



REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 10.8

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL PROGRAMS

1. INTRODUCTION

1.1 Purpose of Guide

This guide describes the type and extent of information needed by the Nuclear Regulatory Commission (NRC) staff to evaluate an application for a specific license for the possession of byproduct material (reactor-produced radionuclides) and its use in or on human beings. This type of license is provided for under 10 CFR Part 35, "Human Uses of Byproduct Material."

The NRC will usually issue a single byproduct material license to cover an institution's entire radioisotope program other than teletherapy. Separate licenses, except for teletherapy, are not normally issued to different departments of a medical institution, nor are they issued to individuals associated with the hospital.

The applicant should carefully study the regulations (see Section 1.2 of this guide) and this guide and should submit all information requested. The NRC will request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests will delay final action on the application.

1.2 Applicable Regulations

In addition to 10 CFR Part 35, other regulations pertaining to this type of license 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 30, "Rules of General Applicability to Domestic Licensing of

Byproduct Material;" and 10 CFR, Part 170, "Fees for Facilities and Materials Licenses."

1.3 Items Requiring Separate Applications

A separate application should be submitted for kilocurie sources used in teletherapy facilities. A specific licensing guide for teletherapy applications is available upon request from the License Management Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Source and Special Nuclear Materials. Except for depleted uranium used for shielding in linear accelerators or teletherapy devices, separate applications should be submitted for these materials in accordance with 10 CFR Part 40, "Domestic Licensing of Source Material," and Part 70, "Domestic Licensing of Special Nuclear Material." Source material is defined in paragraph 40.4(h) of 10 CFR Part 40 as (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores that contain by weight 1/20 of one percent (0.05%) or more of (a) uranium, (b) thorium, or (c) any combination thereof. Source material does not include special nuclear material.

Special nuclear material is defined in paragraph 70.4(m) of 10 CFR Part 70 and includes (1) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235 or (2) any material artificially enriched by any one of the foregoing but does not include source material.

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.

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. However, comments on this guide, if received within about two months after its issuance, will be particularly useful in evaluating the need for an early revision.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

The guides are issued in the following ten broad divisions:

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

Requests for single copies of issued guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Technical Information and Document Control.

1.4 As Low As Is Reasonably Achievable (ALARA)

Paragraph 20.1(c) of 10 CFR Part 20 states that "...persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable." Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," provides the NRC staff position on this important subject. Regulatory Guide 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable," provides ways of applying the ALARA philosophy in medical institutions. License applicants should give consideration to the ALARA philosophy, as described in Regulatory Guides 8.10 and 8.18, in the development of plans for work with radioactive materials. NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable," contains information and references useful in establishing radiation safety programs to maintain exposures ALARA in medical institutions.

1.5 Types of Materials Licenses

The general license provided in §35.31 of 10 CFR Part 35 authorizes the physician to possess and use limited quantities of prepackaged individual doses of iodine-131 for measurement of thyroid uptake, iodine-125 and iodine-131 for blood and plasma volume determinations, cobalt-58 and cobalt-60 for intestinal absorption of cyanocobalamin, and chromium-51 for red blood cell volume and survival time determinations. Section 35.31 explains the general license requirements and requires the physician to register with the Commission and receive a registration number prior to receiving or using the diagnostic radiopharmaceuticals covered by the general license.

Section 31.11 of 10 CFR Part 31, "General Domestic Licenses for Byproduct Material," establishes a general license authorizing physicians, clinical laboratories, and hospitals to possess certain small quantities of byproduct material (iodine-125, iodine-131, carbon-14, hydrogen-3, iron-59, selenium-75, and mock iodine-125 reference sources) for in vitro clinical or laboratory tests not involving the internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals. Section 31.11 explains the general license requirements and requires the applicant to register with the Commission and

receive a registration number prior to receiving or using the byproduct material for in vitro testing.

Licenses issued to physicians for private practice specify the radioisotopes and the clinical uses that may be performed by the physician to whom the license is issued. Such licenses are issued to physicians who are located in private offices and not on hospital premises. It is not required that a medical isotopes* committee be formed. The private practice license does not permit other physicians to obtain clinical radioisotope training and experience under it. Section 35.12 of 10 CFR Part 35 outlines specific requirements for this type of license.

Specific licenses of limited scope issued to institutions specify the radioisotopes and the clinical uses that may be performed by physicians named on the institution's license. The regulations in paragraph 35.11(b) of 10 CFR Part 35 require an institutional licensee to have a medical isotopes committee (see Appendix B to this guide) to evaluate all proposals for clinical research, diagnostic, and therapeutic uses of radioisotopes within the institution.

The physicians named on the institution's license conduct their programs with the approval of the medical isotopes committee. Institutional licenses provide a means whereby nonapproved physicians under the supervision of physicians named on the license may obtain basic and clinical radioisotope training and experience that may enable them to qualify as individual users. Training and experience criteria for physicians are outlined in Appendix A to this guide.

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 a medical isotopes committee.

Individual users are not named on the license nor are radioisotopes limited to specified uses. Individual users and procedures are approved by the institution's medical isotopes committee. Physicians may obtain basic and clinical radioisotope training and experience in the use of radiopharmaceuticals in such programs. This type of license is not appropriate for most institutions using byproduct material in medical programs.

* Alternative titles are "radioisotope" or "radiation safety" committee.

2. LICENSE FEES

An application fee is required for most types of licenses. The applicant should refer to §170.12, "Payment of Fees," and §170.31, "Schedule of Fees for Materials Licenses," of 10 CFR Part 170 to determine the amount of fee that must accompany the application. Review of the application will not begin until the proper fee is received by the NRC.

3. FILING AN APPLICATION

A license application for specific licenses for human use should be submitted on Form NRC-313M, "Application for Materials License--Medical" (see Exhibit A). The applicant should complete all items on the application form in sufficient detail for the NRC staff to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on Form NRC-313M is limited, the applicant should append separate sheets of paper for Items 7-23 listed in the form or may indicate by checking the appropriate box that specific procedures will be followed. Each separate sheet should contain the item number and the application date in the lower right corner.

One copy of the application, with all attachments, should be retained by the applicant, since the license will require as a condition that the licensee follow the statements and representations set forth in the application and any supplement to it. The original and one copy should be mailed to the License Management Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

4. CONTENTS OF AN APPLICATION

The following paragraphs explain the information requested on Form NRC-313M.

Item 1.a. Enter the name, mailing address, and telephone number of the applicant. If the request is for a private license, enter the name of the physician or partnership.

Item 1.b. List the addresses and locations where radioactive material will be used or stored if other than the address stated in Item 1.a. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use.

Item 2. Enter the name and telephone number (including area code) of the individual to be contacted.

Item 3. Indicate whether this is an application for a new license, an amendment, or a renewal.

Item 4. List the full names of all physicians who will use or directly supervise the use of byproduct material. These are the physicians who use the byproduct material directly or who are direct supervisors of physicians, technicians, technologists, or other paramedical personnel to whom specific activities are delegated.

Physicians under direct supervision of the named users may be delegated the following responsibilities:

a. The approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources

b. The prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered.

c. The determination of the route of administration.

d. The interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

Properly trained technicians, technologists, or other paramedical personnel under a user's supervision may be delegated the following activities:

a. Preparation and quality control testing of radiopharmaceuticals and sources of radiation.

b. Measurement of radiopharmaceutical doses prior to administration.

c. Use of appropriate instrumentation for the collection of data to be used by the physician.

d. Administration of radiopharmaceuticals and radiation from radioisotope sources to patients, within limits otherwise permitted under applicable Federal, State, or local laws.

Item 5. State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program.

Item 6.a. For routine human use, the applicant may check the group numbers of Schedule A in §35.100 of 10 CFR Part 35 for which the license is requested. Groups I, II, and III consist of the more commonly used diagnostic procedures that involve radiopharmaceuticals; Groups IV and V consist of routine therapeutic procedures that involve radiopharmaceuticals; and Group VI consists of sealed sources used primarily for therapeutic procedures.

For Groups I, II, IV, and V, possession limits are not listed on the license.

For Group III, the possession limit will be two curies of each radioactive material listed unless a larger limit is requested in the application. State the requested possession limit for Group VI and any radioactive material listed separately from Groups I through V. The possession limit for each radionuclide includes material held as radioactive waste.

Item 6.b. For routine human use not listed in Groups I through VI and for nonhuman use, list each radionuclide to be used, the chemical and physical form, and the maximum quantity (in millicuries).

List the manufacturer's name, model number, and activity (in millicuries) for all sealed sources. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under paragraph 35.14(d) of 10 CFR Part 35 and should not be listed.)

A specific authorization must be obtained from the NRC to perform studies involving the use of radioactive material in animals.

Describe the intended use for each radionuclide and form listed in Item 6.b. If the radioactive material is for human use and has not been approved for routine human use by the Food and Drug Administration (FDA), submit evidence that procurement, preparation, and use of the material will be in accordance with the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. If the study is conducted under a "Notice of Claimed Investigational Exemption for a New Drug" (IND) sponsored by the physician or institution, state the radionuclide, chemical form, possession limit, and use, and submit a copy of the IND acceptance letter from the FDA.

Item 7 Medical Isotopes Committee. In accordance with paragraph 35.11(b) of 10 CFR Part 35, an institution applying for a byproduct material license for human use is required to establish a medical isotopes committee of at least three members. This committee evaluates all proposals for research, diagnosis, and therapeutic use of radioisotopes. Membership of the committee should include:

a. At least one physician specializing in nuclear medicine, internal medicine, hematology, therapeutic radiology, diagnostic radiology, or pathology, who will use or directly supervise the use of radioactive materials in humans.

b. A person with special competence in radiation safety.

c. A representative of the institution's management.

Submit the following information:

a. The responsibility and duties of the committee.

b. The meeting frequency of the committee (at least quarterly).

c. The name and specialty of each member of the committee.

Appendix B to this guide contains an example of typical responsibilities and duties for a medical isotopes committee. Indicate, by checking the appropriate box in Item 7, that the responsibilities, duties, and meeting frequency will be as described in Appendix B, or propose alternatives. If the responsibilities, duties, or meeting frequency will be different from those described, submit a complete description.

Item 8 Training and Experience

a. **Authorized User(s).** If the physician has been previously authorized to use the radioactive material requested in this application, it is necessary to submit only the previous license number (if issued by the AEC or NRC) or a copy of the license (if issued by an Agreement State).

If the physician has not been previously authorized to use the radioactive material being requested, state where he is licensed to practice medicine, and submit a complete description of his training and experience. Use Supplements A and B to Form NRC-313M (see Exhibit A) for the description of the physician's training and experience. Criteria for acceptable training and experience are contained in Appendix A.

b. **Radiation Safety Officer.** If the radiation safety officer is not one of the physicians named in Item 4, submit a complete description of his training and experience. Supplement A to Form NRC-313M may be used for the description of the radiation safety officer's training and experience.

Item 9 Instrumentation. Instruments required in a typical nuclear medicine laboratory are:

a. Survey Instruments

(1) A low-level survey meter capable of detecting 0.1 milliroentgen per hour to perform contamination surveys.

(2) A high-level survey meter such as an ionization type capable of reading up to 1 roentgen per hour to measure radiation exposure rates that may exist in the vicinity of Mo-99/Tc-99m generators and therapeutic quantities of radioactive material.

b. Dose calibrators and other instruments to assay radiopharmaceuticals.

c. Diagnostic instruments for all procedures (e.g., gamma camera, well counter, thyroid probe).

d. Other pertinent instrumentation (e.g., liquid scintillation counter, area monitor).

Appendix C to this guide contains a form that may be used to describe the instruments. Complete this form by listing the instruments to be used. If this form is not used, attach equivalent information. Check the appropriate box in Item 9 of Form NRC-313M.

Item 10 Calibration of Instruments

a. Survey Instruments. An adequate calibration of survey instruments cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily constancy checks of survey instruments should be supplemented at least every 12 months with a battery check and two-point calibration on each scale of the instrument. One point should be in each half of the scale, and the two points should be separated by 35-50% of full scale. Survey instruments should also be calibrated after repair and after battery replacement.

A survey instrument may be considered properly calibrated at one point when the exposure rate measured by the instrument differs from the true exposure rate by less than 10% of full scale.

If you propose to calibrate your own radiation survey and monitoring instruments, submit a detailed description of your planned calibration procedures. Include in the description:

- (1) The manufacturer's name and model number of the source(s) to be used.
- (2) The nuclide and activity (in millicuries) of radioactive material contained in the source.
- (3) The accuracy* of the source(s).
- (4) The step-by-step procedures, including associated radiation safety procedures. These procedures should include a two-point calibration of each scale of each instrument with the points separated by 35-50% of full scale.

*The maximum deviation of the nominal value of the source from the true value. This information is normally provided by the manufacturer.

If a consultant or outside firm will perform the calibration of your radiation survey and monitoring instruments, specify his name, address, and the license number. Contact the firm or consultant that will provide the calibration to determine if information concerning calibration services and procedures has been filed with the Commission. If this information has not been filed, submit it with your application.

Section 1 of Appendix D to this guide contains an acceptable procedure for calibrating survey instruments and a form that may be used to supply the information required in Item 10 of the application form. Indicate, by checking the appropriate box in Item 10 of Form NRC-313M, if the procedure described in Appendix D will be followed. If the procedure in Appendix D is not followed, submit equivalent procedures.

b. Dose Calibrator. All radiopharmaceuticals should be assayed for activity to an accuracy of 10% prior to being administered to patients. The usual method for performing assays is with a dose calibrator. Upon installation and periodically thereafter, dose calibrators should be tested for accuracy of response for the energies commonly used, for geometrical variation, for linearity of response over the entire range of activities to be used, and for day-to-day constancy of operation.

Submit a description of your calibration procedures. These should include as a minimum:

- (1) The manufacturer's name and model number of any sealed sources to be used (unless authorized by paragraph 35.14(d) of 10 CFR Part 35).
- (2) The nuclide and activity (in millicuries) of radioactive material in the standards.
- (3) The accuracy of the standard.
- (4) The step-by-step procedures used for calibration.

If an instrument other than a dose calibrator is used to assay patient doses, submit a complete description of:

- (1) The assay method.
- (2) The method of calibration.
- (3) The frequency of calibration.
- (4) The standards to be used for calibration (radionuclide, activity, accuracy).

Section 2 of Appendix D contains a description of an acceptable procedure for calibrating dose calibrators and a form that may be used to

supply the information required in Item 10 of this application form. Indicate, by checking the appropriate box in Item 10 of Form NRC-313M, if the procedure in Appendix D for calibrating dose calibrators will be followed. If Appendix D is not followed, submit equivalent procedures.

c. Diagnostic Instruments. The manufacturer's directions should be followed for calibration and maintenance of diagnostic instrumentation.

Item 11 Facilities and Equipment. Describe the available facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage (including waste), preparation, and measurement of radioactive material.

Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. Indicate any wall shielding, special storage area shielding, or movable shielding around storage areas, generators, kit preparation areas, etc.

For facilities in which radioactive material may become airborne, include schematic descriptions of the ventilation system in the diagrams with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Draw diagrams to a specified scale, or indicate dimensions.

Figures 1 and 2 contain examples of acceptable facility and equipment descriptions.

Item 12 Personnel Training Program. Describe the training required for all personnel who work with or in the vicinity of radioactive materials. Include the form of training (e.g., formal course work, lectures), frequency of training, duration of training, and subject matter. The training program should be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, housekeeping, and security personnel, receive proper instruction in the items specified in §19.12 of 10 CFR Part 19, including:

- a. Areas where radioactive material is used or stored.
- b. Potential hazards associated with radioactive material.
- c. Radiological safety procedures appropriate to their respective duties.
- d. Pertinent NRC regulations.
- e. Rules and regulations of the licensee.
- f. Pertinent terms of the license.

g. Their obligation to report unsafe conditions.

h. Appropriate response to emergencies or unsafe conditions.

i. Their right to be informed of their radiation exposure and bioassay results.

j. 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.

Verify that personnel will be properly instructed:

a. Before assuming duties with or in the vicinity of radioactive materials.

b. During annual refresher training.

c. Whenever there is a significant change in duties, regulations, or the terms of the license.

Item 13 Procedures for Ordering and Receiving Radioactive Material. Describe procedures for ordering radioactive materials, for receiving materials during off-duty hours, and for notifying responsible persons upon receipt of radioactive materials. These procedures should be adequate to ensure that possession limits are not exceeded, that radioactive materials are secured at all times against unauthorized removal, and that radiation levels in unrestricted areas do not exceed the limits specified in §20.105 of 10 CFR Part 20.

Security personnel, nursing personnel, or anyone else who receives packages during off-duty hours should be issued written instructions as to procedures to be followed for receiving, examining, and securing the package; for notification procedures if the package is found or suspected to be leaking; and the immediate steps to be taken to prevent spread of contamination.

Appendix E to this guide contains sample procedures and instructions for ordering and receiving packages containing radioactive material. Attach a copy of your procedures.

Item 14 Procedures for Safely Opening Packages Containing Radioactive Materials. Describe your procedures for examining incoming packages for leakage, contamination, or damage, and for safely opening packages in accordance with §20.205 of 10 CFR Part 20. Perform the monitoring as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending on the quantity of radioactive material received but should, at a minimum, include instructions for surveying packages, wearing gloves while

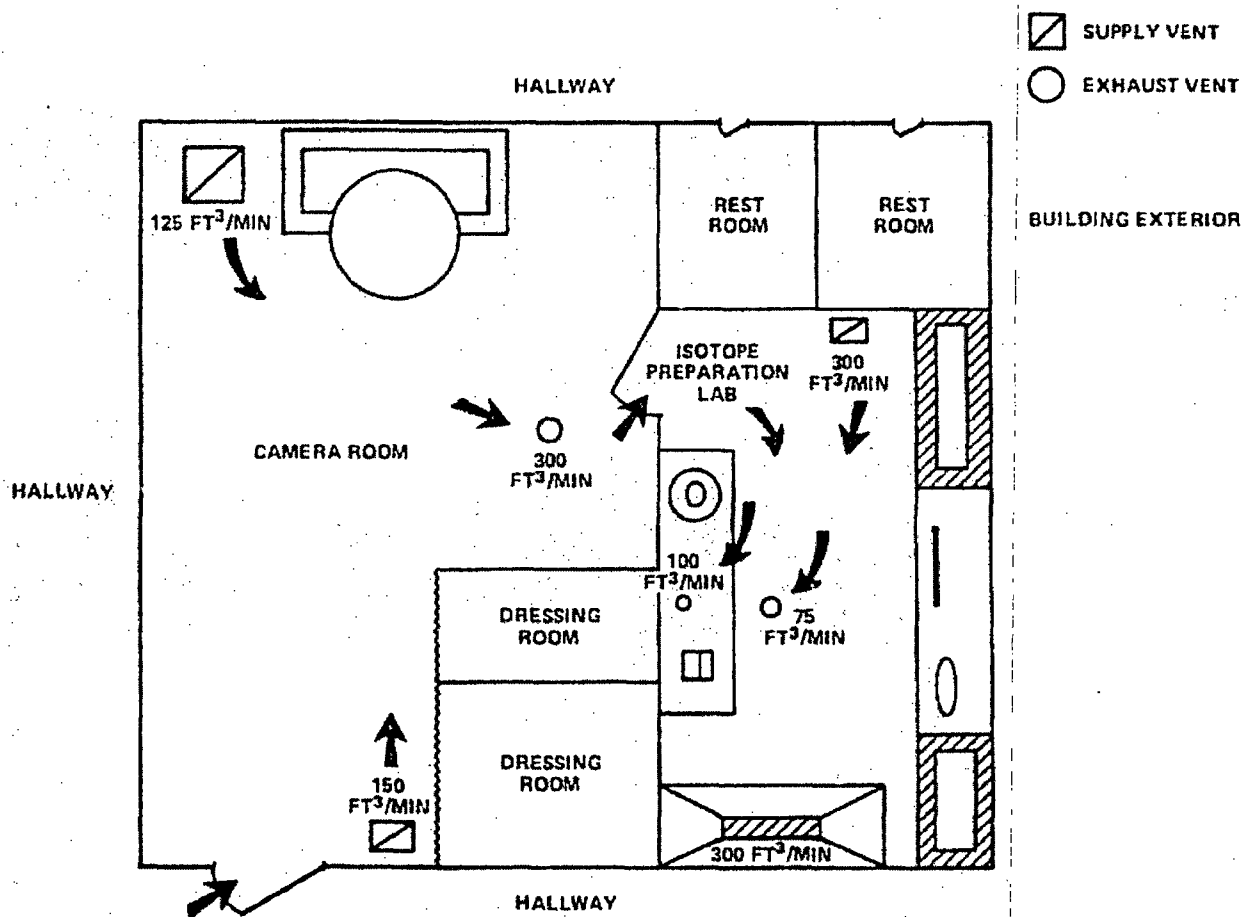


FIGURE 1.
EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR
A FACILITY DESCRIPTION INCLUDING VENTILATION FLOW RATES

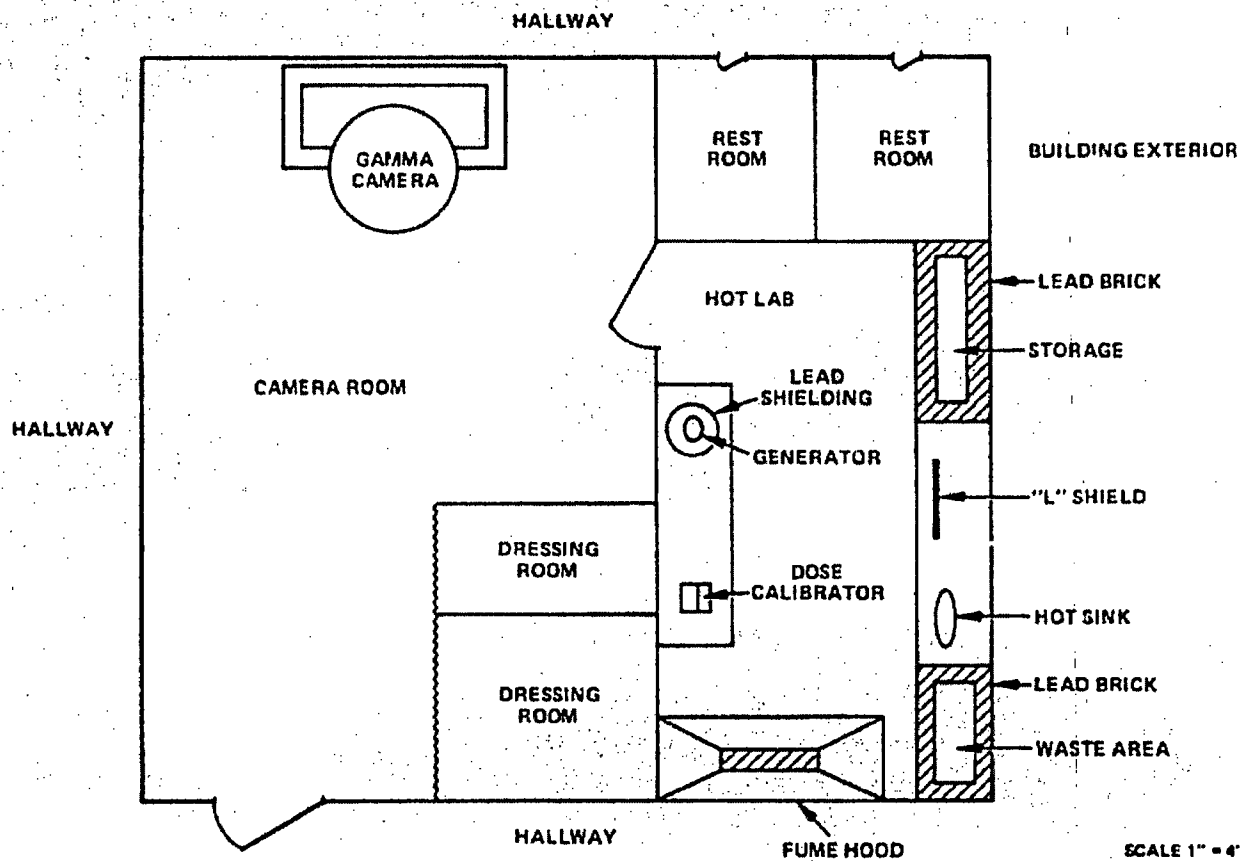


FIGURE 2.
EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR
A FACILITY DESCRIPTION INCLUDING SHIELDING PROVISIONS

opening packages, and checking packing material for contamination after opening. Even though §20.205 exempts certain packages from immediate monitoring, it is necessary that procedures be established for safely opening all packages containing radioactive material.

Appendix F to this guide contains a description of an acceptable procedure for safely opening packages. Indicate, by checking the appropriate box in Item 14 of Form NRC-313M, that the procedure in Appendix F will be followed, or attach equivalent procedures.

Item 15 General Rules for the Safe Use of Radioactive Material. Describe the general instructions to be followed by physicians and technologists while working with radioactive materials. The instructions should:

a. Outline control procedures for obtaining permission to use radioactive material at the institution.

b. Explain what laboratory apparel to wear and what equipment to use, e.g., wearing of laboratory coats and use of disposable gloves and trays.

c. Prescribe limitations and conditions for handling liquid or loose radioactive materials and the laboratory equipment to use in working with them. For example, specify which materials and operations should be confined to radiochemical fume hoods or gloveboxes.

d. Specify the shielding or remote handling equipment to be used when hard beta- and/or gamma-emitting materials are handled. Preparation of radiopharmaceuticals from reagent kits should be done behind shielding. Syringe shields should be used for the preparation and administration of patient doses.

e. Give instructions for preparation and assay of patient doses.

f. Give instructions concerning movement of material between rooms, in halls, or in corridors, if applicable.

g. Explain requirements for storage of materials, labeling of containers, and identification of areas where radioactive materials are used. Describe the shielding used for areas where large amounts of byproduct material are stored.

h. Specify personnel monitoring devices to be used, where to obtain them, and instructions for recording exposure results or properly turning in personnel monitoring devices for processing at appropriate intervals.

i. Describe waste disposal procedures to be followed for each type of waste (e.g., liquids, gases, solids, long-lived, short-lived).

j. Describe contamination control procedures, including prohibitions against smoking, eating, drinking, or applying cosmetics in restricted areas and instructions for individuals who prepare doses and radiopharmaceuticals to monitor their hands after each procedure and at the end of the day.

For smaller programs, Appendix G to this guide contains an acceptable set of laboratory rules for the safe use of radioactive material. Indicate, by checking the appropriate box in Item 15 of Form NRC-313M, if Appendix G rules will be followed, or attach equivalent procedures.

Item 16 Emergency Procedures. Describe the emergency instructions to be posted in all laboratory areas where radioactive materials are used. These instructions should (a) describe immediate action to be taken in order to prevent contamination of personnel and work areas (e.g., turning off the ventilation, evacuation of the area, containment of the spill), (b) state the names and telephone numbers of the responsible persons to be notified in case of an emergency, and (c) instruct personnel on appropriate methods for re-entering, decontaminating, and recovering facilities that may have been accidentally contaminated.

An acceptable set of emergency procedures is contained in Appendix H to this guide. Indicate, by checking the appropriate box in Item 16 of Form NRC-313M, that you will follow the emergency procedures in Appendix H, or submit a copy of equivalent procedures.

Item 17 Area Survey Procedures. Describe the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable, and provisions for maintaining records of surveys. (A regulatory guide on radiation safety surveys at medical institutions is now under development.)

If the application is to cover multiple users and areas of use, the individual user should perform surveys of his own work areas in addition to those performed by the radiation safety staff. Acceptable procedures and frequencies for routine surveys are described in Appendix I to this guide. Indicate, by checking the appropriate box in Item 17 of Form NRC-313M, that you will follow survey procedures in Appendix I, or submit equivalent procedures.

Item 18 Waste Disposal. Describe specific methods used for disposal of waste byproduct material. A licensee may dispose of waste by:

a. Transfer to a person properly licensed to receive such waste, e.g., commercial waste disposal firms. (See §20.301 of 10 CFR Part 20.) Submit the name and the NRC or Agreement State license number of the commercial firm selected.

b. Release into a sanitary sewer in conformance with §20.303 of 10 CFR Part 20. Describe your methods for controlling the sewage disposals of radioactive wastes in order to ensure that disposals do not exceed the limits specified in §20.303 of 10 CFR Part 20.

c. Burial in soil in conformance with §20.304 of 10 CFR Part 20.

d. Release into the air in conformance with §20.106 of 10 CFR Part 20.

e. Other methods specifically approved by the Commission pursuant to §20.302 of 10 CFR Part 20.

Note: No licensee may dispose of byproduct material waste by incineration unless specifically approved by the Commission. (See §20.305 of 10 CFR Part 20.)

Appendix J to this guide contains a form that may be used to supply the information requested in Item 18 of the application form. Indicate, by checking the appropriate box in Item 18 of Form NRC-313M, that you will dispose of wastes as specified on the form in Appendix J, or attach equivalent information.

Item 19 Therapeutic Use of Radiopharmaceuticals. Describe special precautions for patients treated with byproduct material listed in Groups IV and V, Schedule A, §35.100 of 10 CFR Part 35. Although Group IV procedures are often performed on an outpatient basis, hospitalization is sometimes required.

Establish appropriate procedures for all patients treated with byproduct material and include:

a. Method for preparation and administration of therapeutic doses of iodine-131. Instruct personnel to wear gloves and to open containers of iodine-131 in a fume hood with adequate airflow or to take other precautionary measures to prevent contamination of themselves and surrounding areas.

b. Methods for contamination control

- (1) Assignment to private room.
- (2) Use of disposable items (e.g., dishes, utensils).

c. Procedures for surveys of

- (1) Unrestricted areas.
- (2) Linens and other items removed from patient's room.
- (3) Patient's room before it is reassigned to another patient.

[Licensees should also perform surveys (e.g., measurement of iodine-131 in air; measurement of iodine-131 in the thyroid gland of laboratory personnel; contamination surveys of personnel, equipment, and facilities) to determine compliance with §§20.103 and 20.106 of 10 CFR Part 20.]

d. Instructions to nursing staff.

e. Procedures for disposal of waste.

(1) Patient excreta.

(2) Surgical dressings.

(3) Disposable items.

f. Procedures to be followed in case of emergency surgery or death.

g. Procedures for release of patients.

(1) Criteria for release of patients.

(2) Instructions to patients and families.

h. Procedures for bioassay of personnel. Significant thyroid uptakes have been detected in individuals who open and prepare oral solutions of iodine-131 for therapeutic doses. Guidance on situations requiring bioassay for iodine-131 and appropriate action levels may be found in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

Guidance for the management of therapy patients can be found in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."* Other pertinent references are given in Regulatory Guide 8.18 and NUREG-0267.

Appendix K to this guide contains a description of precautions to be followed for patients treated with iodine-131, gold-198, and phosphorus-32. Indicate, by checking the appropriate box in Item 19 of Form NRC-313M, that you will follow Appendix K procedures, or submit equivalent procedures. In either case, attach a separate description of facilities and detailed procedures for preparation and administration of therapeutic doses of iodine-131, phosphorus-32, and gold-198.

Item 20 Therapeutic Use of Sealed Sources. Describe special procedures for patients treated with byproduct materials listed in Group VI on Schedule A, §35.100 of 10 CFR

*NCRP reports are available from NCRP Publications, P.O. Box 30175, Washington, D.C. 20014.

Part 35. These procedures* should include descriptions of:

a. The areas where sealed sources will be stored, including (1) placement and thickness of shielding and (2) proximity of the storage area to unrestricted areas.

b. Special precautions to be used while handling sealed sources.

c. Special instructions for nursing care of patients who are treated with sealed sources. (Appendix L to this guide contains a description of procedures to be followed for patients treated with sealed sources.)

d. Your method for determining the radiation doses to the extremities of personnel handling sealed sources.

e. The equipment and shielding available for transporting sources from storage sites to the place of use.

f. Your method for maintaining source accountability at all times. This should include a description of sign-in and sign-out procedures, periodic inventory, and the method for determining that all sources are accounted for and returned to storage following treatment.

g. Surveys to be performed during the course of treatment and at the conclusion of treatment. The patient and room should be surveyed with a radiation survey instrument after the end of treatment and before dismissal. Your dismissal survey should include a source count and should be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied.

Submit detailed responses to Item Nos. 20.a, 20.b, 20.d, 20.e, 20.f, and 20.g. In response to Item 20.c, indicate that the procedures described in Appendix L will be followed, or submit equivalent procedures.

Item 21 Procedures and Precautions for Use of Radioactive Gases (e.g., Xenon-133). The use of radioactive gases (e.g., xenon-133 gas or gas in saline) requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive gas in restricted and unrestricted areas. The NRC requires that each applicant make such determinations for his own unique situation and submit sufficient evidence to the Commission in support of his request.

*Guidance on facilities, equipment, and procedures is available in NUREG-0257, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Is Reasonably Achievable," Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, December 1977. Guidance on brachytherapy procedures is given on pp. 3-16 to 3-19 of this report.

Appendix M to this guide contains instructions for submitting an application to use xenon-133. The information requested in Appendix M should be submitted.

Item 22 Procedures and Precautions for Use of Radioactive Material in Animals. Describe procedures to be followed if radioisotopes will be used in animals including (a) a description of the animal housing facilities, (b) a copy of instructions provided to animal caretakers for the handling of animals, animal waste, and carcasses, (c) instructions for cleaning and decontaminating animal cages, and (d) procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

Item 23 Procedures and Precautions for Use of Radioactive Materials Specified in Item 6.b. Clearly state any additional radiation safety procedures to be followed while individuals are using the materials listed in Item 6.b, e.g., air sampling, other special surveys, bioassays.

Bioassays may be required when individuals work with millicurie quantities of hydrogen-3, iodine-125, or iodine-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that the radioactive material will be ingested, inhaled, or absorbed into the body. Show in the application that the need for bioassays has been thoroughly considered and that the proposed bioassay program is appropriate for the intended use of radioactive material. Guidance on bioassay programs for iodine-125 and iodine-131 is provided in Regulatory Guide 8.20. Guidance for bioassay programs for tritium and other radionuclides is available as staff criteria from the License Management Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Item 24 Personnel Monitoring Devices. State the name of the organization furnishing film badge or thermoluminescent dosimeter (TLD) service. Specify the frequency with which the badges are changed and evaluated, and give a description of the type, e.g., whole-body, wrist, or finger badge. Where wrist badges are worn to monitor extremity exposures and exposures to fingertips are likely to be greater than the wrist exposures, describe how fingertip exposures will be estimated from the wrist badge data in lieu of fingertip monitors, and provide any backup data used to perform or verify these estimates.

Item 25 (For Private Practice Applicants Only).

Item 25.a. State the name and address of the hospital that has agreed to admit patients containing radioactive material.

Item 25.b. Submit a copy of the letter of authorization, signed by the administrator, from the hospital that has agreed to admit patients containing radioactive material.

Item 25.c. If patients treated with therapeutic quantities under this license are admitted to the hospital, (1) describe the radiation detection instruments available at the hospital and (2) submit a copy of radiation safety procedures to be followed.

Item 26.a. Licensee Fee Category and Licensee Fee Enclosed may be selected from information pertaining to medical institutions in §170.31 of 10 CFR Part 170.

Items 26.b and c. Provide the signature of an individual authorized by management to represent an applicant institution or the signature of an individual physician, in the case of Category 7C of §170.31, with the date of signature.

5. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make any changes in the facilities, equipment (including types of monitoring and survey instruments), procedures, authorized users or radiation safety officer, or byproduct material to be used.

Applications for license amendments may be filed either on the application form or in letter form. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. A fee must accompany amendment applications as indicated in Item 26.a. An original and two copies of the application for amendment should be prepared, the original and one copy should be submitted, as in the cases for new or renewal applications. See Appendix N for commonly requested amendments.

6. RENEWAL OF A LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the NRC as provided for in paragraph 30.37(b) of 10 CFR Part 30.

Renewal applications should be filed on Form NRC-313M appropriately supplemented, should contain complete and up-to-date information about the applicant's current program, and should meet all licensing and regulatory requirements in effect at the time of renewal. Renewal applications should also include the user physicians' training and experience (Supplements A and B of Exhibit A) or make a clear and specific reference to previous applications on which individual users received approval.

In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information (except for previously approved users). If such references cannot be avoided, they are acceptable provided:

a. The reference is made in response to a particular item of required information (e.g., bioassay procedures).

b. The reference is clear and specific (e.g., title of document, date of submission, page, and paragraph).

c. The referenced document contains all information required for a particular item at the time of renewal.

Prepare an original and two copies of the application. Retain one copy of the application, with all attachments, because the license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplement to it. Mail the original and one copy to the License Management Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. A fee must also accompany renewal applications, as indicated in Item 26.a.

LIST OF APPENDICES

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APPENDIX A ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF BYPRODUCT MATERIAL

Paragraph 35.11(d) of 10 CFR Part 35 provides that the Commission will approve a license application by an institution for medical use of byproduct material if it determines, among other things, that the physician designated as the individual user is adequately trained and experienced in (1) basic radioisotope handling techniques and (2) the clinical use of byproduct material proposed in the application. Similar criteria are established in paragraph 35.12(c) of 10 CFR Part 35 for the approval of licenses for medical use of radiopharmaceuticals by individual physicians. Outlined below are training and experience criteria that the Commission, with the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI), has found acceptable for physicians who use radiopharmaceuticals. Each physician's training and experience are examined on a case-by-case basis. If a physician wishes to use radiopharmaceuticals but does not have the training and experience described, he may submit an application listing his specific qualifications and these will be reviewed by the Commission with the assistance of the ACMUI.

I. General Training

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups I, II, and/or III in §35.100 of 10 CFR Part 35, a physician should have:

- | | |
|---|-------------|
| a. Training in basic radioisotope handling techniques consisting of lectures, laboratory sessions, discussion groups, or supervised experience in a nuclear medicine laboratory in the following areas: | (200 hours) |
| (1) Radiation physics and instrumentation | (100 hours) |
| (2) Radiation protection | (30 hours) |
| (3) Mathematics pertaining to the use and measurement of radioactivity | (20 hours) |
| (4) Radiation biology | (20 hours) |
| (5) Radiopharmaceutical chemistry | (30 hours) |

(The hours listed next to each of the five subjects above are suggested values and should not be interpreted as specific requirements.)

- b. Experience with the types and quantities of byproduct material for which the application is being made, or equivalent (500 hours).
- c. Supervised clinical training in an institutional nuclear medicine program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:
 - (1) Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.
 - (2) Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data.
 - (3) Followup of patients when required.
 - (4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

Note A:

The requirements specified in Sections I.a, b, and c may be satisfied concurrently in a 3-month training program if all three areas are integrated into the program.

Note B:

For each physician named in Item 4 of Form NRC-313M, complete Supplements A and B of Form NRC-313M (Preceptor Statement and the statement of training in basic radioisotope handling techniques). For each subject covered in basic training, state where the training was obtained, the dates, total number of hours, and type of training (e.g., lectures, laboratory sessions).

Alternatives:

Certification by the American Board of Nuclear Medicine will be accepted as evidence that a physician has had adequate training and experience to use Groups I, II, and III.

Certification by the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology will be accepted as evidence that a physician has had adequate training in basic radioisotope handling techniques and has had adequate clinical experience to use Groups II and III.

2. Training Requirements for Specific Diagnostic Procedures

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of byproduct material being requested. Such requests will be examined on a case-by-case basis by the Commission with the assistance of the ACMUI.

3. Training Requirements for Therapy Procedures Involving Radiopharmaceuticals

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups IV and/or V in §35.100 of 10 CFR Part 35, a physician should have:

a. Training in basic radioisotope handling techniques (80 hours) including:

- | | |
|--|------------|
| (1) Radiation physics and instrumentation | (25 hours) |
| (2) Radiation protection | (25 hours) |
| (3) Mathematics pertaining to the use and measurement of radioactivity | (10 hours) |
| (4) Radiation biology | (20 hours) |

(These requirements are in lieu of, not in addition to, those specified in Section 1.a, above.)

b. Clinical training in specific therapy procedures:

For Group IV

- (1) Iodine-131 for treatment of hyperthyroidism and/or cardiac conditions:

Clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten patients.

- (2) Phosphorus-32 for treatment of polycythemia vera, leukemia, and/or bone metastases:

Treatment of three patients with any combination of these three conditions.

- (3) Colloidal phosphorus-32 intracavitary treatment:

Active participation in the treatment of three patients.

For Group V

- (1) Iodine-131 for treatment of thyroid carcinoma:

Clinical experience in diagnosis of thyroid function and treatment of hyperthyroidism and/or cardiac dysfunction and active participation in the treatment of three patients with thyroid carcinoma.

- (2) Colloidal gold-198 for intracavitary treatment:

Active participation in the treatment of three patients.

4. Training Requirements for Therapy Procedures Involving Sealed Sources

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Group VI in §35.100 of 10 CFR Part 35, a physician should have:

a. Training in basic radioisotope handling techniques (200 hours) consisting of lectures, laboratory sessions, discussion groups, or supervised experience in the following areas:

- | | |
|--|-------------|
| (1) Radiation physics and instrumentation | (110 hours) |
| (2) Radiation protection | (40 hours) |
| (3) Mathematics pertaining to the use and measurement of radioactivity | (25 hours) |
| (4) Radiation biology | (25 hours) |

(The hours listed next to each of the four subjects above are suggested values and should not be interpreted as specific requirements.)

b. Clinical training in specific therapy procedures:

- (1) Radiation sources for interstitial, intracavitary, or surface treatment of cancer:

Active practice in therapeutic radiology with a minimum of 3 years experience.

- (2) Beta ray applicators for the treatment of superficial eye disease:

Active practice in therapeutic radiology or ophthalmology and experience in the therapeutic use of beta rays or soft X-rays.

Note:

Evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology, certification as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR), or a Canadian certification from the Royal College of Physicians and Surgeons (RCPS) may be submitted in lieu of the information requested in Sections 4.a and b above.

APPENDIX B

MEDICAL ISOTOPES* COMMITTEE

Responsibility

The committee is responsible for

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.
2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties

The committee shall

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.
2. Review the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.
3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material

*Alternative titles are "radioisotope" or "radiation safety" committee.

(e.g., nursing, security, and housekeeping personnel) are properly instructed as required by §19.12 of 10 CFR Part 19.

4. Review and approve all requests for use of radioactive material within the institution.
5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.
6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and management control system.
7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
8. Maintain written records of all committee meetings, actions, recommendations, and decisions.
9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

Meeting Frequency

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

APPENDIX C
INSTRUMENTATION

1. Survey meters

- a. Manufacturer's name: _____
Manufacturer's model number: _____
Number of instruments available: _____
Minimum range: _____ mr/hr to _____ mr/hr
Maximum range: _____ mr/hr to _____ mr/hr
- b. Manufacturer's name: _____
Manufacturer's model number: _____
Number of instruments available: _____
Minimum range _____ mr/hr to _____ mr/hr
Maximum range _____ mr/hr to _____ mr/hr

2. Dose calibrator

Manufacturer's name: _____
Manufacturer's model number: _____
Number of instruments available: _____

3. Diagnostic instruments

<u>Type of Instrument</u>	<u>Manufacturer's Name</u>	<u>Model No.</u>
---------------------------	----------------------------	------------------

4. Other

APPENDIX D

CALIBRATION OF INSTRUMENTS*

Section 1

METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY

A. Calibration of survey meters shall be performed with radionuclide sources.

1. The sources shall be approximate point sources.
2. The source activities shall be traceable within 5% accuracy to the U.S. National Bureau of Standards (NBS) calibrations.
3. The frequency shall be at least annually and after servicing.
4. Each scale of the instrument shall be calibrated at least at two points such that (a) one point is in each half of the scale and (b) the two points are separated by 35-50% of full scale.
5. The exposure rate measured by the instrument shall differ from the true exposure rate by less than 10% of full scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within $\pm 20\%$ will be considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

Note:

Sources of Cs-137, Ra-226, or Co-60 are appropriate for use in calibrations. The activity of the calibration standard should be sufficient to calibrate the survey meters on all ranges, or at least up to 1 R/hr on the higher-range instruments. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation.

B. A reference check source of long half-life, e.g., Cs-137 or Ra D and E, shall also be read at the time of the above calibration. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:

* See ANSI N42.1.3, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides." Copies may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.

1. Before each use and also after each survey to ensure that the instrument was operational during the survey.
2. After each maintenance and/or battery change.
3. At least quarterly.

If any reading with the same geometry is not within $\pm 20\%$ of the reading measured immediately after calibration, the instrument should be recalibrated (see item A).

C. The instrument must be calibrated at lower energies if its response is energy dependent and it is to be used to measure in the Xe-133 or Tc-99m energy ranges.

This calibration may be done either

1. As in item A above with calibrated standards of radionuclides at or near the desired energies or
2. As a relative intercomparison with an energy-independent instrument and uncalibrated radionuclides.

D. Records of the above items A, B-2, B-3, and C must be maintained.

E. Use of Inverse Square Law and Radioactive Decay Law

1. A calibrated source will have a calibration certificate giving its output at a given distance measured on a specified date by the manufacturer or NBS.
 - a. The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.
 - b. The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

2. Inverse Square Law

$$S \propto (R_1)^2 (R_2)$$

$$* \propto P_1$$

$$\propto P_2$$

Exposure rate at P_2 :

$$R_2 = \frac{(P_1)^2}{(P_2)^2} (R_1)$$

where

S is the point source

R_1 and R_2 are in the same units (mR/hr or R/hr)

P_1 and P_2 are in the same units (centimeters, meters, feet, etc.)

3. Radioactive Decay Law

Exposure rate t units of time after specified calibration date

$$R_t = R_o \times e^{-\left[\frac{0.693}{T_{1/2}} \times t\right]}$$

where

R_o and R_t are in the units mR/hr or R/hr

R_o is exposure rate on specified calibration date

R_t is exposure rate t units of time later

$T_{1/2}$ and t are in the same units (years, months, days, etc.)

$T_{1/2}$ is radionuclide half-life

t is number of units of time elapsed between calibration and present time

4. Example: Source output is given by calibration certificate as 100 mR/hr at 1 foot on March 10, 1975. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on March 10, 1977 (2.0 years)?

a. Output at 1 foot, 2.0 years after calibration date:

$$R = 100 \text{ mR/hr} \times e^{-\frac{(0.693 \times 2.0)}{5.3}}$$

$$= 100 \times 0.77 = 77 \text{ mR/hr at 1 foot on March 10, 1977.}$$

b. Output at 3 feet, 2.0 years after calibration date:

$$\begin{aligned} R_{3 \text{ feet}} &= \frac{(1 \text{ foot})^2}{(3 \text{ feet})^2} \times 77 \text{ mR/hr} \\ &= \frac{1}{9} \times 77 = 8.6 \text{ mR/hr at 3 feet, 2.0 years after calibration.} \end{aligned}$$

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

_____ 1. Survey instruments will be calibrated at least annually and following repair.

_____ 2. Calibration will be performed at two points on each scale.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within $\pm 10\%$ of the calculated or known values for each point checked. Readings within $\pm 20\%$ are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

_____ 3. Survey instruments will be calibrated

_____ a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____

Model no. _____

Activity in millicuries _____

Accuracy _____

Traceability to primary standard _____

_____ (2) The calibration procedures in Section I of Appendix D will be used

or

_____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

_____ c. By a consultant or outside firm

(1) Name _____

(2) Location _____

(3) Procedures and sources

_____ have been approved by NRC and are on file in
License No. _____

_____ are attached

APPENDIX D (Continued)

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR

All radiopharmaceuticals must be assayed for activity to an accuracy of 10%. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument linearity (at installation and quarterly thereafter)
2. Geometrical variation (at installation)
3. Instrument accuracy (at installation and annually thereafter).

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Daily or before each use of the instrument:

1. Measure and record the activity of at least one reference source (e.g., 1-2 mCi of Co-57). This check should be repeated during the day whenever sample readings are not within 10% of the anticipated assay. Variation greater than 5% in this test will indicate the need for instrument repair, adjustment, or recalibration.
2. Measure and record the apparent activity of a long-lived standard radionuclide such as Cs-137 or Ra-226 at all the commonly used radionuclide settings (when the unit was first calibrated against NBS-traceable standards). Choose a source with activity in the 100 μ Ci range.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will utilize a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator and subtract background level to obtain net activity in millicuries.
2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time (hr)	Correction Factor
0	32
6	16
24	2
30	1
48	0.125

Example: If the net activity measured at 30 hours was 15.625 mCi, the predicted activity for 6 and 48 hours would be $15.625 \text{ mCi} \times 16 = 250 \text{ mCi}$ and $15.625 \text{ mCi} \times 0.125 = 1.95 \text{ mCi}$, respectively.

4. Plot the measured net activity for each time interval versus the predicted activity on log-log graph paper.
5. The activities plotted should be within $\pm 5\%$ of the predicted curve if the instrument is linear and functioning properly. Errors greater than $\pm 5\%$ indicate the need for repair or adjustment of the instrument.
6. If instrument linearity cannot be corrected, it will be necessary in routine assays to either assay an aliquot of the eluate that can be accurately measured or to use the graph constructed in step 4 to relate measured activities to true activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant,

i.e., greater than $\pm 2\%$ (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting and subtract background level to obtain net activity.
2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1.
3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected,

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.
5. The true activity of a sample is calculated as follows:

$$\text{True Activity} = \text{Measured Activity} \times \text{Correction Factor}$$

where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial and a correction factor may be calculated.
7. It should be noted that differences of 200% in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125. Hence, adequate correction factors must be established for this type of syringe.

An alternate to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

G. Test For Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides such as Cs-137, Co-57, and Ba-133 using appropriate reference standards whose activity is traceable to NBS. The activity levels of the reference sources used should approximate those levels normally encountered, giving adequate attention to source configuration. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.
2. Repeat step 1 for a total of 3 determinations, and average results.
3. The average activity determined in step 2 should agree with the certified activity of the reference source within $\pm 5\%$ after decay corrections.
4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.
5. Keep a log of these calibration checks.
6. Calibration checks that do not agree within $\pm 5\%$ indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.
7. At the same time the instrument is being initially calibrated with the NBS-traceable standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more NBS-traceable standards. Keep a log of these initial and subsequent readings.

H. Test for Instrument Constancy

Assay two reference sources such as Cs-137 and Co-57 using a reproducible geometry before each daily use of the instrument.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
2. Measure background level at same instrument setting.
3. Calculate net activity of each source subtracting out background level.
4. For each source, plot net activity versus the day of the year on semi-log graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the $\pm 5\%$ limits on the graph as illustrated.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than $\pm 5\%$ from the predicted activity indicate the need for instrument repair or adjustment.
9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

_____ First elution from new Mo-99/Tc-99m generator

or

_____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

<u>Radionuclide</u>	<u>Activity (mCi)</u>	<u>Accuracy</u>
Co-57	_____	_____
Ba-133	_____	_____
Cs-137	_____	_____
_____	_____	_____
_____	_____	_____

C. _____ The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator

or

_____ Equivalent procedures are attached.

* Must be equivalent to the highest activity used.

APPENDIX E

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Chief Nuclear Medicine Technologist must place all orders for radioactive material and must ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. During normal working hours, carriers must be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
3. During off-duty hours, security personnel must accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.

SAMPLE MEMORANDUM

MEMORANDUM FOR: Security Personnel

FROM: John Jones, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:30 p.m. and 7 a.m. or on Sundays shall be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: _____

OFFICE PHONE: _____

HOME PHONE: _____

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O. # _____ Survey Date _____ Time _____
Surveyor _____
2. CONDITION OF PACKAGE:
_____ O.K. _____ Punctured _____ Status _____ Wet
_____ Crushed _____ Other _____
3. RADIATION UNITS OF LABEL: _____ Units (mRem/hr)
4. MEASURED RADIATION LEVELS:
a. Package surface _____ mRem/hr
b. 3 feet or 1 meter from surface _____ mRem/hr
5. DO PACKING SLIP AND VIAL CONTENTS AGREE?
a. Radionuclide _____ yes _____ no, difference _____
b. Amount _____ yes _____ no, difference _____
c. Chem Form _____ yes _____ no, difference _____
6. WIPE RESULTS FROM:
a. Outer _____ CPM = _____ DPM
eff = ()
b. Final source container _____ CPM = _____ DPM
eff = ()
8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mRem/hr,
CPM
9. DISPOSITION OF PACKAGE AFTER INSPECTION _____
10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS
NOTIFIED.

Signature

Date

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
2. Measure exposure rate at 3 feet from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer.
3. Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.
4. Put on gloves.
5. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on bottle), and check integrity of final source container (inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material). Check also that shipment does not exceed possession limits.
6. Wipe external surface of final source container with moistened cotton swab or filter paper held with forceps; assay and record.
7. Monitor the packing material and packages for contamination before discarding.
 - a. If contaminated, treat as radioactive waste.
 - b. If not contaminated, obliterate radiation labels before discarding in regular trash.

In all the above procedures, take wipe tests with a paper towel, check wipes with a thin-end-window G-M survey meter, and take precaution against the spread of contamination as necessary.

APPENDIX G

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

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. Monitor hands and clothing for contamination after each procedure or before leaving the area.
4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances such as pediatric cases when their use would compromise the patient's well-being.
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.
7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level.
8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.
9. Dispose of radioactive waste only in specially designated receptacles.
10. Never pipette by mouth.
11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.
12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.
13. Always transport radioactive material in shielding containers.

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

1. **NOTIFY:** Notify persons in the area that a spill has occurred.
2. **PREVENT THE SPREAD:** Cover the spill with absorbent paper.
3. **CLEAN UP:** Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.
4. **SURVEY:** With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.
5. **REPORT:** Report incident to the Radiation Safety Officer.

Major Spills

1. **CLEAR THE AREA:** Notify all persons not involved in the spill to vacate the room.
2. **PREVENT THE SPREAD:** Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all

personnel potentially contaminated to prevent the spread.

3. **SHIELD THE SOURCE:** If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. **CLOSE THE ROOM:** Leave the room and lock the door(s) to prevent entry.
5. **CALL FOR HELP:** Notify the Radiation Safety Officer immediately.
6. **PERSONNEL DECONTAMINATION:** Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: _____
OFFICE PHONE: _____
HOME PHONE: _____

ALTERNATE NAMES AND TELEPHONE
NUMBERS DESIGNATED BY RSO:

APPENDIX I

AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with a low-range thin-window G-M survey meter and decontaminated if necessary.
2. Laboratory areas where only small quantities of radioactive material are used (less than 100 μCi) will be surveyed monthly.
3. All other laboratory areas will be surveyed weekly.
4. The weekly and monthly survey will consist of:
 - a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem/hr.
 - b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm per 100 cm^2 for the contaminant involved.
5. A permanent record will be kept of all survey results, including negative results. The record will include:
 - a. Location, date, and type of equipment used.
 - b. Name of person conducting the survey.
 - c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
 - d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).
 - e. Detected contamination levels, keyed to locations on drawing.
 - f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
6. Area will be cleaned if the contamination level exceeds 100 dpm/100 cm^2 .

Note:

For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey reports will be recorded.

APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of (check as appropriate)

_____ By commercial waste disposal service (see also item 4 below).

_____ In the sanitary sewer system in accordance with §20.303 of 10 CFR Part 20.

_____ Other (specify): _____

2. Mo-99/Tc-99m generators will be (check as appropriate)

_____ Returned to the manufacturer for disposal.

_____ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants.)

_____ Disposed of by commercial waste disposal service (see also item 4 below).

_____ Other (specify): _____

3. Other solid waste will be (check as appropriate)

_____ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

_____ Disposed of by commercial waste disposal service (see also item 4 below).

_____ Other (specify): _____

4. The commercial waste disposal service used will be

_____ (Name) _____ (City, State)

NRC/Agreement State License No. _____

APPENDIX K

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. All patients treated with iodine-131 or gold-198 will be placed in a private room with a toilet. The room and toilet areas more likely to be contaminated will be covered with protective material as appropriate to the amounts of contamination to be expected. Particular attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate.
2. The patient's room will be properly posted in accordance with §20.203 of 10 CFR Part 20.
3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, 3 feet (or 1 meter) away, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on his door.
4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131, will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.
5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20.
6. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.
7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer or his designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.
8. Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.
9. Urine and vomitus from iodine-131 therapy patients will be stored for decay in the radioactive waste storage area. When it has reached background levels, as measured with a low-level survey meter, it may be released to the sanitary sewer system.
10. Before a therapy patient's room is re-assigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed.
11. Nursing Instructions
 - a. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patients. Call the Nuclear Medicine Department with any questions about the care of these patients.
 - b. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.
 - c. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet from the patient.
 - d. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.
 - e. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.
 - f. Attending personnel should wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers

having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

g. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer or his designee for proper disposal of the contents of the designated waste container.

h. All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

i. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

j. Surgical dressings should be changed only as directed by the physician. Gold-198 leaking from a puncture wound will stain the dressings dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k. For iodine-131 patients:

(1) Urine from iodine-131 patients will be collected in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

(2) If the nurse helps to collect the excreta, disposable gloves should be worn. Afterwards, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste

container for disposal by the Radiation Safety Officer or his designee.

(3) Disposable plates, cups, and eating utensils will be used by patients who are treated with iodine-131.

(4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext. _____. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) All vomitus must also be kept in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times).

l. Utmost precautions must be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer or his designee.

m. If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

n. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

o. When the patient is discharged, call the Radiation Safety Officer or his designee or the Nuclear Medicine Department, and request that the room be surveyed for contamination before remaking the room.

Date: _____

**NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH
PHOSPHORUS-32, GOLD-198, OR IODINE-131**

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Exposure Rates in mRem/hr

<u>Date</u>	<u>3 feet from bed</u>	<u>10 feet from bed</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

(Comply with all checked items.)

- ____ 1. Visiting time permitted: _____
- ____ 2. Visitors must remain _____ from patient.
- ____ 3. Patient may not leave room.
- ____ 4. Visitors under 18 are not permitted.
- ____ 5. Pregnant visitors are not permitted.
- ____ 6. Film badges must be worn.
- ____ 7. Tag the following objects and fill out the tag:
 - ____ door
 - ____ bed
 - ____ chart
 - ____ wrist
- ____ 8. Gloves must be worn while attending patient.
- ____ 9. Patient must use disposable utensils.
- ____ 10. All items must remain in room until approved by the Radiation Safety Officer or his designee.
- ____ 11. Smoking is not permitted.
- ____ 12. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.
- ____ 13. Other instructions.

In case of an emergency contact:

RSO
Name _____

On-duty/Off-duty Telephone Nos.

APPENDIX L

THERAPEUTIC USE OR SEALED SOURCES

1. All patients treated with brachytherapy sources will be placed in a private room with toilet.
2. The patient's room will be properly posted in accordance with §20.203 of 10 CFR Part 20.
3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, 3 feet (or 1 meter) from the patient, 3 feet (or 1 meter) from the bed, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times and the exposure rate at 3 feet (or 1 meter) from the patient on the patient's chart.
4. Immediately after sources are implanted, the form "Nursing Instructions for Patients Treated with Brachytherapy Sources" will be completed and placed on the patient's chart.
5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20.
6. Nurses caring for brachytherapy patients will be assigned film badges. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient.
7. At the conclusion of treatment, a survey will be performed to ensure that all sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time, all radiation signs will be removed and all film and TLD badges assigned to nurses will be collected.
8. Instructions to Nurses
 - a. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these instructions before administering to the patient. Call the Radiation Safety Office or his designee with any questions about the care of these patients in regard to radiation safety precautions.
 - b. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Obtain and wear a film badge.
 - c. When a nurse receives an assignment to a therapy patient, a film or TLD badge should be obtained immediately from the Radiation Safety Officer or his designee. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.
 - d. Pregnant nurses should not be assigned to the personal care of these patients.
 - e. Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact Radiation Therapy, the Radiation Safety Officer, or the Nuclear Medicine Department at once.
 - f. Bed bath given by the nurse should be omitted while the sources are in place.
 - g. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary unless orders to the contrary have been written.
 - h. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist, and MAY NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Safety Officer or his designee.

Special orders will be written for oral hygiene for patients with oral implants.
 - i. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered, but these items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into these items.
 - j. All bed linens must be checked with a radiation survey meter before being

removed from the patient's room to ensure that no dislodged sources are inadvertently removed.

- k. These patients must stay in bed unless orders to the contrary are written. In any event, patients will remain in their assigned rooms during the treatment period.
- l. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precaution sheet on the patient's chart.
- m. Visitors should sit at least 3 feet (or 1 meter) from the patient and should remain no longer than the time specified on the form posted on the patient's door and on his chart.
- n. No nurse, visitor, or attendant who is pregnant should be permitted in the room

of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.

o. Emergency Procedures

- (1) If an implanted source becomes loose or separated from the patient, or
- (2) If the patient dies, or
- (3) If the patient requires emergency surgery, immediately call _____

Telephone No. (days) _____
(nights) _____

- p. At the conclusion of treatment, call the Radiation Safety Officer to (1) survey the patient and room and (2) count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient.

**NURSING INSTRUCTIONS FOR PATIENTS TREATED
WITH BRACHYTHERAPY SOURCES**

Patient's Name: _____

Room Number: _____ Physician's Name: _____

Isotope Activity: _____

Date and Time of Administration: _____

Date and Time Sources Are To Be Removed: _____ Isotope: _____

Exposure Rates in mR/hr

Bedside

3 feet from bed

10 feet from bed

(Comply with all checked items.)

- ☐ 1. Wear film badge.
- ☐ 2. Wear rubber gloves.
- ☐ 3. Place laundry in linen bag and save.
- ☐ 4. Housekeeping may not enter the room.
- ☐ 5. Patient may not have visitors.
- ☐ 6. Patient may not have pregnant visitors.
- ☐ 7. Patient may not have visitors under 18 years of age.
- ☐ 8. A dismissal survey must be performed before patient is discharged.
- ☐ 9. Patient must have a private room.
- ☐ 10. Other instructions.

RSO _____
Name

On-duty/Off-duty/Telephone Numbers

APPENDIX M

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., XENON-133)

The following information should be submitted in support of requests to use xenon-133:

1. Quantities to be used

a. Patient information

(1) Number of studies expected per week

(2) Average activity per patient

b. State the desired possession limit. This should be sufficient to provide for shipments whose calibration dates are several days after receipt.

2. Use and Storage Areas

a. Describe the area(s) in which you plan to use and store xenon-133. Include a diagram indicating the availability of shielding materials and the proximity to unrestricted areas.

b. Describe the ventilation in all areas where xenon-133 is used and stored. The location of supply and exhaust vents, the measured airflow rates for each vent, and the fraction of air that is recirculated by the system should be indicated.

c. All areas where xenon is used should be under negative pressure. State how you will ensure that all airflow rates are maintained as specified in this application.

3. Procedures for Routine Use

a. Describe the procedures to be followed for routine use of xenon-133, giving particular attention to radiological safety factors.

b. If you plan to use a special apparatus for administration and collection of xenon-133, specify the manufacturer's name and model number and include a description of its design characteristics. (Inclusion of a brochure would be helpful.)

c. Describe any special procedures that you plan to employ to reduce leakage, e.g., use of nose clamps or special enclosures.

4. Emergency Procedures

Describe the emergency procedures to be used in case of an accidental release of xenon-133. This should include such considerations as temporary evacuation of the area or increasing the ventilation of the area.

5. Air Concentrations of Xenon-133 in Restricted Areas

No licensee shall permit any individual in a restricted area to inhale a quantity of radioactive material in any period of one calendar quarter greater than the quantity that would result from inhalation for 40 hours per week for 13 weeks at uniform concentrations of radioactive material of 1×10^{-5} $\mu\text{Ci/ml}$.

You may evaluate your situation by making actual measurements of xenon-133 concentrations or by means of calculations. If you choose the latter approach, you may make simplifying assumptions, PROVIDING they are reasonable, conservative, and stated explicitly in your request.

In actual use and storage, some xenon-133 will be released into the room from the storage and administration devices, re-breathing apparatus, collection systems, and escape from the patient. All sources of loss must be considered when estimating the fraction of xenon-133 that is lost.

The following procedures may be used to calculate the air concentration of xenon-133 in restricted areas:

a. Estimate the maximum amount of activity to be used per week (A).

b. Estimate the fraction of xenon-133 that is lost during use and storage (f). This fractional loss must include ALL sources of loss, e.g., during patient administration, storage, and disposal.

c. Determine the measured airflow rate in the area(s) of interest, and calculate the volume of air available per week for dilution of the xenon-133 (V).

d. For restricted areas, §20.103 of 10 CFR Part 20 requires that

$$\frac{A}{V} \times f \leq 1 \times 10^{-5} \mu\text{Ci/ml.}$$

e. Sample Problem

A nuclear medicine laboratory plans to use 10 mCi xenon-133 per patient and will perform a maximum of 10 studies per week. What ventilation rate is required to ensure compliance with §20.103 of 10 CFR Part 20?

Maximum activity used per week

$$A = \frac{10 \text{ mCi}}{\text{patient}} \times \frac{10 \text{ patients}}{\text{week}} \\ \times 1 \times 10^3 \frac{\mu\text{Ci}}{\text{mCi}} \\ = 1 \times 10^5 \frac{\mu\text{Ci}}{\text{week}}$$

Assume a loss rate of 20% (f)

$$V = \frac{A \times f}{1 \times 10^{-5} \mu\text{Ci/ml}} \\ = \frac{1 \times 10^5 \mu\text{Ci/week} \times 0.20}{1 \times 10^{-5} \mu\text{Ci/ml}} \\ = 2.0 \times 10^9 \text{ ml/week.}$$

The required ventilation rate is

$$\frac{2.0 \times 10^9 \text{ ml/week}}{40 \text{ hr/week}} \\ \div \frac{1.7 \times 10^6 \text{ ml/hr}}{\text{ft}^3/\text{min}} = 30 \text{ ft}^3/\text{min}$$

The answer shows that, in order to meet the requirements of §20.103 of 10 CFR Part 20, the imaging room (RESTRICTED AREA) must have a ventilation rate of at least 30 ft³/min with no recirculation of air. Where practical, the ventilation rate should be greater than that shown necessary by the calculations. Consider every alternative in order to maintain the air concentration of xenon-133 as low as reasonably achievable in accordance with paragraph 20.1(c) of 10 CFR Part 20.

If the ventilation rate is inadequate to meet the requirements of §20.103 of 10 CFR Part 20, consider methods of increasing ventilation or reducing the patient load.

The following table gives the amount of xenon-133 that can be released per week without exceeding the permissible levels for xenon-133 in restricted areas.

Ventilation Rate (ft ³ /min)	Maximum Xenon-133 Released per 40-Hour Week (mCi)
100	67.9
500	339.7
1,000	679.4

6. Methods of Xenon-133 Disposal

a. Dilution through Exhaust Systems (less desirable).

One method for disposal of xenon-133 is by release to the atmosphere through an air exhaust system. Licensees are required to perform surveys (measurements or calculations) to ensure that they are in compliance with paragraph 20.1(c) and §20.106 of 10 CFR Part 20. Paragraph 20.1(c) requires that the concentrations of xenon-133 in effluents to unrestricted areas be as low as is reasonably achievable by the current state of technology, and §20.106 requires that the concentrations, averaged over a period of 1 year, shall not exceed $3 \times 10^7 \mu\text{Ci/ml}$.

Many facilities do not have sufficient airflow to achieve the necessary dilution. The following procedure may be used to estimate the concentrations of xenon-133 in effluents to unrestricted areas.

- (1) Estimate the maximum amount of xenon-133 to be released per year (A). This should include all anticipated losses during administration, storage, and disposal.
- (2) Determine the flow rate of the exhaust system, and describe the methods and equipment used for measuring the airflow rates.
- (3) Calculate the airflow per year (V).
- (4) Calculate the average concentrations for unrestricted areas. Section 20.106 of 10 CFR Part 20 requires that

$$C = \frac{A}{V} \leq 3 \times 10^{-7} \mu\text{Ci/ml.}$$

(5) Sample Problem

A nuclear medicine laboratory plans to use 10 mCi per patient

and will perform a maximum of 10 studies per week. A fume hood is available for disposal of xenon-133 and has a measured airflow of 168 ft/min with an opening of 8 ft². What is the average concentration of xenon-133 at the point of release from the fume hood exhaust? (NOTE: All xenon that has been released, e.g., collection bags, filters, must be considered.)

$$A = \frac{10 \text{ patients}}{\text{week}} \times \frac{10 \text{ mCi}}{\text{patient}} \times \frac{10^3 \text{ } \mu\text{Ci}}{\text{mCi}} \times \frac{52 \text{ weeks}}{\text{yr}}$$

$$A = 5.2 \times 10^6 \text{ } \mu\text{Ci/yr}$$

$$V = 168 \frac{\text{ft}}{\text{min}} \times 8 \text{ ft}^2 \times 1.49 \times 10^{10} \frac{\text{ml/yr}}{\text{ft}^3/\text{min}}$$

$$V = 1344 \frac{\text{ft}}{\text{min}} \times 1.49 \times 10^{10} \frac{\text{ml/yr}}{\text{ft}^3/\text{min}}$$

$$V = 2.01 \times 10^{13} \text{ ml/yr}$$

$$C = \frac{5.2 \times 10^6 \text{ } \mu\text{Ci/yr}}{2.01 \times 10^{13} \text{ ml/yr}}$$

$$C = 2.6 \times 10^{-7} \text{ } \mu\text{Ci/ml}$$

The following table gives the amount of xenon-133 that can be released per week without exceeding an average concentration of $3 \times 10^{-7} \text{ } \mu\text{Ci/ml}$.

Exhaust rate (ft ³ /min)	Average Release of Xenon-133 per Week (mCi)
100	8.6
500	42.8
1,000	85.6
1,500	128.4

If the exhaust is released to a restricted area, e.g., a roof to which access is controlled, or from a tall stack, Sutton's equation (Refs. 1 and 2) may be used to calculate the concentrations at the nearest unrestricted area. If this approach is used, describe the location of the exhaust system outlet, including proximity to unrestricted areas, air intakes, and open windows. Methods for controlling access to the area where the exhaust is located should also be described.

b. Adsorption onto Charcoal Traps

This is the disposal method of choice. The advantage of this disposal method is

that xenon-133 is trapped onto charcoal or other adsorbing medium. Filters containing xenon-133 are then stored for decay.

One difficulty with this approach is that charcoal is not 100% efficient for trapping xenon-133. If this is your method of disposal, you should consider the following points.

- (1) Describe how you will handle the problem of leakage from such trapping devices. If the exhaust is vented to the outdoors (UNRESTRICTED AREA), show that air concentrations of xenon-133, averaged over 1 year, do not exceed $3 \times 10^{-7} \text{ } \mu\text{Ci/ml}$. (See example in item 6.a.)
- (2) Describe how you will ensure that collection and trapping devices are performing according to specifications, both initially and on a continuing basis. Include in your description how you will monitor traps to determine when saturation occurs and filter must be replaced.
- (3) Describe your procedures for handling saturated filters. Your discussion should include a description of the area (a diagram would be useful), available shielding, proximity to restricted areas, ventilation, and an evaluation of average concentrations of xenon-133 in air. (See example in item 5.e.)

USEFUL CONVERSIONS

1 mCi	= $10^3 \text{ } \mu\text{Ci}$
1 ft ³	= $2.832 \times 10^{-2} \text{ m}^3 = 2.832 \times 10^4 \text{ ml}$
1 ft ³ /min	= $1.699 \times 10^6 \text{ ml/hr}$ = $6.797 \times 10^7 \text{ ml/40-hr week}$ = $1.484 \times 10^{10} \text{ ml/yr}$
1 week	= 168 hr

REFERENCES

1. Blatz, Hanson, *Radiation Hygiene Handbook*, McGraw-Hill (New York, 1959), pp. 22-7.
2. Cember, Herman, *Introduction to Health Physics*, Pergamon Press (New York, 1969), pp. 334-9.

APPENDIX N

GUIDANCE ON REQUESTS FOR LICENSE AMENDMENTS AND LICENSE TERMINATIONS

1. License Amendment Requests

a. To add a new user

- (1) Give NRC license number (with specific references as indicated in Item 6 of this guide) under which the person was previously listed as a user, if applicable; or
- (2) Give Agreement State license number (preferably including a copy of the license), if applicable; or
- (3) Send letter of request, attaching Supplements A and/or B (see Item 8 of this guide) if new user has not been previously approved for this type of license.

b. To add a user for Groups I-III*

- (1) Give NRC license number (with specific references as indicated in Item 6 of this guide) under which the person was previously listed as a user, if applicable; or
- (2) Give evidence of certification by the American Board of Nuclear Medicine, or other certifications as specified in Section 4 of Appendix A to this guide, and year of certification; or
- (3) Give information requested in Section 1 of Appendix A (i.e., 200 hours training in basic radioisotope handling techniques; 500 hours training and experience in handling the types and quantities of material requested; and 500 hours clinical experience).

c. To add a user for Groups IV-V*

- (1) Give NRC license number (with specific references as indicated in Item 6 of this guide) under which the person was previously listed as a user, if applicable; or
- (2) Give evidence of certification by the American Board of Nuclear Medicine, or other certifications as specified in Section 4 of Appen-

dix A to this guide, and year of certification; or

- (3) Give information requested in Section 3 of Appendix A to this guide (i.e., 80 hours training in basic radioisotope handling techniques and clinical experience as described in Section 3 of Appendix A).

d. To add a user for Group VI*

- (1) Give NRC license number (with specific references as indicated in Item 6 of this guide) under which the person was previously listed as a user, if applicable; or
- (2) Give evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology, or other applicable certifications in radiation oncology as specified in Section 4 of Appendix A to this guide; or
- (3) Give evidence of three years active experience in therapeutic radiology (see Section 4 of Appendix A to this guide).

e. To add Group III

The following specific information should be referenced to the previous application or should be given special attention if it has not been previously submitted:

- (1) Calibration frequency, procedures, and standards for high-level survey meter capable of reading up to 1 R/hr.
- (2) Room diagram showing location of generator, kit preparation, patient dose preparation areas, etc., with special attention paid to shielding.
- (3) Use of syringe shields.
- (4) Method for assaying patient doses prior to administration.
- (5) Use of ring badges for personnel who elute generators, prepare radiopharmaceuticals from reagent kits, and prepare patient doses.

*See §35.100 of 10 CFR Part 35.

- (6) Daily survey of areas used for generator elution, preparation of radiopharmaceuticals from reagent kits, and preparation of patient doses.
- (7) Rules for personnel who elute generators or prepare radiopharmaceuticals from reagent kits to monitor hands and clothing after each procedure or before leaving these areas.

f. To add Groups IV and V*

The following specific information should be referenced to the previous application or should be given special attention if it has not been previously submitted:

- (1) Room assignment.
- (2) Instructions to nurses.
- (3) Procedures for handling contaminated linen and other contaminated items.
- (4) Use of disposable items, primarily for iodine-131 patients.
- (5) Survey procedures, including dismissal survey.
- (6) Procedures for preparing oral iodine-131 doses, including procedures for controlling and monitoring airborne iodine-131 and thyroid uptake by personnel.**

g. To add Group VI***

The following specific information should be referenced to the previous application or should be given special attention if it has not been previously submitted:

- (1) Diagram of storage area with special attention paid to shielding and security.

*Additional guidance on planning an acceptable radiation safety program for these uses is provided in NCRP Report 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," Regulatory Guide 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable," and NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable."

**See Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

***Guidance on facility, equipment, and procedures for brachytherapy is provided in Regulatory Guide 8.18 and in NUREG-0267.

- (2) Procedures for handling sealed sources.
- (3) Instructions for nurses.
- (4) Use of ring badges by personnel handling sealed sources.
- (5) Procedures for transporting sources from storage area to area of use and return.
- (6) Inventory procedures to ensure that all sources are accounted for after treatment.
- (7) Survey procedures. Dismissal survey, including radiation survey of patient and room after removal of sources, must ensure that all permanent sources are removed from patient and from those areas the patient occupied.

h. To add xenon-133

- (1) Follow xenon-133 licensing guidance carefully (see Appendix M to this guide).
- (2) Other concerns not expressed specifically in guidance.
 - (a) Area in which xenon-133 is used and stored should be under negative pressure.
 - (b) Air in these areas should not be recirculated.
 - (c) All losses of xenon-133 to restricted area should also be assumed to go to unrestricted areas. Concentrations in unrestricted areas must not exceed levels specified in §20.106.

i. To move Nuclear Medicine Department

- (1) Provide diagram of new areas (see Item 11 of this guide).
- (2) Provide survey showing all previously occupied areas are free of contamination and all sources have been removed. A decontamination guide is available from the License Management Branch.†

j. To terminate a License

- a. Submit a signed Form NRC-314 indicating the disposition of the radioactive material.

†A regulatory guide on radiation safety surveys at medical institutions is now under development.

- b. Submit survey showing all previously occupied areas are free of contamination and all sources have been removed.

2. Actions Not Requiring Amendments

- a. To add naturally occurring or accelerator-produced radionuclides (e.g., radium-226, cobalt-57, gallium-67, thallium-201). NRC has no authority over these materials.
- b. To add use of particular radiopharmaceutical for participation in manufac-

turer-sponsored IND. This use is already covered in §35.100 of 10 CFR Part 35, provided the licensee obtains the radiopharmaceutical from a company authorized by NRC or an Agreement State to distribute the radioactive drug to NRC's group medical licensees.

- c. To add sealed sources of less than 3 mCi for calibration or reference purposes. These sources are authorized by §35.14(d) provided the licensee obtains them from a company authorized by NRC or an Agreement State to distribute them to NRC's group medical licensees.

EXHIBIT A

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved. GAO R0557
INSTRUCTIONS – Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the License is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.		
1.a. NAME AND MAILING ADDRESS OF APPLICANT (Institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE TELEPHONE NO.: AREA CODE () _____		1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE
2. PERSON TO CONTACT REGARDING THIS APPLICATION TELEPHONE NO.: AREA CODE () _____	3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input type="checkbox"/> AMENDMENT TO LICENSE NO. _____ c. <input type="checkbox"/> RENEWAL OF LICENSE NO. _____	
4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)	5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)	
6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE		
RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		
ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		
6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)		
ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
<input type="checkbox"/>	Names and Specialties Attached; and	<input type="checkbox"/>	Appendix G Rules Followed; or
<input type="checkbox"/>	Duties as in Appendix B; or _____ (Check One)	<input type="checkbox"/>	Equivalent Rules Attached
<input type="checkbox"/>	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE		<input type="checkbox"/>	Appendix H Procedures Followed; or
<input type="checkbox"/>	Supplements A & B Attached for Each Individual User; and	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES (Check One)	
9. INSTRUMENTATION (Check One)		<input type="checkbox"/>	Appendix I Procedures Followed; or
<input type="checkbox"/>	Appendix C Form Attached; or	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	List by Name and Model Number	18. WASTE DISPOSAL (Check One)	
10. CALIBRATION OF INSTRUMENTS		<input type="checkbox"/>	Appendix J Form Attached; or
<input type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or _____ (Check One)	<input type="checkbox"/>	Equivalent Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
<input type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One)	<input type="checkbox"/>	Appendix K Procedures Followed; or
<input type="checkbox"/>	Equivalent Procedures Attached	<input type="checkbox"/>	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
<input type="checkbox"/>	Description and Diagram Attached	<input type="checkbox"/>	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM		<input type="checkbox"/>	Appendix L Procedures Followed; or _____ (Check One)
<input type="checkbox"/>	Description of Training Attached	<input type="checkbox"/>	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
<input type="checkbox"/>	Detailed Information Attached	<input type="checkbox"/>	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
<input type="checkbox"/>	Appendix F Procedures Followed; or	<input type="checkbox"/>	Detailed Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
<input type="checkbox"/>		<input type="checkbox"/>	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES			
TYPE <small>(Check appropriate box)</small>		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	FILM		
	TLD		
	OTHER <i>(Specify)</i>		
b. FINGER	FILM		
	TLD		
	OTHER <i>(Specify)</i>		
c. WRIST	FILM		
	TLD		
	OTHER <i>(Specify)</i>		
d. OTHER <i>(Specify)</i>			

25. FOR PRIVATE PRACTICE APPLICANTS ONLY			
a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.	
NAME OF HOSPITAL		c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.	
MAILING ADDRESS			
CITY	STATE		

26. CERTIFICATE <small>(This item must be completed by applicant)</small>	
The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.	
a. LICENSE FEE REQUIRED <small>(See Section 170.31, 10 CFR 170)</small>	b. APPLICANT OR CERTIFYING OFFICIAL <i>(Signature)</i>
(1) LICENSE FEE CATEGORY:	(1) NAME <i>(Type or Print)</i>
(2) LICENSE FEE ENCLOSED: \$ _____	(2) TITLE
	c. DATE

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 Form NRC-313M. 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 30-36 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 used: (a) to provide records to State health departments for their information and use; and (b) to provide information 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 a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.
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.
5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

**TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER			2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE	
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		
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D	
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	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

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. APPLICANT PHYSICIAN'S NAME AND ADDRESS		KEY TO COLUMN C PERSONAL PARTICIPATION SHOULD CONSIST OF: 1-Supervised examination of patients to determine the suitability for radiolotope 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.
FULL NAME		
STREET ADDRESS		
CITY	STATE ZIP CODE	

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
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

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 or Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	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

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