



U.S. NUCLEAR REGULATORY COMMISSION

# 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." This guide does not cover requirements for naturally occurring or accelerator-produced radioactive materials that may be subject to licensing by individual States. This guide is also not applicable to academic programs, including medical, on campuses that do not include hospitals or clinics where byproduct material is used in or on humans. Guidance for medical teaching programs that do not involve human use is provided in Regulatory Guide 10.2, "Guidance to Academic Institutions Applying for Specific Byproduct Material Licenses of Limited Scope," or in Regulatory Guide 10.5, "Guide for the Preparation of Applications for Type A Licenses of Broad Scope for 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 21, "Reporting of Defects and Noncompliance"; 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 and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended."

#### 1.3 Items Requiring Separate Applications

**Teletherapy.** 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 Material Licensing 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,

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

#### USNRC REGULATORY GUIDES

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

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. This guide was revised as a result of substantive comments received from the public and additional staff review.

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                       |

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uranium enriched in the isotope 233 or in the isotope 235 or (2) any material artificially enriched by any one of the foregoing but not including source material.

#### 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.

Effective August 15, 1980, applications for new licenses, renewal requests, and requests for significant license amendments (i.e., to broaden programs; to increase possession limits) should be accompanied by a description of the applicant's/licensee's ALARA program. Applicants/licensees may adopt the model program described in Appendix O to this guide or may develop and submit for NRC review an equivalent alternative program. If the model program in Appendix O is adopted, Appendix O should be removed from this guide, should be dated and signed by an individual authorized to make commitments for the applicant/licensee, and should be attached to the request for licensing action.

#### 1.5 Types of Materials Licenses

##### 1.5.1 General 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 I-131 for measurement of thyroid uptake, I-125 and I-131 for blood and plasma volume determinations, Co-58 and Co-60 for intestinal absorption of cyanocobalamin, and Cr-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, veterinarians, clinical laboratories, and hospitals to possess certain small quantities of byproduct material (I-125, I-131, C-14, H-3, Fe-59, Se-75, and mock I-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.

##### 1.5.2 Specific Licenses - Limited Scope

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<sup>1</sup> 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.

##### 1.5.3 Specific Licenses - Broad Scope

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

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<sup>1</sup> Alternative titles are "radioisotope" or "radiation safety" committee. A rule change is expected in 1980 to change the name of this committee to the radiation safety committee and to revise the composition and scope of the committee.

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.

## 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 the 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,<sup>2</sup> "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, personnel training and qualifications, 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. When completely filled out, Form NRC-313M should be signed and dated on Item 26b by a representative of the institution's management. The fee required by §170.31 of 10 CFR Part 170 must accompany the application as indicated in Item 26a.

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 Material Licensing 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 1a.** 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. It is particularly important that the mailing address be sufficiently complete that all NRC correspondence to the

licensee will reach persons responsible for the radiation safety program.

**Item 1b.** List the addresses and locations where radioactive material will be used or stored if other than the address stated in Item 1a. 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. The actual locations of use should be listed, whether or not they are the same as the mailing address in Item 1a; e.g., a P.O. box may be most suitable for Item 1a in some cases, but this address does not adequately describe the location 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 names of all persons who will use, supervise, or direct the use of byproduct material. This list should include the physicians who supervise other physicians in training and/or who direct technologists or other paramedical personnel who use byproduct material for human or nonhuman use. Nonphysicians may be authorized to use byproduct material for nonhuman use (e.g., instrument calibration).

Authorized physician-users have 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 amount or dose 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.

Items a through d may be delegated to physicians who are in training under the supervision<sup>3</sup> of authorized physician-users.

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

a. The preparation and quality control testing of radiopharmaceuticals and sources of radiation.

<sup>2</sup> A newly revised Form NRC-313M and changes in requirements for radiation safety committee and physician education and training are under review. Publication of these changes is expected in late 1980.

<sup>3</sup> Supervision means that the physician-user has adequately instructed the physician(s) in training in the specific human use and has ascertained that they are receiving training in the safe use of these materials in humans. It also means that the physician-user periodically reviews the work of those supervised and assures himself that proper medical records are made of each use. It does not mean that the physician-user is necessarily present for each radiopharmaceutical administration.

b. The measurement of radiopharmaceutical doses prior to administration.

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

d. The administration of radiopharmaceuticals and radiation from radioisotope sources to patients, if 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. If the radiation safety officer is assisted by a consultant or part-time employee, state the consultant's name and describe his/her duties, responsibilities, and the amount of time to be devoted to the radiation safety program. Also submit the name and a description of the training and experience of the person responsible for the radiation program on a day-to-day basis.

*Item 6a.* 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. The possession limit for each radionuclide should be sufficient to include material held as radioactive waste.

*Item 6b.* 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.)

Describe the intended use for each radionuclide and form listed in *Item 6b*. A specific authorization must be obtained from the NRC to perform studies involving the use of radioactive material in animals. The information required is specified in *Item 22*.

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. If a study is to be conducted under a protocol approved by an FDA-approved Radioactive Drug Research Committee, submit a copy of the FDA letter granting approval; state the radionuclide, chemical form, possession limit, and use; and submit a copy of the protocol.

*Item 7 Medical Isotopes Committee.*<sup>4</sup> 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. Physicians specializing in nuclear medicine, internal medicine, and either hematology or pathology, at least one of whom will use or directly supervise the use of radioactive materials for diagnosis or treatment of 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

<sup>4</sup> A rule change is under review to revise the name of this committee to the radiation safety committee and change its functions to emphasize its role in establishing and reviewing the institution's radiation safety program.

description of his training and experience. Use Supplements A and B to Form NRC-313M (see Exhibit A) to describe the physician's training and experience. Criteria for acceptable training and experience are contained in Appendix A to this guide.

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 to describe the radiation safety officer's training and experience. Where a consultant is employed to assist the radiation safety officer, the institution will still be responsible for the proper performance of the radiation safety program as required by the license, and the institution's radiation safety officer will be expected to review the consultant's work and sign the required reports and records.

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

a. Survey Instruments

- (1) A low-level survey meter, with a thin window of about  $2 \text{ mg/cm}^2$ , 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 such as I-131 or Ir-192.

b. Dose calibrators and other instruments to assay radiopharmaceuticals.

c. Instruments used for diagnostic procedures in nuclear medicine (e.g., gamma camera, thyroid probe, well counter, scintillation counter for in vitro studies).

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 made before and after each use and should be supplemented

at least every 12 months with a battery check and two-point calibration (at about 1/3 and 2/3 of full scale) on each scale of the instrument to be used for radiation protection surveys.<sup>5</sup> Survey instruments should also be calibrated after repair or maintenance that may affect the calibration of the instrument.

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 percent.

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. The source should be of sufficient strength to give at least a 2/3-scale reading on the highest scale to be calibrated when the source is 20 cm from the effective center of the detector.
- (2) The nuclide and either (a) activity (in millicuries or equivalent SI units) of radioactive material contained in the source or (b) exposure rates at fixed distances from the source as certified by measurements involving direct comparisons with sources or dosimeters calibrated at the National Bureau of Standards.
- (3) The accuracy<sup>6</sup> of the source(s).
- (4) The step-by-step procedures, including associated radiation safety procedures. For each instrument, these procedures should include a two-point calibration (at about 1/3 and 2/3 of full scale) on each scale used for radiation protection surveys.<sup>5</sup>

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 whether information concerning calibration services and procedures has been filed with the Commission. If this information has not been filed, submit it with your application, including details of the information the outside firm will supply you about the results of the calibration.

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

<sup>5</sup>Scales up to 1 R/hr should be calibrated but, in order to keep personnel exposures ALARA, high-range scales above 1 R/hr need not be calibrated when they will not be needed in a particular institution. Scales above 1 R/hr that are not calibrated should be checked for operation when possible. The results should be noted on the instrument. The user should be alerted to scales not calibrated or checked.

<sup>6</sup>The maximum deviation of the nominal value of the source from the true value. This information is normally provided by the manufacturer.

Item 10 of the application form. A sample "Certificate of Instrument Calibration" is also provided in Appendix D for use by a consultant in reporting calibration results. Indicate, by checking the appropriate boxes in Item 10 of Form NRC-313M, if the procedures described in Appendix D will be followed. If the procedures in Appendix D are not followed, submit equivalent procedures.

b. *Dose Calibrator.* All radiopharmaceuticals should be assayed for activity to an accuracy of  $\pm 10$  percent of the true value 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 or equivalent SI units) of radioactive materials 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. *Instruments Used for Diagnostic Purposes.* Calibration, quality control, and maintenance of instrumentation used for diagnostic procedures should be performed routinely in accordance with the manufacturer's recommendations.

*Item 11 Facilities and Equipment.*<sup>7</sup> 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 detailed diagram of the facility, indicating the type, dimensions, position, and thickness of shielding that will be used for:

- a. Use and storage of Tc-99m generators.
- b. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).
- c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. (This area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste. If this area is located outside your department, describe how the material will be secured. Confirm that this area will be surveyed at least weekly.)
- d. Preparation and dispensing of Group III kit radiopharmaceuticals (e.g., lead glass L-block).

Identify adjacent areas across the walls from use and storage locations, and show that adequate steps have been taken to ensure that radiation levels in unrestricted areas do not exceed the limits specified in paragraph 20.105(b) of 10 CFR Part 20 (see Figure 1).

Shielding requirements for the walls, floor, and ceiling should be evaluated for each nuclear medicine room based on total workload (in mCi/week), the energy of radiation, and the presence of patients with activity in the room. Adequate distances should be allowed between technologists and patients being scanned or imaged.

If Xe-133 is to be used, submit a version of your facility diagram that specifies the location and the measured airflow rate of each air exhaust vent and each air supply vent in areas where Xe-133 will be used or stored. This information is necessary in order to determine that the vents are properly located and that use and storage areas are under negative pressure. (See Figure M-1 of Appendix M for an example of the type of diagram to be submitted.)

For other 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.

*Item 12 Personnel Training Program.* Radiation workers (e.g., technologists) must receive instruction as specified in §19.12 of 10 CFR Part 19. Note that many of these items pertain to circumstances at a particular institution; therefore,

<sup>7</sup>See also Regulatory Guide 8.18 and NUREG-0267 for checklists of facilities, equipment, and procedures to consider in designing hospitals for medical uses of byproduct material.

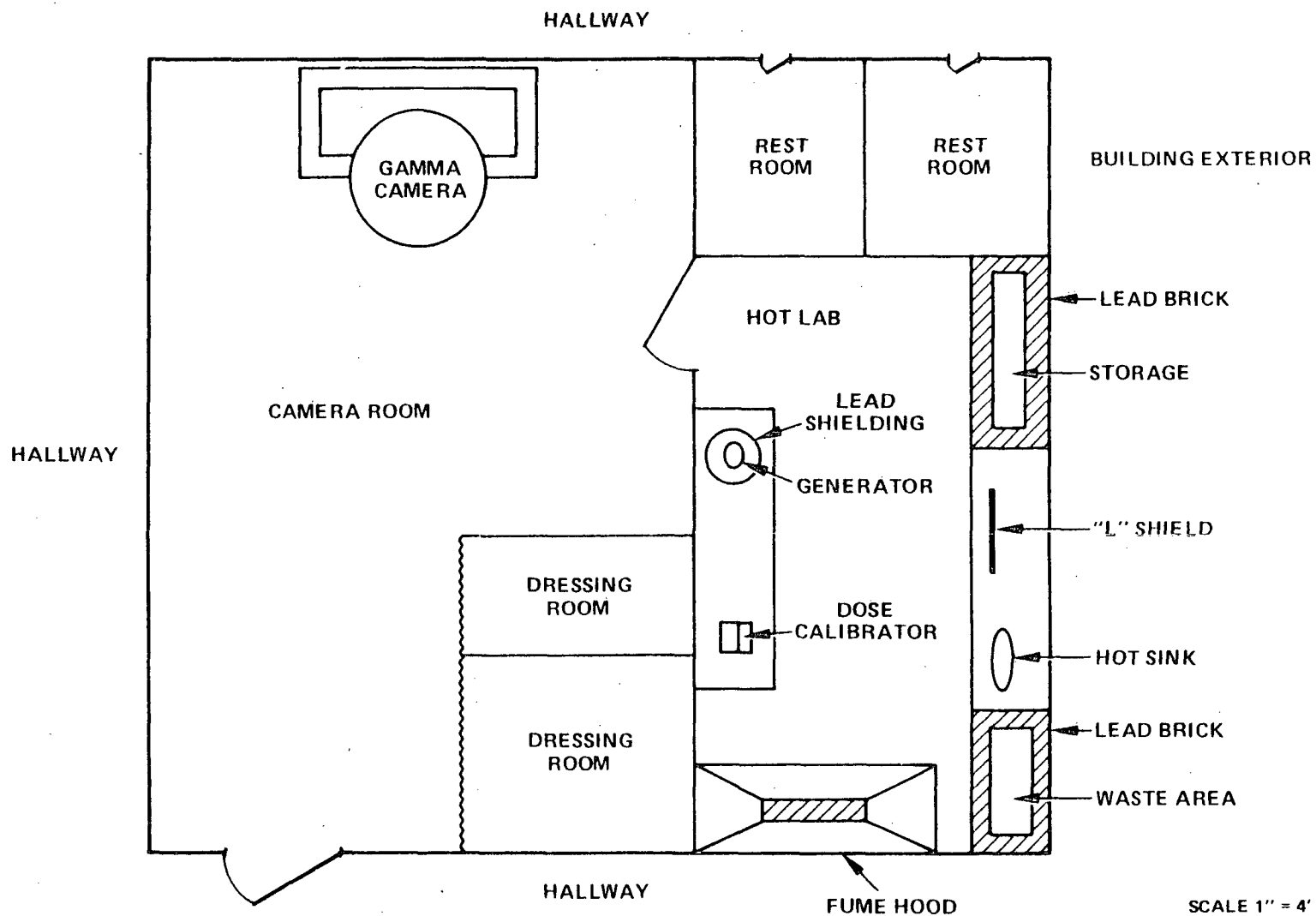


FIGURE 1

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

it may not be assumed that this instruction has been adequately covered by prior occupational training, Board certification, etc. Outline and submit the program for providing the necessary instruction.

Ancillary personnel (e.g., clerical, nursing, housekeeping, security personnel) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions.

Describe the training that will be provided to 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.

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.

Instruction as required by 10 CFR Part 19 should include:

- a. All terms of the license pertinent to radiation safety.
- b. Areas where radioactive material is used or stored.
- c. Potential hazards associated with radioactive material.
- d. Radiological safety procedures appropriate to their respective duties.
- e. Pertinent NRC regulations.
- f. Rules and regulations of the licensee.
- g. Obligation to report unsafe conditions to the radiation safety officer.
- h. Appropriate response to emergencies or unsafe conditions.
- i. 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.

**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 ordered for human use are adequately verified upon receipt and checked before use, 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 paragraph 20.105(i) 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 (a) receiving, examining, and securing packages and (b) notifying specific personnel (including names and telephone numbers of persons to be contacted) 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.** Although §20.205 of 10 CFR Part 20 exempts certain packages from immediate monitoring, paragraph 20.205(d) requires that each licensee establish procedures for safely opening *all* packages containing licensed material.

Describe your procedures for examining incoming packages for leakage, contamination, or damage, and for compliance with §20.205 of 10 CFR Part 20. Monitoring should be performed 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 (a) surveying packages, (b) wearing gloves while opening packages, (c) checking packing material for contamination after opening, and (d) verifying package contents.

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, radiopharmacists, 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., wear laboratory coats and disposable gloves and use trays.
- c. Prescribe limitations and conditions for handling liquid or loose radioactive materials and the laboratory equipment to be used 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 always be done behind shielding and within appropriate hoods or enclosures. Syringe shields should be used for the routine preparation and administration of patient doses, except on the rare occasions where difficulties in properly administering the dose to the patient would warrant expedited use of lighter syringes. Even in these cases, syringes with the best possible finger protection or remote delivery of the dose (e.g., through use of a butterfly valve) should be used.

e. Give instructions for preparation and assay of patient doses, including instructions to check each therapy dose against the ordering physician's written request.

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, procedures for properly turning in personnel monitoring devices for processing at appropriate intervals, and instructions for recording exposure results. Also describe where personnel monitoring devices and control dosimeters will be stored to ensure accuracy in monitoring employee occupational exposures and to avoid inadvertent exposure of the devices when they are not being worn.

i. Describe waste disposal procedures to be followed for each type of waste (e.g., liquids, gases, solids, long-lived, short-lived). Properly shielded waste receptacles should be employed for used syringes and other radioactive wastes.

j. Describe contamination control procedures, including (1) prohibitions against smoking, eating, drinking, or applying cosmetics in restricted areas, (2) prohibition against storing food, beverages, and personal effects with radioactive materials, and (3) instructions for individuals who prepare and administer doses of 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.<sup>8</sup>

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. Careful segregation of nonradioactive waste from radioactive waste, decay of radioactive waste in storage, monitoring, and release to normal trash. Wastes may be held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. Then, after radiation labels have been removed or obliterated, the waste may be disposed of in normal trash.

b. Release into a sanitary sewer in conformance with §20.303 of 10 CFR Part 20. Describe the 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.<sup>9</sup>

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

e. Other methods specifically approved by the Commission in accordance with §20.302 of 10 CFR Part 20. Amendments to licenses will be considered to allow the addition of volatile laboratory wastes to fuel oil or the disposal of very low activity laboratory wastes containing C-14 or H-3 in the pathology department incinerators.

<sup>8</sup>Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions," provides further information on acceptable survey procedures.

<sup>9</sup>A rule change is pending to delete the provision for burial of wastes under §20.304 of 10 CFR Part 20. This provision will likely be replaced by a provision that requires specific approval by license amendment for burial.

**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.)

f. Transfer to a person or firm 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(s) selected.

In view of the recent problems with the shallow-land burial sites used by commercial waste disposal firms, the NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials into the sanitary sewer (paragraphs a and b above).

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<sup>10</sup> 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, appropriate procedures should be established because hospitalization is sometimes required.

a. Describe radiation safety procedures directly involved with care of therapy patients, including:

- (1) Procedures for assigning patients to rooms. Private rooms should be designated for I-131 therapy patients or any other patients that may constitute an internal or external exposure hazard for roommates.
- (2) Procedures for contamination control in the patient's room (e.g., protective covering for areas of likely contact, use of disposable dishes and utensils, and procedures for posting and controlling radiation areas or potentially contaminated areas (see NUREG-0267)).
- (3) Procedures for surveys of:
  - (a) Areas, equipment, personnel involved in administration of radiopharmaceuticals,
  - (b) The patient's room on a daily basis,
  - (c) Unrestricted areas (i.e., areas adjacent to the patient's room),

(d) Linens and other items removed from the patient's room, and

(e) The patient's room before it is reassigned to another patient.

- (4) Records of surveys to be recorded on patient's chart and in radiation safety office records.
- (5) Instructions to nursing staff (see Appendix K).
- (6) Personnel monitoring procedures for medical and nursing staff.
- (7) Procedures for disposal of wastes, including:
  - (a) Patient excreta,
  - (b) Surgical dressings, and
  - (c) Other disposable items.
- (8) Procedures to be followed in case of emergency surgery or death (see NCRP Report Nos. 37 and 48).
- (9) Procedures for release of patients, including:
  - (a) Criteria for release of patients and
  - (b) Instructions to patients and families (see NCRP Report Nos. 37 and 48).

b. Describe radiation safety procedures involved with all other aspects of therapy procedures, including:

- (1) Criteria for determining when it is appropriate to use protective facilities, equipment, or supplies (e.g., hoods, shielding blocks, tongs, disposable gloves) and procedures for their use. Personnel should always wear gloves and work within fume hoods or special enclosures whenever opening vials containing therapeutic quantities of volatile radiopharmaceuticals such as I-131. These hoods should have adequate airflow, and operating procedures should be designed to prevent contamination of personnel and surrounding areas.
- (2) Criteria and procedures for bioassay of personnel. Significant thyroid uptakes have been detected in individuals who open and prepare oral solutions of I-131 for therapeutic doses. Bioassays should also be considered for personnel (e.g., radiation safety, nursing) who are involved in other aspects of therapy procedures. Guidance on situations requiring bioassay for I-131 and appropriate action levels may be found in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."
- (3) Surveys to limit the spread of contamination and procedures for decontamination. Surveys

<sup>10</sup>See Regulatory Guide 8.23 and NUREG-0267.

(e.g., measurement of I-131 in air; measurement of I-131 in the thyroid glands of laboratory personnel; contamination surveys of personnel, equipment, and facilities) should also be performed to determine compliance with §§ 20.103 and 20.106 of 10 CFR Part 20.

Submit detailed responses to Items 19a and 19b. In lieu of submitting a detailed response to Item 19a, you may state that you will follow the procedures in Appendix K.

*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 Part 35. These procedures<sup>11</sup> should include descriptions of:

a. The areas where sealed sources will be stored, including (1) placement and thickness of shielding, (2) proximity of the storage area to unrestricted areas, and (3) any calculations or measurement data used to check the adequacy of the shielding and other facility protection specifications. Radiation levels in unrestricted areas must be less than 2 millirems in any 1 hour and less than 100 millirems in any 7 consecutive days (see paragraphs 20.105(b)(1) and (b)(2) of 10 CFR Part 20).

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

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

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

e. 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 immediately following the conclusion of treatment.

f. 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 immediately following the conclusion of treatment and before the patient is discharged. This 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.

g. 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.)

Submit detailed responses to Item Nos. 20a through 20f. In response to Item 20g, indicate, by checking the appropriate box in Item 20, 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., Xe-133) and Aerosols.* The use of radioactive gases (e.g., Xe-133 gas or gas in saline) and aerosols requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive gas or aerosol 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.

Appendix M to this guide contains instructions for submitting an application to use Xe-133 or aerosol. 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. Instructions to animal caretakers should reflect the types of studies done at the institution.

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

Bioassays may be required when individuals work with millicurie quantities of H-3, I-125, or I-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 I-125 and I-131 is provided in Regulatory Guide 8.20. Guidance for bioassay programs for tritium and other radionuclides is available as staff criteria from the Material Licensing 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.* Provide 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

<sup>11</sup>Guidance on facilities, equipment, and procedures is available in NUREG-0267. Guidance on brachytherapy procedures is given on pp. 3-16 through 3-19 of this report.

will be estimated from the wrist badge data in lieu of using finger monitors, and provide any backup data used to perform or verify these estimates. Wrist or ring badges should be worn toward the palm side of the hand for measuring hand exposures. Where feasible, ring badges should be worn on the index finger facing toward the palm side of the hand. When pocket ionization chambers (pocket dosimeters) are to be used for personnel monitoring, give the manufacturer's name, model number, range of scale readings, calibration and check procedures, frequency of calibration, and frequency of reading and recording exposures.

*Item 25 (For Private Practice Applicants Only)*

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

*Item 25b.* 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 25c.* 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 26a.* License fee category and license fee may be determined from information pertaining to medical licenses in §170.31 of 10 CFR Part 170.

*Items 26b 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.

Amendment applications should be signed and dated by a representative of the licensee's administrative management (e.g., the hospital administrator). A fee must accompany amendment applications as indicated in Item 26a. An original and two copies of the application for amendment should be prepared, and 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, should meet all licensing and regulatory requirements in effect at the time of renewal, and should be signed and dated by a representative of the licensee's administrative management (e.g., hospital administrator). Renewal applications should also include the physician-users' 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), and
- 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 Material Licensing 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 26a.

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## APPENDIX A

### ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF BYPRODUCT MATERIAL\*

#### I. General Criteria

Any human use of byproduct material (i.e., the internal or external administration of byproduct material, or the radiation therefrom, to human beings) must be carried out by or under the supervision of a physician. As defined in paragraph 35.3(b) of 10 CFR Part 35, a *physician* means an individual licensed by a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine.

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 (a) basic radioisotope handling techniques and (b) the clinical management of patients to whom radiopharmaceuticals have been administered. Similar criteria are established in paragraph 35.12(a)(4) 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.

This training and experience must have been obtained within a 5-year period preceding the date of the license application or must be supplemented by continuing education or experience. Also, the original training and experience should have been received in a formal residency program in an accredited medical institution. 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.

#### 2. Training for Routine Diagnostic Procedures (Groups I-III)

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 applicable to the use of unsealed sources. This training should consist of lectures, laboratory sessions, discussion groups, or supervised experience in a nuclear medicine laboratory (i.e., on-the-job training in a formalized training program) in the following areas:

- (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). For authorization for Group III (generators and reagent kits), this experience should include personal participation in five procedures to elute Tc-99m, including testing of eluate, and five procedures to prepare radiopharmaceuticals from Group III reagent kits.

- 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.

\* Changes in these requirements are anticipated in the near future (after publication of this guide) and will be published in a revision to this guide.

\*\* The hours are in terms of hours of class, laboratory, or clinical experience rather than semester hours.

- (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 2a, 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 (Training and Experience) and B (Preceptor Statement) of Form NRC-313M. For each subject covered in basic training, state where the training was obtained, the dates, total number of hours, and type of training. Hours of training should be broken down into lecture or laboratory hours or on-the-job training (OJT). OJT must have been obtained in a formalized training program. Be sure that individual hours of training can be traced to the institution where the training was received. Each hour of training should be listed under only *one* subject category (i.e., the most applicable subject category).

**Alternatives**

Certification by (a) the American Board of Nuclear Medicine, or (b) 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 and experience to use Groups I, II, and III.

**3. Training 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.

**4. Training 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 applicable to the use of unsealed sources for therapy procedures, including (80 hours)

- (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 2a above.)

**b. Clinical training in specific therapy procedures:**

*For Group IV*

- (1) I-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) Soluble P-32 for treatment of polycythemia vera, leukemia, and/or bone metastases:

Active participation in the treatment of *three patients* with any combination of these three conditions.

- (3) Colloidal P-32 for intracavitary treatment:

Active participation in the treatment of *three patients*.

*For Group V*

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

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

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

Active participation in the treatment of *three patients*.

**5. Training 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 applicable (200 hours)



to the use of sealed sources for therapy procedures, 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. Experience with the types and quantities of radioactive material for which the application is made, or equivalent (500 hours).

- c. Clinical training in Group VI procedures:

Active practice in therapeutic radiology with a minimum of 3 years experience of which at least 1 year should have been spent in a formal training program accredited by the Residency Review Committee of Radiology and the Liaison Committee on Graduate Medical Education.

As evidence of the foregoing training and experience, the applicant should complete Supplements A and B of Form NRC-313M. Supplement B should be completed and signed by each preceptor-physician under whom the applicant-physician gained experience or training. Submission of letters of evaluation from each preceptor-physician on behalf of the applicant-physician should be included with the application. These letters of evaluation should describe the scope and extent of the applicant-physician's training and experience and should include an appraisal of the applicant-physician's competency to use Group VI sources independently for therapy procedures.

**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 Canadian certification from the Royal College of Physicians and Surgeons (RCPS) in therapeutic radiology may be submitted in lieu of the information requested in Sections 5a through c

above. Physicians certified by the FFR or FRCR must also submit evidence of specialization in radiotherapy. Evidence of previous approval by the NRC or an Agreement State may also be submitted in lieu of the information requested above. In this case, the applicant should specify the number of the NRC license or submit a copy of the Agreement State license on which the applicant-physician was specifically listed as an authorized user.

**6. Training for Physicians Wishing to Use Sr-90 Ophthalmic Eye Applicators Only**

To qualify as adequately trained to use or supervise the use of an Sr-90 eye applicator only, a physician should submit:

- a. Evidence of certification by the American Board of Radiology in radiology or therapeutic radiology, or

- b. Evidence of:

- (1) Active practice in therapeutic radiology or ophthalmology, and

- (2) Training in basic radioisotope handling techniques, including

- (a) Radiation physics and instrumentation (6 hours)

- (b) Radiation protection (6 hours)

- (c) Mathematics pertaining to the use and measurement of radioactivity (4 hours)

- (d) Radiation biology (8 hours)

This information may be submitted on Supplement A of Form NRC-313M. The hours listed next to each of the four subjects are suggested minimum values and should not be interpreted as specific requirements.

- (3) Evidence of active participation in the treatment of *five patients* (to be submitted on Supplement B (Preceptor Statement) of Form NRC-313M).

"Active participation" should include supervised examination of patients, collaboration and calculations concerning the dose to be used, administration of the dose to the patient, and followup and study of patient case histories.



## 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 all individuals who use radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that their 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 (e.g., nursing, security, and house-

keeping 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 the adequacy of the institution's 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, as specified in the license.

#### 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.

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\* A rule is expected in 1981 that would change the name, composition, and functions of this committee.



**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. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
--------------------	------------------------	-----------

4. Other (e.g., liquid scintillation counter, area monitor, velometer)



**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 or exposure rates at given distances shall be traceable by documented measurements to a standard source certified within 5 percent 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 located at approximately 1/3 and 2/3 of full scale.
5. The exposure rate measured by the instrument shall differ from the true exposure rate by less than 10 percent at the two points on each scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within  $\pm 20$  percent will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret meter readings to within 10 percent for radiation protection purposes.

**Note:**

Sources of Cs-137, Ra-226, or Co-60\* are appropriate for use in calibrations. Since these sources emit rather high-energy photons, they are not suitable for low-energy calibrations that may be required under special circumstances (see Item C below). The activity of the calibration standard should be sufficient to calibrate the survey meters on each scale to be used for radiation protection purposes. Scales up to 1 R/hr should be calibrated, but higher-range scales above 1 R/hr need not be calibrated when they will not be needed for radiation protection surveys. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation. Other-

\* Minimum activities of typical sources are 85 mCi of Cs-137, 21 mCi of Co-60, and 34 mCi of Ra-226 (to give at least 700 mR/hr at 20 cm).

wise, a cautionary note that they have not been checked should be placed on the instrument.

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 or as soon as the instrument is received from a calibration laboratory. 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:

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  $\pm 20$  percent 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 if the instrument is to be used for quantitative measurements in the Xe-133 or Tc-99m energy ranges.

The 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.

Alternatively, the manufacturer's energy response curve(s) may be used to correct instrument readings appropriately when lower-energy radiation is monitored.

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 exposure rate at a given distance.

or its activity, 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 exposure rates or source activities at times other than the calibration date.

## 2. Inverse Square Law

Consider a "point" source of radiation at position S, as shown in Figure D-1. Then, the relationship between exposure rates  $R_1$  and  $R_2$  at detector positions  $P_1$  and  $P_2$ , which are at distances  $D_1$  and  $D_2$  from S, respectively, is given by the following equation:

$$R_2 = \frac{D_1^2}{D_2^2} \times R_1$$

where  $R_1$  and  $R_2$  are exposure rates in the same units (e.g., mR/hr, R/hr), and  $D_1$  and  $D_2$  are the distances in Figure D-1 in the same units (e.g., m, cm, ft).

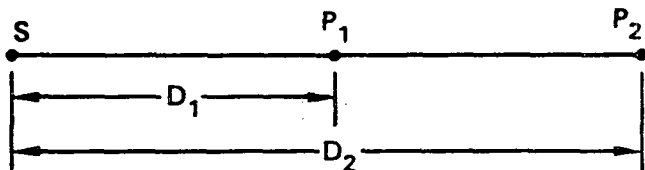


Figure D-1

## 3. Radioactive Decay Law

Exposure rate  $t$  units of time after specified calibration date

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

\* A source may be considered a "point" source when the source and the radiation detector are small, in any dimension, compared to the distances at which radiation is to be measured. The center of the detector should be at distances  $D_1$  or  $D_2$  as shown in Figure D-1.

where

$R_o$ and $R_t$	are in the same units (e.g., mR/hr or R/hr).
$R_o$	is exposure rate on the 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:

$$\begin{aligned}
 R &= 100 \text{ mR/hr} \times e^{-\frac{(0.693 \times 2.0)}{5.3}} \\
 &= 100 \times 0.77 = 77 \text{ mR/hr at} \\
 &\quad \text{1 foot on March 10, 1977.}
 \end{aligned}$$

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

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



## 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 used for radiation protection purposes, i.e., at least up to 1 R/hr.

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  $\pm 10$  percent of the calculated or known values for each point checked. Readings within  $\pm 20$  percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within  $\pm 10$  percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on 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 \_\_\_\_\_  
or  
Exposure rate at a specified distance \_\_\_\_\_  
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. \_\_\_\_\_

\_\_\_\_\_ have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

\_\_\_\_\_ the attached "Certificate of Instrument Calibration."  
\_\_\_\_\_ the consultant's reporting form as attached.

\_\_\_\_\_ are described in the attachment, and the consultant's report will contain the information on

\_\_\_\_\_ the attached "Certificate of Instrument Calibration."  
\_\_\_\_\_ the consultant's reporting form as attached.

# CERTIFICATE OF INSTRUMENT CALIBRATION

For:

Instrument:

Manufacturer \_\_\_\_\_

Type \_\_\_\_\_

Model No. \_\_\_\_\_

Serial No. \_\_\_\_\_

Calibration Data:

Scale	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)

Comments:

	Activity or	
<u>Nuclide</u>	<u>Exposure Rate at Specified Distance</u>	<u>Calibration Accuracy</u>

Calibration Source:

Calibrated by \_\_\_\_\_ Date \_\_\_\_\_

## APPENDIX D (Continued)

### Section 2

#### METHODS FOR CALIBRATION OF DOSE CALIBRATOR\*

All radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. 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 constancy (daily)
2. Instrument accuracy (at installation and annually thereafter)
3. Instrument linearity (at installation and quarterly thereafter)
4. Geometrical variation (at installation)

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

##### C. Test for Instrument Constancy

*Instrument constancy* means that there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57,\*\* or Ra-226\*\* using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi of Co-57 and 100-200  $\mu$ Ci of Cs-137 or 1-2 mg Ra-226 (with appropriate decay corrections) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

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, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.

\* See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018).

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

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 semilog graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the  $\pm 5$  percent limits on the graph.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than  $\pm 5$  percent 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.

##### 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 use 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	31.633
6	15.853
24	1.995
30	1
48	0.126

*Example:* If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be  $15.625 \text{ mCi} \times 15.853 = 247.7 \text{ mCi}$  and  $15.625 \text{ mCi} \times 0.126 = 1.97 \text{ mCi}$ , respectively.

- On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).
- The activities plotted should be within  $\pm 5$  percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than  $\pm 5$  percent indicate the need for repair or adjustment of the instrument.
- If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated 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  $\pm 2$  percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

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.

- Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.
- 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

\* Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of  $T_{1/2} = 6.02$  hours has been used in calculating these correction factors.

as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

- 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,

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

- 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.
- 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.

- 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.
- It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

An alternative 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, including Cs-137, Co-57, and Ba-133, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. Identify in your application the three sources that you will use. State nuclide, activity, and calibration accuracy. 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  $\pm 5$  percent 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  $\pm 5$  percent 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 at the licensee's facility with the reference 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 reference standards. Keep a log of these initial and subsequent readings.

## 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>Suggested Activity (mCi)</u>	<u>Activity (mCi)</u>	<u>Accuracy</u>
Co-57	3-5	_____	_____
Ba-133	0.1-0.5	_____	_____
Cs-137	0.1-0.2	_____	_____
Ra-226	1-2	_____	_____
_____		_____	_____

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

or

\_\_\_\_\_ Equivalent procedures are attached.

\_\_\_\_\_  
\*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

## APPENDIX E

### PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

1. The Supervisory Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
  2. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following:
    - a. Ordering of routinely used materials
      - (1) Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.
      - (2) The written records will be referenced when opening or storing radioactive shipment.
    - b. Ordering of specially used materials (e.g., therapeutic uses)
      - (1) A written request\* will be obtained from the physician who will perform the procedure.
      - (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.
      - (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.
    - c. It is essential that written records\* be maintained for all ordering and receipt procedures.
  3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
  4. During off-duty hours, security personnel or other designated individuals will accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.
- \* In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

#### 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 7:00 a.m. and 4:00 p.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, do not open it. Contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined whether he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: \_\_\_\_\_

OFFICE PHONE: \_\_\_\_\_

HOME PHONE: \_\_\_\_\_

\*\* Submit a copy of your own institution's memorandum.





## APPENDIX F

### PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds  $0.01 \mu\text{Ci}/100 \text{ cm}^2$  or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).
  - (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition,\* packing slip, and label on bottle.
  - (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
  - (4) Check also that shipment does not exceed possession limits.
2. For all packages, the following additional procedures for opening packages will be carried out:
  - a. Put on gloves to prevent hand contamination.
  - b. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
  - c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If  $>10 \text{ mR/hr}$ , stop procedure and notify Radiation Safety Officer.
  - d. Measure surface exposure rate and record. If  $>200 \text{ mR/hr}$ , stop procedure and notify Radiation Safety Officer.
  - e. Open the package with the following precautionary steps:
    - (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.
    - f. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g.,  $\mu\text{Ci}/100 \text{ cm}^2$ , etc.). Check wipes with a thin-end-window G-M survey meter, and take precautions against the spread of contamination as necessary.
    - g. Monitor the packing material and packages for contamination before discarding.
      - (1) If contaminated, treat as radioactive waste.
      - (2) If not contaminated, obliterate radiation labels before discarding in regular trash.
3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

---

\* In the case of special orders (e.g., therapy doses), also compare with physician's written request.

### RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O. No.: \_\_\_\_\_ Survey Date \_\_\_\_\_ Time \_\_\_\_\_  
Surveyor \_\_\_\_\_
2. CONDITION OF PACKAGE :  
\_\_\_\_\_ O.K. \_\_\_\_\_ Punctured \_\_\_\_\_ Status \_\_\_\_\_ Wet  
\_\_\_\_\_ Crushed \_\_\_\_\_ Other \_\_\_\_\_
3. RADIATION UNITS OF LABEL: \_\_\_\_\_ Units (mR/hr)
4. MEASURED RADIATION LEVELS :
  - a. Package surface \_\_\_\_\_ mR/hr
  - b. 3 feet or 1 meter from surface \_\_\_\_\_ mR/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 \_\_\_\_\_ mR/hr, CPM
9. DISPOSITION OF PACKAGE AFTER INSPECTION \_\_\_\_\_
10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## APPENDIX G

### GENERAL RULES FOR 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. Always use syringe shields for routine 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. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).
5.
  - a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
  - b. Do not store food, drink, or personal effects with radioactive material.
6.
  - a. 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 percent.
  - b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.
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. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.
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 and properly shielded 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 shielded 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.
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 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.

\* The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.



## APPENDIX I

### AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with an appropriately low-range survey meter and decontaminated if necessary.\*
  2. Laboratory areas where only small quantities of radioactive material are used (less than 200  $\mu\text{Ci}$ ) will be surveyed monthly.
  3. Waste storage areas and all other laboratory areas will be surveyed weekly.
  4. The weekly and monthly surveys will consist of:
    - a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
    - b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100  $\text{cm}^2$  for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.
  5. A permanent record will be kept of all survey results, including negative results. The record will include:
    - a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.
    - 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 200 dpm/100  $\text{cm}^2$ .
- \* For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.





## APPENDIX J

### WASTE DISPOSAL

**Note:** In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)
- \_\_\_\_\_ In the sanitary sewer system in accordance with § 20.303 of 10 CFR Part 20.
- \_\_\_\_\_ By commercial waste disposal service (see also Item 4 below).
- \_\_\_\_\_ 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 in a low background area 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 will be disposed of as normal trash.\*\*
- \_\_\_\_\_
- \* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).
- \*\* These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
- \_\_\_\_\_ 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 in a low background area 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

### RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF RADIOPHARMACEUTICALS\*

1. All patients treated with I-131 or Au-198 will be placed in a private room that has a toilet. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amounts of contamination to be expected. 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. Plastic bags or wrappings that are waterproof and easily disposable should be used on the smaller items.
2. The patient's room will be properly posted or attended in accordance with §§ 20.203 or 20.204 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 and 3 feet (or 1 m) from the patient after administration 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 (or a similar form containing all the requested information), 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. If urine and vomitus from I-131 therapy patients are collected, they will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels, as measured with a low-level survey meter. They will then be released to the sanitary sewer system.
10. Before a therapy patient's room is reassigned 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 or the Radiation Safety Officer with any questions about the care of these patients. Nursing personnel who attend the patient will wear personnel monitoring devices as advised by the Radiation Safety Office.
  - 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 (or 1 m) 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,

\* Be sure to submit a complete response to Item 19b in addition to referencing procedure\* in Appendix K.

- 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. Au-198 leaking from a puncture wound may 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 I-131 patients:
    - (1) To the degree possible with cooperative patients, urine 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. Afterward, 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 I-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 situation where the patient's room may be contaminated 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) Keep all contaminated wastes and vomitus in plastic bags 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). The Radiation Safety Officer will establish procedures for disposal of wastes (see Item 12 below).
  - l. 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.
  - m. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.
  - n. 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.
12. Waste Disposal
 

When contaminated wastes are transported to the Waste Storage/Disposal area, precautions will be taken to minimize external irradiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas ALARA.

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 mR/hr

Date	3 feet from bed	10 feet from bed
11/1/54	100	100
11/2/54	100	100
11/3/54	100	100
11/4/54	100	100
11/5/54	100	100
11/6/54	100	100
11/7/54	100	100
11/8/54	100	100
11/9/54	100	100
11/10/54	100	100
11/11/54	100	100
11/12/54	100	100
11/13/54	100	100
11/14/54	100	100
11/15/54	100	100
11/16/54	100	100
11/17/54	100	100
11/18/54	100	100
11/19/54	100	100
11/20/54	100	100
11/21/54	100	100
11/22/54	100	100
11/23/54	100	100
11/24/54	100	100
11/25/54	100	100
11/26/54	100	100
11/27/54	100	100
11/28/54	100	100
11/29/54	100	100
11/30/54	100	100
12/1/54	100	100
12/2/54	100	100
12/3/54	100	100
12/4/54	100	100
12/5/54	100	100
12/6/54	100	100
12/7/54	100	100
12/8/54	100	100
12/9/54	100	100
12/10/54	100	100
12/11/54	100	100
12/12/54	100	100
12/13/54	100	100
12/14/54	100	100
12/15/54	100	100
12/16/54	100	100
12/17/54	100	100
12/18/54	100	100
12/19/54	100	100
12/20/54	100	100
12/21/54	100	100
12/22/54	100	100
12/23/54	100	100
12/24/54	100	100
12/25/54	100	100
12/26/54	100	100
12/27/54	100	100
12/28/54	100	100
12/29/54	100	100
12/30/54	100	100
12/31/54	100	100

---

[illegible]

---

\_\_\_\_\_

(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 or TLD badges must be worn.

7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.

- \_\_\_\_\_ 8. Tag the following objects and fill out the tag:

- \_\_\_\_\_ door                      \_\_\_\_\_ chart

- \_\_\_\_\_ bed                      \_\_\_\_\_ wrist

9. Disposable gloves must be worn while attending patient.

- \_\_\_\_\_ 10. Patient must use disposable utensils.

- \_\_\_\_\_ 11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.

- \_\_\_\_\_ 12. Smoking is not permitted.

- \_\_\_\_\_. 13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.

- \_\_\_\_\_ 14. Other instructions.

In case of an emergency contact:

RSO

Name

### On-duty/Off-duty Telephone Numbers



## APPENDIX L

### RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF SEALED SOURCES\*

1. All patients treated with brachytherapy sources will be placed in a private room that has a toilet.
  2. The patient's room will be properly posted or attended in accordance with §§ 20.203 or 20.204 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 3 feet (or 1 m) from the patient with sources implanted, at the patient's bedside, at 3 feet (or 1 m) 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 m) 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 attached to the patient's chart.
  5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraphs 20.105(b)(1) and (b)(2) of 10 CFR Part 20.
  6. Nurses caring for brachytherapy patients will be assigned film or TLD badges. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient. Pocket dosimeters may be assigned in addition to a film or TLD badge.
  7. At the conclusion of treatment, a survey will be performed in accordance with paragraph 35.14(b)(5)(vii) of 10 CFR Part 35 to ensure that all sources other than permanent implants have been removed from the patient and that no sources remain in the patient's room or in 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. If the patient is to be discharged, the final survey will also include a notation on the patient's chart that the activity remaining in the patient meets conditions for release from the hospital.
  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. The Radiation Safety Officer should be contacted to answer 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 or TLD badge or a pocket chamber as instructed by the Radiation Safety Officer.
    - c. When a nurse is assigned 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 among 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.
    - 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 them.
- Special orders will be written for oral hygiene for patients with oral implants.
- \* Be sure to submit complete responses to Items 20a through 20f in addition to referencing procedures in Appendix L.

- 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 m) 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, (2) count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient, and (3) record a summary of the final survey results on the patient's chart. If any permanent implants are to remain in the patient, the Radiation Safety Officer will brief the patient on precautions for minimizing radiation exposure to others after discharge from the hospital.



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

Patient's Name: \_\_\_\_\_

Room Number: \_\_\_\_\_ Physician's Name: \_\_\_\_\_

Isotope and 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 or TLD badge.
- \_\_\_\_\_ 2. Wear pocket chambers for supplementary personnel monitoring of individual tasks.
- \_\_\_\_\_ 3. Wear rubber gloves.
- \_\_\_\_\_ 4. Tag the following objects and fill out the tag:
 

\_\_\_\_\_ door    \_\_\_\_\_ chart  
 \_\_\_\_\_ bed    \_\_\_\_\_ wrist
- \_\_\_\_\_ 5. Place laundry in linen bag and save.
- \_\_\_\_\_ 6. Housekeeping may not enter the room.
- \_\_\_\_\_ 7. Visiting time permitted: \_\_\_\_\_
- \_\_\_\_\_ 8. Visitors must remain \_\_\_\_\_ from patient.
- \_\_\_\_\_ 9. Patient may not leave the room.
- \_\_\_\_\_ 10. Patient may not have visitors.
- \_\_\_\_\_ 11. Patient may not have pregnant visitors.
- \_\_\_\_\_ 12. Patient may not have visitors under 18 years of age.
- \_\_\_\_\_ 13. Patient must have a private room.
- \_\_\_\_\_ 14. A dismissal survey must be performed before the patient is discharged.

- \_\_\_\_\_ 15. All items must remain in the room until approved for disposal by the Radiation Safety Officer or his designee.
- \_\_\_\_\_ 16. Contact the Radiation Safety Office when temporary sources (nonpermanent implants) are removed to perform a survey to be sure all sources are removed from the patient, to do a physical source count, and to be sure no sources remain in the room.
- \_\_\_\_\_ 17. Contact the Radiation Safety Office when the patient is discharged to survey the room prior to its assignment to another patient.
- \_\_\_\_\_ 18. Other instructions.

RSO

Name

On-duty/Off-duty Telephone Numbers

## APPENDIX M

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

The following information should be submitted in support of requests to use Xe-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 Xe-133. A diagram such as that in Figure M-1 is acceptable. Include in the diagram the availability of shielding materials and the proximity to unrestricted areas.
- b. Describe the ventilation in all areas where Xe-133 is used and stored. (Ventilation features should also be indicated on a diagram such as that in Figure M-1.) 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. Describe any changes in flow rates that may exist between heating and cooling seasons.
- c. All areas where xenon is used should be under negative pressure. State the type and frequency (at least semiannually) of periodic measurements that you will make to determine that airflow rates are maintained as described in Item 2b.

#### 3. Procedures for Routine Use

- a. Describe the procedures to be followed for routine use of Xe-133, giving particular attention to radiological safety factors.
- b. If you plan to use a special apparatus for administration and collection of Xe-133, specify the manufacturer's name and model number and include a description of its design characteristics. (Inclusion of a brochure would be helpful.)

#### 4. Emergency Procedures

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

#### 5. Air Concentrations of Xe-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  $1 \times 10^{-5} \mu\text{Ci/ml}$ .

You may evaluate your situation by making actual measurements of Xe-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 Xe-133 will be released into the room from the storage and administration devices, rebreathing apparatus, collection systems, and escape from the patient. All sources of loss must be considered when estimating the fraction of Xe-133 that is lost.

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

- a. Estimate the maximum amount of activity to be used per week (A).
- b. Estimate the fraction of Xe-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 Xe-133 (V).
- d. For restricted areas, § 20.103 of 10 CFR Part 20 requires that

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

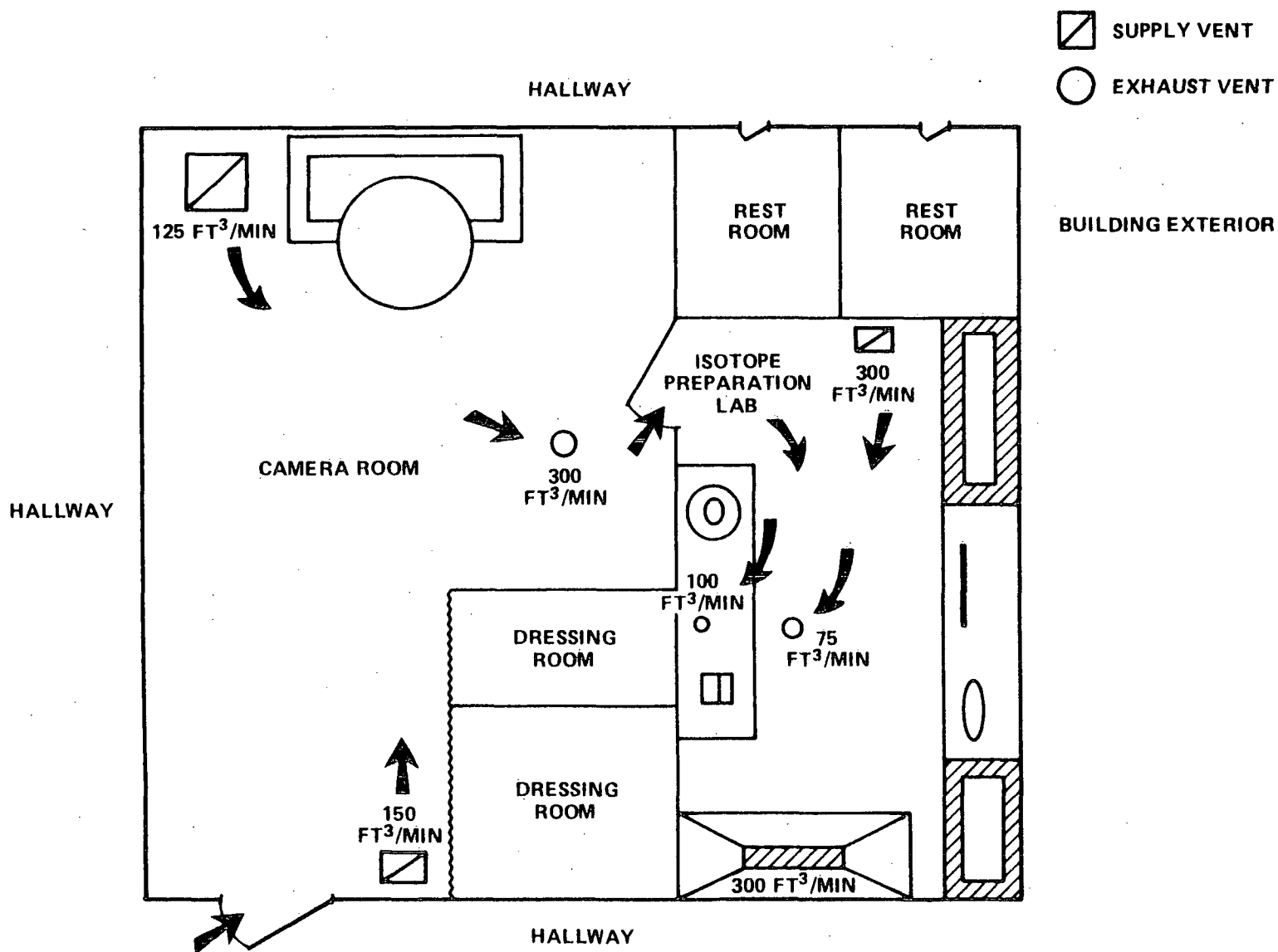


FIGURE M-1

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

e. Sample Problem

A nuclear medicine laboratory plans to use 10 mCi Xe-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 percent (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 ft<sup>3</sup>/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 Xe-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 Xe-133 that can be released per week without exceeding the permissible levels for Xe-133 in restricted areas.

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

6. Air Concentrations of Xe-133 in Unrestricted Areas

- a. Disposal of Xe-133 by Dilution through Exhaust Systems (less desirable).

One method for disposal of Xe-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 Xe-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 Xe-133 in effluents to unrestricted areas.

- (1) Estimate the maximum amount of Xe-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 Xe-133 and has a measured airflow of 168 ft/min with an opening of 8 ft<sup>2</sup>. What is the average concentration of Xe-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.)

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

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

$$V = 168 \frac{\text{ft}}{\text{min}} \times 8 \text{ ft}^2 \times 1.49$$

$$\times 10^{10} \frac{\text{ml/yr}}{\text{ft}^3/\text{min}}$$

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

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

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

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

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

<i>Exhaust Rate (ft<sup>3</sup>/min)</i>	<i>Average Release of Xe-133 per Week (mCi)</i>
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, you should also describe the physical controls you use to restrict access to the restricted area; the number, wording, size, and location of warning signs placed in the vicinity of the restricted area; your program for ensuring that personnel entering the restricted area receive proper instruction in accordance with § 19.12 of 10 CFR Part 19; your program for ensuring that personnel entering the restricted area are monitored in accordance with § 20.202 of 10 CFR Part 20; and the surveys you

will perform in accordance with § 20.201 of 10 CFR Part 20.

#### b. Adsorption of Xe-133 onto Charcoal Traps

This is the disposal method of choice. The advantage of this disposal method is that Xe-133 is trapped onto charcoal or other adsorbing medium. Filters containing Xe-133 are then stored for decay.

One difficulty with this approach is that charcoal is not 100 percent efficient for trapping Xe-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. Exhaust from trapping devices and from areas of use and storage may be vented to the outdoors or other unrestricted areas. Submit calculations to show that air concentrations of Xe-133, averaged over 1 year, do not exceed  $3 \times 10^{-7} \mu\text{Ci/ml}$ . (See example in Item 6a.)
- (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. Where adequate, manufacturer's instructions relevant to trap testing may be incorporated in the application.
- (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 Xe-133 in air. (See example in Item 5e.)

#### USEFUL CONVERSIONS

1 mCi	= $10^3 \mu\text{Ci}$
1 ft <sup>3</sup>	= $2.832 \times 10^{-2} \text{ m}^3 = 2.832 \times 10^4 \text{ ml}$
1 ft <sup>3</sup> /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

## APPENDIX N

### GUIDANCE ON REQUESTS FOR LICENSE AMENDMENTS AND LICENSE TERMINATIONS

#### 1. License Amendment Requests

License amendment requests should be prepared in three copies, one to be retained by the applicant and two to be submitted to the NRC. They should be filled out on Form NRC-313M, should be signed by an authorized representative of management (e.g., the hospital administrator), and should be dated. The appropriate fee (see 10 CFR Part 170, "Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended") must also be enclosed with the amendment request. Review of an amendment request will not begin until the appropriate fee has been paid.

##### a. To add a new user (see Items 4 and 8 of Form NRC-313M and Appendix A to this guide)

- (1) Provide detailed information requested in Items 4 and 8 to show that (a) the new physician-user is licensed to dispense drugs in the practice of medicine (see paragraph 35.3(b) of 10 CFR Part 35), and (b) his/her training and experience meet or exceed the criteria in Appendix A, or
- (2) State the AEC/NRC license number on which the new user was specifically named as an authorized user, or
- (3) Submit a copy of the Agreement State license on which the new user was specifically named as an authorized user.

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

- (1) Provide the information in 1a(1) through (3) above (specific training and experience criteria are found in Section 2 of Appendix A), or
- (2) Submit evidence of licensure (see paragraph 35.3(b) of 10 CFR Part 35) and evidence of certification by (a) the American Board of Nuclear Medicine, or (b) the American Board of Radiology, in Diagnostic Radiology with Special Competence in Nuclear Radiology and year of certification.

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

Provide the information in 1a(1) through (3) above (specific training and experience criteria are found in Section 4 of Appendix A).

##### d. To add a user for Group VI\*

- (1) Provide the information in 1a(1) through (3) above (specific training and experience criteria are found in Section 5 of Appendix A), or
- (2) Submit evidence of licensure (see paragraph 35.3(b) of 10 CFR Part 35) and evidence of certification by one of the medical specialty boards listed in the Note in Section 5 of Appendix A.

##### e. To add a user for Sr-90 eye applicator.

- (1) Provide the information in 1a(1) through (3) above (specific training and experience criteria are found in Section 6 of Appendix A), or
- (2) Submit evidence of licensure (see paragraph 35.3(b) of 10 CFR Part 35) and evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology and the year of certification.

##### f. To add Group III\*

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

- (1) High-level survey meter capable of reading up to 1 R/hr.
  - (a) Manufacturer's name and model number.
  - (b) The frequency, procedures, and standards used to calibrate the high-level survey meter (see Item 10 and Appendix D, Section 1).
- (2) Room diagram showing location of generator, kit preparation, patient dose preparation areas, etc., with special attention paid to shielding (see Item 11).

\* See Section 35.100 of 10 CFR Part 35.

- (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.
  - (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.
- g. To add Groups IV and V\*† (Group V may be added to institutional licenses only)

Provide detailed responses to Items 19a and 19b of Form NRC-313M. In lieu of submitting a detailed response to Item 19a, you may state that you will follow the procedures in Appendix K.

- h. To add Group VI\*†† to an institutional license

Provide detailed responses to Items 20a through 20g of this guide. In lieu of submitting a detailed response to Item 20g, you may state that you will follow the procedures in Appendix L.

- i. To add Xe-133

Provide the information requested in Item 21, as described in detail in Appendix M.

- j. To move Nuclear Medicine Department

- (1) Provide diagram of new areas (see Item 11 of this guide).

\* See Section 35.100 of 10 CFR Part 35.

† 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 also 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) If you are currently authorized to use Xe-133 and you wish to continue, include the information in Item 21 and in Appendix M to describe the new facilities and equipment, the new location and ventilation, and calculations pertaining to air concentrations in restricted and unrestricted areas.
- (3) Provide survey showing that all previously occupied areas are free of contamination and all sources have been removed. A decontamination guide is available from the Material Licensing Branch.

## 2. License Termination Requests

- a. Submit a signed Form NRC-314 indicating the disposition of the radioactive material. Form NRC-314 is available from the Material Licensing Branch.
- b. Submit survey showing that all previously occupied areas are free of contamination and all sources of radioactive material have been removed. A decontamination guide is available from the Material Licensing Branch.

## 3. Actions Not Requiring Amendments

- a. To add naturally occurring or accelerator-produced radionuclides (e.g., Ra-226, Co-57, Ga-67, Tl-201). NRC has no authority over these materials. However, most States do regulate the possession and use of these materials. The radiation control program of the State (and locality, where applicable) should be contacted regarding its requirements.
- b. To add use of particular radiopharmaceutical(s) for participation in a manufacturer-sponsored IND. This use is already covered in §35.100 of 10 CFR Part 35, provided the licensee obtains the radiopharmaceutical(s) from a company authorized by NRC or by 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 paragraph 35.14(d), provided the licensee obtains them from a company authorized by NRC or by an Agreement State to distribute them to NRC's group medical licensees.



## APPENDIX O

### MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

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(Licensee's Name)

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(Date)

#### 1. Management Commitment

- a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)<sup>1</sup> and a Radiation Safety Officer (RSO).
- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

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<sup>1</sup> Private practice physician licenses do not include an RSC.

#### 2. Radiation Safety Committee (RSC)<sup>2</sup>

- a. Review of Proposed Users and Uses
  - (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
  - (2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.
  - (3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).
- b. Delegation of Authority

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

  - (1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
  - (2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

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<sup>2</sup> The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2.

c. Review of ALARA Program

- (1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- (2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).<sup>3</sup>
- (3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

- (1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
- (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.
- (3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

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

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

c. Cooperative Efforts for Development of ALARA Procedures

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

- (1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

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

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

- (1) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.
- (2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision

- (1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.
- (2) The authorized user will ensure that persons under his/her supervision who are

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<sup>3</sup>The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations.

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

## 5. Persons Who Receive Occupational Radiation Exposure

- a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.
- b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

## 6. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table O-1 below. These levels apply to the exposure of individual workers.

Table O-1

*Investigational Levels  
(mrems per calendar quarter)*

	<i>Level I</i>	<i>Level II</i>
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

\* Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

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

- a. Quarterly exposure of individuals to less than Investigational Level I.

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

- b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

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

- c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

- d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table O-1.

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

The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. **Signature of Certifying Official<sup>4</sup>**

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

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<sup>4</sup>The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensed physician.

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Signature

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Name (print or type)

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Title

Institution (or Private Practice) Name and Address:

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## APPENDIX P

### BIBLIOGRAPHY

#### Title 10, Code of Federal Regulations<sup>1</sup>

- Part 19 - Notices, Instructions, and Reports to Workers: Inspections
- Part 20 - Standards for Protection Against Radiation
- Part 21 - Reporting of Defects and Noncompliance
- Part 30 - Rules of General Applicability to Domestic Licensing of Byproduct Material
- Part 31 - General Domestic Licenses for Byproduct Material
- Part 32 - Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material
- Part 33 - Specific Domestic Licenses of Broad Scope for Byproduct Material
- Part 35 - Human Uses of Byproduct Material
- Part 40 - Domestic Licensing of Source Material
- Part 70 - Domestic Licensing of Special Nuclear Material
- Part 71 - Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions
- Part 170 - Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended

#### Regulatory Guides

Regulatory Guide 8.4, "Direct-Reading and Indirect-Reading Pocket Dosimeters."

Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable."

Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure."

Regulatory Guide 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable."

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

Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions."

Regulatory Guide 10.2, "Guidance to Academic Institutions Applying for Specific Byproduct Material Licenses of Limited Scope."

Regulatory Guide 10.5, "Guide for the Preparation of Applications for Type A Licenses of Broad Scope for Byproduct Material."

#### Other NRC Publications

NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Is Reasonably Achievable," Office of Standards Development, USNRC, Washington, D.C. 20555.

NUREG-0339, "Draft Licensing Guide for Teletherapy Programs," Office of Nuclear Material Safety and Safeguards, USNRC, Washington, D.C. 20555.

#### Technical Reports

International Atomic Energy Agency (IAEA)<sup>2</sup> Technical Report Series No. 120, "Monitoring of Radioactive Contamination on Surfaces," 1970.

IAEA Technical Report Series No. 133, "Handbook on Calibration of Radiation Protection Monitoring Instruments," 1971.

International Commission on Radiological Protection (ICRP)<sup>3</sup> Report No. 12, "General Principles of Monitoring for Radiation Protection of Workers," Pergamon Press, 1969.

International Commission on Radiation Units and Measurements (ICRU)<sup>4</sup> Report No. 12, "Certification of Standardized Radioactive Sources," September 12, 1968.

National Council on Radiation Protection and Measurements (NCRP)<sup>5</sup> Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," 1970.

NCRP Report No. 48, "Radiation Protection for Medical and Allied Health Personnel," issued August 1, 1976.

NCRP Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection," 1978.

<sup>2</sup>IAEA (International Atomic Energy Agency) reports may be obtained from UNIPUB, Inc., P.O. Box 433, New York, N.Y. 10016.

<sup>3</sup>ICRP (International Commission on Radiological Protection) reports may be obtained from Pergamon Press, Maxwell House, Fairview Park, Elmsford, N.Y. 10523.

<sup>4</sup>ICRU (International Commission on Radiation Units and Measurements) reports may be obtained from ICRU Publications, P.O. Box 30165, Washington, D.C. 20014.

<sup>5</sup>NCRP (National Council on Radiation Protection and Measurements) reports may be obtained from NCRP Publications, P.O. Box 4867, Washington, D.C. 20014.

<sup>1</sup>Title 10 of the Code of Federal Regulations is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

NCRP Report No. 58, "A Handbook of Radioactivity Measurement Procedures," 1978.

#### Standards

ANSI<sup>6</sup> N13.2-1969, "Administrative Practices in Radiation Monitoring (A Guide for Management)."

ANSI N13.4-1971, "Specification of Portable X- or Gamma Radiation Survey Instruments."

ANSI N13.5-1972, "Performance and Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation."

ANSI N13.6-1966 (R1972), "Practice for Occupational Radiation Exposure Records Systems."

ANSI N14.5-1977, "Leakage Tests on Packages for Shipment of Radioactive Materials."

ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides."

ANSI N44.1-1973, "Integrity and Test Specifications for Selected Brachytherapy Sources."

ANSI N44.2-1979, "Leak Testing Radioactive Brachytherapy Sources."

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<sup>6</sup>ANSI (American National Standards Institute) standards may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018.

ANSI N44.3-1973, "Thyroid Radioiodine Uptake Measurements Using a Neck Phantom."

ANSI N323-1978, "Radiation Protection Instrumentation Test and Calibration."

ANSI N449-1974, "Guidelines for Maintaining Cobalt-60 and Cesium-137 Teletherapy Equipment."

ANSI N449.1-1978, "Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment."

#### Other Resources

Blatz, Hanson, "Radiation Hygiene Handbook," McGraw-Hill, New York, 1959, pp 22-7.

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Steere, Norman V., Editor, *Handbook of Laboratory Safety*, chapter on "Determining Industrial Hygiene Requirements in Installations Using Radioactive Materials," pp 482-502; also "Basic Units of Radiation Measurement," pp 391-426. CRC Press, Inc., 2000 N.W. 24th Street, Boca Raton, Florida 33431, 1970.

Wang, Yen, Editor, *Handbook of Radioactive Nuclides*, Part VIII, "Radiation Protection and Regulation," pp 573-831, CRC Press, Inc., 2000 N.W. 24th Street, Boca Raton, Florida 33431, 1969.

# EXHIBIT A

<b>FORM NRC-313M</b> (8-78) 10 CFR 35	<b>U.S. NUCLEAR REGULATORY COMMISSION</b> <b>APPLICATION FOR MATERIALS LICENSE – MEDICAL</b>	Approved: GAO R0557																																												
<b>INSTRUCTIONS</b> – 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 Licensee 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.																																														
<b>1.a. NAME AND MAILING ADDRESS OF APPLICANT</b> (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE   TELEPHONE NO.: AREA CODE (    )		<b>1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED</b> (If different from 1.a.) INCLUDE ZIP CODE   																																												
<b>2. PERSON TO CONTACT REGARDING THIS APPLICATION</b>   TELEPHONE NO.: AREA CODE (    )	<b>3. THIS IS AN APPLICATION FOR:</b> (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. _____																																													
<b>4. INDIVIDUAL USERS</b> (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)	<b>5. RADIATION SAFETY OFFICER (RSO)</b> (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)																																													
<b>6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE</b>																																														
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<b>6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a.</b> (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.)																																														
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### 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: \_\_\_\_\_

<b>7. MEDICAL ISOTOPES COMMITTEE</b>	<b>15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)</b>
<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	<b>16. EMERGENCY PROCEDURES (Check One)</b>
<b>8. TRAINING AND EXPERIENCE</b>	<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.	<b>17. AREA SURVEY PROCEDURES (Check One)</b>
<b>9. INSTRUMENTATION (Check One)</b>	<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	<b>18. WASTE DISPOSAL (Check One)</b>
<b>10. CALIBRATION OF INSTRUMENTS</b>	<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	<b>19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)</b>
<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
<b>11. FACILITIES AND EQUIPMENT</b>	<b>20. THERAPEUTIC USE OF SEALED SOURCES</b>
<input type="checkbox"/> Description and Diagram Attached	<input type="checkbox"/> Detailed Information Attached; and
<b>12. PERSONNEL TRAINING PROGRAM</b>	<input type="checkbox"/> Appendix L Procedures Followed; or _____ (Check One)
<input type="checkbox"/> Description of Training Attached	<input type="checkbox"/> Equivalent Procedures Attached
<b>13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL</b>	<b>21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)</b>
<input type="checkbox"/> Detailed Information Attached	<input type="checkbox"/> Detailed Information Attached
<b>14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)</b>	<b>22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS</b>
<input type="checkbox"/> Appendix F Procedures Followed; or	<input type="checkbox"/> Detailed Information Attached
<input type="checkbox"/> Equivalent Procedures Attached	<b>23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b</b>
	<input type="checkbox"/> Detailed Information Attached



24. PERSONNEL MONITORING DEVICES					
TYPE <i>(Check appropriate box)</i>			SUPPLIER	EXCHANGE FREQUENCY	
a. WHOLE BODY	<input type="checkbox"/>	FILM			
	<input type="checkbox"/>	TLD			
	<input type="checkbox"/>	OTHER <i>(Specify)</i>			
b. FINGER	<input type="checkbox"/>	FILM			
	<input type="checkbox"/>	TLD			
	<input type="checkbox"/>	OTHER <i>(Specify)</i>			
c. WRIST	<input type="checkbox"/>	FILM			
	<input type="checkbox"/>	TLD			
	<input type="checkbox"/>	OTHER <i>(Specify)</i>			
d. OTHER <i>(Specify)</i>					
<b>25. FOR PRIVATE PRACTICE APPLICANTS ONLY</b>					
a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL					
NAME OF HOSPITAL			b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.  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	ZIP CODE			
<b>26. CERTIFICATE</b> <i>(This item must be completed by applicant)</i>					
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 <i>(See Section 170.31, 10 CFR 170).</i>			b. APPLICANT OR CERTIFYING OFFICIAL <i>(Signature)</i>		
			(1) NAME <i>(Type of Print)</i>		
(1) LICENSE FEE CATEGORY:			(2) TITLE		
(2) LICENSE FEE ENCLOSED: \$ _____			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**

FULL NAME

STREET ADDRESS

CITY

STATE

ZIP CODE

**KEY TO COLUMN C**

**PERSONAL PARTICIPATION SHOULD CONSIST OF:**

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

**2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN**

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
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	CONDITIONS DIAGNOSED OR TREATED	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION	COMMENTS <i>(Additional information or comments may be submitted in duplicate on separate sheets.)</i>
A	B	C	D
P-32 <i>(Soluble)</i>	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 <i>(Colloidal)</i>	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
	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