

VETERANS ADMINISTRATION MEDICAL CENTER
50 Irving Street, N.W.
Washington, DC 20422

MEDICAL CENTER POLICY MEMORANDUM NO. 11-19

August 9, 1985

PURPOSE	1
POLICY	2
RESPONSIBILITY	3
PROCEDURE	4
REFERENCE	5
RESCISSION	6

RADIATION SAFETY GUIDE FOR RADIOISOTOPE USE

1. PURPOSE: To establish a policy for radiation safety for radioisotope use.
2. POLICY: The attached Medical Center Radiation Safety practices and procedures conform to VA and Nuclear Regulatory Commission rules, regulations and guidelines.
3. RESPONSIBILITY: The Radioisotope and Radioactive Drug Research Committee has supervisory responsibility for the Radiation Safety Program. The Radiation Safety Officer has the responsibility for management of the Radiation Safety Program. Individual responsibilities are described in the text of the guide.
4. PROCEDURE: The attached publication is divided into four sections:
 - Section I: Administrative Procedures
 - Section II: Rules and Regulations
 - Section III: Special Instructions
 - Section IV: Appendices
5. REFERENCE: M-2, Part XX, Medical Center Policy Memorandum Nos. 151-2, 115-1, and 11-34, DM&S Circular 10-80-253; Title 10, CFR, Parts 19 and 20. NRC Regulatory Guide 10.8, Rev 1.
6. RESCISSION: Medical Center Policy Memorandum No. 11-19 dated November 1, 1981

8510240018 850930
REG1 LIC70
SNM-1605 PDR

A. A. Gavazzi
A. A. GAVAZZI
Medical Center Director

Distr: S
100 copies to 11

FOREWARD

Radiation safety is dedicated to the philosophy that all exposure to radiation should be as low as is reasonably achievable for all personnel.

The use of radioisotopes in clinical medicine and research has increased at this medical center in the past years. In view of this expanding field, it is appropriate to issue a general guide on the necessary precautions and regulations in the safe handling of radioactive materials.

The scope of this guide is necessarily broad. It contains information for all personnel whether their contact with radioactive emanations is only a casual one or actually involves the direct use of radioisotopes. Such contact may apply to the staff physician, nurse, research investigator, medical student and technician, housekeeping personnel, etc. All should have a proper understanding of the pertinent information which relates to his/her own field of activity.

Under a hybrid broad license issued by the Nuclear Regulatory Commission (NRC), Title 10, CFR Chapter 1, Parts 19, 20, 21, 30, 32, 33, 35 and 60, are considered to be an integral part of this guide, and must be adhered to by users of radioactive materials within this medical center. To insure that all requirements of the broad license are being followed, the medical center is subject to periodic inspections by the Inspection and Enforcement Division of the NRC. These inspections are very thorough and include monitoring checks of the laboratory areas, inspection of procurement and disposition records, and a review of the qualifications of individual users. Violations of license requirements can result in the loss of our broad license. Thus, it is clearly imperative for all personnel to comply with the precepts and instructions contained in this guide.

This guide is divided into four sections. Section I details the administrative procedures for radioisotope licensing and the procedures for ordering, use and disposal of radioactive materials. Section II lists the rules and regulations for the safe use of radioisotopes at this medical center. Section III is a compilation of special procedure instructions for nursing personnel and general instructions that apply to the support services of this medical center. Section IV contains the appendices.

SECTION I
ADMINISTRATIVE PROCEDURES

A. Radioisotope and Radioactive Drug Research Committee (RI&RDRC) . This committee is established as the administrative body responsible for the safe use of radioactive materials within the medical center and has the following responsibilities and authority:

1. Review and grant permission for, or disapprove, all proposals for research, diagnostic, and therapeutic uses of radioisotopes in human subjects, animals, and in-vitro laboratory procedures.
2. Establish policy regarding the safe use of radioisotopes.
3. Assure the observance of all safety standards established by the NRC and this medical center.
4. Assure that any investigator who uses radioactive isotopes is qualified by training and experience, has the facilities to handle the materials safely, and proposes a use which is safe to all concerned.
5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays and physical examinations of users, minimum level of training and experience of users, etc.
6. Provide technical advice to the radioisotope users and to the Radiation Safety Office.
7. Receive and review records and reports from the Radiation Safety Office concerning health and safety practices in this medical center.
8. Periodically review the overall use of radioisotopes in the medical center.
9. Review all instances of alleged infraction of usages and /or safety procedures with the Radiation Safety Office and recommend appropriate remedial action.
10. To suspend or terminate any project or procedure which it finds to be a threat to health or property.

The RI&RDRC functions under the following administrative procedures:

1. The full committee meets routinely on the first Friday of the second month of the calendar quarter. The regular schedule is supplemented by additional meetings as required by specific problems that relate to the use of radioisotopes.
2. A majority of the committee members must be present before the meeting is called to order. The approval of the majority of the members must be obtained to approve an application for radioisotope use.

3. The minutes of the meetings are recorded by the Radiation Safety Office and copies are sent to: members; the Medical Center Director through the Chief of Staff, the HSRO Coordinator, and the AA/COS for Research and Development for distribution to the R&D Committee members.

B. Radiation Safety Office.

This office is established to assure compliance with all applicable NRC regulations and medical center policy through personal inspection of all laboratories utilizing radioactive materials. The office has the following responsibilities:

1. Insure that all laboratories and personnel involved with the use of radioactive materials are operating within the prescribed rules and regulations of the medical center and NRC.

2. Assist individual users of radioisotopes in the development of safety procedures and periodically checking to see that approved procedures are being used.

3. Report all instances of non-compliance to the RI&RDRC for their review and action.

4. Perform periodic radiation surveys and wipe tests as required for radiation safety.

The Radiation Safety Officer (RSO) has the authority to:

1. Enter any laboratory where radioactive materials are being used or stored, at any time, for the purpose of conducting radiological surveys, records inspections, or for observing laboratory procedures.

2. Suspend, pending RI&RDRC review, any project or procedure which is believed to be a threat to property or to the health of the worker.

The RSO observes the following administrative procedures:

1. The RSO reports to the RI&RDRC and Medical Center Director, through the Chief of Staff, quarterly, and the HSRO Coordinator annually, on the status of the radiation safety program.

2. The RSO produces and maintains those records required to assure maintenance of radiation safety.

3. The RSO develops, for review and approval by the RI&RDRC, radioisotope laboratory safety procedures and administrative procedures required to insure compliance with the dictates of this guide and NRC regulations.

4. The RSO formulates, in consultation with the RI&RDRC institutional training programs for the safe use of radioisotopes.

5. The RSO Reviews any suspended radioisotope projects or procedures with the RI&RDRC in special session.

C. Procedures and Requirements for Investigator Authorization for Radioisotope Use.

1. A separate application is required for each protocol that includes the use of radioisotopes. The RI&RDRC recognizes four basic types of applications: in-vitro laboratory, animal research, routine human use, and non-routine human use. Each requires distinct levels of training and experience and supporting information.
2. The RI&RDRC recommends that the investigator call on the RSO whenever a project involving radioisotopes is contemplated to provide an informal review of the project. The RSO can then delineate those areas that may require specific attention.
3. Upon completion, the application should be forwarded to the RSO. If the application is approved by the RI&RDRC, a radioisotope use permit will be issued to the investigator. This constitutes authorization, under the terms of the application, to procure and use radioactive materials for the purposes described in the application.
4. Each authorization will be marked with an expiration date, which will be two years after the month of approval. The investigators should apply for renewal one month before the permit expires. To apply for renewal of a current authorization, the investigator should submit a memorandum to the RSO. Requests for renewal of a permit sixty days or more after the expiration date must be accompanied by new applications.
5. If questions regarding details of an application should arise in the course of the RI&RDRC's consideration, the investigator may be invited to meet with the Committee.

D. In-Vitro Laboratory Application

1. Investigators (and their primary users) applying for this type of use must have the following qualifications:
 - a. A working knowledge of the principles and practices of radiation safety, radioactivity measurements, standardization and monitoring techniques, instrument use, biological effects of radiation, and mathematics and calculations basic to the use and measurement of radioactivity.
 - b. Experience in the use of the by-product material for the types and quantities for which the application is being made, or an equivalent experience.
2. The application must contain the following:
 - a. A copy of the protocol submitted to the R&D Committee.
 - b. A description of laboratory facilities available, including a diagram of the area where the radioisotopes will be stored and used. The diagram may be referenced if one is on file from a previous application.
 - c. The specific step-by-step procedure to be followed.

~~E.~~ Animal Research Applications

1. Investigators applying for this type of use must satisfy the preceding requirements and must also have experience or training in handling radioactive animals.
2. Applications must include the following, in addition to the information required under In-Vitro Applications:
 - a. The type of animal to be used (including weight), how it is to be cared for, and the number to be used in the study.
 - b. The isotope and amount to be given to each animal, the dose frequency and the effective half-life of the isotope in the animal.
 - c. An estimate of the exposure rate at one meter from the animal cages.
3. The application must have contemporaneous approval of the Animal Research Subcommittee.

~~F.~~ Routine Diagnostic and Therapeutic Human Use Applications

1. Diagnostic and therapeutic human use applications fall into the same category as "routine use" as defined by the NRC. A listing of acceptable routine uses is listed in the NRC Licensing Guide for Medical Programs and is available in the Radiation Safety Office. The RI&RDRC also exercises jurisdiction over those radioactive materials which are not subject to the NRC regulation.
2. Investigators applying for use of accelerator produced radioisotopes must also satisfy the requirements established in NRC regulatory guide 10.8, Appendix A. The requirements are in Appendix 1 of this policy memorandum.
3. The application must contain a description of:
 - a. The laboratory facilities.
 - b. The methods used to insure radioisotope purity, sterility and non-pyrogenicity, if the radioisotope compound is not obtained in sterile pyrogen-free form from a manufacturer who has certified its fitness for human use.
4. All such use shall be under the direct supervision of the Chief, Nuclear Medicine Service.

G. Non-Routine Diagnostic and Therapeutic Human Use Applications

1. Physicians who wish to use radioactive materials in human subjects must meet the requirements described in the NRC Licensing Guide for Medical Programs (Appendix 1) before their application is approved. The RI&RDRC also exercises jurisdiction over those radioactive materials which are not subject to NRC licensure.

2. A protocol is submitted to each member of the RI&RDRC. It must contain the following information:

a. A narrative description of the project, which shall include the title of the project, a statement of the purpose and justification for the use of radioactive materials, the methods for administering doses, and the anticipated results.

b. A reference to previous work published by the applicant or others concerning animal experimentation or human use. If no prior reference work is available and basic knowledge concerning the investigation is meager, pertinent animal studies by the investigator regarding the biological fate, excretion and toxicity data of the compound must be included.

c. The number, age, nature of disease process, and methods of patient selection for the study, together with similar data on any control subjects.

d. A confirmation that an informed consent will be obtained from patients who will participate in the study. If the study plans provide for the use of radioactive material for normal human subjects, the minimum age of the subjects must be specified and the fact that they will be fully informed of possible radiation or other hazards of such studies must be included.

e. The chemical and physical characteristics of the radioisotope (half-life, nature and energy of emission, mode of decay, etc.).

f. The estimated dose range in millicuries of the radioisotope to be used and the rationale for using the dose range selected.

g. The estimated radiation dose delivered to the subjects, based on the expected half-life of the radioisotope in various tissues of the body. (The RI&RDRC requires a clear, concise calculation of the anticipated whole body and critical organ dose in rems and a statement of the time period of the dose. The formula used for dose calculations should be clear, with all terms defined. Formulas should be referenced and the reliability of the formula should be indicated. The investigator should state all simplifying assumptions).

h. The effects of complementary or supplementary drugs on radioisotope distribution or excretion.

i. The methods used to determine the radioisotopic calibration, the methods of processing to insure chemical purity, sterility, and absence of pyrogenicity, etc., of the radioisotopic compound; if such a compound is not obtained as a precalibrated, refined, sterile and pyrogen-free radiopharmaceutical.

j. The safety precautions that will be initiated to protect the patient, other patients in the vicinity, the patient care staff and adjunct personnel.

k. A statement of the resources and facilities available to the investigator.

1. The estimated time needed to complete the study.

3. The investigator must immediately notify the Chairman of the RI&RDRC if a patient exhibits any adverse reactions to the radiopharmaceutical administered. The investigator should describe the reaction and include an interpretation of its nature and cause. The Chairman can decide whether or not the project should be continued, modified, or terminated, pending review by the entire committee.

4. Research studies involving the use of radioactive drugs in human subjects are also regulated by the Food and Drug Administration, Department of Health and Human Services. The RI&RDRC is authorized to approve the use of radioactive drugs provided the conditions listed in Title 21, CFR 370.100 are met.

5. Clinical trials intended to determine the safety and/or effectiveness of a radioactive drug are subject to the requirements of an investigation new drug protocol as defined in 21 CFR, Part 321.1, in addition to approval by the RI&RDRC.

6. All such use shall be under the direct supervision of the Chief, Nuclear Medicine Service.

H. Criteria for Approval

1. The policy of the NRC Subcommittee on Human Application is that radioactive substances should never be used in humans except when the investigation or treatment justifies the risk involved. It is the policy of this medical center to encourage the use of the most sensitive instrumentation and assay procedures available and to promote progressively better techniques, all aimed at reducing radiation doses. All research and diagnostic procedures should be designed with these policies in mind. The therapeutic uses of radiation in other than malignant diseases require sound justification.

2. As a general guide for the maximum permissible dose, we are subject to the NRC restrictions and regulations listed in Appendix 2. As much as is practical in diagnostic and experimental procedures, the RI&RDRC considers that irradiation exposure of patients should be kept within the dose limitations specified. When it is anticipated that the purposes of research or diagnosis make it necessary to exceed this dosage, the application will be required to provide complete justification.

a. The guideline for radiation exposures to patients follow the maximum permissible dose outlined for "Radiation Worker" in Appendix 2. For all normal volunteer subjects, this radiation limit is reduced by a factor of one-quarter.

b. The use of larger doses may be considered by the RI&RDRC in patients with limited life expectancy (two years or less). The applicant must justify the procedure adequately and demonstrate the importance of a definite clinical or experimental contribution which is anticipated to be achieved by the use of such doses.

c. The RI&RDRC considers carefully the following factors when evaluating the use of radioactive materials for research and diagnosis in humans:

- (1) Whole-body retention of the radioactive materials.
- (2) Accumulation in critical organ and tissues.
- (3) Size of the critical organ.
- (4) Radiosensitivity of the tissue.
- (5) Biological half-life.
- (6) Effective half-life.
- (7) Relative biological effectiveness of the emissions.
- (8) Energy of the radiation.
- (9) Accumulation of potential effects from sequentially administered radioactive materials.

3. Prior to their human administration, all isotopes are to be calibrated and tested for radiochemical purity, sterility and pyrogenicity.

4. The lot number, type and amount of and dose of a radioisotope administered to a patient will be recorded.

5. The radioactive contamination of room air and sewerage will not exceed the limits allowed by the NRC as stated in Appendix B, 10 CFR Part 20 (available from the Radiation Safety Office).

I. Procurement of Radioisotopes

1. The following procedures for procurement of radiation sources are intended to insure compliance with the terms of the broad license issued by the NRC and the regulations.

2. The Radiation Safety Office must approve, in advance, the procurement of all radioisotopes. Purchase orders for radioactive materials will be approved and packages of radioisotopes will be delivered only if the following criteria are met:

a. The user has an approved protocol for the isotope compound on file with the Radiation Safety Office.

b. The millicurie units ordered will not exceed the user's limits or the medical center's license limits.

c. The user's radioisotope inventory on file with the Radiation Safety Office is up to date.

3. The radioisotope may be requisitioned in the usual manner by completing VA Form 90-2237. The purchase order should be completed as usual, with the following exceptions:

- a. Purchase orders for radioactive materials must not include

requests for non-radioactive materials or other laboratory supplies, unless the supplies are part of a kit.

- b. Purchase orders must be clearly labeled with the words:

"RADIOISOTOPE ORDER"

c. Delivery must be specified to the Radiation Safety Office radioisotope receiving room, GD-210 (Except that Nuclear Medicine Service may have routine diagnostic isotopes delivered directly to the Service).

4. Authorized users may call the Radiation Safety Office for approval to purchase a radioisotope. The Radiation Safety Officer will give the user an authorization number. Each radioisotope purchase order must have an authorization number before the purchasing office will process the number. Volume users, such as Nuclear Medicine Service, or Hepatitis Research may request a standing authorization number to simplify the procurement process. Radiation safety audits of volume users will include a close review of user inventory and orders. The Radiation Safety Office will provide a list of standing authorizations to Supply Service.

5. All purchase orders placed by outside agencies, hospitals, universities, etc. for radioactive materials that are to be delivered to this medical center must also be approved by the radiation safety office. The radiation safety office will issue approval numbers for outside orders. Users must have an approval number from the Radiation Safety Office before placing the order.

7. The Radiation Safety Office is the official receiving point for all radioactive materials delivered to the medical center (except Nuclear Medicine Service radiopharmaceuticals). The investigator will be notified by telephone upon delivery of a radioisotope. The Radiation Safety Officer will maintain an approval log. The approval log will provide information for the disposition of packages when they are delivered.

8. The investigator must notify the RSO instead of the Shipping and Receiving Unit when radioactive material is to be shipped from the medical center. Such material will be packed by the investigator under the supervision of the RSO.

9. The ordering investigator must first notify the Radiation Safety Office when empty radioisotope containers are to be returned to the supplier. After they have been demonstrated to be free of contamination, the containers may be returned through normal channels.

10. The investigator is cautioned that the medical center license covers only those areas under VA Medical Center control.

J. Procedures for Receiving and Monitoring Packages

1. Nuclear Medicine Service is authorized to receive, inspect, and log radioisotope shipments directly. All other radioisotopes must be delivered immediately to Radiation Safety and locked in Room GD-210 for temporary storage. Nuclear Medicine Service must complete an isotope receipt report, following the procedure listed below. Nuclear Medicine Service must provide the reports to the Radiation Safety Office daily.

All other radioisotope shipments are received and are logged in upon their receipt by the radiation safety office. The date of receipt, radioisotope, compound, millicurie units of activity, manufacturer, and the ordering department are noted.

2. Each package of radioactive material will be inspected upon receipt. If paragraphs 3 or 4 below do not apply, the following tests following must be performed.

- a. Visual inspection of the package for external damage.
- b. Meter survey of the package to insure adequate shielding. Results of these tests will be recorded in the radioisotope receipt log.
- c. Inspection of the isotope container for leakage.
- d. Wipe test of the exterior of the shipping package for significant removable contamination.

3. If the package contains quantities of radioisotopes less than 100 times the quantities listed in Appendix C of 10 CFR 20, then only a visual inspection is required.

4. If the package is not exempt from required inspection, the tests specified at 10 CFR 20.205 must be performed within three hours (if received during normal working hours, or within 18 hours if received after normal working hours). These tests are:

- a. Measure and record the exposure rate at one meter from the package surface. If the reading is greater than 10 mR/hr, notify the carrier and the NRC Regional Office (10 CFR 20, Appendix D).

- b. Measure and record the surface exposure rate. If the reading is greater than 200 mR/hr, notify the carrier and the NRC.

- c. Wipe a 100 square cm area with a dry wipe. If the assay indicates greater than 0.01 microcurie (22,000 DPM) of removable contamination, notify the carrier and the NRC.

K. Radioisotope Inventory

1. Under the provisions of the broad license issued to this medical center by the NRC, we are limited to certain millicurie amounts of radioactive materials than ~~can be~~ in our possession at any one time. The NRC also requires us to maintain detailed reports of the receipt, transfer, and disposal of all radioisotopes in this medical center.

2. Each authorized user has a maximum authorized inventory for each species authorized. These limits are determined by current radioisotope inventory and by the needs of each user, as indicated by the radioisotope project protocols on file with the RSU. The limits will be set by the RI&RDRC and will be reviewed periodically. Temporary increases in the permitted limits may be obtained through the Radiation Safety Office provided there is adequate justification for the increase. All such requests will be reviewed at the next RI&RDRC meeting.

3. A log of radioisotope use must be maintained by each authorized user. A summary report of this log must be sent to the Radiation Safety Office at the end of each month. The total millicurie amount of each radioisotope in the laboratory must be listed. This report may be combined with the monthly wipe test report that each user must provide to the Radiation Safety Office.

4. It should be noted that many isotopes have a short half-life. The inventory sheets should be adjusted accordingly to account for this.

5. All inventory lists and records shall be made available to RSO on request.

L. Interdepartmental Transfer of Radioactive Materials

1. A User must not transfer radioactive material to any other user without prior approval of the Radiation Safety Office. Authorized users must control access to their radioisotopes and must account for all receipts (Do not provide radioisotopes to researchers unless they have been authorized by the RI&RDRC).

2. A record of the transfer of any radioisotope to another authorized user must be provided to the radiation safety office.

M. Radioactive Waste Packaging Instructions

1. Do not package non-radioactive waste such as left-over cold reagents, boxes, disposable test-tube racks, etc. Obliterate all trefoils by removal or by marking with a pen or china pencil.

2. Dry waste has no visible liquid. Examples are disposable gowns, gloves, counter-top paper, glassware, dry titer plates, etc. Do not include any vial, tube, reagent bottle, etc., which has any visible liquid. Package the dry waste in small, clear plastic bags so that the total content of each bag can be inspected prior to disposal. While in use, the bags should be in a container with a tight fitting lid. If several bags will be brought to the waste room at one time, put them in a cardboard box to avoid spillage in transit.

3. Liquid waste of neutral pH which presents no known environmental hazards (carcinogens, heavy metals, infectious agents, and flammables to present environmental hazards) and which is readily soluble in water may be discarded in a posted lab sink. Do not discard more than 100 uCi in one day. Log the date, isotope, activity, and your initials.

4. Liquid waste, other than LSCW, which cannot be discarded in a posted lab sink can be absorbed in half-gallon plastic containers available from the Radiation Safety Office. The container should be tightly capped during storage. Do not put more than 500 cc liquid in one container. There must be absolutely no visible standing liquid when finished. Label with date, isotope, estimated activity in mCi or uCi, department, and your name.

5. The medical center is recycling liquid scintillation vials. It is the user's responsibility to empty and air dry vials and caps and then transport them to the Radiation Safety Office for storage. The vials and caps will be washed and dried by Research Central Glassware personnel. They may be stored in GD-213 until needed. Bulk liquid scintillation cocktail must be brought to GD-213 in the original delivery bottles. The bottles will be shipped to a recovery center. Do not mix high activity waste with scintillation cocktail waste (LSCW). LSCW is counted and disposed of as non-radioactive waste. Users who contaminate LSCW waste may be billed directly for its disposal and may have their permits suspended.

6. The proper method for carcass disposal depends on the isotope, total activity administered, and biodistribution. Carcasses with less than 0.05 μCi of ^3H or ^{14}C per gram animal weight are not regulated and may be disposed of without regard to their radioactivity, provided however that tissue may not be disposed of under this exemption in a manner that would permit its use as food for humans or as animal feed. Carcasses with other radioisotopes or higher concentrations are either incinerated here or transferred to a disposal agent. Consultation with the RSO prior to initiation of work is required to determine the appropriate disposal method.

SECTION II
RULES AND REGULATIONS

A. Individual Responsibilities: (bench workers; chemists; technicians; technologists; and laboratory assistants) Each individual in the medical center who uses radioactive materials is obligated to comply with medical center policy and good radiation safety procedures. Users must take precautions to protect themselves, other employees, and members of the public from unnecessary exposure to ionizing radiation.

B. Investigator Responsibility: (Authorized User)

Investigators who use radioisotopes are responsible for the immediate supervision of employees under their control, who work with radioisotopes. Investigators must assure that their employees have adequate training and experience for the types and amounts of licensed material used in their laboratories. Investigators must assure that their employees comply with NRC regulations and medical center policy regarding the safe use of radioisotopes. Investigators must assure that their permit records are kept in accordance with medical center policy (records of receipts, use, disposal, and all required surveys). The following guidance is provided to help investigators assume their responsibilities.

1. Plan your experiments and determine the quantities of radioisotopes that you will use. Review the type of radiation involved to assure that you have adequate protection. If you believe you need better protection, consult with the Radiation Safety Officer.
2. Define the procedure, then perform the process without a radioisotope to assure that the plan is workable.
3. Instruct your subordinates in the use of safe techniques and in the application of approved radiation safety practices.
4. Furnish the Radiation Safety Office with information concerning individuals and activities in their areas, particularly pertinent changes in their personnel rosters.
5. Contact the Radiation Safety Office whenever major changes in operational procedures, alterations in physical plant, or when you anticipate new operations which might lead to personnel exposure.
6. Be familiar with your permit and this radiation safety guide.
7. Obtain radioactive materials by authorized purchase or by a transfer approved by the RSO.
8. Post radiation areas and assure that each sign carries the name of the person currently responsible for the radiation area.
9. Account for the amounts and disposition of radioactive materials under your control.
10. Assure that all radioactive waste materials are consigned to

the Radiation Safety Office for disposal.

11. Prevent transfer of radioactive materials to unauthorized individuals.

C. Regulations for the Use of Radioisotopes:

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

2. Wear disposable gloves when you use radioactive material. Gloves are mandatory when you have out on your counter top or work surface:

- a. Millicurie quantities of Tritium (3H), or
- b. More than 100 microCuries of Carbon-14 (14C)
- c. More than 1 microCurie Iodine-125 (125I), except from kits distributed under 10 CFR, Part 31.11 (Exempt Kits).
- d. Any radioactive material not listed above, in quantities exceeding the quantities listed in Appendix C of 10 CFR Part 20.

3. If you use gamma emitters, monitor your hands and clothing for contamination after each procedure or before leaving the area. If you detect contamination, then wash your hands and arms and monitor again. If your laboratory coat is contaminated, then keep it in the laboratory.

4. Use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances 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 the 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. You should store personnel monitoring devices in a designated low background area when you are not using them. For further information on personnel monitoring, see Medical Center Policy Memorandum 11-34, PERSONNEL RADIATION MONITORING.

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. Work in trays on absorbent paper to prevent permanent contamination of working surfaces.

12. Survey generator, kit preparation area, and injection areas for contamination after each procedure, or at the end of the day. Decontaminate if necessary.

13. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

14. Always transport radioactive material in shielded containers (low energy beta sources are adequately shielded by most containers). All containers of radioactive liquids should be transported in secondary containers that will prevent the containers from breaking, or prevent spillage, if the container does break.

15. Immediately notify the supervisor and/or Radiation Safety Office in the event of any radiological emergency.

16. The authorized user is responsible for radioisotopic contamination will be required to provide the labor for any decontamination. The RSO will supervise decontamination procedures.

D. Radioisotopes in Experimental Animals:

The use of radioisotopes in experimental animals must be approved by Chief of the Animal Research Facility, the RI&RDRC, Animal Studies Subcommittee, and the R&D Committee.

1. The investigator is responsible for the care of the animals for the duration of the experiment and for safe use of the radioisotopes involved. The RSO or his designee is responsible for insuring that the use of radioisotope complies with rules and regulations of the NRC and this medical center. The Animal Research Facility is responsible for insuring that animals are maintained according to the American Association for Laboratory Animal Care regulations.

2. All long term in-vivo animal experiments involving the use of radioisotopes should be performed in the Animal Radioisotope Room (GD-242). Some experiments involving administration of radioisotopes to animals and subsequent sacrifice of the animal may be performed in the user's laboratory if the RI&RDRC has reviewed and specifically approved the location of the experiment. If the user does not acquire approval from the committee to perform the experiment in his laboratory (clearly indicating that he plans an in-vivo experiment), then all animals will be maintained in GD-242 for the duration of the experiment.

To assure that radioactive animals are secure, keep the door locked at all times. Animal Research Facility personnel have keys to room GD-242. All cages containing radioactive animals must bear the radiation caution sign indicating the isotope, total activity used, and date of administration. Cages may be cleaned by the conventional cage cleaning method. Any contamination from the cages will be flushed into the sewerage system by the cage cleaning process. The investigator must estimate the activity disposed of by cleaning the cages and include that estimate in his sink disposal log to assure that he can account for all of the isotope he used. The investigator will dispose of animal feces and uneaten animal food, by flushing it down a designated toilet. The investigator will flush the toilet at least three times. The investigator will account for all radioisotopes discarded into the sanitary sewerage.

3. Investigators using the animal radioisotope room must immediately notify the Radiation Safety Office and Chief, Animal Research Facility, if contamination is suspected.

4. Upon termination of the experiment, if the animals must be sacrificed, the investigator will assure that the animal carcasses are packaged properly. The appropriate packaging and disposition of carcasses is based on an estimate of the activity that each animal contains. Contact the RSO for instructions. All cages, equipment used, and the room shall be considered as contaminated. The investigator is responsible for requesting a radioisotope contamination survey. Radiation Safety personnel will monitor the area. The investigator is responsible for decontamination of the area and equipment.

5. Each unit using the facility must post names and telephone numbers on the door of room GD-242 for notification in case an emergency develops involving their animals during off-duty hours. Physical emergencies during off-duty hours will be reported by the medical center police to the supervisor, Animal Research Facility, who will notify individuals involved.

E. Policies and Procedures for Radioisotope Areas:

1. All laboratory areas where radioactive materials are used or stored must have "CAUTION RADIOACTIVE MATERIALS" conspicuously posted on the doors. The signs must not be removed from any room except by Radiation Safety Personnel following an inspection survey.

2. Containers in which materials are transported or stored must bear a durable, clearly visible label bearing the radiation caution symbol. This label must also state the quantities and kinds of radioisotopes in the containers (This does not apply to containers exempted at 10 CFR 20.203(F)(3)).

3. All equipment contaminated with radioactive material must be marked with signs, decals, or other conspicuous means.

4. Radioactive sources or stock solutions in the laboratory must be appropriately shielded. Various shielding materials should be readily available. Low energy beta emitters are shielded by their containers.

5. Procedures involving aerosols, dusts or gaseous products, or procedures which might produce airborne contamination must be conducted in a hood, dry box, or other suitable closed system. Radioactive gases must be stored in gas tight containers and must be kept in areas having approved ventilations.

6. All work areas (bench tops, hoods, etc.) as well as storage areas and areas adjacent to permanent setups and sinks should be covered at all times with stainless steel or plastic trays, uncracked glass plates, or other impervious materials. For some purposes absorbent paper will be satisfactory. However, if such paper is used, it should be discarded frequently to prevent radioactive materials from dusting off the surface.

7. Equipment once used for radioactive substances must not be used for other work or sent from the laboratory to cleaning facilities, repair shops, surplus, or returned to the source of supply, until demonstrated to be free from contamination.

8. Equipment to be repaired by shop and maintenance personnel or by commercial service contractors must be demonstrated to be free of contamination prior to servicing. If it becomes necessary to make emergency repairs on contaminated equipment, the work will be supervised by Radiation Safety personnel who will assure that necessary safeguards are taken. It is the responsibility of the laboratory personnel to request this supervision from the Radiation Safety Office.

9. Medical center vacuum lines are vulnerable to contamination. If vacuum lines are to be used, precautions must be taken to ensure that the withdrawn gas is free of radioactivity. It is most advisable to use a separate vacuum system whenever possible, or to use a vacuum pump exhausting into a hood.

10. Certain hood trays, dry boxes, stainless steel trays, or other equipment which is used frequently for radioactive work may become temporarily contaminated. All of these must be clearly marked with the standard radiation caution signs or stickers. Any contamination that is not confined to protected surfaces should be reported immediately to the Radiation Safety Office, and decontamination procedures should be started.

F. Periodic Surveys of Radioisotope Laboratories:

1. All who use millicurie amounts of radioisotopes must check their laboratory for contamination at least once daily, or on any day when a millicurie or more is used or transferred from one primary container to another. The user must record the wipe test results and keep the results. Any time you suspect contamination, perform wipe tests on the area in question. Wipe test records are inspectable, and the user must keep them

for two years. Users with authorized inventories of less than 1 millicurie, are only required to perform monthly surveys and surveys when they suspect contamination.

2. All users must must perform monthly wipe tests and report the results to the RSO. If you are an authorized user but you have not received, or used any radioisotopes during the month, you may return the form with the statement "NO USE THIS MONTH." However, you must provide an inventory report on the same form, if your inventory has not changed. The RSO will mail forms to each user. The user will complete the form and return it to the RSO by the suspense date indicated on the form.

3. The Radiation Safety Office will perform periodic wipe tests of the laboratories as a further check against contamination by radioactive materials.

4. All laboratory areas must be decontaminated when a wipe test reveals more than 2,200 DPM for each 100 square centimeter wiped. When a meter survey shows a reading of more than twice room background (with no radiation sources present), that area must be considered contaminated. A wipe test must be taken to determine the extent of contamination.

G. Spills:

1. As used here, the term "spill" applies to any incident involving the uncontrolled release of radioactive substances. Users must report any spill that involves more than a microcurie of tritium or carbon-14. If you are unsure of the quantity involved, report the spill. If you have spill a vial of scintillation cocktail with less than 0.05 microcurie of tritium or carbon-14 per milliliter no report is necessary.

2. If you have an accident (accidental spill) with radioactive material or if you discover that someone else has had an accident with radioactive material, you must notify the RSO immediately. The RSO, or his representative, will evaluate the accident to determine whether a radiological health emergency exists.

3. In case you have an accident, you should be familiar with the following emergency procedures:

a. If the contamination is airborne, hold your breath and leave the room. Close and lock the door.

b. Call the RSO at ext. 7586. If the RSO is not available, leave a message with the Nuclear Medicine Service Secretary (8390).

c. If the contamination is in a solid or liquid form, make every effort to contain the spill.

(1) Permit no one to leave the area without clean footwear. If you are anyone else must leave to avoid overexposure, then remove your shoes at the doorway and leave them in the room. You can test your shoes for contamination later, and decontaminate them, if necessary.

(2) Do not allow any personnel to enter the contaminated area until the RSO arrives. Be prepared to assist the RSO with the evaluation. You should tell the RSO the isotope and compound that you were using and the approximate activity that was spilled.*

c. Be prepared to decontaminate your laboratory. The RSO will provide guidance.

4. Removal of radioactive contaminants falls into two general categories: decontamination of "people" and decontamination of "things". Every effort should be made to control and limit the spread of contamination.

5. People are decontaminated for two reasons: (a) to prevent possible transfer to internal organs by ingestion or absorption, and (b) to prevent external exposure or possible radiation burns. In both cases prompt removal of radioisotopes will reduce the potential hazard, but methods used to effect decontamination must not spread material that was initially localized or assist the contaminant to enter the body (e.g., excessive scrubbing which abrades the skin).

a. Notify the laboratory supervisor immediately after a contamination accident. The supervisor will contact the Radiation Safety Office.

b. Wash the area thoroughly for two to three minutes repeatedly soaping and rinsing. Consideration should be given to the chemistry of the contaminant and an attempt made to find a suitable agent for removing it. Any cleansing agent may be used but synthetic detergents are preferred to soaps. Avoid prolonged use of any one decontamination procedure. Irritation of the skin may impede the success of more suitable procedures. Avoid the use of organic solvents on the skin. These may make the skin more permeable to contamination.

c. Flush well under running tap water any contaminated open cuts or wounds.

d. Remove any contaminated clothing.

e. Seek medical aid to induce vomiting if radioactive material has been ingested. Vomiting should be induced repeatedly, with ingestion of two to four glasses of lukewarm water between times.

f. Notify the RSO and proceed at once to the Medical Officer in charge of the Employee Health Unit. Special decontamination agents such as Versene, Radiacwash, etc., may be used under the direction of the Medical Officer.

g. Make a report to the Radiation Safety Office concerning the accident.

6. In case an area becomes contaminated, preparations for decontamination should be started promptly.

a. Prevent flow of liquid radioisotopes; apply absorbers, raise barriers (putty, etc).

b. Remember that all run-off solutions, mop, rags and brushes used are potentially contaminated.

c. Notify the RSO who will assist in determining the extent and hazard of contaminated.

d. Methods of decontamination:

(1) Solutions of detergents, EDTA, Radiacwash, etc., may be used to decontaminate many smooth, non-porous surfaces.

(2) Metals - oily surfaces may have to be removed first. High normality acids, concentrated acids, or aqua regia may be used if needed and if the surfaces will withstand this treatment.

(3) Concrete or brick - solutions of HCL used with commercial scrubbers.

(4) Glassware - ordinary chromic acid cleansing solution, or discard.

(5) Linoleum - if well waxed before contamination, removal of wax with solvents or scouring power and steel wool with decontaminate. It may be replaced.

(6) Wood - sand, plane, or discard.

(7) Painted surfaces - painted removers.

f. An area is considered free from radioactive contamination when a wipe test shows less than 2,200 DPM per 100 square centimeters.

H. Personnel Monitoring:

1. Film badges will be issued by the RSO (see Medical Center Policy Memorandum 11-34).

2. Persons working with Hydrogen-3, Carbon-14, or Sulphur-35 in millicurie quantities as an unsealed source may be required to submit urine samples to the Radiation Safety Office. The frequency of the bioassay will be determined by the RSO.

3. Persons working with radioiodine in millicurie quantities must have thyroid uptake studies performed on a quarterly basis. All persons involved in iodinations procedures must have thyroid uptake studies performed 24 hours after the iodination.

4. If there is a suspected accidental inhalation, ingestion, or skin puncture involving radioactive material, the RSO should be contacted immediately.

5. The Radiation Safety Office maintains permanent records of all personnel exposures on appropriate forms. Each individual's record is available for review (see Medical Center Policy Memorandum 11-34).

I. Nuclear Powered Cardiac Pacemakers:

Under a special license issued by the NRC, this medical center is authorized to implant pacemakers using Plutonium-238 as a sealed source. The Chief, Cardiology Section, will submit semi-annual reports on the status of each patient who has received a nuclear pacemaker to the Radiation Safety Office. Any malfunction, adverse reaction, or patient related problem must be reported immediately to the RSO who will determine if a report must be submitted to the NRC.

J. Radiation Therapy Cobalt-60 Unit:

1. Under a special license issued by the NRC, this medical center is authorized to treat patients using Cobalt-60 as a sealed source.

2. The Chief, Radiation Therapy Service, is responsible for the safe operation of the teletherapy unit and is responsible for notifying the Radiation Safety Office in case of a radiological emergency.

3. The Radiation Safety Office is responsible for performing wipe tests, meter surveys and other surveys and tests as may be required to assure compliance with NRC regulations.

SECTION III
SPECIAL INSTRUCTIONS

A. General Instructions to Nurses for Sealed Source Radiation Therapy

1. The patient will be put in a private room and restricted to this room for the duration for the therapy.
2. The Radiation Safety Office will indicate a "safe distance line" by a strip of tape on the floor. This line indicates those areas where the radiation is below 2 mR/hr. Generally, personnel are to remain outside this line as much as possible until the restrictions are lifted.
3. The patient may or may not be allowed to have visitors. This will depend on the radiation levels in the room. Visiting times will generally be limited to a few minutes.
4. Building Management personnel should be in the room only long enough to perform their duties.
5. The nursing staff should be alert to any sealed source which has moved from its original position. If any implant source becomes separated from the patient, the physician in charge must be notified immediately. The source must not be picked up with the hands, but by long forceps. A lead receptacle is available for temporary storage.
6. All dressing, bedclothes, sanitary napkins, bedpans, etc., or any material removed from the vicinity of the treatment site must be carefully monitored in order to assure that the source has not been removed or disturbed.
7. Pregnant women should be informed (NRC Regulatory Guide 8.13) before they are permitted to enter the patient's room.
8. In situations requiring prolonged bedside care, all staff engaged in handling the patient will be issued pocket dosimeters and readings will be monitored by a member of the Radiation Safety Office.

B. General Instructions to Nurses for Radioisotope Radiation Therapy
Above 30 mCi

1. It is the responsibility of any person involved with radioisotope procedures to minimize his exposure to radiation as much as possible. This may be accomplished by keeping as much distance and shielding between the radioactive patient and attendant personnel as possible and by spending the minimum time in the vicinity of the patient. Contamination with radioactive fluids should always be avoided by wearing rubber gloves and other suitable protective clothing when necessary.

2. Not all procedures involve the same radiation hazard. With most diagnostic isotope procedures and with some isotopes like Phosphorus-32, the radiation hazard may be very small. With some other procedures, the hazard may be considerable.
3. Amounts of radioactive materials that do not exceed certain "safe levels" are to be regarded as requiring no special precautions other than the application of the general principles in (a) above. The "safe levels" is defined as that amount of isotope delivering 1.0mR/hr or 40mR/week at a distance of one meter from the patient.
4. The Radiation Safety Office has indicated a "safe distance line" by a strip of tape on the floor. This line indicates those areas where the radiation is below 2 mR/hr. Generally, all personnel are to remain outside this line until the restrictions are lifted.
5. The patient will be in a private room with toilet facilities.
6. Ambulatory and self-care patients will take care of their own wants, collect their own specimens, etc., when possible.
7. The patient may or may not be allowed to have visitors. This will depend on the radiation levels in the room. Visiting times will generally be limited to a few minutes.
8. Urine from the patient will be disposed of via the patient's toilet. The toilet will be flushed three times per disposal. Special care in the collection and handling of urine should be noted in order to avoid contamination. The nursing staff should wear gowns and rubber gloves when handling radioactive fluids. Incontinence or spillage of urine should be prevented by suitable means.
9. Feces should be passed in the toilet when feasible. If a bedpan must be used, it must be handled with rubber gloves. The same bedpan will be used by the patient during the treatment period.
10. If an emesis occurs within the first few hours after the patient received the therapeutic dose, or if there is spillage of or contamination by urine within the room within the first few days, the area of contamination shall be restricted and the Radiation Safety Office notified for monitoring and decontamination procedures.
11. When possible, ~~linens~~, pillows coverings, etc., will be disposable. ~~Mattresses~~ should be covered with a protective rubber or plastic sheet.
12. Dressers, chairs, etc., should be covered by absorbent paper to be discarded as necessary.
13. All objects and materials coming in contact with the patient in the first few days shall remain in the room and placed in marked plastic bags to be monitored and handled by the Radiation Safety Office for disposal. Dinnerware and silverware are included.

14. During the first few days, meals will be served on disposable plates.

15. In situations requiring prolonged bedside care, all ward staff engaged in handling the patient will receive pocket dosimeters and daily readings will be recorded by the Radiation Safety Office.

16. After the patient has been discharged, a representative from the Radiation Safety Office will monitor the room, prior to reuse.

C. Laboratory Specimen Following Therapeutic Doses of Radioisotopes:

All specimens from patients under radioisotope therapy which are to be sent to a laboratory must be labeled "RADIOACTIVE." Preferably, the laboratory should be called in advance to provide additional information such as the amount of activity and special handling techniques required, if any. This includes tissue specimens ascetic fluids, blood, urine, feces, emesis, etc. EXCEPTIONS: When the time between administering the isotope and the time of obtaining the specimen is long enough, the amount of radioactivity in the specimen may no longer be a hazard from either a health or a contamination standpoint. This will require an opinion from the physician in charge or the RSO. When the radioisotope is administered in such a way that it remains localized and does not enter significantly into the general circulation (for example, colloidal gold injected into prostate), it may be unlikely that the specimen contains a significant amount of the radioisotope used.

D. Safe Handling of Bodies Containing Radioactive Materials

1. If a patient who has received a therapeutic dose of any radioisotope dies in the medical center while still under therapy precautions, the physician in charge shall follow the procedures listed below:

a. Cover the top sheet of the patient's chart with a new sheet with the word "RADIOACTIVE BODY" written on it.

b. Notify the Radiation Safety Office. During off duty hours, the Medical Administrative Officer (MAO) should be requested to notify one of the persons on the call list maintained for such emergencies.

2. Embalming Procedures

a. No special procedures are required with bodies containing less than 30 millicuries of any radioisotope provided that the embalming is done with the standard aspiration and injected methods and that the body is not opened.

b. All persons coming in contact with the body should wear rubber gloves and protective clothing to prevent contamination.

c. The Radiation Safety Office must be contacted if the body contains more than 30 millicuries of any radioisotope, as special precautions must be taken. A detailed listing of procedures is in the National Bureau of Standards Handbook 65, "Safe Handling of Bodies Containing Radioactive Isotopes (A Guide for Surgeons, Pathologists and Funeral Directors)," dated May 1965. This handbook is available in the Radiation Safety Office.

3. Autopsy Procedures

a. Procedures for autopsy will depend on the amount of radioactive material present in the body at the time of autopsy. The chart accompanying the body will include data such as the radioisotope, amount administered, and date administered. From this information, the amount of radioisotope remaining in the body may be determined from Table 1 of the handbook. The RSO will assist in needed calculations.

b. If there is less than 5 millicuries of any isotope in the body at the time of autopsy, no special precautions are required other than wearing rubber gloves and protective clothing.

c. If there is more than 5 millicuries of any radioisotope in the body, the following procedures must be followed:

(1) The RSO, or his designee, will be present during the autopsy to assure that all aspects of radiation safety are observed.

(2) The physician doing the autopsy must:

(a) Wear goggles or eye glasses.

(b) Wear double thick autopsy gloves unless the delicacy of the procedure prohibits this; then two pair of surgical gloves must be worn.

(c) Work with long handled instruments to keep the hands as far as possible from the radioactive areas.

(3) Additional special procedures will be instituted on a case-by-case basis. NBS Handbook 65 will be the reference guide for these procedures.

E. Instructions for Supply Personnel

1. The Radiation Safety Office is the official receiving point for radioactive materials packages.

a. The packing slip must remain with the package as it is needed for Radiation Safety Office records.

b. The receiving report is signed by the RSO upon receipt of the package and the paperwork is sent on to the appropriate office.

2. It is important to deliver all (except as noted below) shipments of radioisotopes to the Radiation Safety Office promptly where they can be classified, logged, and inspected. Note: Nuclear Medicine Service has been authorized to receive radioisotope deliveries. Nuclear Medicine Service follows the same procedures for package receipt as the Radiation Safety Office.

3. Shipments of radioisotopes are shielded in accordance with Department of Transportation regulations and pose a minimal hazard. The necessary handling instructions are usually listed on the package.

4. Radioisotope shipments are sent back to the supplier on occasions. These are monitored for safety by the Radiation Safety Office prior to shipping to ensure safe handling.

F. Instructions for Building Management Personnel

1. Radiation precautions signs apply to all personnel. However, this does not mean that Building Management personnel cannot enter laboratories for ordinary cleaning duties. The sign indicates that shielded radioactive materials are present and that all personnel should be aware of this fact. It further indicates that radioactive labeled bottles, reagents, etc., should not be touched or moved. Levels of radiation are frequently checked in working areas of the laboratories to be sure they are safe areas in which to clean.

2. Building Management personnel must not enter rooms occupied by patients undergoing radioisotope therapy unless authorized to do so by the nurse in charge, who will in turn be guided by the precautions listed in the patient's chart.

G. Instructions to Women of Child Bearing Age

1. Available Information: We recognize the concerns that anyone may have with regard to the possibility of exposing an unborn child to unnecessary risks. If you have questions about occupational exposure to ionizing radiation and the effect on the unborn child, you should see the Radiation Safety Officer. The Nuclear Regulatory Commission has published an informative document for employees of Licensed Facilities, entitled "Instructions Concerning Prenatal Radiation Exposure." The Radiation Safety Office will provide a copy of this publication on request.

2. Policy: The Radiation Safety Office has no additional radiation safety requirements for pregnant employees. A radiation worker who becomes pregnant may request a change of duties during the term of her pregnancy. The Radiation Safety Office encourages supervisors to understand the concerns of an employee regarding prenatal exposure.

Section IV

Appendices

- Appendix 1 Required Training and Experience for Medical Use of
Byproduct Material (From Appendix A of NRC Regulatory Guide
10.8).
- Appendix 2 Radiation Exposure Limits
- Appendix 3 Appendix C from 10 CFR 20 (Standards for Protection Against
Radiation).
- Appendix 4 For More Information

SECTION IV
APPENDICES

Appendix 1

Acceptable Training and Experience for Medical
Uses of By-product Material

1. 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 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 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 a 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 (200 hours)
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 (20 hours)
measurement of radioactivity
- (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 by-product material for which the application is being made, or equivalent experience (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 include:

(1) Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.

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

(3) Follow-up 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 specifies in Sections A, B, and C may be

satisfied concurrently in a three 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 will Special Competence in Nuclear Radiology will be accepted as evidence that a physician has had adequate training and experience to use Groups I,II,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 by-product material listed in Groups IV and/or V in Section 35.100 of 10 CFR Part 35, a physician should have:

a. Training in basic radioisotope handling techniques applicable to the use of sealed 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 IA above).

b. Clinical training in specific therapy procedures:

For Group IV

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

Clinical experience in the diagnosis of thyroid function, 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) Soluble phosphorus-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 phosphorus-32 for intracavitary treatment:

Active participation in the treatment of three patients.

2. Group V

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

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

(2) Colloidal gold-198 for intracavitary treatment:

Active participation in the treatment of three patients.

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 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 and appraisal of the applicant-physician's competency to use Group VI source 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) "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 (24 hours)

- 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.

PART 20 • STANDARDS FOR PROTECTION AGAINST RADIATION

Appendix C		Material	Microcuries	Material	Microcuries	Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition
		Americium-241	100	Osmium-191m ¹	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Antimony-122	10	Osmium-191	100	
		Antimony-124	10	Osmium-196	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Antimony-128	10	Palladium-103	100	
		Arsenic-73	100	Palladium-105	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Arsenic-74	10	Phosphorus-32	10	
		Arsenic-76	10	Platinum-191	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Arsenic-78	10	Platinum-193m	100	
		Arsenic-77	100	Platinum-195	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Barium-131	10	Platinum-197m	100	
		Barium-132	10	Platinum-197	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Barium-134	10	Plutonium-239	100	
		Barium-136	10	Polonium-210	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Bismuth-210	1	Potassium-42	10	
		Bromine-82	10	Praseodymium-142	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Cadmium-106	10	Praseodymium-143	100	
		Cadmium-115m	10	Promethium-147	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Cadmium-115	100	Promethium-148	10	
		Calcium-45	10	Radium-226	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Calcium-47	10	Rhenium-186	100	
		Carbon-14	100	Rhenium-188	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Cerium-141	100	Rhodium-103m	100	
		Cerium-143	100	Rhodium-106	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Cerium-144	1	Rubidium-86	10	
		Cesium-131	1,000	Rubidium-87	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Cesium-134m	100	Ruthenium-97	100	
		Cesium-134	1	Ruthenium-100	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Cesium-135	10	Ruthenium-102	10	
		Cesium-136	10	Ruthenium-106	1	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Cesium-137	10	Samarium-151	100	
		Chlorine-36	10	Samarium-153	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Chlorine-38	10	Scandium-44	10	
		Chromium-51	1,000	Scandium-47	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Cobalt-60m	10	Scandium-48	10	
		Cobalt-60	10	Selenium-75	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Cobalt-60	1	Silicon-31	100	
		Copper-64	100	Silver-106	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Dysprosium-165	10	Silver-110m	1	
		Dysprosium-166	100	Silver-111	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Erbium-169	100	Sodium-24	10	
		Erbium-171	100	Strontium-89	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Europtium-152 9.2 h	100	Strontium-90	1	
		Europtium-152 13 yr	1	Strontium-91	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Europtium-154	1	Strontium-92	10	
		Europtium-155	10	Sulphur-35	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Fluorine-18	1,000	Tantalum-182	10	
		Gadolinium-153	10	Technetium-96	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Gadolinium-156	100	Technetium-97m	100	
		Gallium-72	10	Technetium-97	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Germanium-71	100	Technetium-99m	100	
		Gold-198	100	Technetium-99	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Gold-199	100	Tellurium-125m	10	
		Hafnium-181	10	Tellurium-127m	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Holmium-166	100	Tellurium-127	100	
		Hydrogen-3	1,000	Tellurium-128m	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Indium-113m	100	Tellurium-129	100	
		Indium-114m	10	Tellurium-131m	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Indium-115m	100	Tellurium-132	10	
		Indium-115	10	Terbium-160	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Iodine-125	1	Thallium-200	100	
		Iodine-126	1	Thallium-201	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Iodine-129	0.1	Thallium-202	100	
		Iodine-131	1	Thallium-204	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Iodine-132	10	Thorium (natural) ¹	100	
		Iodine-133	1	Thulium-170	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Iodine-134	10	Thulium-171	10	
		Iodine-135	10	Tin-113	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Iridium-192	10	Tin-125	10	
		Iridium-194	100	Tungsten-181	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Iron-55	100	Tungsten-186	10	
		Iron-59	10	Tungsten-187	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Krypton-83	100	Uranium (natural) ²	100	
		Krypton-87	10	Uranium-233	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Lanthanum-140	10	Uranium-234	100	
		Lutetium-177	100	Uranium-235	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Manganese-52	10	Vanadium-48	10	
		Manganese-54	10	Xenon-131m	1,000	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Manganese-56	10	Xenon-133	100	
		Mercury-197m	100	Xenon-136	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Mercury-197	100	Ytterbium-175	100	
		Mercury-203	10	Yttrium-90	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Molibdenum-99	100	Yttrium-91	10	
		Neodymium-147	100	Yttrium-92	100	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Neodymium-148	100	Yttrium-93	100	
		Nickel-58	100	Zinc-65	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Nickel-63	10	Zinc-69m	100	
		Nickel-65	100	Zinc-69	1,000	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Niobium-93m	10	Zirconium-93	10	
		Niobium-95	10	Zirconium-95	10	Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition...
		Niobium-97	10	Zirconium-97	10	
		Osmium-186	10			

Note: For purposes of § 20.303, where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows. Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e., "unity").

¹ Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

² Based on alpha disintegration rate of U-238, U-235, and U-233.

* Amended 16 FR 16898.

** Amended 19 FR 23440.

Appendix 3

Radiation Exposure Limits

Exposure of individuals to radiation:

No person shall possess, use, receive or transfer sources of radioactive materials in such a manner as to cause any individual to receive a dose in excess of the following:

Type of Exposure	Rems per Calendar Quarter		Rems per Year
	Avg	Max	
Whole Body, head and trunk, active blood forming organs, gonads, lens of eye	1 1/4	3	5
Skin of whole body, thyroid	7 1/2	10	30
Hands and forearms, feet and ankles	18 3/4	25	75
Other organs	—	5	15

The total accumulated whole body dose must not exceed 5(N-18) Rems, where N = the individual's age in years at his last birthday.

Appendix 4

For More Information

The Radiation Safety Office maintains a library of health physics and radiation safety publications. The documents and publications listed below are available for review in the Radiation Safety Office:

1. The Radiation Safety Office Maintains the Medical Center License file. The License and supporting documents are available for review.

2. NRC Regulations - Title 10 Code of Federal Regulations:

Parts 19 Notices, Instructions and Reports to Employees; Inspections

20 Standards for Protection Against Radiation

21 Reporting of Defects and Noncompliance

30 Rules of General Applicability to Domestic Licensing of Byproduct Material

31 General Domestic Licenses for Byproduct Material

33 Specific Domestic Licenses of Broad Scope for Byproduct Material

35 Human Uses of Byproduct Material

70 Domestic Licensing of Special Nuclear Material

3. NRC Publications:

Various NRC publications such as regulatory guides, NUREG publications and Information Notices are available.

4. National Council on Radiation Protection (NCRP) Reports:

The National Council on Radiation Protection has published recommendations for many special areas of radiation safety. The radiation safety office maintains an extensive library of NCRP Reports.

5. Health Physics Handbook

6. Health Physics Textbooks

7. Radiological Physics regulations and publications.