be placed on private practitioners as well as medical institutions. Two recommended either no change or lessening of the requirement. Of those that addressed the provision for minor changes in licensees' radiation safety programs, individuals associated with state regulatory programs were unanimous in recommending that all program changes require license amendment. The other comments indicated satisfaction with the provision. Of the 17 letters that addressed the misadministration reporting requirement, 13 recommended deletion of the diagnostic misadministration reporting requirement, and 4 recommended no change.

The NRC mailed notices to all 1,100 general medical licensees that are licensed under the current § 35.31. Ten requested more information, and 5 indicated that they wanted a license that would allow them to continue their work. The Postal Service returned 141 of the notices as undeliverable.

General Comments

1. *Consolidation and clarification.* Commenters were almost unanimous in complimenting the agency for publishing

the proposed consolidation of requirements. Many endorsed the NRC's view that noncompliance is frequently born of ignorance rather than negligence, and that this problem is best dealt with by putting all requirements in one place. Furthermore, the timing of the revision is appropriate given the growth over the past two decades of the professional literature and various professional organizations.

2. *Word use.* In the notice of proposed rulemaking, the NRC clarified several terms of art that it proposed to use when dealing with medical licensees. Several comments were received.

Licensee. Several commenters noted that the regulations should be revised to allow contractors to do certain chores, noting that the regulation requires "the licensee" to perform certain tasks, while in practice licensees frequently hire outsiders to perform these tasks. The NRC stated in the Notice of Proposed Rulemaking, "The person (individual, partnership, corporation, or agency) listed on the license as the 'licensee' is responsible for compliance with regulations and license conditions. The licensee may effect compliance through full-time or part-time employees, contracts with consultants or service organizations, or other business arrangements. The word 'licensee' is used throughout the regulation to stress the fact that, no matter which method is used, the licensee is legally responsible in case of noncompliance." Therefore, there is no need to revise the regulations in this regard.

Operable. Some commenters suggested that the word "operable" should be inserted "where appropriate to obviate the need, in the future, to constantly explain to licensees that meters must, in fact, *be* operable." The NRC can only repeat what was stated in the notice of proposed rulemaking. "The word 'operable' is not used in the proposed regulation because every piece of equipment must be operable. If a piece of equipment is not operable or reliable, whether due to old or absent batteries, incomplete or improper maintenance, damage, inappropriate use, or improper use, it cannot be used to meet a regulatory requirement because there is no assurance that it accomplished the task for which it was used." The NRC repeats: Every piece of equipment used to meet a regulatory requirement must be operable.

Teletherapy physicist. The current Part 35 uses the term "qualified expert," which is usually used to denote an individual with special training and experience in a field determined in context by the reader. The proposed Part 35 used the term of art "qualified teletherapy calibration expert" to denote the field of special expertise. The final regulation uses the less unwieldy term of art "teletherapy physicist." Although the terminology was changed, the functions of the individual have not.

Roentgen, rad, and rem. These base units are used to measure three different quantities: exposure, dose, and dose equivalent respectively. The NRC notes in 10 CFR 20.4(c) that a dose of one rem is equal to an exposure of one roentgen of x or gamma radiation or a dose of one rad of x, gamma, or beta radiation. In this final rule the NRC has used the base unit rem throughout.

Dose and dosage. In pharmacy, the word "dose" is used to indicate the amount of chemical administered; in radiation biology it is used to indicate the amount of ionizing energy absorbed per unit mass; and in radiation safety it is used as a shorthand term to indicate a worker's exposure to radiation. In order to avoid confusion, the word "dosage" is used in the revised Part 35 to indicate quantities of radioactivity that are measured with the base unit Curie. The word dose is used to indicate quantities of radiation absorbed dose or dose equivalent that are measured with the base unit rad or rem.

Record and report. A record is a user-retrievable notation or complete document. It may consist of something as small as a check-mark on a form or something as extensive as a survey of a newly installed teletherapy unit with appended calculations to demonstrate compliance with the limits on exposure in unrestricted areas. A report is a transfer of information which might be made face to face, by telephone, telegram, computer link, or hard copy transmittal.

Test and check. For many pieces of equipment, drafting committees comprised of industry experts have prepared standards of performance and complete calibration protocols. If a piece of equipment is subjected to the protocol in the calibration laboratory and meets all the standards, then the ability of the equipment to perform as expected in normal field use is assured. In the revised Part 35, this concept of complete examination is referred to as a "test." During field use it is common practice to subject a piece of equipment to a quick examination to determine whether it is working. This procedure does not examine all parameters of equipment performance. In the revised Part 35, this perfunctory examination is referred to as a "check."

Address of use, facility, and area of use. The phrase "address of use" is used to describe the building or buildings (typically identified by a single street address) where byproduct material is used. The word "facility" connotes a room or contiguous rooms where byproduct material is used, such as a nuclear medicine clinic comprised of an office, an imaging room, and a dosage preparation and waste storage room. The phrase "area of use" connotes the space used by a worker when performing a specific task connected with receiving, handling, or storing byproduct material.

Dedicated check source. A long-lived radioactive source can be used to check the day-to-day constancy of an instrument. The *same* source (a "dedicated" source) must be used every day so that the user knows what reading to expect from the instrument. The source may also be used for other purposes.

3. *Instruction.* Several commenters asked if instruction for workers had to be in classroom lecture format. The NRC recognizes that instruction can be in the form of lectures, laboratory exercises, audiovisual packages, printed handouts, preceptorials, or apprenticeships. The important point here is not the format of the instruction, but rather that the instruction be retained and used by the worker. To help correct misunderstandings, an opportunity for questions and answers should be an integral portion of each instruction module.

The NRC did not address the frequency of review sessions because that judgment must be made on-site. If employees are performing all their assigned tasks correctly, there is no need to spend time reviewing procedures with the employees. If instruction has not been followed by regular use of the procedures taught, then review instruction is probably necessary. If an employee is unable to do things correctly, then review and continued close supervision, or re-assignment, is necessary.

4. *Signatures on records.* Several commenters stated that the requirement that a certain individual sign a record or report implicitly required that individual to perform the survey, check, or test that is documented by the record or report. No such implication was or is intended. The NRC realizes that technicians, students, and residents do many of the tasks required by the regulations. The purpose of having a particular individual sign a report is to assure that someone with special training or radiation safety program oversight responsibilities has reviewed the document for correctness, completeness, and need for follow-up action.

5. *Temporary absence.* Several commenters asked if a license amendment or notification was required if an authorized user, Radiation Safety Officer, or Teletherapy Physicist was absent for illness, vacation, sabbatical, or continuing education. Because the specific facts and circumstances would dictate the appropriate action by the licensee, it would be impossible for the NRC to make generic determinations in advance of the situation.

The point can not be reiterated sufficiently that the licensee, despite the absence of personnel, remains responsible for assuring continued compliance with NRC radiation safety requirements.

6. *Deletion of the general medical license in § 35.31.* As noted in the discussion of the transition policy for general licensees for medical use, the general medical license, which authorizes a few radiopharmaceuticals for a few listed clinical procedures, is not frequently used and therefore no longer an efficient way of regulating the medical use of byproduct material. Thus, it has been deleted. However, current general medical licensees will be allowed to continue using materials under specific licenses that the NRC will issue.

7. *Fees.* One licensee said NRC should reduce its medical license fees when applicants propose to use radiation safety procedures that are published in regulatory guides because that reduces the time NRC needs to review the application. The comment can not be addressed in this rulemaking because the proposed rulemaking did not propose any changes to the fee schedule in 10 CFR Part 170. A petition for rulemaking to change Part 170 may be submitted.

8. *Records.* A few commenters said the detailed nature of some recordkeeping requirements ran counter to the philosophy of flexibility on which the revision is based, and may require a change in other administrative procedures. The NRC has retained the detailed prescriptive requirements that describe the information that must be included in each record. The NRC has carefully reviewed each element of data required and believes each is an important part of the record or indicates completion of an important step in a procedure.

Some commenters said a certain record requirement duplicated other records kept elsewhere—for example, diagnostic radiopharmaceutical dosages may be listed in a clinical procedures manual. There is no need to duplicate that information unless the regulation specifically requires that the information be posted or recorded in a certain place.

The NRC notes that, as a separate rulemaking, it is reviewing *all* of its record retention requirements. Some of the retention periods in this final rulemaking may be changed as a result of that project, which will be published for public comment.

9. *SI Units.* A few commenters recommended that the newer International System of Units (SI), which has new units for amount of radioactivity, radiation exposure, radiation dose, and dose equivalent, be used in place of the special radiation units because the SI system is now being used more frequently. The NRC believes that, if indicated, such a change should be made through all NRC regulations at one time, not where it would affect only one group of licensees.

10. *Specialty certification.* Some commenters questioned whether certain physicians who have successfully completed an examination in a medical speciality (diplomates) should be authorized to serve as Radiation Safety Officer, and some recommended that other additional certifications be recognized. The NRC compared the examination criteria applied to diplomates to the responsibilities shouldered by certain individuals and made a judgment that the certifications identified for certain individuals provide an appropriate demonstration of adequate training and experience. Thus, some certifications have been added that were not listed in the proposed rule: American Board of Nuclear Medicine or Board of Pharmaceutical Specialties in Nuclear Medicine for Radiation Safety Officer; and American Board of Radiology for therapeutic use of radiopharmaceuticals.

11. *Training and experience criteria.* Several commenters recommended changes in the training and experience criteria the NRC applies to physicians who want to use radiopharmaceuticals for diagnostic clinical procedures. In the notice of proposed rulemaking the NRC noted that it had "received and is reviewing suggested alternative training standards for some methods of use. The review is being handled as a separate project. If any changes in training standards come out of that project, they will be published for public comment. . . ." The NRC is continuing to review recommendations for alternative training criteria; they will be published for public comment at a later date.

A few commenters said authorized users and Teletherapy Physicists should be at least "board eligible," meaning that they have training and experience sufficient to allow the individual to apply for the certification examination. The NRC notes that most boards do not use this term (instead saying an individual is certified, not certified, or in the examination process), and believes the use of the term might create more confusion than it would resolve.

A few commenters said the required hour-by-hour distribution of content in the classroom and laboratory portions of the training and experience sections was overly restrictive, and would not recognize differences in students or programs. The NRC agrees, and has simply listed required topics, but has retained the *total time* requirements.

12. *Effect on medical broad licensees.* A few commenters said the NRC should indicate which sections apply to broad licensees authorized for medical use under Part 33; some are allowed to name authorized users and some are also allowed to develop new byproduct materials for medical use. The NRC has retained the solution to this question that was in the notice of proposed rulemaking, "These licensees would be required to comply with the proposed prescriptive and performance criteria of Part 35, but would be exempted from the training and experience requirements of Subpart J and the authorized materials and authorized use restrictions in proposed §§ 35.49, 35.100, 35.200, 35.300, 35.400, and 35.500." These changes will not limit broad licensees' authority to conduct medical research and identify authorized users.

13. *Therapy patients.* One commenter suggested that requirements be drafted regarding the handling of deceased patients who had been administered therapeutic radiopharmaceuticals or implants. The NRC notes that § 35.404 requires that the licensee retrieve temporary implants. The regulations, in §§ 35.315 and 35.415, require prompt notification of the Radiation Safety Officer in case of the patient's death, who then is responsible for taking steps to ensure compliance with requirements in Part 20. In case of death after release from confinement for radiation safety purposes, the NRC expects licensees to take steps to reduce doses to pathologists, morticians, and other individuals, but also recognizes the licensee may no longer have control over the remains. Therefore, the NRC can not expect that the licensee is able to take appropriate action.

14. *Voluntary submission of economic data.* Several commenters noted that the application form asks applicants to indicate their annual receipts, number of employees, number of beds, and willingness to furnish additional cost information on the economic impact of

NRC regulations, and said this has nothing to do with NRC's responsibility to assure the public health and safety. The NRC notes that the Regulatory Flexibility Act of 1980 requires Federal agencies to fit requirements to the scale of the entity being regulated. That Act requires that each agency consider the economic effect of its regulations on small entities and that, if a proposed regulation will have a "significant economic impact on a substantial number of small entities," the agency prepare an analysis of the impact. Thus, the NRC requests voluntary submission of economic data to determine what portion of affected licensees are small entities, how they are affected, and whether the regulation could be changed to alleviate adverse effects.

Comments on Specific Sections

Section 35.14 Notification.

Comment: There is no need for a licensee with several authorized users to notify the NRC when one of them leaves. The collective expertise is still sufficient to assure the public health and safety.

Response: The NRC believes this notification is important because high turnover in professional staff may indicate inadequate management of the radiation safety program. The requirement has been retained.

Section 35.20 ALARA program.

Comment: All medical licensees should have such a program because the hazards are the same, whether in a hospital or a clinic. Although it may be burdensome, the private practitioners' programs should be reviewed by an outside consultant.

Comment: "It appears that the principle of ALARA is replacing maximum permissible dose as a standard in matters of radiation exposure. This means that an objective standard with a widely recognized and approved set of limits can no longer be relied upon in quality control and risk management. Instead, radiation exposure will be weighed, *post hoc*, by the 'reasonable man.'"

Response: The NRC agrees that individuals may have difficulty defining what is reasonable, although most can offer "reasonable" solutions to hypothetical problems. However, ALARA is an operating philosophy or principle on which safety programs should be based. It does not prescribe permissible exposure limits.

The NRC has broadened the requirement to apply to all medical licensees. Although on occasion this may result in a private practitioner having a "one-participant conversation," the NRC believes that reviewing a radiation safety program from the perspective of worker protection rather than from clinical or business need may allow for insight or alternative methods that provide for increased safety. Moreover, the requirement for an ALARA program may help inculcate the philosophy of reducing unnecessary exposure in operating procedures.

The NRC agrees that an independent outside review may be helpful, but believes there is inadequate basis for imposing such a requirement. It is beyond the ken of a federal agency to know whether an outsider is needed to review the program managed by the Radiation Safety Officer.

Comment: There is no need for two trigger levels that initiate investigation of higher than usual worker doses; one is sufficient.

Response: The lower level initiates a timely investigation into the cause of a worker dose; the higher level initiates a prompt investigation *and* a review of viable mitigating actions because the investigation may indicate possibility of high worker dose or likelihood of unnecessary worker dose.

Section 35.21 Radiation Safety Officer.

Comment: It is unlikely that an authorized user/Radiation Safety Officer will have the time or inclination to do all the required tasks.

Response: The assigned responsibilities are essential elements of a radiation safety program. Because its inspection program has indicated a high degree of voluntary compliance, the NRC does not foresee adequate motivation as a problem. The NRC repeats that tasks, but not responsibility, can be delegated.

Section 35.22 Radiation Safety Committee.

Comment: The requirement that a licensee's Radiation Safety Committee approve each clinical procedure is unnecessarily burdensome. The NRC has acknowledged that physicians are motivated to act in the best interest of their patients, yet, because of the time needed to conduct the approval process, the physician may not be able to offer services needed by the patient. It is difficult to conceive of radiation safety issues that warrant this requirement.

Response: The NRC agrees that physicians need latitude to provide care for their patients. Once a physician has demonstrated training and experience adequate to safely use a group of materials with similar radiation hazards, an additional internal review is unnecessarily burdensome. The requirement has been withdrawn.

However, to allow the Radiation Safety Committee to meet its oversight responsibilities, the authorized user should report these new diagnostic clinical procedures so they may be incorporated as part of the annual Radiation Safety Program review.

Comment: To avoid potential conflicts, the regulation should identify who should chair the Radiation Safety Committee.

Response: It is beyond the ken of a Federal agency to know which individual or officer in each of 2500 local organizations is best suited to chair a committee.

Comment: NRC should require that a radiopharmacist sit on each committee because medical use includes the use of new radiopharmaceuticals.

Response: FDA's review of new radiopharmaceuticals and package inserts provides adequate assurance that materials distributed for medical use can be used safely. Furthermore, diagnostic radiopharmaceuticals do not present a credible risk to the patient. Therapy radiopharmaceuticals are not compounded or reconstituted by medical licensees.

Comment: The proposed regulation would allow several committees to share the responsibilities of the Radiation Safety Committee. This may cause coordination problems.

Response: The NRC believes that allowing more than one committee to oversee the radiation safety program may lead to misunderstandings about jurisdiction and responsibility that result in incomplete oversight of the program. The section has been changed to call for a single committee. That committee may of course consult with other committees and individuals.

Comment: The Radiation Safety Committee should be allowed to name authorized users. Other committees in a hospital are allowed to confer certain medical privileges.

Response: The NRC considered this, but believes that an independent review of training and experience credentials is necessary to assure the public health and safety.

Section 35.23 Statements of authority and responsibilities.

Comment: The NRC should clarify the regulation to indicate that the Radiation Safety Committee and the Radiation Safety Officer should have not only technical responsibilities, but authority to assure that the policy is adhered to and that the radiation safety program is

managed in a businesslike and efficient way.

Response: The section has been modified to indicate that both must have the authority to manage the program so as to assure that materials are used in accordance with NRC regulations.

Section 35.25 Supervision.

Comment: There may be only one authorized user on a hospital's license. If the authorized user is absent, the hospital has to hire an authorized user from another area to care for the patients. There may be capable residents at a nearby medical college who cannot be hired only because they are not listed as authorized users on a license. Yet, they may have been supervised by the authorized user before and found capable of delivering proper care for patients.

Comment: The NRC should require that each physician authorized user and technologist be certified by the appropriate board. This would help assure that individuals have been trained.

Comment: Requiring the authorized user to be physically present on one hour's notice is arbitrarily stringent. Choose a more reasonable time.

Comment: There should be a time limit on use of the supervision clause with respect to a physician-in-training in order to avoid use of the supervision clause in lieu of licensure.

Response: The purpose of supervision is to provide assurance that technologists and physicians do not use byproduct materials in a manner that is contrary to the requirements of the license, the regulations, or that is hazardous to the public health and safety. The proposed requirement that the authorized user be immediately available by telephone and physically present on one hour's notice was an attempt at a prescriptive definition of supervision in the medical setting.

NRC recognizes that medical practice is regulated differently in each state, but that, in the end, the physician is responsible for providing quality medical care. A prescriptive definition that describes delegable tasks, timely response in case of untoward events, and training requirements that are suited for one setting may hinder the delivery of medical care in another setting. The authorized user physician identified on the license is responsible for delivering quality medical care, and is best situated to determine what tasks a certain physician or technologist is capable of performing and the amount of personal supervision that each needs.

Under the final regulation, a licensee may delegate to unnamed individuals performance of any task associated with the medical use of byproduct material from package receipt through quality control, prescription, administration, interpretation or follow-up for individual clinical procedures, and radioactive waste disposal. The delegations must be consistent with other institutional requirements and the state's regulation of medicine. The NRC did not retain the "immediately available by telephone and physically present on one hour's notice" clause.

The licensee can not delegate *responsibility* to supervised individuals. If a supervised individual, through misunderstanding, negligence, or commission, acts contrary to the requirements of the license, the regulations, or an order, the *licensee* remains responsible.

The NRC believes this strikes the best balance between its responsibility to assure the public health and safety and a physician's responsibility to deliver quality medical care.

Section 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.

Comment: The proposed requirement that mobile service not be provided to NRC-licensed hospitals because of clouded responsibilities eliminates an option a hospital needs for delivery of medical care in case of prolonged nuclear medicine department downtime. There could be significant delay in providing necessary clinical procedures and patients may have to be transported to another hospital. The regulation could result in inferior health care delivery to patients and could be counterproductive to health care cost containment.

Response: To respond to its charge to protect the public health and safety, it is appropriate for NRC to place restrictions on where and by whom byproduct material may be used. These restrictions make compliance more likely and corrective action simpler in case of hazards or noncompliance.

In this case, however, commenters properly pointed out that the regulation could have an adverse impact on the public health by making certain clinical procedures unavailable or inconvenient. The NRC's responsibility to assure public safety must be balanced with the responsibility of the NRC-licensed hospital-client of a mobile nuclear medicine service to provide care for its patients.

The regulation has been changed to allow mobile nuclear medicine services to provide service to NRC-licensed hospitals because they may need this option to provide timely medical care. However, when an NRC-licensed hospital exercises its authority to invite a mobile nuclear medicine service to provide medical service, the NRC will deal with this as though the hospital has delegated tasks to another licensee. The NRC-licensed hospital, not the mobile nuclear medicine service, will normally be held responsible for items of noncompliance that occur at the hospital.

The same considerations and decision apply to NRC-licensed private practitioners who invite a mobile nuclear medicine service to provide service.

Comment: Can a mobile nuclear medicine service receive byproduct material at a client's address of use.

Response: This is not allowed because there is no assurance that the client knows what safety measures to initiate. The section has been clarified by adding a paragraph that clearly forbids such practice.

Section 35.31 Radiation Safety Program Changes.

Comment: Although the proposed section will relieve the licensing staff of some casework, the responsibility to assure that new radiation safety procedures are adequate will fall on the inspector's shoulders. An inspector does not have time to review procedures in the field, and will not have the opportunity to consult reference works or colleagues if necessary.

Comment: Many licensees do not have the expertise needed to properly review a proposed change. A licensee may unwittingly degrade a radiation safety procedure or the Radiation Safety Officer may be pressured into changing it; the degraded procedure could be in effect for years before an NRC inspection triggers its correction.

About 40 percent of amendment requests are deficient. This demonstrates that many licensees are not capable of making an adequate safety review of a proposed change. The NRC should reduce the scope of the term "minor change" or continue to review all changes.

Comment: The NRC is shirking its responsibility. Why is the NRC bothering to require applicants to submit radiation safety procedures if licensees won't be required to follow them?

Comment: A licensee should earn the authority to make minor changes. NRC should grant this authority case-by-case after examining a licensee's inspection history and radiation safety staff. Perhaps only those with certified physicists would be allowed to make changes.

Comment: Although the proposed policy will give management the opportunity to promptly implement new or better safety procedures, it may also allow for increased productivity at the expense of safety. Committee members might be removed without cause. This could be precluded by requiring licensees to notify the NRC of membership changes.

Comment: The Joint Commission on the Accreditation of Hospitals states that "The service of a health or radiation physicist should be available, at least on a consultant basis, for educational purposes and for safety evaluations of all equipment and storage and handling practices." This negates the argument made by some that inadequately trained hospital staff will make changes in radiation safety procedures without guidance.

While accreditation of hospitals is a voluntary system, it is important to note that if a hospital does not volunteer for accreditation, it cannot be reimbursed by Federal programs such as Medicare and Medicaid, and other insurance organizations will not reimburse that hospital either. Although this is a carrot and stick system, the stick is so large that very few hospitals are not accredited.

Therefore, national voluntary standards and business considerations provide alternative assurance that hospital licensees will not make untoward changes in their radiation safety programs.

Private practitioners and small medical institutions do not look for ways to change procedures so frequently because they are disinclined to change things if their most recent inspection was favorable and business is running smoothly.

Comment: NRC should clarify the distinction between major and minor changes. The examples given are extreme.

Response: Changes that require a license amendment are listed in §§ 35.13 and 35.606, License amendments. Before publishing the proposed rule, the NRC analyzed 5 percent of the requests for medical license amendments received in a one year period. A summary of the analysis appears in Table 1. The NRC believes the list of major changes that are potentially important to safety provides adequate guidance regarding those cases in which an amendment request must be submitted.

Table 1. Analysis of Medical License Amendment Requests

Number of completed actions that were analyzed	[1] 100
Number of requests that included a major change which would require an amendment under the proposed revision of 10 CFR Part 35	69
Users	51
Type of use	15
Address of use	5
Inventory	2
Number of requests for an administrative change, e.g., name change, change of address but not location, short-term extension, etc	6
Number of requests that included a minor change which would not require an amendment under the proposed revision of 10 CFR Part 35	37
Area of use [2]	21
Replacement equipment	5
Equipment quality assurance procedures	11
Service contractor	8
Handling procedure	6

[1] Some requests contained both Major and Minor changes and therefore were tallied twice; thus the division by Major, Administrative and Minor does not add up to 100.

[2] The proposed rule would have allowed licensees to use byproduct material in areas of use that were not identified in the application. On further consideration the Commission believes that such changes are potentially important to safety and should be reviewed by the staff.

The NRC has clarified the concept of "minor change" by using a new word and providing a list of examples. Minor changes should be ministerial in nature. As used by NRC in this section, a ministerial change is one that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements are needed in the case at hand to assure the public health and safety. A licensee may not make discretionary judgments about things such as survey frequencies, minimum detectable amounts of radioactivity or dose rates, or what information constitutes a minimally adequate record of an action. The NRC has already made a discretionary judgment about such matters.

The examples provided in the regulatory text were taken from recently submitted amendment requests and staff suggestions. They are not the only kinds of minor changes that may be made. There will undoubtedly be unclear cases in which the licensee is not certain whether an amendment request should be submitted. In unclear cases, licensees may consult the licensing staff.

Before selecting a course, NRC reviewed its inspection and enforcement record for medical licensees. In 1985, the NRC took escalated enforcement action against 35 byproduct materials licensees. Only eight involved medical licensees, and none of those eight involved overexposures to workers or the public. In 1982, NRC conducted 1,568 inspections of medical licensees. Almost all of the 1,240 line items that were cited were for minor safety infractions that did not represent a worker or public safety hazard. More recent data are similar. The NRC believes that its inspection findings demonstrate a high level of voluntary compliance with its requirements, whether they be couched in terms of regulations or site-specific license conditions.

The NRC believes the deficiency rate in the current application process is caused by having requirements scattered in several documents and not caused by ignorance of basic radiation safety practice. Thus, the deficiency rate is not a valid measure of a licensee's ability to design and operate a radiation safety program.

The NRC does not believe that administrators will pressure Radiation Safety Officers into compromising their programs. The impact of the adverse publicity that accompanies an escalated enforcement action far outweighs the potential short-term savings of a compromised program.

The NRC will provide, in Regulatory Guide 10.8, a list of questions that should be considered when a licensee makes an internal review of a proposed change. The NRC notes that many licensees use the services of radiation safety consultants to periodically review their programs now, and assumes that, in many cases, these consultants will also be asked to provide an independent review before a change is made. However, even absent an independent review, the NRC is convinced that safety will not be endangered by permitting licensees to make minor changes that are not potentially important to safety in their radiation safety programs.

The NRC notes that it currently receives about 800 requests for amendment each year from its 2,500 medical licensees for license amendments that are characterized as "minor changes" under this rule. This represents a minor radiation safety program change about once each three years for each licensee. The NRC does not believe it likely that licensees will make frequent changes in their radiation safety programs, even when spared the amendment fee.

The requirement to submit a detailed radiation safety program as part of the application process provides assurance that the licensee will have a program in place when byproduct materials are received. However, the NRC recognizes that a licensee's needs and resources change with time. At issue here is

whether a regulatory agency must approve minor changes in a licensee's day-to-day radiation safety program. Does a desk review of minor operational changes contribute significantly to public health and safety? The NRC is convinced that it does not.

The NRC believes the essential elements of a medical licensee's radiation safety program are well defined and have been consolidated in the regulation. The present review policy is resource intensive, causes backlogs due to the bulk of material submitted for review and the number of license amendments needed, and results in a different set of radiation safety requirements for each licensee. Inspectors may occasionally review changes to assure that the process required for making changes was followed. However, inspectors will examine the working day-to-day radiation safety program for compliance with the regulations.

The NRC believes this change in licensing policy provides both necessary flexibility by permitting licensees to make minor changes in their radiation safety programs and yet provides for NRC oversight of changes that might affect the public health and safety.

The NRC notes that the proposed rule would have allowed licensees to use byproduct material in areas of use that were not described in the application for license. The NRC now believes that such a change should require a license amendment because physical structures often provide features that are potentially important to safety. Such a change might also compromise NRC's ability to conduct an unannounced inspection.

Section 35.33 Records and reports of misadministrations.

Comment: The level of public emphasis that NRC has placed on misadministrations has proven to be an effective mechanism to limit their number. No change is needed.

Comment: At least to the extent that it deals with diagnostic clinical procedures, the misadministration rule should be deleted or substantially modified. The case for its deletion is made by the misadministration reports submitted to the NRC.

The misadministration rate for radiopharmaceuticals is much less than for non-radioactive drugs. The hazard to the patient is much less than that associated with the misadministration of physiologically active drugs or with other medical mistakes. In virtually all instances, the patient sustains neither actual nor theoretically significant potential injury. The hazard to workers and the public is almost non-existent.

Misadministrations are precipitated by human error, such as momentary distraction or miscommunication, not radiation safety program deficiencies. Although a fail-safe system might be achieved through multiple levels of checking and cross-checking, the added costs would far outweigh the marginal benefit that would accrue to society.

Response: The NRC is well aware that the misadministration rate for radiopharmaceuticals is much lower than for other drugs, that there is no reporting requirement for misadministrations of cyclotron-produced radiopharmaceuticals, x-rays, and nonradioactive drugs, and that the risk to patients, workers, and the public is small. None of the assertions are at issue.

The fact that there are other greater potential hazards found in the medical arena does not relieve NRC of its responsibility to assure public health and safety as it may be affected by material under its jurisdiction. Rather, at issue is whether there is a safety problem, and, if so, can it be corrected at an expense that is reasonable compared to the hazard.

Therapy clinical procedures, in the view of the NRC, present a greater risk to the public and patients than diagnostic clinical procedures. Given the increased risk to the public health and safety, the reasoned judgment of the NRC requires the maintenance of the current misadministration rule for therapy uses of byproduct material. The NRC will continue to carefully review therapy misadministration reports. The NRC staff is also considering an advance notice of proposed rulemaking that would request public comment on regulations regarding quality assurance in radiation therapy as well as other NRC actions resulting from therapy misadministrations. This request for early public comment will be published at a later date.

The NRC believes that misadministrations that result in a dose to the patient greater than a dose to a member of the public permitted under § 20.105(a) should require a report to the NRC and the referring physician. Furthermore, licensees should keep records of all misadministrations. As a result, the diagnostic administration reporting requirement has been changed to require reports for misadministrations when such misadministrations result in a whole body dose greater than 500 millirem or an organ dose greater than 2 rem. (Licensees may use dosimetry tables in package inserts, corrected only for administered millicuries, to determine whether a report is required.)

In order to assure that diagnostic misadministrations are not occurring in a particular licensee's program with excessive frequency, the NRC believes that there should be an internal investigation and report by the Radiation Safety Officer. The NRC will review these reports during its field inspections. In addition, the reports will assist the licensee in carrying out the ALARA principles of Parts 20 and 35.

Because of the public health and safety nature of the reporting requirement, the NRC will require Agreement States to implement compatible requirements.

Comment: While it should be retained, the therapy misadministration report trigger should be relaxed from 10 percent error to 20 percent error. That range better reflects the diversity of medical opinion on the optimum dose for a particular patient.

Response: The NRC has not changed its requirements that apply to therapy misadministrations because of their importance to public health and safety. The NRC reiterates that the 10 percent trigger level is *not* based on the diversity of medical opinion regarding the optimum radiation dose for a certain disease stage. Rather, the NRC recognizes there are uncertainties in the measurement and administration of radiation that make it impossible to demonstrate that the exact radiation dose that was prescribed was delivered. However, when the dose delivered is more than 10 percent different than the dose prescribed, it is clear that a mistake has been made. The mistake should be investigated and steps should be taken to prevent its recurrence.

Comment: NRC should take enforcement action against licensees who administer radioactive material when it might have serious consequences for the patient.

Comment: Enforcement actions may reduce compliance with the misadministration reporting requirement.

Response: The diagnostic misadministration reporting requirement will continue to require reports to the NRC for certain diagnostic misadministrations that are listed in the regulations. The reporting requirement for all therapy misadministrations has been retained.

The NRC deals with misadministrations case-by-case. Various levels of enforcement are available. It does not appear that NRC's enforcement program has caused

noncompliance in any area of its jurisdiction.

Section 35.50 Possession, use, calibration, and check of dose calibrators.

Comment: Does this possession and use requirement mean that even small licensees that use only precalibrated unit dosages of radiopharmaceuticals will have to buy a dose calibrator?

Response: The NRC believes that requiring licensees to ensure that the desired dosage has been prepared is essential to fulfilling its statutory responsibilities. The NRC recognizes that the overwhelming majority of its licensees use a dose calibrator to meet this requirement, and therefore, in the regulations, directly addresses their use. This does not prevent an applicant from proposing an alternative method for measuring dosages and requesting an exemption in the application. If the applicant is able to demonstrate that the alternative provides adequate accuracy and reliability, the licensee will be allowed, by license condition, to use the alternative method.

Comment: Is a volumetric determination of a dosage from a calibrated multi-dose vial an acceptable alternative method for measuring dosages?

Response: No. Any alternative must provide for the measurement of the amount of radioactivity in the individual dosage.

Comment: Sealed sources that are used for dose calibrator accuracy tests should be traceable to the National Bureau of Standards.

Response: The NRC reviews proposed label wording and traceability assertions before a manufacturer is authorized to distribute sealed sources. This provides adequate assurance of accuracy.

Comment: The regulation requires mathematical correction or repair if the dose calibrator shows inaccuracy greater than 10 percent; Regulatory Guide 10.8 has a 5 percent trigger level. Which is the requirement?

Response: The regulation imposes the requirement; the Regulatory Guide provides a method for meeting the requirement. The guide has a more stringent trigger level so the licensee can take action *before* the regulatory limit is passed instead of *after*. However, the licensee is not required to follow the Regulatory Guide. The licensee can specify an alternative method in the application. The NRC will review the alternative method to determine whether it provides adequate assurance of public health and safety.

Section 35.51 Calibration and check of survey instruments.

Comment: Not all survey instruments have a built-in check source. If an instrument is shipped to a calibration laboratory, the check source reading that is required at the time of calibration could be made instead when the instrument is returned.

Response: The NRC believes the check source reading made at the time of calibration is important to demonstrate that the instrument has not stopped operating properly since it was calibrated. Thus the source should accompany the instrument to the calibration laboratory. For instruments that do not have a built-in check source, the NRC notes that uncalibrated 10 microcurie Cs-137 sources are available for only $25.

Comment: This requirement will increase personnel dose from handling the check source, and takes time. A daily or weekly check is sufficient.

Response: The NRC does not believe the check source presents a significant exposure source when compared to other sources in the laboratory, but agrees that a requirement to check instruments before and after each period of use may be unnecessarily burdensome. The section has been changed to require a daily check.

Comment: With all the errors inherent in measuring radiation, there is no need to calibrate a survey instrument within 20 percent; a factor of 2 would suffice.

Response: The NRC believes that a range of 20 percent provides adequate leeway in the calibration process. This is consistent with the recommendation in ANSI N323-1978, Radiation Protection Instrumentation Test and Calibration, section 4.2.2.1.[4]

Section 35.53 Measurement of radiopharmaceutical dosages.

Comment: Clarify when the measurement should be made.

Response: The NRC has purposefully not specified when the measurement must be made so as to allow for different licensees' procedural needs.

Comment: It is difficult to remove iodine-131 therapy dosage containers from their radiation shields and they should therefore be exempted from the measurement requirement.

Response: It is very important to assure that the manufacturer has supplied the prescribed therapy dosage so the patient will receive the prescribed radiation dose. The requirement to measure therapy dosages remains. The majority of commenters did not mention difficulty making the measurement.

Comment: The NRC should allow the licensee to use the trade name or abbreviation in place of the generic name in the dosage measurement record. These alternative identifications are equally well-recognized.

Response: The alternative has been allowed.

Comment: The need for verifying the activity of manufacturer-supplied unit dosages is unclear.

Comment: Dose calibrators are too expensive to require their use for small programs.

Response: The NRC believes it is necessary to require an independent measurement, to the extent possible, to assure that the patient is receiving the prescribed dosage. Licensees that believe the expense of acquiring a dose calibrator is unwarranted may request permission to use an alternative method of assuring that the prescribed dosage is being administered.

Comment: The rule should not require the measurement of radiopharmaceuticals that emit only beta radiation. Such measurements are difficult when made in a calibration laboratory and tenuous when made in the clinical setting.

Response: The rule has been clarified only to require the measurement of photon-emitting radiopharmaceuticals.

Comment: It is not clear whether the proposed rule applies to brachytherapy sources.

Response: The proposed rule only applies to radiopharmaceuticals. The NRC recognizes that there are special problems associated with the measurement of brachytherapy source activity that must be worked out before a measurement requirement could be proposed.

Comment: It is not clear whether NRC expects licensees to suspend operations if the dose calibrator breaks.

Response: The NRC expects each licensee to measure dosages before administering them. Licensees may want to make arrangements that provide alternative measurement procedures in case of equipment breakdown.

Comment: The requirement to measure each dosage will increase technologist finger exposure.

Response: Any time radioactive material is handled there is the potential for exposure. The magnitude of the exposure must be balanced against the need to handle the material. NRC believes that the measurement is important because if the incorrect amount of radiopharmaceutical is administered to the patient, the

[4] This report is available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

diagnosis or therapy may be compromised. The NRC believes its calculations and dose records of workers who measure dosages indicate that the amount of exposure is small compared to the benefit that comes with assurance that the correct amount of activity is being administered.

Section 35.57 Authorization for calibration and reference sources.

Comment: You should raise the sealed source design limit from 6 millicuries to 15 millicuries. These reference and calibration sources are needed by nuclear medicine clinics for quality assurance checks and do not pose a significant radiation hazard when used in that setting.

Response: The change has been made.

Section 35.60 Syringe shields and labels.

Comment: NRC should recommend, but not require, that licensees use syringe shields when drawing individual dosages. In some cases experience has revealed that only a leaded-glass syringe shield permits viewing the miniscus when drawing dosages—these syringe shields are expensive and fragile.

Response: No change has been made. However, the section has been reworded to clarify that syringe shields are only required when preparing radiopharmaceutical kits.

Comment: The open literature is ambiguous on the effectiveness of syringe shields.

Response: The NRC disagrees. Syringe shields may dramatically reduce finger dose ("Efficacy of various syringe shields for 99mTc," NL McElroy, *Health Physics*, v41 n3 pp 535–542, September 1981).

Comment: In some hospitals one individual draws a dosage and then immediately administers it. In this case a syringe label is not needed.

Response: The NRC does not believe this is an unreasonably burdensome requirement for the few licensees that fit that description. The NRC considered drafting criteria that addressed clinics with one technician but notes that, even in that case, some misadministrations have been caused by accidentally transposing syringes after drawing two dosages. Therefore, the benefits from avoiding misadministrations outweigh the costs to the licensee.

Comment: More information, such as amount of activity and time of syringe preparation, should be included on the label.

Response: The NRC believes the required information supplies sufficient information to those handling the syringes.

Comment: The NRC should allow color coding of syringes with different radiopharmaceuticals rather than requiring the name or abbreviation.

Response: Different manufacturers use different color schemes for the same radiopharmacuetical. Allowing the use of color coding in place of labeling may lead to misadministrations. Therefore labeling is required.

Section 35.61 Vial shields and labels.

Comment: This label should also include the lot number, activity, and expiration time.

Response: This information may be included in the dosage measurement records, but is not required by NRC because these are matters of pharmacy.

Section 35.70 Surveys for contamination and ambient radiation exposure rate.

Comment: A licensee may occassionally administer a dosage in the patient's room. Is a survey necessary there?

Response: No. However, employees should be reminded to take care to collect all potentially contaminated material.

Comment: The regulation allows a licensee flexibility in setting removable contamination levels, then removes that flexibility by arbitrarily setting a sensitivity limit of 200 disintegrations per minute. Can't wipe samples be evaluated by holding them next to the GM tube of a survey instrument?

Response: The purpose of setting a sensitivity limit is to ensure that samples are not simply compared to the background counting rate of the measurement system; that comparison does not provide a measure of the amount of radioactivity on the sample. Action levels indicate when mitigating action should be taken. The regulation allows the Radiation Safety Officer to set different trigger levels for different areas of use because different levels of contamination are to be expected in different areas of use.

Comment: The sensitivity limit of 200 disintegrations per minute is unnecessarily restrictive.

Response: The NRC agrees. For most of the radionuclides used in medical use, a sensitivity limit of 2000 disintegrations per minute provides adequate assurance of public health and safety. (The NRC has retained the 200 disintegrations per minute limit for radiopharmaceutical therapy rooms. See § 35.315 Safety Precautions.)

Section 35.75 Release of patien's containing radiopharmaceuticals or permanent implants.

Comment: The NRC should require that patients released with residual radiopharmaceutical or permanent implants be provided information regarding the activity of the byproduct material so that special precautions can be taken if the patient is re-hospitalized elsewhere.

Response: The NRC believes the release criteria, which are similar to criteria recommended by NCRP (NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," Chapter 4 [8]) provide adequate assurance of safety. Although the suggestion is well taken, it seems most likely that the patient would visit a physician familiar with the patient's medical history. In case of emergency treatment there is no assurance the patient would be capable of reporting the information to the attending physician.

Comment: The proposed rule stated that the 30-millicurie release limit is based on NCRP guidance. In fact, NCRP provides a range of limits.

Response: The NRC meant to imply that the limit was based on considerations addressed in the subject chapter, not that it was adopting an NCRP recommendation.

Release limits are based on approximate dose rates emanating from the source-patient and time-at-a-distance assumptions for household members. Although the calculations are straightforward, the validity of the assumptions (biological half-life of the radioactive material in the patient for the radiopharmaceutical used, physical size of the patient, duration of proximity and exact distance of household members) for a specific case is tenuous. The NRC believes that a 30-millicurie release limit provides an adequate measure of public health and safety.

The alternative 6 millirem per hour criterion has been reduced to 5 millirem per hour to provide a more conservative and more easily remembered criterion. It is the approximate dose rate that would be expected from a patient with a 30-millicurie burden of I-131, the most radiotoxic byproduct material used for medical use.

[8] This report is available from NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

Section 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.

Comment: A ban on the mobile use of generators seems unnecessary.

Response: The NRC considered this when drafting the proposed regulation, but believed the greater public benefit accrued from the present system under which generators are received, stored, and eluted only at a base station. There were no commenters who demonstrated that this system deprives some members of the public of the benefits of diagnostic nuclear medicine, or that the requirement to use generators only in a base station is unduly burdensome.

Comment: Mobile service licensees should be allowed to reconstitute radiopharmaceuticals at a client's facility.

Response: The NRC recognizes that many radiopharmaceuticals should be used within six hours after reconstitution, and in some cases within one hour. Thus, it is possible that the proposed requirement for mobile diagnostic nuclear medicine services to transport only prepared radiopharmaceuticals may adversely impact the delivery of services because the licensee may not be able to reach all the day's patients within a few hours after reconstituting the radiopharmaceuticals at the base station. Therefore, the section has been reworded to allow licensees to transport radiopharmaceutical kits in addition to prepared radiopharmaceuticals.

Comment: You should not require quality assurance programs for imaging equipment. Quality assurance is the responsibility of the user.

Response: Nuclear medicine equipment is generally not designed for daily highway transportation (some nuclear medicine imaging equipment is designed to be transported within a hospital). The possibility of damage to the equipment during transportation might lead to useless administration of byproduct material. Thus, the NRC believes an equipment performance check prior to the administration of radiopharmaceuticals is indicated and is not unduly burdensome. No change has been made.

Section 35.90 Storage of volatiles and gases.

Comment: There is no apparent need for additional containment systems when storing xenon. The manufacturer's original packaging is sufficient. The ventilation posting requirement should take care of any problems.

Comment: Clarify what is meant by storing these materials "in a container with two barriers against release."

Response: The NRC has re-examined this proposed requirement and agrees with the comments. The NRC has determined that storage in the original shipping container will provide adequate control. This does not require retention of the entire package, but rather just the radiation shields and containers.

Section 35.92 Decay-in-storage.

Comment: The requirement to store waste for ten half-lives is unduly burdensome. The requirement that the container surface dose rate be at background is sufficient.

Response: This section allows for uncontrolled release of material that was contaminated with large amounts of radioactivity. Given that, the NRC believes that the storage requirement, which reduces the amount of radioactivity in the container by radioactive decay, coupled with a confirmatory survey is not unduly burdensome.

Sections 35.100 Use of radiopharmaceuticals for uptake, dilution, and excretion studies, and 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

Comment: The requirements to use diagnostic radiopharmaceuticals in accordance with the FDA-approved package insert should be removed. The risk associated with the administration of diagnostic radiopharmaceuticals is too small to justify a regulation that denies nuclear medicine practitioners the latitude needed to provide up-to-date medical care for their patients.

The package insert represents a summary of available scientific evidence indicating that a drug is safe and effective for a particular indication when used in accordance with the directions in the package insert. The FDA does not intend for the package insert to be a restrictive document; a physician may use any drug in any fashion deemed to be in the best interest of the patient. This is predicated on the assumption that physicians are motivated to act in the best interest of their patients.

New uses of approved radiopharmaceuticals are developed at medical research institutions and reported, along with safety and effectiveness information, in the scientific literature. However, the package insert is usually not updated because the process for revising a package insert is expensive and slow. Manufacturers are not inclined to shoulder this burden because the additional sales that would result would not justify the expense of the revision.

Response: NRC's concern for worker and public health and safety must be balanced by the physician's need to provide proper medical services to the patient. The NRC believes that diagnostic radiopharmaceuticals have proven to be safe when handled by individuals with appropriate training. For diagnostic radiopharmaceuticals, the requirement to follow the package insert may have an adverse impact on the public health and safety because it prevents physicians from performing diagnostic clinical procedures needed by their patients, and is therefore withdrawn.

Comment: The NRC should not allow licensees to change the chemical form of a radiopharmaceutical.

Response: If a licensee altered the chemical form of a radiopharmaceutical, the modified radiopharmaceutical would be a new radiopharmaceutical that would not be the subject of an FDA acceptance or approval. Therefore it would not be authorized for use.

Comment: Why does NRC list approved radiopharmaceuticals in the regulations? It is only necessary to have a list available.

Response: The list has been deleted from the regulation; it will be available from NRC's regional offices.

Sections 35.120, 35.220, 35.320, 35.520, 35.620 Possession of survey instruments, and 35.420 Availability of survey instrument.

Comment: A low level survey meter cannot be used to survey around a stuck teletherapy source.

Comment: The NRC should require a low level meter for brachytherapy programs.

Response: Quoting at length from NCRP Report No. 57, Instrumentation and Monitoring Methods for Radiation Protection, Chapter 5, Instrumentation:

"If the dose equivalents are small compared to the maximum permissible value, then measurement errors by a factor of 2 are acceptable . . . For dose equivalents close to the maximum permissible value, an accuracy of about 30 percent is desirable . . . Most of the x-ray and gamma-ray *exposure* rate measurements . . . are made with small, portable ionization chambers . . . G–M counters are used in surveys for the detection of x- and gamma-ray fields. This generally limits their use to *exposure* rates in the range from background up to a few mR/h. . . . The counters respond to the number of

ionizing events within them and give no information about the energy associated with the events. Therefore, they do not respond with equal count rates to equal *exposure* rates from photons of different energies. . . . They are generally used only for detection rather than measurement . . . G–M counters are sometimes used to estimate *exposure* rates where the rate is low enough for the resulting inaccuracy of its measurement to be unimportant. . . ."

The NRC has reviewed its rationale as stated in the notice of proposed rulemaking for requiring certain licensees to have certain survey instruments on hand or available. The only change that has been made is to require that brachytherapy licensees have a detection instrument on hand because it might be needed to find a lost brachytherapy source. The wording of each section has been revised to better indicate the range of dose rates the instrument must be capable of detecting or measuring.

Section 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

Comment: The NRC should not list xenon-133 in a group with radiopharmaceuticals that are administered by injection. The regulations should require agency approval of areas of use because there are special ventilation needs for its safe use.

Response: The training and experience needed for safe use and the radiological hazard of all the materials permitted under each subpart are similar. The NRC realizes that special ventilation is necessary for the safe use of gases and aerosols, and therefore placed additional requirements in § 35.205 Control of aerosols and gases.

Section 35.204 Permissible molybdenum-99 concentration.

Comment: The NRC notes that dose calibrators cannot measure accurately below 10 microcuries, yet proposes that radiopharmaceuticals not have more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m. How is this to be measured?

Response: The amount of Mo-99 in an elution of Tc-99m is usually measured, and recorded as a concentration of microcuries of Mo-99 per millicurie of Tc-99m, before using the elution. If the fresh elution has as little as 200 millicuries of Tc-99m, then the licensee need only demonstrate that there is less than 15 microcurie of Mo-99 in the elution. Note that this is one-half the allowed concentration: for sake of this explanation the NRC assumes that the freshly eluted Tc-99m is administered over the next six hours, at which time, due to the radioactive decay of the Tc-99m, the Mo-99 concentration would be about doubled.

Comment: The NRC should require licensees to notify the NRC in case of excessive Mo-99 concentration. This could indicate a widespread manufacturing defect.

Response: Notification is required under 10 CFR 21.21(b).

Section 35.205 Control of aerosols and gases.

Comment: The need for negative pressure in a room where aerosols and gases are used is not apparent given the other safety measures that are required.

Response: The NRC disagrees. A patient who is having trouble breathing, is under mental stress, or is disoriented may remove the breathing mask that is used to administer the xenon gas and spill the dosage. Dispersion of a spill throughout the workplace, which would result if the room were at positive pressure, is not an acceptable cleanup method. The requirement has been retained.

Comment: Trapping units should be checked more frequently.

Response: The NRC notes that there has not been much study of breakthrough rates of collection systems that are used in the clinical setting. Given the simplicity of the procedure used to check for breakthrough, the NRC believes that a more frequent check may be beneficial and is not unduly burdensome.

Section 35.315 Safety precautions, and § 35.415 Safety precautions.

Comment: It is not necessary for the Radiation Safety Officer and authorized user to authorize each visit by an individual under age 18 on a case-by-case basis.

Comment: Visits by individuals under age 18 should only be allowed in special cases.

Response: The NRC did not mean to imply that each individual visit need be approved. Rather, the NRC recognizes that the benefits that might be derived by the patient must be balanced against the radiation dose incurred by the visitor. If the physician determines that the greater benefit derives from allowing visits, then a notation on the patient's chart or door that visits are allowed is all that is needed. No changes have been made.

Comment: The patient release criteria in § 35.75 may cause unnecessary radiation dose to members of the patient's household and the public from patients who still have radioactivity.

Response: The sections have been modified to require the licensee to provide radiation safety guidance to the patient prior to release. "Guidelines for Patients Receiving Radioiodine Treatment,"[6] published by the Society of Nuclear Medicine, and NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides,"[7] provide appropriate guidance.

Section 35.315 Safety precautions.

Comments: The proposed rule appears to require that extensive safety precautions be taken when caring for *any* patient receiving radiopharmaceutical therapy while hospitalized. This does not differentiate between patients who receive low dosages and patients who receive high dosages.

Response: The wording has been revised to clarify that the safety precautions are only required when patients must be hospitalized until the amount of radioactivity in them is low enough to allow their release.

Comment: It is not necessary to measure the thyroid burden of personnel who administer encapsulated iodine-131.

Response: The NRC disagrees. It has been observed ("Contamination from Therapeutic I–131 Capsules," by D. R. Shearer, et al., *Health Physics* v49 p81, July 1985) that individuals who handle encapsulated iodine-131 may be exposed to levels of surface contamination for which thyroid monitoring is indicated. No change has been made.

Comment: Does the 2000 dpm/100cm ^{2} removable contamination requirement apply to patient rooms that are released for unrestricted patient use?

Response: No. Because of its greater radiotoxicity, the removable contamination limit for iodine-131 in patient rooms following completion of high level radiopharmaceutical therapy is 200 dpm/100cm ^{2}.

Comment: This section should require a survey of the ambient dose rate in contiguous restricted and unrestricted areas to demonstrate compliance with the requirements of Part 20.

Response: The requirement has been added.

---

[6] This publication is available through the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016.

[7] This publication is available through NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

Comment: We administer several dosages of I–131 each week. A weekly measurement of the technician's thyroid burden would be sufficient.

Response: The regulation assumes administration of a therapeutic dosage is an occasional event. Those licensees who frequently administer I–131 may propose an alternative monitoring program that would be approved by license condition.

Comment: There is no need to quarter a radiopharmaceutical therapy patient in a private room. These patients can be quartered safely with teletherapy patients.

Response: The NRC disagrees. This would unnecessarily expose patient care staff and visitors for the teletherapy patient to removable contamination from the radiopharmaceutical therapy patient.

Section 35.400 Use of sources for brachytherapy.

Comment: The NRC should require source intensity checks for brachytherapy sources.

Response: The NRC considered this but is not convinced that the requisite equipment and procedures are readily available. The NRC may address this matter at a later date in a separate rulemaking proceeding.

Section 35.406 Brachytherapy sources inventory.

Comment: The requirement to count all the sources after returning to storage the few that were used will increase personnel dose.

Response: The licensee need only count the number of sources returned to storage, and add that to the number on hand to determine the total number in storage. There is no need to count each source that remained in storage.

Section 35.415 Safety precautions.

Comment: A hospital may have a radiation-shielded room designed for two brachytherapy patients. The proposed requirement to provide a private room for each patient would not allow it to efficiently use this resource.

Comment: Because the dose rate around an I–125 implant patient is only about 0.2 millirem per hour at one meter, there is no need for a private room.

Response: In the past, most licensees ensured low dose rates in uncontrolled areas by providing brachytherapy patients with private rooms. The NRC notes that some licensees have gone to the expense of shielding a room for these patients. Portable radiation shields specifically designed for brachytherapy use are now commercially available. Therefore, shielding is available and provides an acceptable method of keeping doses in uncontrolled areas within limits. The section has been changed to allow quartering more than one radiation therapy patient in a room. Licensees are reminded that, for patient care staff and visitors, dose limits in Part 20 for workers and the public apply.

Because the dose rate around these I–125 implant patients is very low, the section has been revised to allow a licensee to quarter an implant patient with a patient who is not receiving radiation therapy if the licensee can show compliance with criteria for dose rates in unrestricted areas.

Comment: This section should require a survey of the ambient dose rate in contiguous restricted and unrestricted areas to demonstrate compliance with the requirements of Part 20.

Response: The requirement has been added.

Comment: The NRC should also prescribe radiation safety procedure requirements for cases in which the sources are loaded in other than the patient's room.

Response: The dose rate limits in Part 20 apply. In this case, the NRC cannot prescribe safety measures specifically suited to each licensee's needs.

Section 35.500 Use of sealed sources for diagnosis.

Comment: This subpart should also allow the use of bone mineral analyzers that use gadolinium-153.

Response: When the proposed regulation was drafted the NRC did not foresee the extent of medical interest that would develop regarding the gadolinium-153 scanner. However, several commenters recommended it be included here. The NRC has determined that the training and experience and radiation safety procedures needed for use of gadolinium-153 in a bone mineral analyzer are similar to those for other devices in this subpart. The NRC has added this device to this subpart.

Section 35.632 Full calibration measurements, and § 35.633 Periodic spot-checks.

Comment: Timer accuracy is not important because the same timer that is used in source calibration is used in patient treatments. Timer constancy is important and is indirectly checked each month by measuring the output. However, timer linearity need not be checked under the proposed regulation but is important because many dosimetry systems can only measure about 70 rads, while a single treatment dose may be much higher than this.

Response: The requirement to measure timer accuracy has been changed to timer constancy and linearity. The NRC agrees that constancy is indirectly checked by measuring the output, but believes that the additional assurance of accuracy that is provided by an independent check far outweighs the minimal cost.

Section 35.900 Radiation Safety Officer.

Comment: Authorized users have sufficient training and experience to oversee the management of a radiation safety program. To require an authorized user to be authorized for all of the types of use authorized by the license before being designated as the Radiation Safety Officer is unduly burdensome.

Response: The requirement has been modified to allow any authorized user listed on the license to serve as Radiation Safety Officer.

Comment: Revise the wording regarding the one year of full time experience you require so that a consultant who gets experience by working at several institutions over a year can be listed as Radiation Safety Officer.

Response: The NRC believes that the experience should be gained working full time at one institution because an individual serving as a consultant is not likely to be exposed to the day-to-day business management problems that must be effectively dealt with in a radiation safety program.

Comment: The grandfather clause in § 35.901 would require a Radiation Safety Officer to get additional training and experience if only one new material is added to a license.

Response: The NRC recognizes that new developments in medical care require changes in radiation safety procedures for which formal training of experienced individuals is unnecessary. Similarly, Radiation Safety Officers are capable of determining what requirements apply to the receipt, use, storage, and disposal of new byproduct material that comes under their jurisdiction. The requirement has been relaxed.

Section 35.930 Training for therapeutic use of radiopharmaceuticals.

Comment: The proposed rule requires that authorized users who are not certified have experience using soluble phosphorus-32 and colloidal intracavitary radiopharmaceuticals. These clinical procedures are not frequently performed, so it may not be possible for physicians to get the

required clinical experience. Furthermore, physicians who only want to treat hyperthyroidism do not need experience treating thyroid carcinoma.

Response: The infrequently performed clinical procedures have been removed from the clinical experience requirement because experience with them would be difficult to obtain and they no longer reflect the current state of medical practice. New sections have been added delineating training and experience criteria for physicians who only want to treat either hyperthyroidism or thyroid carcinoma.

Section 35.961 Training for Teletherapy Physicist.

Comment: One cannot become expert in teletherapy physics after doing just one full calibration and working for just one year. The criteria should be more stringent.

Response: The NRC notes that the proposed regulation required one year of full time training *and also* one year of supervised full time experience. The NRC's training criteria are not designed to provide assurance of clinical expertise, but rather adequate assurance of public health and safety. The NRC believes this assurance can be gained with two years of full-time training and experience.

Section 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

Comment: The requirement to list in vitro use on the medical application will cause more confusion than letting the current system stand. It has proven adequate to assure protection of public health and safety.

Response: The NRC agrees that the current method is adequate. The section has been revised to reflect current drafting conventions but is, for practical purposes, unchanged.

Sections 32.72 Manufacture and distribution of radiopharmaceuticals containing byproduct material for medical use under group licenses, 32.73 Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing byproduct material, and 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

Comment: The NRC should not require manufacturers to pay an amendment fee to request approval of word changes on package inserts that are necessitated solely because of NRC's change in nomenclature. The NRC should also provide a transition period during which manufacturers may continue to use package inserts that are in stock.

Response: The NRC agrees. The final regulation simply prescribes the necessary wording. NRC expects manufacturers to incorporate this ministerial change in their programs, and will check for compliance during its inspections. A transition period has been added.

Comment: Because some of the old Part 35 groups were divided and some were amalgamated, you should provide a table that clarifies what a manufacturer can deliver to a medical licensee whose license is drafted in terms of the old Groups I–VI.

Response: A manufacturer may only deliver to a licensee the byproduct material authorized by the license. If a license only lists some of the materials in a subpart, the licensee is not authorized to receive the other materials in the subpart.

V. Derivation Table

The following derivation table identifies the origin of each section of the regulation. Origins of sections include current 10 CFR Parts 19, 20, 30, and 35, Federal Register Notices (FR), frequently used license conditions, licensing staff policy, current regulatory guides (RG), Office of Inspection and Enforcement bulletins, the United States Pharmacopeia, and new text prepared by staff.

Final section No.	Proposed section No.	Topic	Origin
		Subpart A—General Information	
35.1	35.1	Purpose and scope	35.1 revised.
35.11	35.2	License required	35.2 revised.
35.8	35.8	Reporting, recordkeeping, and application requirements: OMB Approval	New text.
35.2	35.15	Definitions	
		Address of use	New term.
		Agreement State	20.3.
		ALARA	Acronym.
		Area of use	New term.
		Authorized users	Term used on licenses.
		Brachytherapy source	New term.
		Dedicated check source	New term.
		Dental use	New term.
		Dentist	New term.
		Management	New term.
		Medical institution	New term.
		Medical use	35.3(a) revised.
		Misadministration	35.41.
		Mobile nuclear medicine service	New term.
		Output	New term.
		Physician	35.30(b) revised.
		Podiatric use	New term.
		Podiatrist	New term.
		Teletherapy physicist	New term.
		Radiation Safety Officer	Term used on licenses
		Sealed source	30.4(n) verbatim.
		Visiting authorized user	New term; similar to "visiting authorized user" license condition.
35.12	35.16	Application for license, amendment, or renewal	35.4 revised.
35.13	35.17	License amendments	New text; compare 30.36
35.14	35.18	Notifications	New text.
35.18	35.28	License issuance	New text; compare 30.35
35.19	35.29	Specific exemptions	New text; compare 30.11

Final section No.	Proposed section No.	Topic	Origin
		Subpart B—General Administrative Requirements	
35.20	35.30	ALARA Program	New text, see RG 10.8 Appendix O revised
35.21	35.31	Radiation Safety Officer	RG 10.8.
35.22	35.32	Radiation Safety Committee	35.11(b) revised
35.23	35.33	Statements of authority and responsibilities	New text.
35.27	35.34	Visiting authorized user	License condition.
35.29	35.35	Mobile nuclear medicine service administrative requirements	Licensing policy
35.31	35.36	Radiation safety program changes	New text.
35.33	35.37	Records and reports of misadministrations	35.42.
35.25	35.38	Supervision	Expanded from RG 10.8 p. 3
35.49	35.49	Suppliers	35.14 revised
		Subpart C—General Technical Requirements	
35.50	35.50	Possession, use, calibration, and check of dose calibrators	RG 10.8 Appendix D2 revised, and new text
35.51	35.51	Calibration and check of survey instruments	RG 10.8 Appendix D1 revised and new text
35.53	35.53	Measurement of radiopharmaceutical dosages	Proposed rulemaking 35.15 (46 FR 43840, Sept. 1, 1981)
35.58	35.58	Authorization for calibration and reference sources	35.14(d) revised
35.59	35.59	Requirements for possession of sealed sources	35.14(e)(1)(i), 35.14(f) revised
35.60	35.60	Syringe shields	Inspection and Enforcement letter Apr. 16, 1979
35.61	35.61	Vial shields	Inspection and Enforcement letter Apr. 16, 1979
35.60	35.62	Syringe labels	New text.
35.61	35.63	Vial shield labels	New text.
35.70	35.70	Surveys for contamination and ambient radiation exposure rate	RG 10.8 Appendix I revised
35.75	35.75	Release of patients containing radiopharmaceuticals or permanent implants	New text.
35.80	35.80	Mobile nuclear medicine service technical requirements	Licensing policy
35.90	35.90	Storage of volatiles and gases	RG 10.8 Appendix M revised
35.92	35.92	Decay-in-storage	License condition.
		Subpart D—Uptake, Dilution, and Excretion	
35.100	35.100	Use of radiopharmaceuticals, for uptake, dilution, and excretion studies	35.31 and 35.100(a) (Group I) revised.
35.120	35.120	Possession of survey instrument	RG 10.8 page 5
		Subpart E—Imaging and Localization	
35.200	35.200	Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies	35.100 (b) and (c) (Groups II and III) revised
35.204	35.204	Permissible molybdenum-99 concentration	US Pharmacopeia
35.205	35.205	Control of aerosols and gases	RG 10.8 Appendix M revised
35.220	35.220	Possession of survey instruments	RG 10.8 page 5.
		Subpart F—Radiopharmaceuticals for Therapy	
35.300	35.300	Use of radiopharmaceuticals for therapy	35.100 (d) and (e) (Groups IV and V) revised
35.310	35.310	Safety instruction	19.12 revised.
35.315	35.315	Safety precautions	RG 10.8 Appendix K
35.320	35.320	Possession of survey instruments	RG 10.8 page 5
		Subpart G—Sources for Brachytherapy	
35.400	35.400	Use of sources for brachytherapy	35.100(f) (Group VI) revised
35.404	35.404	Release of patients treated with temporary implants	35.14(b)(5)(vv) revised
35.406	35.406	Brachytherapy sources inventory	RG 8.18 page 8.
35.410	35.410	Safety instruction	19.12 revised
35.415	35.415	Safety precautions	RG 10.8 Appendix L
35.420	35.420	Possession of survey instruments	New text.
		Subpart H—Sealed Sources for Diagnosis	
35.500	35.500	Use of sealed sources for diagnosis	New text.
35.520	35.520	Availability of survey instrument	New text.
		Subpart I—Teletherapy	
35.600	35.600	Use of a sealed source in a teletherapy unit	New text.
35.605	35.605	Maintenance and repair restrictions	License condition.
35.606	35.606	Amendments	New text.
35.610	35.610	Safety instruction	License condition and new text.
35.615	35.615	Safety precautions	License condition.
35.620	35.620	Possession of survey instrument	New text.
35.615	35.621	Radiation monitoring device	35.25 (48 FR 2115; January 18, 1983).
35.615	35.622	Viewing system	License condition
35.630	35.630	Dosimetry equipment	35.22, 35.23 revised.
35.632	35.632	Full calibration measurements	35.21 revised.
35.634	35.633	Periodic spot-checks	35.22 revised and license condition.
35.641	35.641	Radiation surveys for teletherapy facilities	License condition.
35.636	35.642	Safety checks for teletherapy facilities	License condition.
35.643	35.643	Modification of teletherapy unit or room before beginning a treatment program	New text.
35.645	35.644	Reports of teletherapy surveys, checks, tests and measurements	license condition.
35.647	35.645	Five-year inspection	License condition.

Final section No.	Proposed section No.	Topic	Origin
		Subpart J—Training and Experience Requirements	
35.900	35.900	Radiation Safety Officer	New text.
35.901	35.901	Training for experienced Radiation Safety Officer	New text.
35.910	35.910	Training for uptake, dilution, and excretion studies	New text.
35.920	35.920	Training for imaging and localization studies	Revision of Federal Register Notice (47 FR 53476, December 2, 1982).
35.930	35.930	Training for therapeutic use of radiopharmaceuticals	Revision of Federal Register Notice (47 FR 53476, December 2, 1982).
35.932	(New)	Training for treatment of hyperthyroidism	Recommended by commenters.
35.934	(New)	Training for treatment of thyroid carcinoma	Recommended by commenters.
35.940	35.940	Training for use of brachytherapy sources	Revision of Federal Register Notice (47 FR 53476, December 2, 1982).
35.941	35.941	Training for ophthalmic use of strontium-90	Revision of Federal Register Notice (47 FR 53476, December 2, 1982).
35.950	35.950	Training for use of sealed sources for diagnosis	New text.
35.960	35.960	Training for teletherapy	Revision of Federal Register Notice (47 FR 53476 December 2, 1982).
35.961	35.961	Training for teletherapy physicist	35.24 revised.
35.970	35.970	Training for experienced authorized users	New text.
35.971	35.971	Physician training in a three month program	New text.
35.972	35.972	Recentness of training	Revision of Federal Register Notice (47 FR 53476 December 2, 1982).
		Subpart K—Enforcement	
35.990	35.990	Violations	New text.
35.999	35.999	Resolution of conflicting requirements during transition period	New text.

VI. Administrative Statements

Finding of No Significant Environmental Impact: Availability

The Commission is revising the regulations governing the medical use of byproduct material. The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that promulgation of this regulation is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The radiation levels and release of byproduct material authorized by this regulation are consistent with the Commission's other regulations and internationally accepted standards. Most radiation experts agree that levels and releases that are within these regulations and standards will not have a significant effect on the quality of the human environment. The assessment analyzes the possible impact of release of radioactive patients, the transportation of byproduct material for medical use, storage and control of aerosols and gases, waste disposal by decay-in-storage, and dose rates outside teletherapy rooms. The environmental assessment and finding of no significant impact on which this determination is based are available for public inspection at the NRC Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the environmental assessment and finding of no significant impact are available from Mr. McElroy (see "**FOR FURTHER INFORMATION CONTACT:**" heading).

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget under OMB Number 3150–0010.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the analysis may be obtained from Mr. McElroy (see "**FOR FURTHER INFORMATION CONTACT:**" heading).

Regulatory Flexibility Certification

In accordance with section 605(b) of the Regulatory Flexibility Act of 1980, the Commission certifies that this rule, will not have a significant economic impact on a substantial number of small entities. The NRC has issued approximately 2500 medical licenses under 10 CFR Part 35. Of these, approximately 2200 are held by institutions, and approximately 300 by individual physicians. Most of the institutional licensees are community hospitals. The NRC has adopted size standards that classify a hospital as a small entity if its average gross annual receipts do not exceed $3.5 million, and a private practice physician as a small entity if the physician's annual gross receipts are $1 million or less. Under these size standards, some NRC medical licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act.

The number of medical licensees that would fall into the small entity category does not constitute a substantial number for purposes of the Regulatory Flexibility Act.

The primary objective of the rule is to simplify the medical licensing process by consolidating requirements without lessening the protection necessary for public health and safety. This has been accomplished by incorporating frequently used license conditions into the regulations and eliminating or modifying requirements that are not essential to the protection of public health and safety. These steps will make it easier for persons to determine what is required to obtain a license and what is required of licensees. Therefore, there should not be a significant economic impact on these small entities.

The Commission has prepared a regulatory analysis for this regulation which contains information concerning the anticipated economic effect of this regulation on licensees and presents the basis for the Commission's belief that the regulation will not result in

significant additional costs to any licensees. It is available for public inspection in the NRC Public Document Room at 1717 H Street NW., Washington, DC. Single copies are available from Mr. McElroy (see "FOR FURTHER INFORMATION CONTACT:" heading).

Resolution of Petition for Rulemaking PRM 35-2

The American Association of Physicists in Medicine filed a petition regarding dosimetry equipment calibration frequency (Petition Docket No. PRM 35-2; see 47 FR 4311, January 29, 1982). This rulemaking resolves that petition in § 35.630 Dosimetry equipment. The petition is granted essentially as recommended by the petitioner.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 31

Byproduct material, Labeling, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 32

Byproduct materials, Labeling, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Drugs, Health devices, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553 the NRC is adopting the following revision of 10 CFR Part 35 and the following amendments to 10 CFR Parts 30, 31, 32, and 40.

APPENDIX T

Considerations in Making Radiation Safety Program Changes (See § 35.31.)

The regulations allow the licensee to make changes that are not potentially important to safety in radiation safety procedures and in equipment. When making changes, it is the licensee's responsibility to ensure that the result will be in accord with the regulations and license conditions. Any change must be reviewed for radiation safety considerations before it is approved.

You should consider the following before making an application for a license amendment or making changes. Not all the questions apply to all changes. There may be other questions you should consider before making changes.

General

1. Proposed changes should be fully explained.
2. Do not include unexplained acronyms, abbreviations, or undefined words.
3. Spell out measurement units such as millicurie, microcurie, and millirem per hour; use the abbreviations only in calculations or log sheets.
4. Identify, by name or office, who is responsible for doing each task.

Room Changes

1. Why is the change needed?
2. What materials, and how much of each, will be used in the room?
3. Can the room be secured in case of spills?
4. Can the room surfaces be cleaned?
5. Is the room adequately ventilated?
6. Does the room provide radiation shielding?
7. What are the anticipated doses each week in the room and in surrounding areas?
8. What are surrounding areas used for? What might they be used for in the future?
9. Can the old room be cleaned, surveyed, and released for unrestricted use?

Equipment Changes

1. Why is the change needed?
2. Was the equipment designed for the intended purpose?
3. For detection and measuring equipment:

    a. What is the lowest level of detection for the equipment?
    b. What is the level of detection required?
    c. Will the instrument be compromised by ambient radiations, light, temperature, humidity, or chemicals in the area?
    d. In case it fails, is backup equipment available, and can it be repaired in a timely fashion?

4. For protection equipment:

   a. What level of protection does it provide?
   b. What is the required level of protection?
   c. In case it fails, is backup equipment available, and can it be repaired in a timely fashion?

Procedure Changes

1. Why is the change needed?
2. What doses or dose rates apply to the individuals affected by the change?
3. For each step in the procedure, what things are likely to go wrong either because of equipment failure or human error?
4. What are the likely consequences of problems noted in Question 3?
5. What steps can be taken to mitigate the consequences noted in Question 4?

APPENDIX U

Recommended Support Equipment and Services

Depending on the type of use and the size of the program, you will need various types of equipment and services to support your radiation safety program. The suggested list provided here does not include the many disposable or reusable items that are also necessary. Also, the list is not all-inclusive, and all items are not absolutely necessary.

Needs are divided to correspond to the subparts of Part 35 that describe different types of medical uses of byproduct material. While instrumentation overlaps among subparts, duplication is generally not necessary unless an instrument is to be dedicated to a single area of use or a single user. Descriptions of some of the items follow the list.

Subpart D

1. Radiation detection survey meter
2. Dose calibrator
3. Constancy check source
4. Sealed sources for dose calibrator accuracy test
5. Constancy check source for uptake, dilution, and excretion equipment
6. Leak-test service for sealed sources
7. Syringe shield
8. Personnel monitoring service
9. Survey meter calibration service
10. Vial shields
11. Personnel shields

Subpart E

1. Radiation detection survey meter
2. Radiation measurement survey meter
3. Dose calibrator
4. Constancy check source
5. Sealed sources for dose calibrator accuracy test
6. Leak-test service for sealed sources
7. Syringe shield
8. Hot lab area monitor
9. Flood source for gamma cameras
10. PLES, bar, orthogonal-hole, or quadrant phantom for gamma cameras
11. Lead L-block
12. Fume hood
13. Radioactive aerosol and gas administration system and trap
14. Personnel monitoring service
15. Survey meter calibration service
16. Vial shields
17. Personnel shields

Subpart F

1. Radiation detection survey meter
2. Radiation measurement survey meter

3. Dose calibrator
4. Constancy check source
5. Sealed sources for dose calibrator accuracy test
6. Leak-test service for sealed sources
7. Syringe shield
8. Fume hood
9. Personnel monitoring service
10. Survey meter calibration service
11. Vial shields
12. Personnel shields

Subpart G

1. Radiation detection survey meter
2. Radiation measurement survey meter
3. Lead L-block
4. Remote handling tools
5. Shielded transport cart
6. Shielded storage safe
7. Leak-test service for sealed sources
8. Personnel monitoring service
9. Survey meter calibration service
10. Personnel shields

Note: If you are authorized for only a Sr-90 ophthalmic applicator, only a storage safe or built-in locked storage cabinet and leak-test service are necessary.

Subpart H

1. Secure storage area
2. Leak-test service for sealed sources
3. Radiation monitoring service for measuring dose rates from packages with replacement sources and decayed sources.

Subpart I

1. Radiation measurement or radiation detection survey meter
2. Room monitor
3. Patient viewing system
4. Leak-test service
5. Calibrated dosimetry system
6. Spot-check dosimetry system
7. Direct-reading pocket dosimeters
8. Personnel monitoring service
9. Teletherapy physicist service
10. Survey meter calibration service

Descriptions

A radiation detection survey meter usually has a GM tube or NaI(Tl) crystal detector. The scale may be labeled in cpm or mR/hr. It is useful for detecting microcurie amounts of radioactivity and indicating approximate exposure levels. If it is calibrated in mR/hr, the most sensitive scale will probably have a

full-scale deflection between 0.1 and 1.0 mR/hr. It can be used for measuring small amounts of radioactivity if the user has measured its detection efficiency (cpm/dpm) for the radionuclide being measured.

A radiation measurement survey meter can actually measure mR/hr. The detector is an ionization chamber, which is usually much larger than a GM tube. The scale is labeled in mR/hr, and the most sensitive scale usually will have a full-scale deflection between 1 and 10 mR/hr.

The dose calibrator uses an ionization chamber or GM detectors to determine the amount of radiation given off by a syringe or vial containing radioactive material. The logic system within the calibrator can then calculate the amount of radioactivity in the sample. Most dose calibrators have a digital display with either a "select range" switch or an automatic range-switching circuit. The final display is in microcuries, millicuries, or curies. A dose calibrator can measure from a few microcuries to a few curies. It is not sensitive enough to measure contamination wipe samples.

A constancy check source is a sealed source with the date of manufacture, radioisotope, and approximate activity noted.

A dedicated check source is a long-lived radioactive source used to check the day-to-day constancy of an instrument. The same source (a "dedicated" source) must be used every day so that the user knows what reading to expect from the instrument. The source may also be used for other purposes.

The sealed sources for dose calibrator accuracy are also sealed sources with the date of manufacture and radioisotope noted. However, the activity will be certified to within a few percent by the manufacturer. These need not be on hand if the dose calibrator accuracy test is done by a contract service.

The leak-test service may be done in-house or performed as a contract service. Leak-test wipes cannot be measured in a dose calibrator, and a GM survey meter may not be sensitive enough to detect contamination on a wipe sample. Usually a well-type NaI(Tl) crystal with a ratemeter is necessary to assay gamma-emitter leak-test wipes. To determine the efficiency of detection, a sealed source with the same radioisotope as the source being tested is used, but its activity should be between 0.1 and 10 microcuries. This activity will be certified by the manufacturer to an accuracy within a few percent.

The hot lab area monitor usually has a GM detector, and the scale may be labeled in cpm or mR/hr. It should be sufficiently sensitive to detect an unshielded patient dose left lying unshielded anywhere in the hot lab.

The flood source for gamma cameras may be either one that is sealed or one that is filled by the user. The sealed sources usually contain about 5 millicuries of Co-57. The sources that can be filled by the user usually have a removable screw in a port through which radioactive material can be injected each morning.

PLES, bar, orthogonal-hole, and quadrant phantoms are used to monitor geometric linearity and resolution capability in gamma cameras. This type of test should be run weekly according to the instructions supplied by the manufacturer or the instructions in Appendix E to this guide.

A fume hood should have an adjustable sash. It should be directly vented to the outside air. The face velocity should be approximately 100 linear feet per minute with the sash at its normal location. This should be measured with a velometer. If one is not available, hang a strip of tissue paper about 1 inch wide and 3 inches long from the bottom of the sash; at the proper face velocity, it will be gently deflected into the hood.

A teletherapy room monitor usually has a GM detector and either a scale labeled in mR/hr or annunciator lights indicating when the source is on and off. It must be installed so it can be easily seen when entering the teletherapy room. A backup power supply must be provided.

When used by teletherapy technicians, direct-reading or indirect-reading pocket dosimeters provide an immediate indication of personnel whole body exposure in case of an accidental exposure. These should be calibrated using the source and procedure used for calibrating survey meters.

Personnel shields are used to shield workers from radioactive patients. They may be mobile upright shields in the nuclear medicine clinic or a patient's room when a technician or nurse must stay beside a patient, or they may be lead sheets used to shield transporters from patients in wheelchairs.

APPENDIX V

Filing System

The purpose of a filing system is to allow for the quick access of records. The system should be constructed to allow a person who is not familiar with the system to use it with minimal training. If you have not established a system, the one described below may be helpful. In addition to NRC-licensed activities, it includes sections for State-licensed natural and accelerator-produced radioactive material programs, x-ray survey and maintenance reports that are sometimes maintained by the Radiation Safety Officer, and various safety committees.

The filing system described contains two parts: The first part includes Sections A and 0-9 for files that are small or occasionally accessed. The second part consists of five looseleaf notebooks used to file records that are large, frequently accessed, or easily filed in alphabetical or chronological order.

Section A -- Active Projects

Set up an individual file for each project, e.g., planning a new radioisotope lab or x-ray installation or a research project. Label each file with a short title. File chronologically with new material in front. For example:

Shielding calculations for new x-ray room
TLD project
Registration and travel to summer meeting

Section 0 -- Forms

Set up a file for master copies of the forms you use in your facility and a file for copies of each form. Label the files as indicated.

0.1 Masters
0.2 Personal Exposure Monitor Applications
0.3 Exposure History Request
0.4 Exposure History Report
0.5 Teletherapy Monthly Check
0.6 Nuclear Medicine Daily Survey
0.7 Survey Meter Calibration
0.8 Sink Disposal Logs
0.9 Vented Release Logs
0.10 Decay-In-Storage Release Records
0.11 Room Survey Master Forms
etc.

Section 1 -- Committees

Each subsection of this section is devoted to a single committee. In some cases, the file will contain only meeting minutes. In other cases, the file may also include a committee charter, curricula vitae of members, and topical reports.

1.1 Radioactive Drug Research Committee
1.2 Hospital Safety Committee
1.3 Research Safety Committee
1.4 Research Review Committee
1.5 Radiation Safety Committee
etc.

Section 2 -- NRC License

2.1 License Applications, License
2.2 Amendment Requests, Amendments
2.3 Photocopies of License
2.4 Records of Minor Changes
2.5 Inspection Reports and Replies
2.6 Visiting Authorized User Credentials
2.7 Misadministration Reports
2.8 Other Correspondence
etc.

Section 3 -- Inventories, Surveys, and Waste

3.0 Inventory Summary Sheet
3.11 Nuclear Medicine Surveys and Inventory Summaries
3.12 Research Lab Surveys and Inventory Summaries
3.21 I-Therapy Room Release Surveys
3.22 Brachytherapy/Sealed Source Quarterly Inventory and Survey
3.23 Leak-Test Records
3.30 Room Survey Sets for Future Use
3.41 Annual Sink Disposal Summary
3.42 Annual Vent Disposal Summary
3.43 Hot Lab Sink Disposal Logs
3.44 Research Lab Sink Disposal Logs
3.45 Decay-In-Storage Release Logs
etc.

Section 4 -- Contract Services

4.1 Personal Dosimetry Service Contract
4.2 Change Forms
4.3 Monthly Exposure Reports
4.4 Waste Shipment Contract
4.5 Transfers of Byproduct Material
etc.

Section 5 -- Training Lecture Outlines, Handouts, and Attendance Logs

5.11 Nonradiology Physicians
5.12 Nonradiology Technologists
5.21 Radiology Physicians
5.22 Radiology Technologists
5.31 Administrators
5.32 Security
5.33 Physical Plant
5.34 Housekeeping
5.35 Animal Research Facility

5.41 Nursing--General Radiation Safety
5.42 Nursing for Brachytherapy
5.43 Nursing for Iodine Therapy
5.51 Brachytherapy Team
5.52 Diagnostic Nuclear Medicine Personnel
5.53 Therapeutic Nuclear Medicine Personnel
5.54 Teletherapy Personnel
5.61 In Vitro Users
etc.

Section 6 -- Radiation Safety Equipment on Hand

Set up an individual file for each piece of equipment. The file should contain the user's manual, guarantee, service reports, and calibration reports. File alphabetically by manufacturer.

Section 7 -- Incidents

7.1 Personnel Exposures
7.2 Spills or Losses with No Personnel Exposure
7.3 Procedural Incidents

Section 8 -- State-Regulated Sources

8.1 X-ray Registration Sheets
8.2 NARM License Application, License

Set up an individual file for each piece of radiographic equipment. The file should contain the user's manual, guarantee, service reports, and inspection and calibration reports. File by room number. For portable x-ray machines, file by manufacturer's name or normal storage location.

Section 9 -- Facility Description

Set up files for blueprints, drawings, and permanently installed equipment such as incinerators, fume hoods, and walk-in boxes.

Loose-Leaf Notebooks

1. Dosimetry Service Monthly Packing Slips. Checkmark each name when the monitor is returned at the end of the monitor period. This will highlight persons who are not returning monitors promptly for processing.

2. Personnel Dosimetry Individual Applications. Behind each individual's application form, file copies of previous employment exposure, incidents, requests for previous employment exposure, and bioassay results.

3. Budget and Purchase Orders

4. NRC Regulatory Guides -- Divisions 8 and 10

5. Standard Operating Procedures

6. NRC Rules and Regulations

APPENDIX W

Bibliography

Title 10, Code of Federal Regulations[1]

Part 19 - Notices, Instructions, and Reports to Workers; Inspections

Part 20 - Standards for Protection Against Radiation

Part 21 - Reporting of Defects and Noncompliance

Part 30 - Rules of General Applicability to Domestic Licensing of Byproduct Material

Part 31 - General Domestic Licenses for Byproduct Material

Part 32 - Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material

Part 33 - Specific Domestic Licenses of Broad Scope for Byproduct Material

Part 35 - Medical Use of Byproduct Material

Part 40 - Domestic Licensing of Source Material

Part 70 - Domestic Licensing of Special Nuclear Material

Part 71 - Packaging and Transportation of Radioactive Material

Part 170 - Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended

USNRC Regulatory Guides[2]

Regulatory Guide 8.4, "Direct-Reading and Indirect-Reading Pocket Dosimeters"

Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable"

Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure"

Regulatory Guide 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable"

---

[1]Title 10 of the Code of Federal Regulations is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

[2]NRC documents may be purchased from the U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013-7082, or the National Technical Information Service, Springfield, VA 22161.

Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131"

Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions"

Regulatory Guide 10.2, "Guidance to Academic Institutions Applying for Specific Byproduct Material Licenses of Limited Scope"

Regulatory Guide 10.5, "Applications for Type A Licenses of Broad Scope"

Draft Regulatory Guide FC 414-4,[3] "Guide for the Preparation of Applications for Licenses in Medical Teletherapy Programs"

Other NRC Publications[2]

A. Brodsky, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable," NUREG-0267, Revision 1, USNRC, Washington, DC, October 1982.

N. L. McElroy and A. Brodsky, "Radiation Protection Training for Personnel Employed in Medical Facilities," NUREG-1134, USNRC, Washington, DC, May 1985.

Technical Reports

Bureau of Radiological Health, "Radiation Safety in Nuclear Medicine: A Practical Guide," Department of Health and Human Services (HHS) Publication FDA 82-8180, November 1981.

Center for Devices and Radiological Health, "Recommendations for Quality Assurance Programs in Nuclear Medicine Facilities," HHS Publication FDA 85-8227, October 1984.

International Atomic Energy Agency (IAEA), "Monitoring of Radioactive Contamination on Surfaces," Technical Report Series No. 120, 1970.[4]

IAEA, "Handbook on Calibration of Radiation Protection Monitoring Instruments," Technical Report Series No. 133, 1971.[4]

International Commission on Radiological Protection (ICRP), "General Principles of Monitoring for Radiation Protection of Workers," Report No. 12, Pergamon Press, Elmsford, NY, 1969.[5]

---

[3]Draft regulatory guides may be obtained at no charge by writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Information Support Services.

[4]IAEA reports may be obtained from UNIPUB, Inc., 345 Park Avenue South, New York, NY 10010.

[5]ICRP reports may be obtained from Pergamon Press, Maxwell House, Fairview Park, Elmsford, NY 10523.

International Commission on Radiation Units and Measurements (ICRU), "Certification of Standardized Radioactive Sources," Report No. 12, Washington, DC, 1968.[6]

National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," Report No. 37, Washington, DC, 1970.[7]

NCRP, "Radiation Protection for Medical and Allied Health Personnel," Report No. 48, Washington, DC, 1976.[7]

NCRP, "Instrumentation and Monitoring Methods for Radiation Protection," Report No. 57, Washington, DC, 1978.[7]

NCRP, "A Handbook of Radioactivity Measurement Procedures, Second Edition" Report No. 58, Washington, DC, 1985.[7]

NCRP, "Operational Radiation Safety Training," Report No. 71, Washington, DC, 1983.[7]

ANSI Standards[8]

American National Standards Institute (ANSI), ANSI N13.2-1969 (R1982), "Administrative Practices in Radiation Monitoring (A Guide for Management)," New York, NY.

ANSI N13.4-1971 (R1983), "Specification of Portable X- or Gamma Radiation Survey Instruments," New York, NY.

ANSI N13.5-1972 (R1982), "Performance and Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation," New York, NY.

ANSI N13.6-1966 (R1982), "Practice for Occupational Radiation Exposure Records Systems," New York, NY.

ANSI N14.5-1977, "Leakage Tests on Packages for Shipment of Radioactive Materials," New York, NY.

ANSI N42.12-1980 (R1985), "Calibration and Usage of Sodium Iodide Detector Systems," New York, NY.

ANSI N42.13-1985, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides," New York, NY. (Revision of ANSI N42.13-1978)

---

[6]ICRU reports may be obtained from ICRU Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

[7]NCRP reports may be obtained from NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

[8]ANSI standards may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

ANSI N42.15-1980 (R1985), "Performance Verification of Liquid Scintillation Counting Systems," New York, NY.

ANSI N44.1-1973 (R1984), "Integrity and Test Specifications for Selected Brachytherapy Sources," New York, NY.

ANSI N44.2-1979 (R1984), "Leak Testing Radioactive Brachytherapy Sources," New York, NY.

ANSI N44.3-1973 (R1984), "Thyroid Radioiodine Uptake Measurements Using a Neck Phantom," New York, NY.

ANSI N323-1978 (R1983), "Radiation Protection Instrumentation Test and Calibration," New York, NY.

ANSI N449-1974 (R1984), "Guidelines for Maintaining Cobalt-60 and Cesium-137 Teletherapy Equipment," New York, NY, 1973.

ANSI N449.1-1978 (R1984), "Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment," New York, NY, 1978.

Other Resources

Blatz, Hanson, Editor, Radiation Hygiene Handbook, McGraw-Hill, New York, NY, pp. 22-27, 1959.

Cember, Herman, Introduction to Health Physics--Second Edition, Pergamon Press, New York, NY, 1983.

Sanborn, Jeffrey, Radiation Safety During Nursing Care of Patients Receiving Internal Radiotherapy, Maine Medical Center, 22 Bramhall Street, Portland, ME, 04102 (undated).

Shapiro, Jacob, Radiation Protection--A Guide for Scientists and Physicians, Second Edition, Harvard University Press, Cambridge, MA, 1981.

Steere, Norman V., Editor, Handbook of Laboratory Safety, chapter on "Determining Industrial Hygiene Requirements in Installations Using Radioactive Materials," pp. 482-502; also "Basic Units of Radiation Measurement," pp. 391-426, CRC Press, Inc., 2000 N.W. 24th Street, Boca Raton, FL 33431, 1970.

Wang, Yen, Editor, Handbook of Radioactive Nuclides, Part VIII, "Radiation Protection and Regulation," CRC Press, Inc., 2000 N.W. 24th Street, Boca Raton, FL 33431, pp. 573-831, 1969.

LIST OF EXHIBITS

EXHIBIT 1

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

EXHIBIT 1 (Continued)

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

EXHIBIT 2

SUPPLEMENT A

SUPPLEMENT — **U.S. NUCLEAR REGULATORY COMMISSION**

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE

EXHIBIT 3

SUPPLEMENT B

SUPPLEMENT — **U. S. NUCLEAR REGULATORY COMMISSION**

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME

STREET ADDRESS

CITY | STATE | ZIP CODE

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
	Thyroid scan		
	Thyroid uptake		
	Lung perfusion scan		
	Xenon ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Dacryocystogram		
	Cardiac perfusion scan.		
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram		
	Gallium scan		

PROPOSED PHYSICIAN USER

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

b. NAME OF INSTITUTION

c. MAILING ADDRESS

d. CITY

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME *(Please type or print)*

8. DATE

EXHIBIT 4

RESIDENT'S SUPPORT TECHNOLOGY TRAINING TASK LOG

Name:_____

Task	Date Performed	Supervising Technologist's Initials
1. Hot lab.		
a. Log and monitor incoming packages.	__-__-__	_____
b. Elute generator.	__-__-__	_____
c. Measure and record Mo and Al concentrations in eluate.	__-__-__	_____
d. Prepare each radiopharmaceutical kit used. Measure tagging efficiency.	__-__-__	_____
e. Calculate volume of radiopharmaceutical needed for prescribed dosage. Draw and measure dosage.	__-__-__	_____
f. Perform constancy, accuracy, linearity, and geometry tests on dose calibrator.	__-__-__	_____
g.		
h.		
2. Camera.		
a. Center photopeak, focus lens and dot.	__-__-__	_____
b. Perform and evaluate extrinsic and intrinsic field uniformity checks.	__-__-__	_____
c. Perform and evaluate spatial resolution checks.	__-__-__	_____
d. Check motion switches for safe operation.	__-__-__	_____
e.		
f.		
3. Processor and dark room.		
a. Operate processor.	__-__-__	_____
b. Prepare fresh chemistry.	__-__-__	_____
Clean transport and crossover racks.	__-__-__	_____
d. Check safelight.	__-__-__	_____
e.		
f.		
4. Safety surveys.		
a. Perform dose rate survey of clinic.	__-__-__	_____
b. Perform removable contamination survey of clinic.	__-__-__	_____
c. Survey and log decayed waste.	__-__-__	_____
d.		
e.		

_____

Preceptor

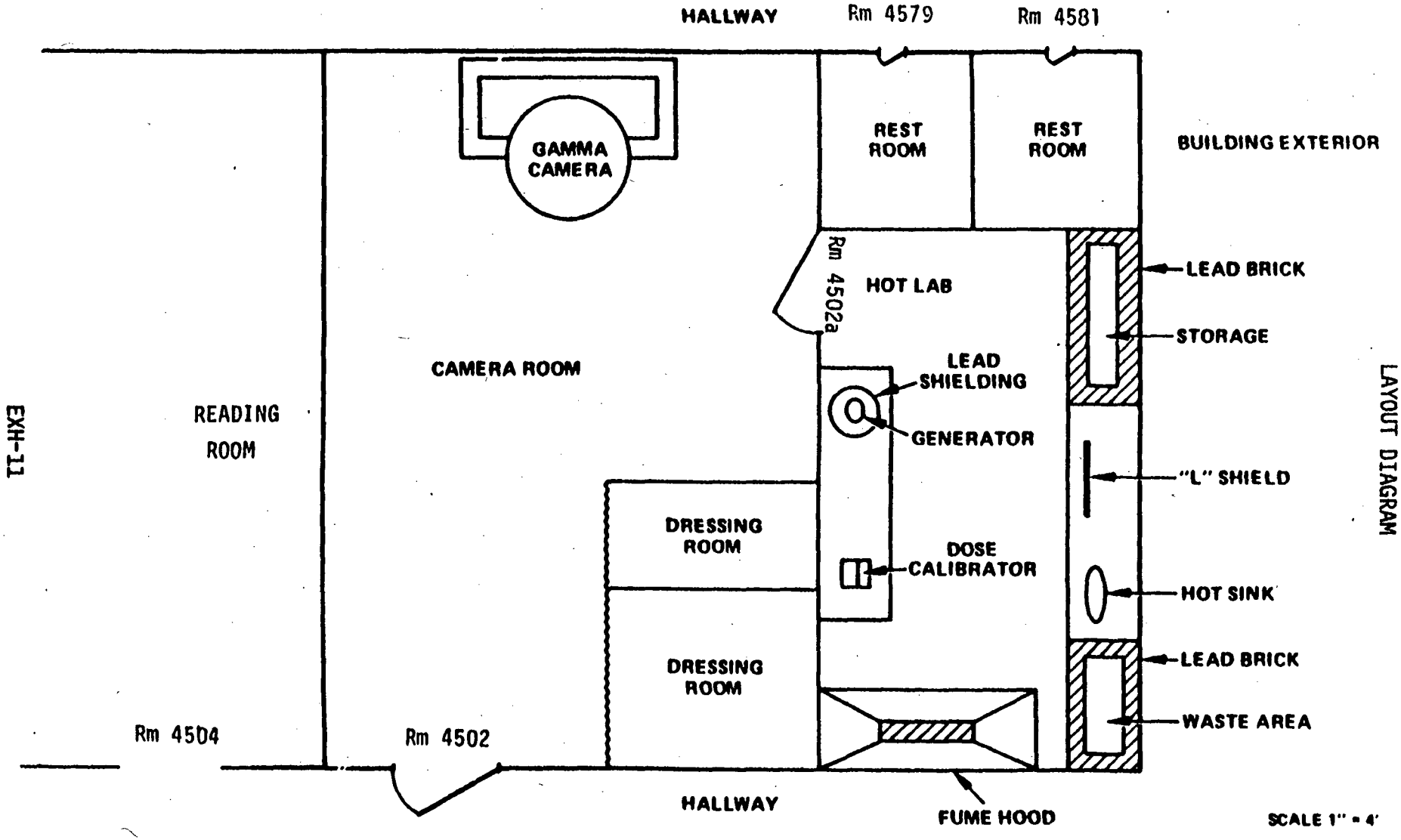
EXHIBIT 5

RESIDENT'S CLINICAL PROCEDURES TRAINING LOG

Name:_____

Clinical Procedure	Date Performed	Supervising Technologist's Initials
Thyroid scan	__-__-__	_____
Thyroid uptake	__-__-__	_____
Lung perfusion scan	__-__-__	_____
Xenon ventilation study	__-__-__	_____
Aerosol ventilation scan	__-__-__	_____
Renal flow scan	__-__-__	_____
Brain scan	__-__-__	_____
Liver/spleen scan	__-__-__	_____
Bone scan	__-__-__	_____
Gastroesophageal study	__-__-__	_____
LeVeen shunt study	__-__-__	_____
Cystogram	__-__-__	_____
Dacryocystogram	__-__-__	_____
Cardiac perfusion scan.	__-__-__	_____
Cardiac stress ventriculogram	__-__-__	_____
Cardiac rest ventriculogram	__-__-__	_____
Gallium scan	__-__-__	_____
_____	__-__-__	_____
_____	__-__-__	_____
_____	__-__-__	_____

_____
Preceptor



EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR A FACILITY DESCRIPTION INCLUDING SHIELDING PROVISIONS

EXHIBIT 7

Survey Meter Calibration Report

Owner:_____ Department:_____

Manufacturer:_____ Type: o Ion Chamber o GM o NaI(Tl) o _____

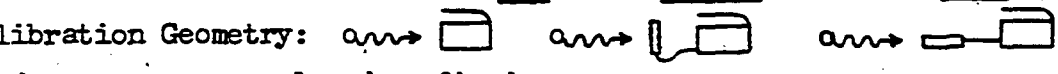
Meter model:_____ Meter S/N:_____ Probe model:_____ Probe S/N:_____

Calibration Source: ___mCi of _____. ____mR/hr at ___in on _____, 19__.

Instrument checks: Battery check:___mR/hr or _____

Constancy check: o integral check source indicates ____mR/hr.

o ___mCi of _____ indicates ____mR/hr.

Calibration Geometry:  o

Window: o open o closed o fixed

dist (feet)	mR/hr today	Scale: Rdng	CorFac	Scale: Rdng	CorFac	Scale: Rdng	CorFac	Scale: Rdng	CorFac

Correction Factors: _____ _____ _____ _____

Name:_____

Date:_____

Calibration Sticker

Cald ___-___-___ with _____
// ⊥, window:_____
scale CorFac
_____ _____ bat:"__mR/hr"
_____ _____
_____ _____ chk:"__mR/hr"

EXHIBIT 7 (Example)

Survey Meter Calibration Report

Owner: County General Hosp Department: Nuclear Medicine

Manufacturer: Metrologia Type: ☒ Ion Chamber ○ GM ○ NaI(Tl) ○ _____

Meter model: 101 Meter S/N: 362 Probe model: na Probe S/N: na

Calibration Source: 93 mCi of Cs-137. 30.7 mR/hr at 100 cm on June, 1986.

Instrument checks: Battery check: ~~mR/hr~~ or green line "BATT"

Constancy check: ☒ integral check source indicates 3.2 mR/hr.

○ ___ mCi of _____ indicates ___ mR/hr.

Calibration Geometry: ☒  ○

Window: ○ open ○ closed ☒ fixed

dist ~~(feet)~~	mR/hr today	Scale: 1000 Rdng	CorFac	Scale: 100 Rdng	CorFac	Scale: 10 Rdng	CorFac	Scale: Rdng	CorFac
20 cm	767	810	.95						
40	192	190	1.01						
60	85			82	1.04				
100	31			29	1.07				
200	7.7					8.1	.95		
300	3.4					3.6	.94		

Correction Factors: .98 1.06 .94 _____

Name: John Hewitt, RSO

Date: 6-06-86

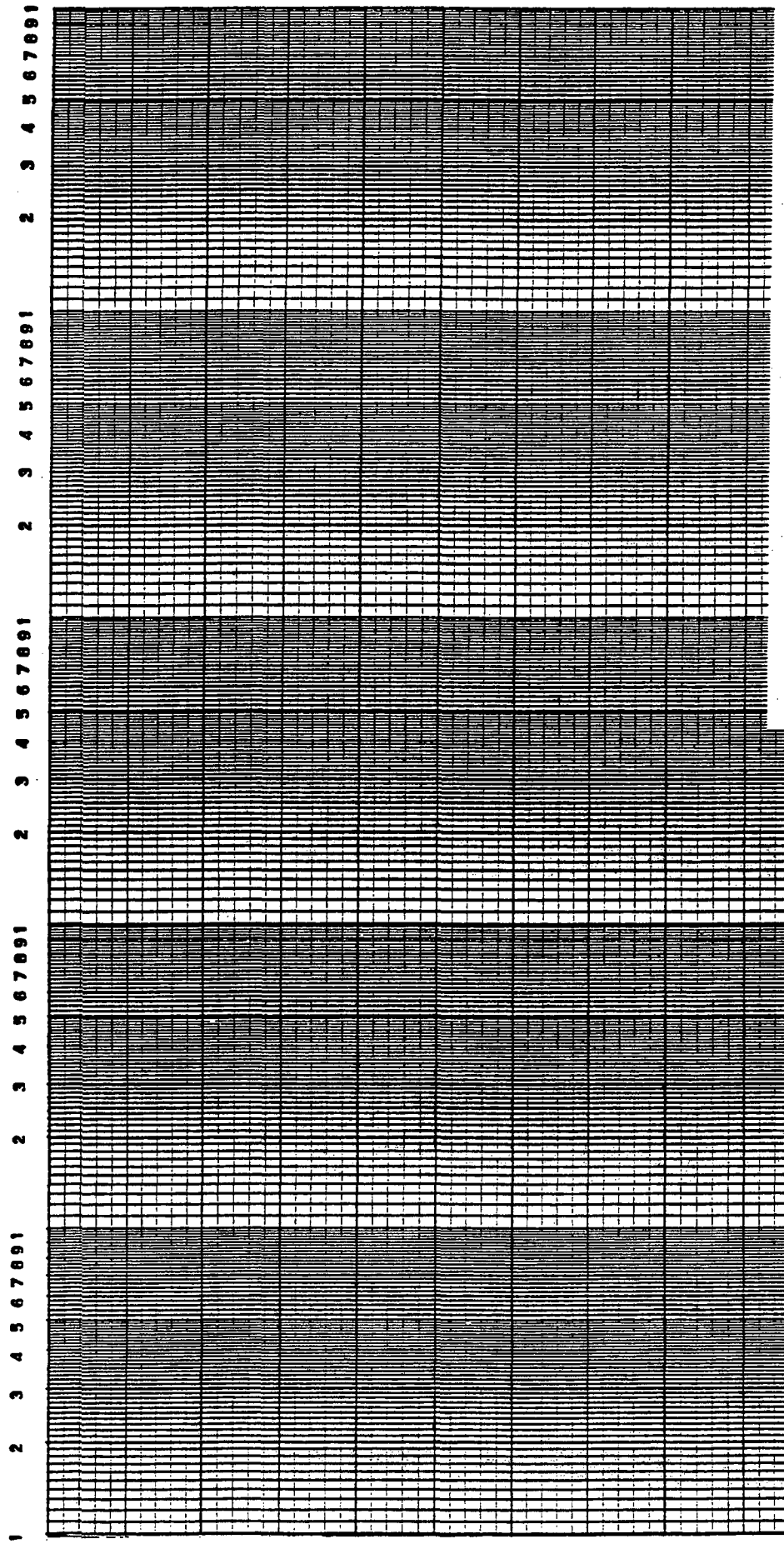
Calibration Sticker

Cald 6-06-86 with Cs 137

(II) I, window: fixed

scale	CorFac	
1000	1.0	bat: "~~mR/hr~~ BATT"
100	1.1	
10	.9	chk: "3.2 mR/hr"

EXHIBIT 8



Dose Calibrator Linearity Test

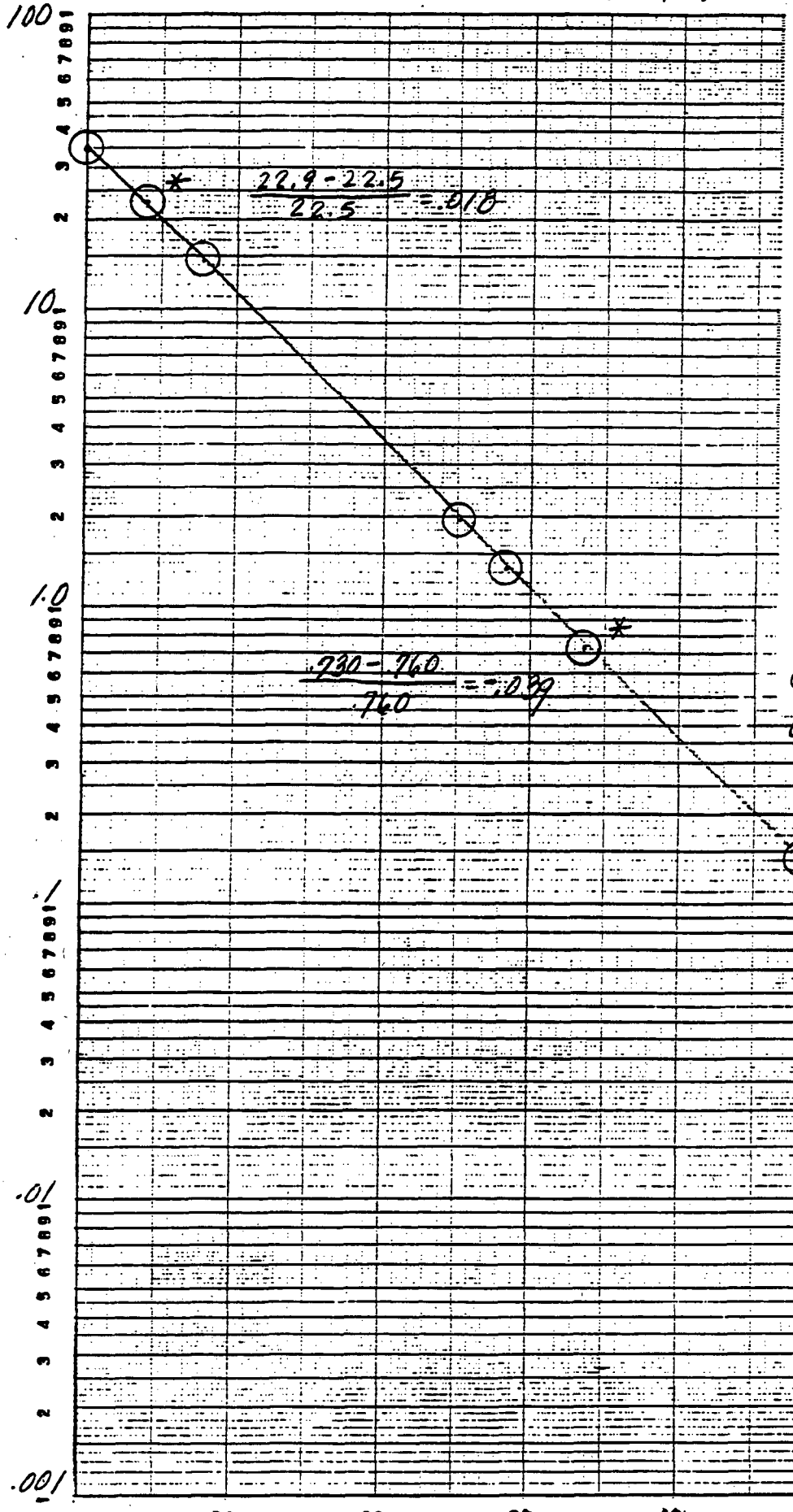
Manufacturer:_____

Model:_____ SN:_____

date	time	mCi assay	hours elapsed

worst point deviation:_____

EXHIBIT 8 (Example)



Dose Calibrator Linearity Test

Manufacturer: Metrologia

Model: IC-3 SN: 352

date	time	mCi assay	hours elapsed	
3 25 86	7:50 a	35.0	0	
	11:30 a	22.9	4	*
	2:45 p	14.6	7.8	
3 26 86	8:05 a	1.95	25.1	
	11:25 a	1.33	28.4	
	4:40 p	.730	33.7	*
3 27 86	7:05 a	.140	48.1	
	1:05 p	.071	54.1	
	4:35 p	.047	57.6	
3 28 86	7:00 a	.009	72.0	

worst point deviation: -.04

Wendy Breeze, Chr Tech

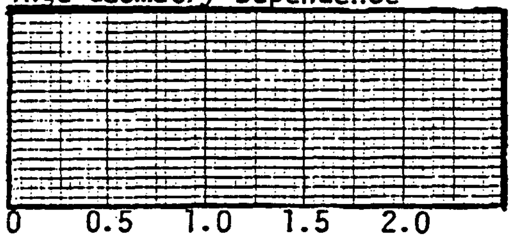
John Hendrix RSO

EXHIBIT 9

Dose Calibrator Geometry and Accuracy

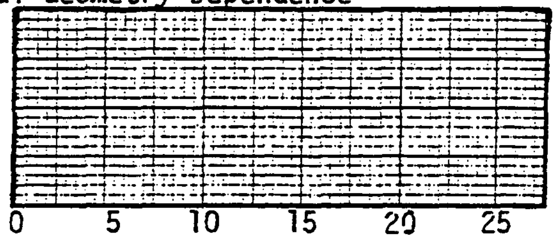
Manufacturer:____________________ Model:________________ SN:__________

Syringe Geometry Dependence



___ ___ ___ ___

Vial Geometry Dependence



___ ___ ___ ___ ___ ___ ___ ___

___ ___ ___ ___ ___ ___

Date:__________ By:____________________ RSO:____________________

Accuracy Sources	19___	19___
_____mCi of _____ Model:__________ SN:__________ Calibration date: __________	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____
_____mCi of _____ Model:__________ SN:__________ Calibration date: __________	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____
_____mCi of _____ Model:__________ SN:__________ Calibration date: __________	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____

Name: ____________________ ____________________

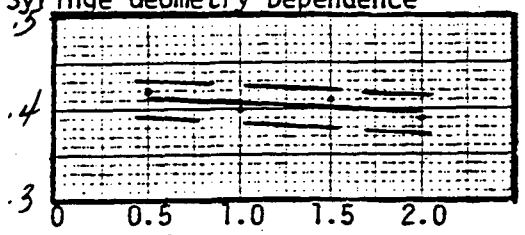
Date: __________ __________

EXHIBIT 9 (Example)

Dose Calibrator Geometry and Accuracy

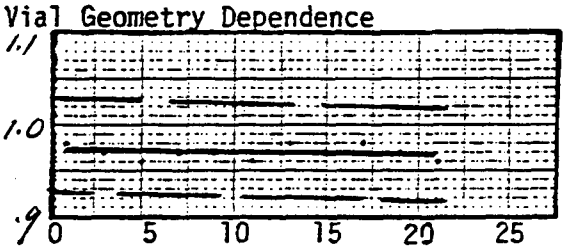
Manufacturer: Metrologia Model: DC-3 SN: 352

Syringe Geometry Dependence



.42 .40 .41 .39

Vial Geometry Dependence



.98 .96 .97 .98 .97 .97 — —
.97 .97 .96 .98 .96 —

Date: 3 29 85 By: Wendy Breeze Ch Tech RSO: J. Hewitt RSO

Accuracy Sources	1985	1986
4.72 mCi of Co-57 Model: S-57-A SN: 407 Calibration date: 1 31 85	first assay: 3.96 mCi second assay: 3.97 mCi third assay: 3.99 mCi average: 3.97 mCi 4.05 mCi dev: -.02	first assay: 1.53 mCi second assay: 1.54 mCi third assay: 1.55 mCi average: 1.54 mCi 1.59 mCi dev: -.03
.103 mCi of Cs-137 Model: S-137-A SN: 407 Calibration date: 1 31 85	first assay: .104 mCi second assay: .105 mCi third assay: .104 mCi average: .104 mCi .103 mCi dev: .01	first assay: .101 mCi second assay: .101 mCi third assay: .101 mCi average: .101 mCi .100 mCi dev: .01
____ mCi of ____ Model: ____ SN: ____ Calibration date: ____	first assay: ____ mCi second assay: ____ mCi third assay: ____ mCi average: ____ mCi ____ mCi dev: ____	first assay: ____ mCi second assay: ____ mCi third assay: ____ mCi average: ____ mCi ____ mCi dev: ____

Name: Wendy Breeze Ch Tech Wendy Breeze Ch Tech

Date: 3 29 85 3 28 86

ok-J Hewitt RSO ok-J Hewitt RSO

EXHIBIT 10

Radioactive Spill Report

The spill occurred at ___:___ am/pm on ___-___-___ room ____.

Instrument used to check for personnel contamination:
Meter model: _____ Meter S/N: _____ Probe model: ____ Probe S/N: _____

Personnel present	Personnel contamination results*
_____	_____
_____	_____
_____	_____
_____	_____

*On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a postcleaning contamination wipe-test.

Radioisotopes present or suspected in the spill:

_____mCi of _____ as _____

_____mCi of _____ as _____

_____mCi of _____ as _____

Give a brief description of the accident: _____

_____

_____

_____

_____

Give a brief description of followup actions taken to prevent recurrence:

_____

_____

_____

Name: _____
Date: _____

EXHIBIT 10 (Example)

Radioactive Spill Report

The spill occurred at 6:50 (am) pm on 5-16-86 in room 450a

Instrument used to check for personnel contamination:
Meter model: 21 Meter S/N: 470 Probe model: 21-B Probe S/N: 319

Personnel present	Personnel contamination results*
Wendy Breuze Ch Tech	< 2000 dpm / 100 cm²
Les Moore Tech	< 2000 dpm / 100 cm²

*On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Instrument used to survey spill area before cleanup: Same
Meter model: _____ Meter S/N: _____ Probe model: _____ Probe S/N: _____
Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a postcleaning contamination wipe-test.

Radioisotopes present or suspected in the spill:
30 mCi of Tc99m as pertechnetate
_____ mCi of _____ as _____
_____ mCi of _____ as _____

Give a brief description of the accident: Les was removing yesterdays Tc from frig to put into waste area. When transferring vial it lead brick, it fell from forceps and broke on floor.

Give a brief description of followup actions taken to prevent recurrence: ordered constant tension forceps with friction boots.

Name: John Hewitt RSO
Date: 5 16 86

Radioactive Spill Contamination Survey

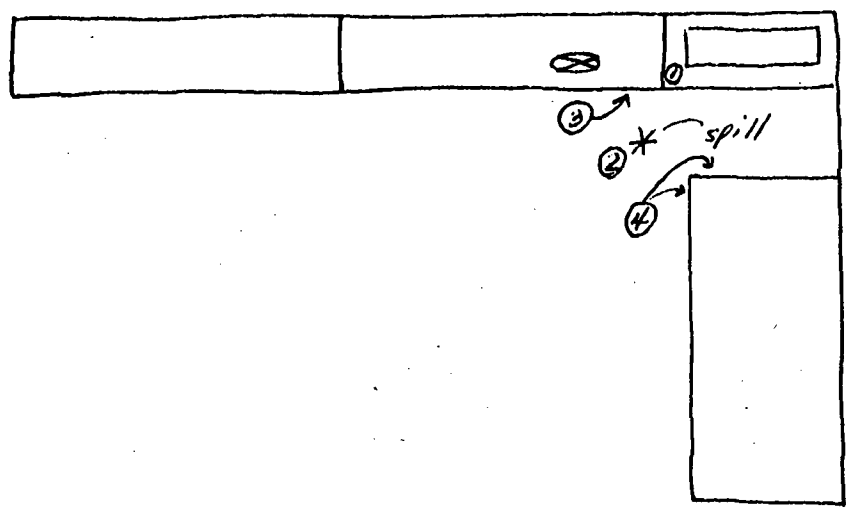
The spill occurred at ___:___ am/pm on ___-___-___ in room _____. Decontamination completed at ___:___ am/pm.

loc	pre-clean mR/hr	post-clean mR/hr	post-clean dpm/100cm^2

Name: _____

Radioactive Spill Contamination Survey

The spill occurred at 6:50 ~~pm~~ am on 5-16-86 in room 4502a. Decontamination completed at 7:10 ~~pm~~ am.



loc	pre-clean mR/hr	post-clean mR/hr	post-clean dpm/100cm^2
1	2	0.4	2500
2	500	3.5	23000
3	50	0.5	1500
4	10	0.2	8000

Name: W. Breeze Ch Tech

EXHIBIT 11 (Example)

EXHIBIT 12

PACKAGE RECEIPT AND MONITOR LOG

date received	purchase order no.	packing slip no.	mCi	iso	chemical	supplier	catalogue number	pkg ok?	mR/hr surf	notes	init

EXHIBIT 12 (Example)

PACKAGE RECEIPT AND MONITOR LOG

date received	purchase order no.	packing slip no.	mCi	iso	chemical	supplier	catalogue number	pkg ok?	mR/hr surf	notes	init
3 25 86	8630042	H862064	1000	Mo99	generator	Disintegrator	G-99	ok	170		wb
			2x3	I201	thallous chloride		C-201				
3 26 86	8630042	4763804	3x10	Xe133	gas		133-3	ok	9		wb

EXHIBIT 13

UNIT DOSAGE RECEIPT AND USE LOG FOR _____ AS _____

date received	supplier	lot	dosage mCi	label time	date dispensed	time	measured mCi	patient	ID number	ini

EXHIBIT 13 (Example)

UNIT DOSAGE RECEIPT AND USE LOG FOR ^{99m}Tc AS Medronate

date received	supplier	lot	dosage mCi	label time	date dispensed	time	measured mCi	patient	ID number	init
3 29 86	Lorata	860329M	20	6:15	3 29 86	9:15a	14.2	Mary Smith	S470316	lm
3 30 86	Lorata	860330M	19	8:15	3 30 86	9:10a	17.2	Chris Kross	K521225	lm
			20	8:15	3 30 86	9:20a	18.1	Art Nouveau	N630517	lm

EXH-25

EXHIBIT 14

MULTIDOSE VIAL PREPARATION AND USE LOG FOR _____ AS _____ ___

date prepared	time	generator received	kit source	kit lot	mCi/cc	cc	measured mCi	patient	ID number	init

EXHIBIT 14 (Example)

MULTIDOSE VIAL PREPARATION AND USE LOG FOR Tc 99m AS sodium gluceptate

date prepared	time	generator received	kit source	kit lot	mCi/cc	cc	measured mCi	patient	ID number	init
4 14 86	7:05	4 13 86	Scintilla	2863	38	5	190			
	7:45				35	.6	20.0	Matt Frame	2170629	lm
	8:35				32	.6	19.1	Mae Flower	2391229	wb
4 15 86							remainder	waste		
4 15 86	6:50	4 13 86	Scintilla	2863	37	5	185			

EXH-27

EXHIBIT 15

SHORT-LIVED IMPLANT SOURCE LOG

Only the following individuals may handle these sources:_____

_____

RSO:_____ date:_____

	no		iso	act
Received on _____,	_____	seeds of _____	@ _____	mCi each
	_____		_____	_____
	_____		_____	_____

date	time	in storage no	in storage mCi	taken out no	taken out mCi	returned no	returned mCi	patient name	mR/hr	init

EXHIBIT 15 (Example)

SHORT-LIVED IMPLANT SOURCE LOG

Only the following individuals may handle these sources: S. Mudd, M.D. SM
Bea Wachen, Therapy Technologist bw John Hewitt, RSO jh

RSO: John Hewitt Date: 5 02 86

Received on 5 02 86, 100 seeds of Ir192 @ 0.5 mCi each

	no	iso	act

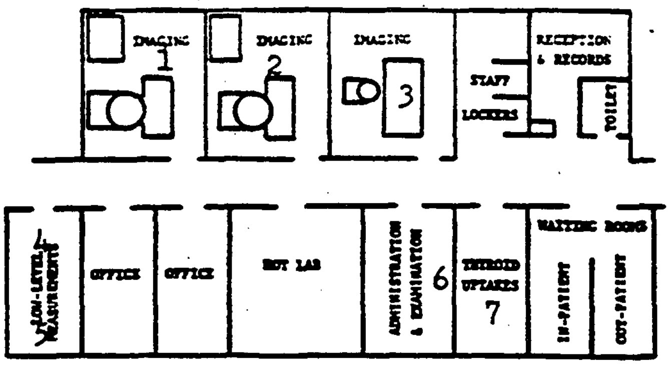
date	time	in storage no	in storage mCi	taken out no	taken out mCi	returned no	returned mCi	patient name	mR/hr	init
5 02 86	3:15 pm	100	50					receipt		jh
5 08 86	10:40 am	50	25	50	25			Windward	10	jh
	11:15 am	60	30	40	20	10	5	Windward		jh
				not needed for implant Jh						
5 09 86	12:15 pm	100	50			40	20	Windward	0.01	jh

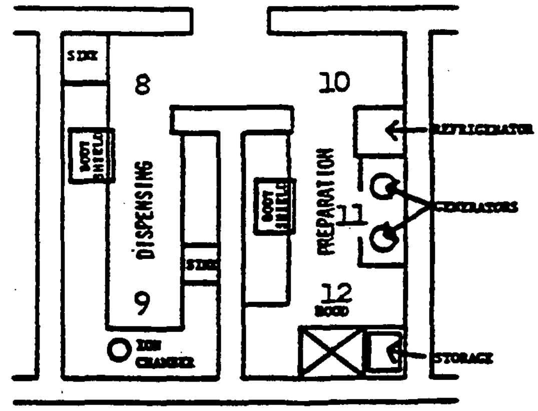
EXHIBIT 16

SAMPLE

Radiation Survey for the month of __________, 19__

Instrument: ________________





EXPANDED VIEW OF HOT LAB

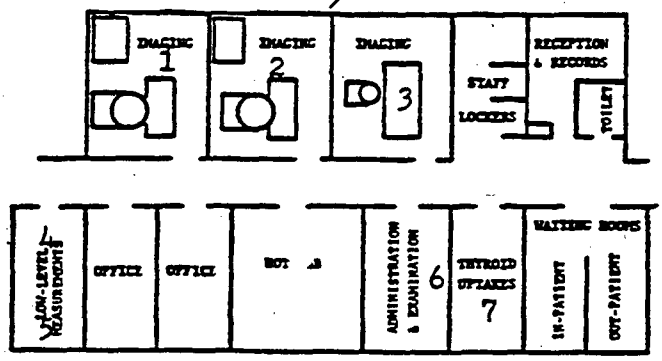
mR/hr at location

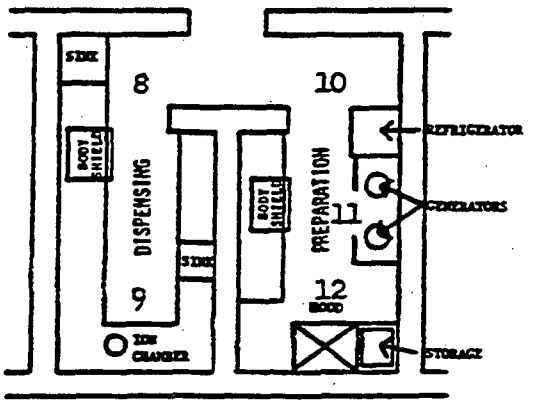
date	1	2	3	4	5	6	7	8	9	10	11	12		init
trigger														

EXHIBIT 16 (Example)

SAMPLE Radiation Survey for the month of April, 1986

Instrument: Nitrologia 2L SN 470





EXPANDED VIEW OF HOT LAB

mR/hr at location

date	1	2	3	4	5	6	7	8	9	10	11	12		init
trigger	.02	.02	.02	0.1	0.1	.02	.02	0.5	0.5	0.7	1.2	1.0		
1	.02	.01	.01	.05	.05	.02	.02	0.4	0.4	0.6	1.0	0.7		lm
2	.02	.02	.02	.04	.04	.02	.02	0.3	0.4	0.5	0.9	0.7		lm
3	.02	.02	.02	.05	.05	.02	.01	0.3	0.5	0.6	1.0	0.6		lm
4	.01	.01	.01	.04	.04	.01	.01	0.4	0.4	0.5	0.9	0.6		lm
7	.03	.02	.02	.06	.06	.02	.02	0.5	0.4	0.7	1.2	0.9		wb
	Lat sump in floor under chair. To waste. .02mR/hr - wb jh.													

EXHIBIT 17

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH IODINE-131, PHOSPHORUS-32, OR GOLD-198

Patient Name:_____ Patient Number:_____
Attending:_____Phone:___ Pager:_____ Patient Room:_____

Dose:_____mCi of _____ as _____ was administered at ___:___ am pm
Signature:_____ Date:___-___-___

RADIATION EXPOSURE RATES

Unrestricted areas: door-___ ___mR/hr; rm___-___mR/hr; rm___-___mR/hr
Patient supine in bed or _____

Date	Time	Bedside	3 ft from bed	Door	_____
___-___-___	___:___ am pm	_____mR/hr	_____mR/h	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/h	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/h	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/h	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm	_____mR/hr	_____mR/h	_____mR/hr	_____mR/hr
___-___-___	___:___ am pm		_____mR/h		

INSTRUCTIONS

Vistor Restrictions:
- ☐ No visitors.
- ☐ No visitors under 18 or pregnant.
- ☐ ___ minutes each day maximum for each visitor.
- ☒ Visitors must stay behind line on floor at all times.

Nursing Restrictions:
- ☐ Patient is restricted to room.
- ☐ No nurses who are pregnant may render care.
- ☐ ___ minutes each day per nurse in the room.

Patient Care:
- ☐ Wear disposable gloves. Wash your hands after caring for patient.
- ☐ Discard linen, bedclothes, plates, utensils, dressings, etc., in boxes in room.
- ☐ Collect urine in containers provided. Discard feces in toilet.
- ☐ Discard urine and feces in toilet. Flush three times.
- ☐ Housekeeping personnel are not permitted in the room.
- ☐ Only RSO may release room to admitting office.
- ☐ Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- ☐ _____
- ☐ _____

In case of emergency, or if you have a question, call:
RSO:_____ Work:_____ Home:___-___ Pager:_____
MD:_____ Work:_____ Home:___-___ Pager:_____

EXHIBIT 17 (Example)

Nursing Instructions for Patients Treated With Iodine-131, ~~Phosphorus-32, or Gold 198~~

Patient Name: June Weddum Patient Number: W45012
Attending: S. Mudd MD Phone: 3556 Pager: 302 Patient Room: 402E

Dose: 150 mCi of I-131 as sodium iodide was administered at 10:50 (am) pm.

Signature: S. Mudd MD Date: 5-05-86

Radiation Exposure Rates

Unrestricted areas: door-~~402E~~ 0.3 mR/hr; rm~~402E~~ 0.3 mR/hr; rm~~403E~~ 0.2 mR/hr
Patient supine in bed ~~or~~

Date	Time	Bedside	3 ft from bed	Door	vis. ch.
5-05-86	11:00 (am) pm	52 mR/hr	22 mR/h	1.8 mR/hr	3.2 mR/hr
5-06-86	10:~~00~~ (am) pm	16 mR/hr	6.7 mR/h	0.6 mR/hr	0.9 mR/hr
___-___-___	___:___ am pm	___ mR/hr	___ mR/h	___ mR/hr	___ mR/hr
___-___-___	___:___ am pm	___ mR/hr	___ mR/h	___ mR/hr	___ mR/hr
5-07-86	11:00 (am) pm	discharge	4.7 mR/h		

Instructions

Visitor Restrictions:
- o No visitors.
- ✓ No visitors under 18 or pregnant.
- ✓ 30 minutes each day maximum for each visitor.
- ✓ Visitors must stay behind line on floor at all times.

Nursing Restrictions:
- ✓ Patient is restricted to room.
- ✓ No nurses who are pregnant may render care.
- ✓ 30 minutes each day per nurse in the room.

Patient Care:
- ✓ Wear disposable gloves. Wash your hands after caring for patient.
- ✓ Discard linen, bedclothes, plates, utensils, dressings, etc., in boxes in room.
- o Collect urine in containers provided. Discard feces in toilet.
- ✓ Discard urine and feces in toilet. Flush three times.
- ✓ Housekeeping personnel are not permitted in the room.
- ✓ Only RSO may release room to admitting office.
- ✓ Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- ✓ 17 yo. daughter may visit 10 min ea. da. S Mudd ok J Hewitt-RSO
- o ___

In case of emergency, or if you have a question, call:

RSO: John Hewitt Work: ___ Home: ___-___ Pager: 369
MD: S. Mudd Work: ___ Home: ___-___ Pager: 302

EXHIBIT 18

RADIATION SAFETY CHECKLIST FOR IODINE THERAPY OVER 30 MILLICURIES

Patient:_____ Room:_____ Date:_____

PREPARATION

- ☐ Schedule a private room, with private sanitary facilities and without carpet, in a low traffic area.
- ☐ Cover large room surfaces with absorbent paper and small surfaces with absorbent paper or plastic bags.
- ☐ Prepare labeled boxes for used linen, disposable waste, and nondisposable contaminanted items.
- ☐ Prepare urine collection containers if urine will be collected.
- ☐ Stock room with disposable gloves, absorbent paper, and "radioactive waste" labels.
- ☐ Mark a visitors' "safe line" on the floor.
- ☐ Order disposable table service.
- ☐ Notify housekeeping to not clean the room until further notice.
- ☐ Brief the nursing staff on radiation safety measures.
- ☐ Supply the nursing staff with personnel radiation dosimeters.

ADMINISTRATION

- ☐ Clear the room of unneeded personnel.
- ☐ Brief the patient on the clinical procedure.
- ☐ Administer the dosage.
- ☐ Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line," and surrounding hallways and rooms.
- ☐ Post the room with a "Radioactive Materials" sign.

FOLLOWUP

- ☐ Measure the thyroid burden of all personnel who were present for the administration.
- ☐ Pick up waste for decay-in-storage or decontamination.
- ☐ Release the patient.
- ☐ Decontaminate and survey the room. Remove the "Radioactive Materials" sign.
- ☐ Call the Housekeeping Office to clean the room.

EXHIBIT 19

RADIATION SAFETY CHECKLIST FOR TEMPORARY IMPLANT THERAPY

Patient:_____ Room:_____ Date:_____

PREPARATION

- ☐ Schedule a private room in a low traffic area.
- ☐ Mark a visitors' "safe line" on the floor.
- ☐ Brief the nursing staff on radiation safety measures.
- ☐ Supply the nursing staff with personnel radiation dosimeters.

IMPLANT

- ☐ Clear the room of unneeded personnel.
- ☐ Brief the patient on the clinical procedure.
- ☐ Insert the implant
- ☐ Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line," and surrounding hallways and rooms.
- ☐ Post the room with a "Radioactive Materials" sign.

FOLLOWUP

- ☐ Make a radiation survey of the patient to assure that all sources have been removed.
- ☐ Count the number of sources removed from the patient to assure that all sources have been removed.
- ☐ Remove the "Radioactive Materials" sign.

EXHIBIT 20

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH TEMPORARY IMPLANT SOURCES

Patient Name:_____ Patient Number:_____
Attending:_____Phone:_____ Pager:_____ Patient Room:_____
Dose:_____mCi of _____ as _____ individual sources was loaded on __-__-__.
Sources will be removed at approximately __:__ am pm on __-__-__.

RADIATION EXPOSURE RATES

Unrestricted areas: door-_____mR/hr; rm__-___mR/hr; rm__-_____mR/hr
Patient supine in bed or _____

Date	Time	Bedside	3 ft from bed	Door _____
__-__-__	__:__ am pm	_____mR/hr	_____mr/h	_____mR/hr _____mR/hr

Release certification: Patient may not be released from the hospital until the following certification is signed and dated by the RSO or the attending physician.

I have removed and counted ____ individual sources from this patient. A low-range GM survey of the patient failed to indicate any remaining sources in the patient.

Signature:_____ Date__-__-__

INSTRUCTIONS

Visitor Restrictions:
- ☐ No visitors under 18 or pregnant.
- ☐ ___ minutes each day maximum for each visitor.
- ☐ Visitors must stay behind line on floor at all times.

Nursing Restrictions:
- ☐ Patient is restricted to room.
- ☐ Patient is restricted to bed.
- ☐ Patient must not move.
- ☐ No nurses who are pregnant may render care.
- ☐ ___ minutes each day per nurse in the room.

Patient Care:
- ☐ Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- ☐ If a source appears dislodged, call the attending physician and the RSO immediately.
- ☐ Omit bed bath.
- ☐ No perineal care. Pad may be changed as necessary.
- ☐ Save surgical dressings for disposal by attending physician or RSO.
- ☐ See special oral hygiene care instructions.
- ☐ _____
- ☐ _____

In case of emergency, or if you have a question, call:
RSO:_____ Work:_____ Home:___-____ Pager:_____
MD:_____ Work:_____ Home:___-____ Pager:_____

EXHIBIT 20 (Example)

Nursing Instructions for Patients Treated With
Temporary Implant Sources

Patient Name: Lee Windward Patient Number: W250101

Attending: S. Mudd MD Phone: 5556 Pager: 302 Patient Room: 3015

Dose: 20 mCi of Ir-192 as 40 individual sourc ; was loaded on 5-07-86

Sources will be removed at approximately 11:00 am/pm on 5-09-86.

Radiation Exposure Rates

Unrestricted areas: door- 1.1 mR/hr; rm 3025 0.3 mR/hr; rm 3035 0.2 mR/hr

Patient supine in bed or ______

Date	Time	Bedside	3 ft from bed	Door	vis. chair
5-07-86	10:50 am/pm	40 mR/hr	10 mR/h	1.1 mR/hr	2.1 mR/hr

Release certification: Patient may not be released from the hospital until the following certification is signed and dated by the RSO or the attending physician.

I have removed and counted 40 individual sources from this patient. A low-range GM survey of the patient failed to indicate any remaining sources in the patient.

Signature: Bea Wacchen Date 5-09-86

Instructions

Visitor Restrictions:
- ✓ No visitors under 18 or pregnant.
- ✓ 30 minutes each day maximum for each visitor.
- ✓ Visitors must stay behind line on floor at all tires.

Nursing Restrictions:
- o Patient is restricted to room.
- ✓ Patient is restricted to bed.
- o Patient must not move.
- ✓ No nurses who are pregnant may render care.
- ✓ 30 minutes each day per nurse in the room.

Patient Care:
- ✓ Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- ✓ If a source appears dislodged, call the attending physician and the RSO immediately.
- o Omit bed bath.
- o No perineal care. Pad may be changed as necessary.
- ✓ Save surgical dressings for disposal by attending physician or RSO.
- ✓ See special oral hygiene care instructions.
- o ______
- o ______

In case of emergency, or if you have a question, call:

Attg RSO: S Mudd MD Work: ______ Home: ___-___ Pager: 369

RSO MD: John Hewitt Work: ______ Home: ___-___ Pager: 302

EXHIBIT 21

SAMPLE CESIUM IMPLANT SOURCE LOG

Only the following individuals may handle these sources:_____

_____

RSO:_____ date:_____

Normal storage configuration

1A 1B 1C
2A 2B 2C
3A 3B 3C
4A 4B 4C

Activity at each storage point

20mCi: 1A 1B 1C 2A
10mCi: 2B 2C 3A 3B 3C
15mCi: 4A 4B
5mCi: 4C

date	time	in storage no	in storage mCi	taken out no	taken out mCi	returned no	returned mCi	patient name	mR/hr	init

EXHIBIT 21 (Example)

SAMPLE CESIUM IMPLANT SOURCE LOG

Only the following individuals may handle these sources: S. Mudd, M.D. SM

Bea Wacchen, Therapy Technologist bw John Hewitt, RSO jh

RSO John Hewitt date: 1 03 85

Normal storage configuration

1A 1B 1C
2A 2B 2C
3A 3B 3C
4A 4B 4C

Activity at each storage point

20mCi: 1A 1B 1C 2A
10mCi: 2B 2C 3A 3B 3C
15mCi: 4A 4B
5mCi: 4C

date	time	in storage no	in storage mCi	taken out no	taken out mCi	returned no	returned mCi	patient name	mR/hr	init
1 15 85	9 am	12	165							jh
1 22 85	3-15 pm	7	95	5	70			Vera Sackt	15	jh
1 25 85	2:10 pm	12	165			5	70	Vera Sackt	0.01	jh

VALUE/IMPACT STATEMENT

A draft value/impact statement was published with the proposed Revision 2 to Regulatory Guide 10.8 (Task FC 415-4) when the draft guide was published for public comment in August 1985. No changes were necessary, so a separate value/impact statement for the final guide has not been prepared. A copy of the draft value/impact statement is available for inspection and copying for a fee at the Commission's Public Document Room at 1717 H Street NW., Washington, DC, under Task FC 415-4.

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