NEW YORK STATE DEPARTMENT OF HEALTH

BUREAU OF ENVIRONMENTAL RADIATION PROTECTION

RADIATION GUIDE 10.1, REV. 2

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL PROGRAMS

PURPOSE OF GUIDE

This guide describes the information needed by the New York State Department of Health staff to evaluate an application for a specific license to possess and use radioactive material in or on human beings. This type of license is provided for under Sections 16.120 and 16.121 of 10 NYCRR 16, "Ionizing Radiation."

The New York State Department of Health normally issues a single radioactive materials license to cover an institution's entire radioisotope program, other than teletherapy, nuclear pacemakers and irradiators. Separate licenses are not normally issued to different departments of a medical institution, nor are they issued to individuals associated with the institution.

The applicant should carefully study the regulations and this guide, and should submit all information requested. The Department 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.

PURPOSE OF APPENDICES TO GUIDE

The regulations require that the licensee develop and implement procedures that will ensure compliance with the regulations. Appendices A through P to this guide describe model radiation safety procedures. Each applicant should carefully read the applicable regulations and model procedures and adopt them as written whenever possible. If you are unable to adopt a particular procedure as written submit a copy of the procedure in the guide with your changes indicated in red ink. You must keep copies of these procedures with the license document when it is issued since they will be made a part of the license.

APPLICABLE REGULATIONS

All regulations pertaining to this type of license are found in Title 10, Chapter 1, Part 16 of the New York Code of Rules and Regulations (10 NYCRR 16). Chapter 1 is entitled "State Sanitary Code" and Part 16 is entitled "Ionizing Radiation." The statutory authority for the rules and regulations is found in the New York State Public Health Law, Section 225.

AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

Item (a) of 10 NYCRR 16.5 requires that persons who operate or permit the operation of radiation installations shall make every effort to maintain radiation exposures and releases of radioactive material as far below the limits of Part 16 as is reasonably achievable.

1. General ALARA Considerations

Each individual who is authorized to use radioactive material should provide appropriate instruction to all individuals who work with or in the vicinity of radioactive material, and should ensure that the facility and equipment are adequate for safe use. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or Radiation Safety Officer (RSO).

FILING AN APPLICATION

A license application for specific licenses for human use should be submitted on Form GEN 307B "Application for Radioactive Materials License" and appropriate attachments. The applicant should complete all items on the application form in sufficient detail for the review staff to determine that the applicant's equipment, facilities, personnel training and qualifications, and radiation safety program are adequate to protect health and minimize danger to life and property.

For Items 5 through 25, submit the required information on supplementary pages. You should identify and key each separate sheet or document submitted with the application to the item number on the application to which it refers. All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches.

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 Bureau of Environmental Radiation Protection, New York State Department of Health, 2 University Place, Albany, New York 12203.

CONTENTS OF AN APPLICATION

The following paragraphs explain the information requested on Form GEN 307B. The item numbers correspond to the appropriate section of the form.

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 so that all correspondence to the licensee will reach persons responsible for the radiation safety program.

1.(cont.)

b. List the addresses and locations where radioactive material will be used or stored in enough detail to allow us to easily locate your facilities. 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; i.e., a post office box may be most suitable for Item 1a. in some cases, but this address does not adequately describe the location of use.

2. Enter the name and telephone number (including area code) of an individual who knows your program and can answer questions about the application. This should be a staff member and not a consultant.

3. Indicate whether this is an application for a new license, an amendment, or a renewal; and enter the license number.

4. a) State the name and title of the person designated by, and responsible to, the applicant's management for the coordination of the applicant's radiation safety program. The radiation safety officer should be a full-time employee of the licensee and must be present at least 50% of the time that radioactive materials are being handled.

b) State the name of the individual who will be the Radiation Therapy Physicist for the license if the application includes teletherapy or brachytherapy. Enter the number of hours per week the physicist will provide to your program.

5. List the names of all persons who will use, supervise, or direct the use of radioactive material. This list should include physicians and persons who will use materials for non-medical purposes.

Broad scope medical use applicants should state that they will approve individual users in accordance with the criteria in Appendix A to this Guide.

The physicians named as authorized users on radioactive material medical use licenses have the following responsibilities with regard to diagnostic and therapeutic use of radioactive materials in humans:

5. A. Making a determination that a radiation procedure is indicated;

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

C. Actual use of, or direction of technologists or other paramedical personnel in the use of, radioactive material;

D. Interpretation of results of diagnostic procedures; and evaluation of their quality;

5. (cont.)

E. Regular review of the progress of patients receiving therapy and modification of the originally prescribed dose as warranted by the patient's reaction to radiation therapy; and

F. Provision of necessary follow-up medical care.

In institutions these duties may be delegated to physicians who are in training under the tutelage of an authorized user. This means that the authorized physician user (1) has adequately instructed the physicians-in-training in the specific human use, (2) has ascertained that they are receiving training in the safe use of these materials in humans, and (3) periodically reviews the work of those supervised and assures that proper medical records are made of each use. The authorized user remains responsible for the acts and omissions of the supervised individuals.

Item (2) requires the authorized user to determine that the physician-in-training has received, or is receiving, the supervised work experience and classroom and laboratory training specified in Appendix A-1 of Radiation Guide 10.1, Rev. 2. The classroom and laboratory training must be obtained as planned instruction outlined in a syllabus, and offered by an individual or organization that has teaching as a primary responsibility. The syllabus must be approved by this Bureau and the course must be accredited by the ACCME for Category I CME credits towards the Physician's Recognition Award of the AMA, or by a State Education Department or equivalent accrediting agency of the state in which the course is given.

It must be comprised of lectures, demonstrations, hands-on laboratory exercises, homework assignments, quizzes and tests. The hours of training submitted in satisfaction of this requirement must be given in a classroom/laboratory setting in the presence of instructors whose credentials qualify them to give such training, and are acceptable to the Department. No home-study or take-home work can be used to satisfy the hours required, nor are take-home tests or quizzes acceptable as evidence of adequate knowledge of subjects covered.

Properly trained technologists 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.

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.

5. (cont.)

d. Injection of radiopharmaceuticals; if they meet the training and experience requirements of Appendix A-4 to this Guide.

6a. For routine human use, the applicant may refer to the group lists outlined in Table 8, Appendix 16-A, of 10 NYCRR 16 to determine those groups which best suit the program. 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. You will also be authorized to use radiopharmaceuticals and sources which have been added to the Groups since the last printing of Part 16. Using the table format of Table 1 as a guide, list the groups you want and the maximum amount. You may say "as needed" in the "amount" column as shown except for molybdenum-technetium generators and Group VI sources, for which you must specify the maximum activity to be possessed at any one time.

NOTE: Group III does not include authorization for generators used to produce positron emission tomographic agents, and Group VI does not include High Dose Rate Remote Afterloading Sources. These authorizations must be applied for separately due to the special safety considerations associated with their use.

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.

7. Describe the intended use for each radionuclide and form listed in Item 6b. A specific authorization must be requested to perform studies involving the use of radioactive material in animals. The procedures and precautions for this use should be included in Item 21.

Table 1

6.	Radioactive Materials	Chemical & Physical Form	Maximum Quantity Licensee May Possess at One Time
A.	Any radioactive material listed in Groups I, II, and III, as found in the State Sanitary Code, Chapter 1,, Part 16, Appendix 16-A, Table 8, "Groups of Medical Uses of Radioactive Material" and any radioactive material added to Groups I, II, and III by notification issued by the New York State Health Department	Any radiopharmaceutical listed in Groups I, II, and III, as found in the State Sanitary Code, Chapter 1, Part 16, Appendix 16-A, Table 8, "Groups of Medical Uses of Radioactive Material" and any radiopharmaceutical added to Groups I, II, and III by notification issued by the New York State Health Department	As needed
B.	Xenon 133	Gas or saline solution	200 millicuries
C.	Cobalt 57	Sealed source (New England Nuclear Model NES-391)	6 millicuries

7. Use

A. Any diagnostic procedure listed in Groups I, II, and III, as found in the State Sanitary Code, Chapter 1, Part 16, Appendix 16-A, Table 8, "Groups of Medical Uses of Radioactive Material" and any diagnostic procedures added to Groups I, II, and III by notification issued by the New York State Health Department for which adequate instrumentation is available.

B. Pulmonary function studies

C. Instrument calibration/check source.

8a. Radiation Safety Officer - The radiation safety officer's curriculum vitae should be submitted with the application if he or she will not be one of the authorized users. The appropriateness of his/her training and experience will be reviewed on a case-by-case basis. See Appendix A-1 for minimum qualifications. Even if the licensee employs a consultant to assist the radiation safety officer, the licensee is still responsible for the radiation safety program as required by the license.

Appendix B to this Guide contains a model "Delegation of Authority" to your Radiation Safety Officer. State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

8b. Radiation Safety Committee - In accordance with Section 16.120 (b) of 10 NYCRR 16, an institution applying for a radioactive material license for human use is required to establish a Radiation Safety Committee which should include:

i. an authorized user from each department where radioactive material is used.

ii. The radiation safety officer.

iii. A representative of the institution's management who is neither an authorized user nor the Radiation Safety Officer.

iv. A representative of the nursing staff.

A model procedure for establishing and operating a Radiation Safety Committee is contained in Appendix B to this Guide. State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

You may describe the makeup of the Committee by title without specifying individual names. This will eliminate the need for license amendments when the membership changes.

8c. Supervision of Staff - Each licensee must ensure that all persons who use radioactive materials under the license are properly supervised by qualified staff.

i. Supervision of Physicians

A Physician under the tutelage of another physician who is named as an authorized user on a radioactive material license may order a study; prescribe the radiopharmaceutical dosage or radiation dose; interpret the results; review the progress of patients receiving therapy and modify prescriptions accordingly, and provide follow-up care as necessary. The supervising physician must ensure that the physician being supervised is receiving instruction in the safe use of radioactive materials, and must periodically review his/her work.

8c. (con't.)

ii. Supervision of Technologists in Hospital Nuclear Medicine Programs:

A qualified technologist may inject patients if a physician with experience in the injection of radiopharmaceuticals is on the premises to supervise. (See also Appendix A-4)

iii. Supervision of Technologists in Private Office Programs:

A qualified technologist may inject patients if a physician with experience in the injection of radiopharmaceuticals is in the office to supervise. (See also Appendix A-4).

iv. Supervision of Radiation Safety Programs:

The Radiation Safety Officer may delegate day-to-day radiation safety and quality assurance tasks if he/she checks on a regular basis to ensure that these tasks are done on schedule, performed properly and recorded. The Radiation Safety Officer needs to be on the premises at least 50% of the time that radioactive materials are in use.

Confirm that supervision will be provided as described in this section.

9. Training and Experience

a. **Authorized users(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 New York State Health Department, or a copy of the complete license if issued by another licensing agency.

If the physician has not been previously authorized to use the radioactive material requested, state where he/she is licensed to practice medicine, and submit a complete description of his/her training and experience. Use Supplements A (Form GEN 307D) to describe the physician's training and experience. Criteria for acceptable training and experience are contained in **Appendix A-1** to this guide.

b. **Radiation Therapy Physicist**. Submit the training and experience of the person or persons who will be the radiation therapy physicist for this license. See **Appendix A-2.**

c. **Radiation Therapy Technologists. See Appendix A-3.**

9. (cont.)

d. **Nuclear Medicine Technologists**. Only technologists who meet the training and experience requirements of **Appendix A-4** may inject patients with radiopharmaceuticals. Prior to permitting such injections the licensee must comply with the other requirements of **Appendix A-4.**

All technologists who participate in nuclear medicine procedures must have adequate training and experience. The Department recommends that all technologists meet the training and experience requirements of **Appendix A-4.**

e. **Personnel Training Program**. You must provide a training program for individuals who work with or in the vicinity of radioactive materials. Many resources are available for use in such training and a partial listing can be found in Appendix Q of this Guide. We strongly recommend that one publication in particular be used as a part of your training program and made available as a reference to employees. The publication is NCRP Report No. 105, "Radiation Protection for Medical and Allied Health Personnel". Ordering information can be found in Appendix Q (pg. 3 and 4).

Appendix A-5 to this Guide contains a model personnel training program.State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

10a. Instrumentation. Instruments generally required in a typical nuclear medicine laboratory are:

i. Survey Instruments

(1) A low-level survey meter, with a thin window of about 2\mg/cm^2, capable of detecting 0.1 milliroentgen per hour to perform contamination surveys. This meter should have an audio function.

(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.

ii. Dose calibrators and other instruments to assay radiopharmaceuticals.

iii. Instruments used for diagnostic procedures in nuclear medicine (i.e. gamma camera, rectilinear scanner, thyroid uptake system, well counter, scintillation counter for in vitro studies).

10a. (cont.)

iv. Other pertinent instrumentation (i.e. liquid scintillation counter, area monitor, velometer, instruments for analyzing wipe test and leak test samples).

Appendix C-1 to this guide contains a form that may be used to describe the instruments which are available and on the premises. Complete this form by listing the instruments to be used and the purpose for which they will be used.

Appendix C-2 contains quality assurance procedures for imaging equipment.
State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

10b. Calibration of instruments

i. Survey instruments. Appendix D to this guide contains procedures for calibrating survey instruments. State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

If your survey meters are sent out for calibration, submit a statement that calibrations will be performed by persons licensed to perform this service by the U.S. Nuclear Regulatory Commission or an Agreement State, and that a copy of this license will be kept on file with the calibration certificates.

ii. Dose calibrator. Appendix D, Section 2 to this guide contains procedures for calibrating dose calibrators. State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

If the dose calibrator will be used to assay radionuclides other than gamma emitters (e.g. P-32) you should also submit your procedures for calibrating the instrument for those radionuclides.

11. Facilities and equipment. Describe the available facilities and equipment (i.e. 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 materials, and security procedures.

Facility diagrams must be submitted for all areas where radioactive materials are used or stored (nuclear medicine scan rooms, hot labs, nuclear cardiology labs, brachytherapy source storage areas, RIA labs, waste storage areas, etc.).

Diagrams should include dimensions and be drawn to scale. Relevant objects and equipment should be shown, as well as the location and wording of warning signs and any shielding used.

11.(cont.)

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 Section 16.7 of 10 NYCRR 16.

Shielding requirements for the walls, floor and ceiling should be evaluated for each nuclear medicine room based on total workload (in mCi/wk), 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.

12. Appendix E to this Guide contains procedures for ordering and receiving radioactive material. State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

13. Appendix F to this Guide contains procedures for package opening. State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

14. Appendix G to this Guide contains model rules for the safe use of radioactive material. State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

15. Appendix H to this Guide contains procedures for responding to spills. State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

16. Appendix I to this Guide contains model area survey procedures. State that you will follow the model procedures or submit a copy of the model procedures with your changes indicated in red ink.

17a. Appendix J to this Guide contains general guidance and model procedures for waste disposal. State that you will follow the model procedures or submit a copy of the model procedures with your changes indicated in red ink.

In addition to the contents of Appendix J you must submit your management programs for wastes that are to be shipped for disposal and wastes that are to be decayed in storage:

17b. Describe your management program for radioactive waste that is shipped for disposal, and include your procedures for preventing such waste from entering other waste streams, such as medical waste shipped for incineration.

17c. Describe your management program for radioactive waste that is decayed-in-storage including a description of:

i. any waste processing that will be done.

ii. the facility used for storage (e.g. an 8 x 10 foot concrete block room without windows that is climate-controlled and sprinklered).

iii. the waste packages to be used. If packages are stored for more than a year they should be sturdy enough for the purpose (e.g. commercially available waste boxes 11" square x 22" high) constructed of heavy cardboard and lined with heavy gauge plastic).

iv. package arrangement (e.g. storage area will hold 60 boxes stacked 3 high with walkways to allow visual inspection of all packages).

v. security; state how access to the room will be controlled (e.g. room will be locked when not in use and only stated individuals will have a key).

vi. staffing; describe who will supervise the program, place packages into storage, conduct wipe tests and surveys, etc.

vii. operations; describe your system for managing the decay-in-storage program. The following model may be used:

- Each box will be assigned an I.D. number.

- A written log will be kept where we will enter the box I.D. number, initial start date for empty box, date and survey reading at box surface when it is full and goes into storage, contents of the box and projected date of removal from storage (after at least 10 half-lives).

- The log information will also be written on each box and a radiation label will be applied.

- Monthly inspections of packages in storage will be done along with wipe surveys of the storage area. Procedures will specify actions to be taken by staff if packaging appears to be degrading.

- At disposal the box will be surveyed in a low background area to ensure that radiation levels do not exceed background, the reading, date and initials of the surveyor will be recorded in the log, radiation labels will be defaced and the waste disposed of.

18. Each licensee must have procedures for minimizing radiation exposure to staff and the general public from radiopharmaceuticals administered to patients, and for preventing misadministrations. These procedures should include advising patients that they are receiving a radiopharmaceutical.

18a. Appendix K to this Guide contains procedures for radiopharmaceutical therapy. State that you will follow the model procedures or submit a copy of the model procedures with your changes indicated in red ink.

18b. Submit a copy of instructions which you will provide to patients who receive therapy doses of iodine-131 as outpatients, or who are being discharged after hospitalization for treatment with greater than 30 millicuries of iodine-131. (A suitable pamphlet may be obtained from The Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760, Tel. No. 212/889-0717)

18c. Submit radiation safety procedures to be implemented when iodine-131 therapy doses of less than 30 millicuries are administered to in-patients. You should include consideration of precautions to be observed for patients who lack control of bladder or bowel function, including management of waste generated by such patients. (See Appendix K for suggested procedures)

18d. Submit procedures for handling specimens such as blood and urine samples from patients who have been administered radiopharmaceuticals. These should include both diagnostic and therapy patients, and should ensure that specimens will be obtained before administration of radioactive materials if that is possible. Procedures should address instruction of laboratory staff, radiation protection, contamination control and waste disposal.

18e. Submit procedures for preventing **misadministrations** to patients. These should include a requirement for a written order by an authorized physician-user (or a physician under his/her tutelage in medical institutions) before any patient is administered a therapeutic radiopharmaceutical or a quantity of iodine-125 or iodine-131 greater than 30 microcuries as sodium iodide. The written order must contain the radiopharmaceutical, dosage and route of administration. Your procedures should also specify that prior to administration the patient's identity will be verified by more than one means.

19a. Appendices L-1 and L-2 contain procedures for the Inventory and Therapeutic use of sealed sources. State that you will follow the model procedures or submit a copy of the model procedures with your changes indicated in red ink.

b. Submit your Quality Assurance Program for brachytherapy procedures utilizing **temporary** implants:

i. Confirm that an authorized physician-user will make, date and sign a written order for the sources to be used prior to the therapy. The order should contain the radionuclide and treatment plan (number of sources, source strengths, treatment time, treatment site, etc.) for a specific patient. Any changes to the

19b. (cont.)

plan must be documented before the completion of treatment and approved in writing by the authorized user.

ii. State the training and experience criteria for staff who will prepare sources for afterloading according to an authorized physician-users' written treatment plan.

iii. Confirm that only physicians authorized for brachytherapy in the license will insert radioactive sources into patients, or name the physicians who will insert sources and state their qualifications and how they will be supervised by an authorized user.

iv. State procedures for ensuring that the intended sources are loaded (e.g.assaying seeds in a dose calibrator, having a second person check the storage safe to confirm that sources of the correct individual and total activity have been removed for the therapy, measuring the exposure rate at a meter from the patient).

v. Describe your procedures for performing a second check of dosimetry calculations before 50% of the prescribed therapy has been delivered.

vi. State your policy on periodic evaluation of patients during treatment to ensure that sources remain properly positioned.

vii. Describe your procedures for source removal (what staff will be involved, the functions they will perform and their training and experience).

viii. Confirm that sources and applicators will be cleaned, sterilized and maintained in accordance with the manufacturers' instructions.

ix. Nurses who care for brachytherapy patients must be instructed in radiation safety precautions and in appropriate responses to unusual or emergency situations such as dislodged or partially-dislodged sources. Instruction must include use of "dummy" sources for all sources that might be used, and dry-runs of emergency procedures. It is essential that nursing staff be familiar with the appearance of all sources and be trained in procedures to minimize unnecessary exposure to patients, themselves and other staff.

Describe your training program for nurses who will care for brachytherapy patients and include a provision that a written test will be given with a specified passing score.

19c. Submit your Quality Assurance Program for brachytherapy procedures utilizing **permanent** implants:

i. Confirm that an authorized physician-user will make, date and sign a written order for the sources to be used prior to the therapy. The order should contain the

radionuclide and treatment plan (number of sources, source strengths, treatment time, treatment site, etc.) for a specific patient. Any changes to the plan must be documented before the completion of treatment and approved in writing by the authorized user.

ii. Confirm that only physicians authorized in the license for brachytherapy will insert radioactive sources into patients, or name the physicians who will insert sources and state their qualifications and how they will be supervised by an authorized user.

iii. State procedures for ensuring that the intended sources are implanted in the patient (e.g. using a safe with marked storage spaces and confirming that the required sources have been removed; assaying seeds in a dose calibrator).

iv. Describe your procedures for performing a second check of dosimetry calculations before the sources are implanted.

v. Submit a copy of typical instructions provided to patients who have received a permanent implant.

vi. Describe your procedures to ensure that patients containing permanent implants meet Part 16 limits for exposure to members of the general public at the time of release from your facility. NCRP Report No. 37 may be used as a guide (See Appendix Q pg. 3 and 4 for further information on this report).

20. Procedures and precautions for use of radioactive gases.

a. Submit your procedures for minimizing worker dose from submersion in noble gases. See Appendix M.

b. Submit your procedure for estimating worker dose from aerosol and gas concentrations. See Appendix M.

c. Submit your procedures for calculating spilled gas clearance times. See Appendix M.

21. 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.

22. Other 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, i.e. air sampling, other special surveys, bioassays, leak testing sealed sources, including radiation safety precautions.

a. 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). Guides for iodine and tritium bioassay programs (USNRC Regulatory Guide 8.20 and 8.32) may be enclosed if they are appropriate to your program. State whether these Guides will be followed. 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. State your bioassay policy.

b. LEAK-TESTING OF SEALED SOURCES. Appendix N to this Guide contains a model procedure for performing leak tests. State that you will follow the model or submit a copy of the appendix with your changes indicated in red ink.

You should also describe the sensitivity of the detector you will use to count test samples and how you have determined this value.

If an outside service will analyze leak-test samples submit a statement that the service will be performed by persons licensed to do so by the U.S. Nuclear Regulatory Commission or an Agreement State and that a copy of this license will be kept on file with the leak-test results.

c. RADIOACTIVE CADAVERS. Submit your procedures for ensuring that if a patient dies while containing more than 5 millicuries of radioactive material, the body will be accompanied by a report when it goes for autopsy or to a funeral director.

The report must include:

The name and address of the hospital; the name of the deceased; the name, address and telephone number of the next of kin; the name, address and telephone number of the funeral home to which the deceased will be sent; the radionuclide involved, the approximate activity on the day of the report and the physical form; the location of the radioactive materials in the body and the external exposure rate at the body surface closest to the source; the precautions to be observed during autopsy or handling of the body by the funeral director; and the name of the person who prepared the form.

NOTE: Your procedures must also address situations where an implanted patient is discharged and later re-admitted to your facility prior to death. In particular, your procedures should ensure that the presence of radioactive materials in the patient is known to all staff involved in the patient's care.

23. Personnel monitoring program. Appendix O to this Guide contains a model program for monitoring personnel for external radiation exposure. State that you will follow the model procedure or submit a copy of the model procedure with your changes indicated in red ink.

24. (For private practice applicants only)

a. State the name and address of the hospital that has agreed to admit your patients containing radioactive material, should hospitalization become necessary.

b. 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.

25a. ALARA (As Low As is Reasonably Achievable) in medical institutions. Each institutional medical licensee must have a formal ALARA program. The success of an ALARA program depends on the cooperation of each person who works at the licensee's facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources. A Radiation Safety Committee composed of individuals who have special expertise in the safe use of radioactive material is required to review each proposed method of use for safety and ALARA considerations.

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

Submit your program for maintaining radiation exposures and releases of radioactive material ALARA. A model ALARA management program is contained in Appendix P to this guide.

25b. Each licensee must also have a policy and procedures for minimizing radiation exposure to the embryo, fetus and nursing infant from diagnostic and therapeutic procedures involving radioactive materials. Appendix P-1 to this guide contains the recommendations of the

United States Food and Drug Administration for diagnostic nuclear medicine procedures which you may use as a reference. Appendix P-2 contains various foreign language translations of the phrases "are you pregnant" and "are you breast feeding" which may be useful to your staff in eliciting this information.

i. You should describe your procedures for ensuring that information on pregnancy and nursing status is elicited and recorded for female patients. Please submit copies of any forms used.

ii. You should also state your policies and procedures in the event that a patient is or may be pregnant, or is nursing. This should include a commitment that an authorized physician user will evaluate each case prior to administration and will advise nursing women on suspending breast feeding.

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

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, radiation therapy physicist, radiation safety officer, or radioactive 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 must be signed as described in Item 26 and dated. 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.

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 New York State Health Department as provided for in Section 16.105 of 10 NYCRR 16.

Renewal applications should be filed on Form GEN 307B 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 must be signed as described in Item 26 and dated. Renewal applications should also include the physician-user's training and experience 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).

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 Bureau of Environmental Radiation Protection, New York State Health Department, 2 University Plaza, Albany, New York 12203.

LICENSE TERMINATION REQUESTS

Submit a signed Form GEN 322 indicating the disposition of the radioactive material. Form GEN 322 is available from the Bureau of Environmental Radiation Protection, New York State Health Department.

Submit survey results showing that all previously occupied areas are free of contamination and all sources of radioactive material have been removed in accordance with Section 16.10 of 10 NYCRR 16. A decontamination guide is available from the Bureau of Environmental Radiation Protection, New York State Health Department.

Such submissions must be made at least 30 days prior to relinquishing possession or control of premises where radioactive material is or has been stored or used.

LIST OF APPENDICES

Appendix

A-1 Acceptable Training and Experience for Medical Uses of Radioactive Material

A-2 Training and Experience Requirements for Radiation Therapy Physicists

A-3 Training and Experience requirements for Radiation Therapy Technologists

APPENDIX A-1

ACCEPTABLE TRAINING AND EXPERIENCE FOR
MEDICAL USES OF RADIOACTIVE MATERIAL

1. General Criteria

Any human use of radioactive material (i.e. the internal or external administration of radioactive material, or the radiation therefrom, to human beings) must be carried out by or under the supervision of a professional practitioner. Such application of, or order to apply, radiation shall be in the course of the practitioner's professional practice and shall comply with the provisions of the license or other authorization of the practitioner under the Education Law of New York State.

Item 16.120 (d) of 10 NYCRR 16 provides that the Department will approve a license application by an institution for medical use of radioactive material if it determines among other things that the professional practitioner 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. Outlined below are training and experience criteria that the Department, with the assistance of its Radiological Health Advisory Committee, has found acceptable for physicians who use radiopharma-
ceuticals.

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.

Any individual wishing to qualify as Radiation Safety Officer (RSO) must meet certain minimum training and experience criteria as outlined in paragraph 2 of this appendix. This training and experience must have been obtained within a 5-year period preceding the date of the application or he or she must have had continuing involvement in radiation safety since the time of the training. An authorized user is automatically determined to have met the minimum training and experience criteria for RSO qualification.

2. Radiation Safety Officer - An individual fulfilling the responsibilities of the Radiation Safety Officer shall:

a. Be certified by:

1) American Board of Health Physics in Comprehensive Health Physics; or

2) American Board of Radiology in Radiological Physics; or

2. a. 3) American Board of Nuclear Medicine; or

4) American Board of Science in Nuclear Medicine; or

5) Board of Pharmaceutical Specialties in Nuclear Pharmacy; or

b. Hold a bachelor's degree in a physical science and have had 200 hours of classroom and laboratory training as follows:

1) radiation physics and instrumentation;

2) radiation protection;

3) mathematics pertaining to the use and measurement of radioactivity;

4) radiation biology;

5) radiation chemistry; and

6) two years of full-time experience in radiation safety at a medical institution under the supervision of the RSO; or.

c. Be an authorized user for those radioactive materials that come within the RSO's responsibilities identified on the licensee's license.

3. Diagnostic Procedures - Group I, Uptake, Dilution and Excretion Studies

Any authorized user using a radiopharmaceutical listed in Appendix 16-A, Table 8, Item (a), Group I, shall be a physician who:

a. is certified in:

1) nuclear medicine by the American Board of Nuclear Medicine; or

2) diagnostic radiology by the American Board of Radiology; or

3) diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

4) nuclear medicine by the American Osteopathic Board of Nuclear Medicine.

b. has completed 40 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience. To satisfy this requirement, the training must include classroom and laboratory instruction and supervised experience in a nuclear medicine laboratory as follows:

1) To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:

3. b. 1) i. radiation physics and instrumentation;

ii. radiation protection;

iii. mathematics pertaining to the use and measurement of radioactivity;

iv. radiation biology; and

v. radiation chemistry.

2) To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:

i. Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations or contraindications;

ii. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

iii. Administering dosages to patients and using syringe radiation shields;

iv. Collaborating with the authorized user in the interpretation of radioisotope test results; and

v. Patient follow-up; or

c. Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

4. Diagnostic Procedures - Groups II and III, Imaging and Localization Studies

Any authorized user using a radiopharmaceutical listed in Appendix 16-A, Table 8, Items (b) and (c), Groups II and III, shall by a physician who:

a. is certified in:

1) nuclear medicine by the American Board of Nuclear Medicine; or

2) diagnostic radiology by the American Board of Radiology; or

3) diagnostic radiology, or radiology by the American Osteopathic Board of Radiology; or

4) nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

4. b. has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared

radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience and 500 hours of supervised clinical experience.

1) To satisfy the requirement for instruction,* 200 hours of classroom and laboratory training must include:

i. radiation physics and instrumentation;

ii. radiation protection;

iii. mathematics pertaining to the use and measurement of radioactivity;

iv. radiation biology; and

v. radiation chemistry.

2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

iii. Calculating and safely preparing patient dosages;

iv. Using administrative controls to prevent the misadministration of radioactive material;

v. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

vi. Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharma- ceuticals.

* NOTE: See page 4 of the Guide for other requirements pertaining to this instruction. **APPENDIX A-1** - Page 5

4. b. 3) To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

i. Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

ii. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

iii. Administering dosages to patients and using syringe radiation shields;

iv. Collaborating with the authorized user in the interpretation of radioisotope test results; and

v. Patient followup; or

c. Has successfully completed a 6-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

5. Therapeutic Procedures - Groups IV and V - Any authorized user using a radiopharmaceutical listed in Appendix 16-A, Table 8, Items (d) and (e), Groups IV and V, shall be a physician who:

a. is certified by:

1) the American Board of Nuclear Medicine; or

2) the American Board of Radiology in radiology or therapeutic radiology; or

b. has completed 80 hours of instruction in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.

1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training must include:

i. radiation physics and instrumentation;

ii. radiation protection;

iii. mathematics pertaining to the use and measurement of radioactivity; and

iv. radiation biology.

5. b. 2) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

i. Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;

ii. Use of soluble phosphorus-32 for the treatment of ascites polycythemia vera, leukemia, or bone metastases in three individuals; and

iii. Use of iodine-131 for treatment of thyroid carcinoma in three individuals; and

iv. Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals.

6.A. Therapeutic Procedures - Group VI, Sealed Sources - Any authorized user using a radioactive source listed in Appendix 16-A, Table 8, Item (f), Group VI, shall be a physician who:

a. is certified in:

1) Radiology or therapeutic radiology by the American Board of Radiology; or

2) Radiation oncology by the American Osteopathic Board of Radiology; or

3) Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology;" or

4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of 3 years of supervised clinical experience:

1) To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

i. radiation physics and instrumentation;

ii. radiation protection;

6. b. 1) iii. mathematics pertaining to the use and measurement of radioactivity; and

iv. radiation biology.

2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. Checking survey meters for proper operation;

iii. Preparing, implanting, and removing sealed sources;

iv. Using administrative controls to prevent the misadministration of radioactive material; and

v. Using emergency procedures to control radioactive material.

3) To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

i. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

ii. Selecting the proper brachytherapy sources and dose and method of administration;

iii. Calculating the dose; and

iv. Post-administration follow-up and review of case histories in collaboration with the authorized user.

B. Therapeutic Procedures - High dose rate remote afterloading sources. See Radiation Guide 10.13.

7. Therapeutic Procedures - A professional practitioner wishing to use strontium-90 ophthalmic radiotherapy shall be a physician who:

a. is certified in:

1) radiology or therapeutic radiology by the American Board of Radiology; or

APPENDIX A-1 - Page 8

7. b. Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy:

1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

i. 6 hours of radiation physics and instrumentation;

ii. 6 hours of radiation protection;

iii. 4 hours of mathematics pertaining to the use and measurement of radioactivity; and

iv. 8 hours of radiation biology.

2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training

must be under the supervision of an authorized user at a medical institution and must include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

i. Examination of each individual to be treated;

ii. Calculation of the dose to be administered;

iii. Administration of the dose; and

iv. Follow-up and review of each individual's case history.

APPENDIX A-2

Training and experience requirements for radiation therapy physicists.

The Department is in the process of establishing training and experience requirements in consultation with its Radiological Health Advisory Committee. You should submit the training and experience of the physicist you propose to use, including copies of any diplomas or board certifications earned.

APPENDIX A-3

Training and experience requirements for radiation therapy technologists.

Only a person who holds a license to practice radiotherapy technology, issued by the New York State Department of Health, may operate teletherapy devices or high dose-rate remote afterloading devices in the treatment of humans.

APPENDIX A-4

Training and Experience Requirements for Nuclear Medicine Technologists
Who Inject Radiopharmaceuticals

Personnel other than physicians or registered professional nurses (i.e. nuclear medicine technologists) involved in the performance of diagnostic procedures utilizing radioactive material, which includes performing parenteral administration of radioactive material by intravenous, intramuscular or subcutaneous methods, (a) shall have satisfactorily completed an educational program in nuclear medicine technology accredited by the Committee on Allied Health Education and Accreditation, or the accrediting agency of the State in which the program was completed, provided such State accreditation requires education and training in the above methods of administration, or (b) shall possess certification as a nuclear medicine technologist by the American Registry of Radiologic Technologists or certification by the Nuclear Medicine Technology Board.

Prior to permitting parenteral administration by a nuclear medicine technologist, the medical board of a hospital, or the radiation protection committee of an institution having no medical board, shall adopt with governing authority approval:

a. procedures to assure that the nuclear medicine technologist possesses the education and training or certification set forth above and is proficient in the competent performance of parenteral administration, and

b. requirements for physician supervision which at a minimum shall require supervision by a physician on the premises when parenteral administration of radioactive material for diagnostic testing is performed by a qualified nuclear medicine technologist.

APPENDIX A-5

MODEL PERSONNEL TRAINING PROGRAM *

It may not be assumed that safety instruction has been adequately covered by prior professional or occupational training, board certification, etc. Also
ancillary personnel (i.e. nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. A training program that provides necessary instruction for all personnel should be written and implemented.

A. Model Program

Personnel will be instructed:

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

2. During annual refresher training.

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

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.

2. Areas where radioactive material is used or stored.

3. Potential hazards associated with radioactive material in each area where the employees will work.

4. Appropriate radiation safety procedures.

5. Licensee's in-house work rules.

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

7. Appropriate response to emergencies or unsafe conditions.

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

* NOTE: An excellent resource for providing information to personnel working where radiation may be used is NCRP Report No. 105, "Radiation Protection for Medical and Allied Health Personnel". See Appendix Q pg. 3 and 4 for information on obtaining copies of this and other NCRP Reports.

9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 NYCRR 16.13.

10. Question and answer period.

B. Records that Document Training

Records of initial and refresher training will be maintained for inspection by the department and will include:

1. The name of the individual who conducted the training,

2. The names of the individuals who received the training,

3. The dates and duration of the training session,

4. A list of the topics covered, and

5. The results of tests administered to determine the effectiveness of training.

APPENDIX B

MODEL PROCEDURE FOR DELEGATION OF AUTHORITY TO RADIAITON SAFETY OFFICER AND FOR ESTABLISHING A RADIATION SAFETY COMMITTEE

DELEGATION OF AUTHORITY

MEMO TO: All Employees

FROM: Chief Executive Officer

SUBJECT: Authority of Radiation Safety Officer

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

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

RADIATION SAFETY 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 Department 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 Department regulations and the conditions of the license.

Duties

The Committee shall:

1. Be familiar with all pertinent New York State Health Department 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 professional practitioners, technologists, physicists and pharmacists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with New York State Health Department regulations and the conditions of the license.

3. Ensure that only professional practitioners and radiation therapy physicists who are named on the institution's license, or persons under their tutelage, perform licensed activities, (See directions for item 5 on page 5 of this guide for specific requirements for physicians in training).

4. Be responsible for monitoring the institution's program to maintain individual and collective doses as low as reasonably achievable.

5. Review quarterly the Radiation Safety Officer's summary report of occupational radiation exposure records of all personnel working with radioactive materials; paying special attention to workers or groups of workers whose exposures appear excessive or are otherwise remarkable due to late or lost badges or absence of expected exposures.

6. Establish a table of investigational levels for occupational radiation exposure, which when exceeded, will initiate an investigation and consideration of action by the Radiation Safety Officer.

7. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (i.e. nursing, security, and housekeeping personnel) are properly instructed as required by Section 16.13 of 10 NYCRR 16.

8. Review and approve all requests for use of radioactive material within the institution.

9. 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.

10A. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with New York State Health Department regulations and the conditions of the license. The review

shall include an examination of records, reports from the Radiation Safety Officer, results of New York State Health Department inspection, written safety procedures, and the adequacy of the institution's management control system.

10B. Review the diagnostic and therapeutic radioactive materials Quality Assurance programs at least annually, to determine that the programs are being conducted in accordance with New York State Health Department regulations and conditions of the license.

11. Recommend remedial action to correct any deficiencies identified in the radiation safety program or quality assurance programs.

12. Maintain written records of all Committee meetings, actions, recommendations, and decisions; including members present and numerical results of all votes taken.

13. Ensure that the radioactive materials license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, radioactive material, possession limits, and personnel, as specified in the license.

14. Identify problems and develop solutions.

Meetings

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

2. A quorum shall consist of at least one-half of the Committee's membership, including the Radiation Safety Officer and the management representative.

APPENDIX C-1

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 (i.e. liquid scintillation counter, area monitor, velometer, wipe/leak test counter)

APPENDIX C-2

MODEL QUALITY ASSURANCE PROGRAM FOR IMAGING EQUIPMENT

Model Procedure

1. Perform the following checks daily before administering radioactive material:

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

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

   If the camera has a uniformity correction device, image a flood field both with and without uniformity correction to ensure that uniformity correction does not replace good detector calibration.

   Process the image as if it were an image of a patient.

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

   d. Retain the images for about a month. (since inspections are unannounced this is adequate to demonstrate that daily checks are done)

   e. Make a record of actions taken when flood field images reveal a problem. Keep these records for three years.

2. Perform the following checks weekly:

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

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

c. If a resolution-quadrant phantom is used, rotate it so that each quadrant is imaged in each quadrant of the crystal.

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

e. If a whole-body imager is used, check the system for the appearance of the "zipper". With the same frequently used collimator in place, place a flood source in the center of the imaging table and obtain a whole body scan. Process the image as if it were an image of a patient.

f. Retain these images for three years, along with records of actions taken when the images reveal a problem.

3. If a SPECT system is used, establish a Quality Assurance Program for the unit which implements the manufacturer's recommended procedures, in addition to the daily and weekly checks described in items 1 and 2 above.

Perform these procedures at the frequency the manufacturer recommends. You should consider the following for inclusion in your Quality Assurance program: Center of Rotation, Motion Correction, Dead Time, Rotational Uniformity, High-count Uniformity Correction Flood, and a Reference Flood for each collimator used.

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

a. Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 4.b.

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

5. Set the equipment in the same manner each time checks are run. Make a record of all these checks. Keep a separate file or ring binder for each camera. Retain the records for 3 years.

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APPENDIX D

Section 1

MODEL PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

You or your contractor may use the following procedure to calibrate survey instruments.

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

Model Procedure

1. The source must be approximately a point source.

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

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

4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of cesium-137, 21 millicuries of cobalt-60, and 34 millicuries of radium-226.

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

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

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

8. If the indicated exposure rate differs from the calculated or documented exposure rate within $\pm$ 20 percent, it will be considered acceptable if a calibration chart or graph is prepared and made available with the instrument, and a correction factor is supplied on the instrument.

8. The following three kinds of scales are frequently used on survey meters:

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

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

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

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

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

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

a. The owner or user of the equipment;

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

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

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

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

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

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

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

i. The name of the person who performed the calibration, the date on which the calibration was performed and the license number (and issuing agency) of any contractor who performed the calibration.

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

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

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

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

1) The average correction factor,

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

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

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

e. The apparent exposure rate from the check source.

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

On the following page is a form you may want to use.

APPENDIX D

Section 2

MODEL PROCEDURE FOR CALIBRATING DOSE CALIBRATOR

You or your contractor may use the following procedure for checking and testing the dose calibrator.

Model Procedure

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.

1. Test for the following at the indicated frequency.

   a. Instrument constancy (daily).

   b. Instrument accuracy (at installation and annually thereafter).

   c. Instrument linearity (at installation and semi-annually thereafter).

   d. Geometrical variation (at installation).

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

3. 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 millicuries of Co-57 and 100-200 microcuries of Cs-137 or 1-2 milligrams of 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.

3. a. Assay each reference source using the appropriate instrument setting (i.e. Cs-137 setting for Cs-137).

   b. Measure background level at the same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.

c. Calculate net activity of each source subtracting out background level.

d. For each source, either plot net activity versus the day of the year on semilog graph paper or log in a book the background level for each setting checked and net activity of each source.

e. Using one of the sources repeat the procedure for all the commonly used radionuclide settings.

f. Establish an action level for each recorded measurement at which the person performing the test will notify a designated person of possible malfunction. These action levels should be written in the log book and posted on the calibrator.

g. Variations greater than $\pm$ 10 percent from the predicted activity shall result in instrument repair or replacement.

4. 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).

5. 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 (i.e. the first elution from a new generator or a radiopharmaceutical therapy dose).

Decay Method

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

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

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

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

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

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

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

Shield Method

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

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

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

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

d. Continue for all sleeves.

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

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

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

h. Continue for all sleeves.

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

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

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

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

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

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

e. Continue for all sleeves.

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

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

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

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

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

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

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

   b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated.

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

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

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

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

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

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

   i. Repeat the process until you have assayed a 19.0-cc volume. The

entire process must be completed within 10 minutes.

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

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

7. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, Co-57, and Co-60, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented by the supplier. The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (i.e. Co-57, 3-5 millicuries) giving adequate attention to source configuration.

a. Assay the reference standard in the dose calibrator at the appropriate setting, and subtract the background level to obtain the net activity.

b. Repeat step a. for a total of 3 determinations, and average results.

c. The average activity determined in step b. should agree with the certified activity of the reference source within $\pm$ 5 percent after decay corrections.

d. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

e. If the average values do not agree within $\pm$ 5 percent with the certified values of the reference sources, 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. If the error exceeds 10 percent the instrument must be repaired or replaced.

f. At the same time the instrument is being calibrated place a long-lived daily constancy 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.

8. The Radiation Safety Officer will review and sign the records of all geometry, linearity and accuracy tests. 9. If the dose calibrator will be used to assay beta-emitting radioactive materials or unusual forms such as iodine seeds, submit your procedures for calibrating the dose calibrator for these applications.

APPENDIX E

MODEL GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Radiation Safety Officer or a sole designate must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

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

   a. For routinely used materials

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

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

   b. For occasionally used materials (i.e. therapeutic dosages)

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

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

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

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

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Sample Memorandum

MEMO TO: Chief of Security

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Material

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

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

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

Name Home Telephone

Radiation Safety Officer _____

Chief of Nuclear Medicine _____

Chief Nuclear Medicine Technologist _____

Nuclear Medicine Technologist on call (call page operator at extension _____)

Nuclear Medicine Physician on call (call page operator at extension _____)

APPENDIX F

MODEL PROCEDURES FOR SAFELY OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL

Model Procedure

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of Type A quantity limits (e.g. more than 20 curies of Mo-99 and Tc-99m or more than 3 curies of I-131, Cs-137, Ir-192, or more than 1 millicurie of RA-226). 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. The Department will be notified if removable contamination exceeds 0.01 uCi/100 cm^2 (22,000 dpm) or if external radiation levels exceed 200mR/hr at the package surface or 10mR/hr at 3 feet (or 1 m).

2. For all packages, the following 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 (i.e. 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 it is higher than usual, stop and notify the Radiation Safety Officer. If it is higher than 10mR/hr notify the Radiation Safety Officer and the Department of Health at once.

   d. Open the package with the following precautionary steps:

      1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

      2) Open inner package and verify that contents agree with those on packing slip.

      3) Check integrity of final source container (i.e. inspect for breakage of seals or vials, loss of liquid, or discoloration of packaging material).

4) If anything is other than expected, stop and notify the Radiation Safety Officer.

e. If there is any reason to suspect contamination, wipe external surface of final source container and remove wipe to low background area. Assay the wipe with an appropriate instrument. The procedure manual should specify the instrument and method to use. Record amount of removable radioactivity (i.e. dpm/100 cm^2, etc.). Take precautions against the spread of contamination as necessary.

f. 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 "Package Receipt and Monitor Log" (see next page) or a form containing the same information.

APPENDIX G

MODEL 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. Do this in an area away from radiation sources using a thin window pancake probe G.M. with the audio function turned on. A crystal probe or camera is preferred.

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 (i.e. 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. Check the patient's name and identification number, the radionuclide, the chemical form, and the activity against the order before administration. Do <u>not</u> administer therapy doses of radiopharmaceuticals, or quantities of iodine-131 or iodine-125 in the form of sodium iodide in excess of 30 microcuries, except in accordance with a written order by a physician authorized on the license, or a physician under the supervision of a physician authorized on the license for these uses.

   c. <u>Identify</u> all patients by two different means before administering a dose.

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 as prescribed by the Radiation Safety Officer. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

8. Wear 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 and labeled receptacles.

10. Never pipette by mouth.

11. Segregate pipetting devices used with radioactive materials from those used with non-radioactive solutions.

12. Survey generator, kit preparation and injection areas for contamination daily. Decontaminate if necessary.

13. Confine radioactive solutions in shielded containers that are clearly labelled and store gaseous or volatile materials in a properly ventilated area. Multidose vials and therapy vials should be plainly identified and labeled with name of compound, radionuclide, date, time of receipt or preparation, activity, and radiation level, if applicable. Radioactive solutions for therapy should be stored in double containment with enough absorbent material to absorb the volume of liquid.

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

15. Use radioactive aerosol devices on surfaces covered with plastic-backed absorbent pads so that any aerosol that escapes, expecially through the exhaust port, will not contaminate surfaces under and around the unit.

16. Use a cart or wheelchair to move flood sources, syringes, waste, and other radioactive material. Always transport material in appropriately shielded containers.

17. If generators are used, for each elution of technetium-99m from a molybdenum-99/technetium-99m generator:

    a. Assay the eluate for technetium-99m in a dose calibrator; record the results and retain the record for 3 years after the assay.

    b. Test for molybdenum-99m concentration; record the results and retain the record for 3 years after the test.

    c. Do <u>not</u> use technetium-99m for human use if the technetium-99m contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m. The concentration of molybdenum-99 must be far enough

below this limit so that it will not exceed 0.15 microcurie per millicuries of technetium-99m at any time up to and including the expiration date and time shown on the package label.

APPENDIX H

MODEL SPILL PROCEDURES

Minor Spills (Less than 1 millicurie of radioiodines or cobalt-60*, and less than 10 millicuries of other radionuclides.)

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 GM survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

* NOTE: Many applicants will add a third category:
less than 30 millicuries of a diagnostic radiopharmaceutical.

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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. If contamination remains induce perspiration by covering the area with plastic, then wash again.

7. The Radiation Safety Officer will supervise the clean-up of the spill and will complete a report.

RADIATION SAFETY OFFICER:
_____**

OFFICE PHONE:_____ HOME PHONE:_____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY THE RADIATION SAFETY OFFICER:

_____

_____

_____

_____

** The appropriate information for your facility should be supplied in these blanks when posting these procedures and should be updated promptly when the information changes.

APPENDIX I

MODEL PROCEDURE FOR AREA SURVEYS

Ambient Exposure Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, (including nuclear cardiology or other use areas remote from the nuclear medicine area) survey at the end of each day of use with a low-range survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. Around devices used for production of radioactive aerosols survey at the end of each day of use with a low-range survey meter, paying special attention to surfaces near the exhaust port.

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

d. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a low-range survey meter.

e. In sealed source and brachytherapy storage areas, survey quarterly with an ionization chamber survey meter.

2. Immediately notify the Radiation Safety Officer if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas (Be sure to include floor surfaces and surfaces near the exhaust ports of radioactive aerosol devices when surveying for contamination)

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

b. Around devices used for production of radioactive aerosols survey weekly for removable contamination, paying special attention to surfaces near the exhaust port.

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

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

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 1000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine. You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute) to dpm.

3. Immediately notify the Radiation Safety Officer if you find unexpectedly high levels.

Records

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

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

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

   c. A drawing of the areas surveyed and contamination and exposure rate action levels as established by the Radiation Safety Officer.

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

   e. Actions taken in the case of excessive exposure rates or contamination and follow-up survey information.

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

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, New York State Department of Health 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 Section 16.8, New York State Sanitary Code (10 NYCRR 16).

General Guidance

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

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

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

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

5. In New York State the Department of Environmental Conservation regulates releases to the environment and has enacted regulations on the transport of low-level radioactive waste in New York State (6 NYCRR Part 381). These regulations require that a properly executied manifest and a valid transport permit issued by Department of Environmental Conservation accompany all waste shipments. For further information contact:

New York State Department of Environmental Conservation
Division of Hazardous Substance Regulation
Bureau of Radiation
50 Wolf Road
Albany, New York 12233-0001

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

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

1. Regulations for disposal in the sanitary sewer appear in 16.8(c), New York State Sanitary Code (10 NYCRR 16). Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Releases to the environment are regulated by the New York State Department of Environmental Conservation in 6NYCRR Part 380. You should be conversant with those regulations and possible permit requirements. For further information contact New York State Department of Environmental Conservation at the address given above.

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

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

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

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

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

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

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

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

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

    c. Remove any shielding from around the container;

    d. Monitor all surfaces of each individual container;

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

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

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

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet, or manifest, that the transfer agent gave you. You must also comply with regulations issued by the New York State Department of Environmental Conservation (6NYCRR Part 381) relating to waste manifests and transport permits.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

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

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

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

3. Perform the dose rate and removable contamination measurements required by paragraph 173-475(i) of 49 CFR Part 173.

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

APPENDIX K

MODEL PROCEDURES FOR RADIATION SAFETY DURING RADIOPHARMACEUTICAL THERAPY
(Iodine Therapy Over 30 Millicuries)*

Model Procedure

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

2. Prepare the room for the procedure as follows:

   a. Cover, with leak-proof absorbent paper, large surfaces (the bed, chairs, and the floor around the toilet) and small items (telephone,

door knobs, bed remote control, television control, and nurse call cord) that are likely to be contaminated. Small items may also be covered with plastic bags.

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

c. Prepare collection containers if urine will be collected.

1) Containers should be unbreakable and closable.

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

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

* If you will treat in-patients with therapy doses of radioiodine which are less than 30 millicuries, you should consider implementing the precautions in paragraphs 2, 3, 5, 6, 7, 11, 13 and 14 of this appendix.

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

5) Supply a wide-mouth anti-splash funnel.

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

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

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

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

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

7. Only those persons needed for medical, safety, or training purposes should be present during the administration. Personnel should wear gloves and work within fume hoods when opening containers of volatile radiopharmaceuticals such as I-131.

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

9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, a 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in Section 16.7, New York State Sanitary Code (10 NYCRR 16). Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.

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

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

12. Do not release any patient until the retained radioactivity is less than 30 millicuries. If the exposure rate measured with a properly calibrated survey meter at one meter from the patient's umbilicus with the patient standing is less than 5 millirem per hour, this criterion may be assumed to have been met.

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

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

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

c. Use a low-range GM survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm . If the contamination is fixed, exposure rates must be less than 0.2 mR/hr with the GM detector in contact with the contaminated surface.

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

14. Each patient must be advised of radiation safety precautions to be followed after release and provided with a written set of instructions.

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Nursing Instructions for Patients Treated With
Phosphorus-32, Gold-198, or Iodine-131

Patient Name:_____ Patient Number:_____
Attending:_____Phone:_____ Pager:_____ Patient Room:_____

Dose:_____ mCi of _____ as _____ was administered at ___:___ am/pm

Signature:_____ Date:___-___-___

Radiation Exposure Rates

Unrestricted areas: door-____ ____mR/hr; rm____-____mR/hr; rm____-____mR/hr
Patient supine in bed or _____

Date	Time	Bedside	3 ft from bed	Door	_____
___-___-___	__:__ am/pm	_____mR/hr	_____mR/hr	_____ mR/hr	_____mR/hr
___-___-___	__:__ am/pm	_____mR/hr	_____mR/hr	_____ mR/hr	_____mR/hr

___-___-___ __:__ am/pm _____mR/hr _____mR/hr _____ mR/hr _____mR/hr

___-___-___ __:__ am/pm _____mR/hr _____mR/hr _____ mR/hr _____mR/hr

Instructions

Visitor Restrictions

___ No visitors.
___ No visitors under 18 or pregnant.
___ ____ minutes each day maximum for each visitor.
___ Visitors must stay behind line on floor at all times.

Nursing Restrictions

___ Patient is restricted to room.
___ No nurses who are pregnant may render care.
___ _____ minutes each day per nurse in the room.

Patient Care

___ Wear disposable gloves. Wash your hands after caring for patient.
___ Discard linen/bedclothes, plates/utensils, dressings, etc. in boxes in room.
___ Collect urine in containers provided. Discard feces in toilet.
___ Discard urine and feces in toilet. Flush three times.
___ Housekeeping personnel are not permitted in the room.
___ Only Radiation Safety Officer may release room to admitting office.
___ Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call Radiation Safety Officer for additional monitors if needed.

In case of emergency, or if you have a question, call:

RSO:_____ Work:_____ Home:_____ Pager:_____

MD:_____ Work:_____ Home:_____ Pager:_____

APPENDIX L-1

MODEL RADIATION SAFETY PROCEDURES FOR
THERAPEUTIC USE OF SEALED SOURCES IN IMPLANTS

Model Procedure

1. All patients treated with brachytherapy sources will be placed in a private room (unless the dose rate at one meter from the implant meets the requirements of 16.7(a)) that has a toilet. The room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care.

2. a) The patient's room will be properly posted with a "Radioactive Materials" sign.

b) The patient will be briefed on radiation safety procedures as appropriate.

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

4. a. 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, at the patient's bedside, and at the visitors' "safe line." 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.

b. The measured exposure rate at 1 meter will be compared to the expected calculated value and deviations will be evaluated as possible indications of error in the source activity implanted.

c. If the implant is performed other than in the patient's room, the area used for the procedure will be surveyed immediately afterward. In the case of seeds, any area where the seeds were handled (i.e. sterilization area, source storage room) will be surveyed immediately after use.

5. Radiation levels in unrestricted areas (surrounding hallways and rooms) will be maintained less than the limits specified in Section 16.7, New York State Sanitary Code (10 NYCRR 16).

6. 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.

7. 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.

8. At the conclusion of treatment, a survey will be performed 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.

9. Instructions to Nurses: Brief the nurses on radiation safety precautions and allow time for questions and answers.

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 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.i. Never touch needles, capsules, ribbons, 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.

ii. If a source or container becomes partially dislodged or appears to have shifted its position, contact Radiation Therapy at once and notify the Radiation Safety Officer.

f. Bed bath given by the nurse should be omitted while the sources are in place.

g. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary unless orders to the contrary have been written.

h. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist and MAY NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Safety Officer or his designee.

Special orders will be written for oral hygiene for patients with oral implants.

i. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specially 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.

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 or not 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)_____

9. 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 or physician authorized in the license to perform implants will brief the patient on the precautions for minimizing radiation exposure to others after discharge from the hospital, and provide the patient with a written or printed copy of the instructions.

Nursing Instructions for Patients Treated
With Brachytherapy Sources

Patient's Name _____
Patient's Room Number _____ Physician's Name _____
Isotope & Activity _____
Date & Time of Administration _____
Date & Time Sources are to be Removed _____

Exposure Rates in mR/hr

Bedside 3 feet from Bed 10 feet from Bed

_____

_____

_____

Comply with all Checked Items

___ Wear film or TLD badge
___ Wear pocket chambers for supplementary personnel monitoring of individual tasks
___ Wear rubber gloves
___ Tag the following objects and fill out the tag:
___ door ___ chart ___ bed ___ wrist
___ Place the laundry in linen bag and save
___ Housekeeping may not enter the room
___ Visiting time permitted:_____
___ Visitors must remain _____ from patient
___ Patient may not leave the room
___ Patient may not have visitors
___ Patient may not have pregnant visitors
___ Patient may not have visitors under 18 years of age
___ Patient must have a private room
___ A dismissal survey must be performed before the patient is discharged and certification below signed
___ All items must remain in the room until approved for disposal by the Radiation Safety Officer or his designee
___ 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
___ Contact the Radiation Safety Office when the patient is discharged, to survey the room prior to its assignment to another patient.
___ Other instructions _____

_____

Radiation Safety Officer_____

On Duty Phone No._____ Off Duty Phone No. _____

APPENDIX L-2

MODEL PROCEDURE FOR KEEPING AN INVENTORY OF IMPLANT SOURCES

1. Use a locking safe to store all implant sources.

2. Make a list of names of those individuals you allow to handle implant sources and the person designated as source custodian, and have them initial beside their names.

3. For all sources, have the source custodian make and maintain a log of all implant sources received under the license.

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

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

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

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

8. Have the source custodian conduct a quarterly inventory of all sources and devices received and possessed. The inventory record must contain the quantities and kinds of radioactive material; location of sources and devices; the date of the inventory; and the name or initials of the person who conducted it.

9. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the Radiation Safety Officer immediately.

APPENDIX M

MODEL PROCEDURES FOR MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS *

Worker Dose from Noble Gases (Item 20a.)

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

If you will collect spent gas in a shielded trap with an effluent air contamination monitor and will follow the monitor manufacturer's instructions for checking its accuracy and constancy, you may respond to Item 20a. saying, "We will collect spent noble gas in a shielded trap and monitor the

trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you will collect spent gas in a shielded trap and will follow the model procedure for checking trap effluent, you may respond to Item 20a. by saying, "We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix M.1. to Radiation Guide 10.1. Rev 1"

M.1.

Model Procedure for Monitoring or Checking Trap Effluent

Charcoal traps can significantly reduce air contamination, They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance. Follow the manufacturer's instructions for maintenance including replacement of trapping agents for moisture and carbon dioxide.

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

*Note: Releases to the environment are regulated by the New York State Department of Environmental Conservation in 6 NYCRR Part 380. For further information contact: New York State Department of Environmental Conservation, Division of Hazardous Substance Regulation, Bureau of Radiation, 50 Wolf Road, Albany, New York 12233-0001

2. If you do not monitor the trap effluent, check it on receipt and after every 10 patient studies. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and comparing its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.

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

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

Worker Dose from Aerosols (Item 20b.)

If you will collect spent aerosol in a shielded trap with an air contamination monitor and will follow the monitor manufacturer's instructions for checking its accuracy and constancy, you may respond to Item 20b. by saying, "We will collect spent aerosol in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you are not monitoring trap effluent, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for review during inspections.) If you will follow the model procedure below for calculating worker dose from aerosols, you may respond to Item 20b. by saying, "We will follow the model procedure for calculating worker dose from aerosols that was published in Appendix M.2. to Radiation Guide 10.1. Rev 1"

M.2.

Model Procedure for Calculating Worker Dose from Concentrations of Gases and Aerosols in Work Areas

1. Collect the following data:

a. Estimated number of studies per week;

1. b. Activity to be administered per study;

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

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

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

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

g. Maximum permissible air concentrations in restricted and unrestricted areas. For soluble Tc-99m, the maximum permissible values are 4 x 10 uCi/ml in restricted areas and 1 x 10 uCi/ml in unrestricted areas. For other gases or aerosols, see 10 NYCRR 16, Appendix 16-A, Table 4.

2. The following calculations must be made:

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

b. The estimated average concentration in restricted areas.

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

2) If this is not the case, plan for fewer studies.

Spilled Gas Clearance Time (Item 20c.)

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described in Appendix M.3. should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted.

If you will calculate spilled gas clearance times according to the following procedure, you may respond to Item 20c. by saying, "We will calculate spilled gas clearance times according to the procedure that was published in Appendix M.3. to Radiation Guide 10.1."

M.3.

Model Procedure for Calculating Spilled Gas Clearance Time

1. Collect the following data:

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

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

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

d.C, Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133 the maximum permissible values are 1 x 10 uCi/ml in restricted areas and 3 x 10 uCi/ml in unrestricted areas. For other gases, see 10 NYCRR 16, Appendix 16-A, Table 4. You should also be familiar with the requirements of the New York State Department of Environmental Conservation in 6 NYCRR Part 380 for discharges to the environment.

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

2. For each room make the following calculation:

The evacuation time $t = \frac{-V}{Q} X \ln (CXV/A)$

APPENDIX N

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

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

2. If you will be testing high-activity sources, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

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

a. For small sealed sources, it is easiest to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators. Storage containers should also be wiped since contamination can accumulate here.

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

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

d. If you are testing iodine sources, they should also be checked for vapor leakage. This can be done by submerging the source in charcoal or vermiculite for a day, removing the source and analyzing the absorbent sample.

4. The samples will be analyzed as follows:

a. Select a suitable detector that is sufficiently sensitive to detect 0.005 microcuries. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler is usually necessary.

b. Assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum in order to estimate the detection efficiency of the analyzer used to assay the wipe samples.

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

d. Calculate the estimated activity in microcuries on the wipe sample.

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4. d. Calculate the estimated activity in microcuries on the wipe sample.

e. Continue same analysis procedure for all wipe samples.

f. If the wipe sample activity is 0.005 microcuries or greater, notify the RSO. The source must be withdrawn from use to be repaired or disposed of and the Health Department must be notified.

g. Record the wipe sample results on the list of sources, and sign and date

the list.

APPENDIX O

MODEL PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

Personnel monitoring devices should be provided for individuals who are exposed to sources of whole-body radiation, or who handle millicurie quantities of energetic beta or gamma emitting radionuclides.

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

2. All individuals who are occupationally exposed to radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis. This service must be accredited under NVLAP (a voluntary program for determining that a dosimetry service meets ANSI standards).

3. All individuals who handle millicurie quantities of radioactive material on a regular basis that emit energetic beta particles or ionizing photons, will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

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

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

Revision date: 12/91 **APPENDIX P**

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA (AS LOW AS REASONABLY ACHIEVABLE)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix P to Radiation Guide 10.1."

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

ALARA Program

_____

(Licensee's Name)

_____

(Date)

1. Management Commitment

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

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

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[1]Private practice physician licenses do not include an RSC.

1. 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 reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee (RSC)[2]

   a. Review of the 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 radioactive 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.

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[2]The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2.

2. b. 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.

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 semi-annual review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table O-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) .

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.

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[3]The New York State Department of Health 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 checkpoints above which the results are considered sufficiently important to justify further investigation.

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.

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

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

The Radiation Safety Officer will review and record on Form GEN 305, "Current Occupational External Radiation Exposures" or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring. The following actions will be taken at the Investigational Levels as stated in Table O-1.

a. Quarterly exposure of individuals 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 GEN 305 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 Department 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 0-1

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 6c. above will be followed.

7. Signature of Certifying Official[4]

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

_____ _____

Signature Name (print or type)

_____

Title

Institution (or private practice) Name and Address:

_____

_____

_____

[4]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.

APPENDIX Q

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8.13 "Instruction Concerning Prenatal Radiation Exposure"

8.18 "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be as Low as is Reasonably Achievable"

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10.1 "Guide for the Preparation of Applications for Medical Programs"

10.2 "Guide for the Preparation of Applications for Academic Programs of Limited Scope"

10.3 "Guide for the Preparation of Applications for Laboratory Programs of Limited Scope"

10.4 "Guide for the Preparation of Applications for Disaster Preparedness Programs"

10.5 "Guide for the Preparation of Applications for Type-A Broad Scope Licenses

10.6 "Guide for the Preparation of Applications for the Use of Sealed Sources in Gas Chromatography Devices and X-ray Fluorescence Analyzers"

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10.7 "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services"

10.8 "Guide for the Preparation of Applications for Medical Teletherapy Programs"

10.9 "Guide for the Preparation of Applications for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments"

10.10 "Guide for the Preparation of Applications for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Radioactive Materials"

10.11 "Guide for the Preparation of Applications for the Use of Sealed Sources for Diagnosis"

10.12 "Guide for the Preparation of Applications for the Use of Gamma Irradiators"

10.13 "Guide for Remote Afterloading Amendment Requests"

10.14 "Radioactive Materials Guide for Small RIA Laboratories"

- General Guide for Lab Ventilation (Hoods) for Radioactive Materials Licensees

- Incinerator Guidelines for Radioactive Materials Licensees

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