

**GUIDE FOR THE PREPARATION OF APPLICATIONS FOR  
RADIOACTIVE MATERIALS LICENSES FOR MEDICAL PROGRAMS**

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Bureau of Air and Radiation  
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## 1.0 Introduction

### 1.1 Purpose Of Guide

This guide describes the type and extent of information needed by the Bureau of Air and Radiation, Radiation Control Program licensing staff to evaluate an application for a specific license for the possession and use of radioactive material in or on human beings. This type of license is provided for under Part 3, "Licensing of Sources of Radiation."

The Radiation Control Program will usually issue a single radioactive material license to cover the institution's entire radioisotope program. Separate licenses are not normally issued to different departments of a medical institution, nor are they issued to individuals associated with the hospital.

The applicant should carefully study the regulations and this guide and submit all information requested. The Radiation Control Program staff will request additional information, when necessary, to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests will delay final action on the application.

### 1.2 Applicable Regulations

a. If the applicant is preparing an application for the use of a remote afterloader or teletherapy unit, the Radiation Control Program licensing staff must be contacted for additional guidance on the information that must be provided.

b. Source and Special Nuclear Materials.

Source material is defined in K.A.R. 28-35-135 (jj)(1)(b) as (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight, 1/20 of one percent (0.05 percent) or more of (a) uranium, (b) thorium or (c) any combination thereof. Source material does not include special nuclear material.

Special nuclear material is defined in K.A.R. 28-35-135 (jj)(1)(c) and includes (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, (2) any material artificially enriched by anyone of the foregoing but does not include source material.

### 1.3 As Low As Reasonably Achievable (ALARA)

K.A.R. 28-35-211d(b) states "The licensee or registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are As Low As Reasonably Achievable (ALARA)."

Appendix S describes an acceptable ALARA program. In response to Item 7, you may state that the responsibilities, duties and meeting frequency will be as described in Appendix B to this guide.

### 1.4 Types of Materials Licenses

a. K.A.R. 28-35-178(h) established a general license authorizing physicians, clinical laboratories, and hospitals to possess certain small quantities of radioactive material (iodine-125, iodine-131, carbon-14, hydrogen-3, iron-59) for in-vitro clinical or laboratory tests not involving the internal or external administration of radioactive material or the radiation therefrom to human beings or animals. K.A.R. 28-35-178(h) explains the general license requirements and

requires the applicant to register with the Bureau and receive a registration number prior to receiving or using the radioactive material for in- vitro testing.

- b. Licenses issued to physicians for private practice specify the radioisotopes and the clinical uses that may be performed by the physician to whom the license is issued. Such licenses are issued to physicians who are located in private offices and not on hospital premises. It is not required that a Radiation Safety Committee (Radioisotope, or Medical Isotopes Committee) be formed. The private practice license does not permit other physicians to obtain clinical radioisotope training and experiences under it. K.A.R. 28-35-181b outlines specific requirements for this type of license.
- c. Specific licenses of limited scope issued to institutions specify the radioisotopes and the clinical uses that may be performed by physicians named on the institution's license. The regulations in K.A.R. 28-35-181a require an institutional licensee to have a Radiation Safety Committee (Radioisotope, or Medical Isotopes Committee) to evaluate all proposals for clinical research, diagnostic, and therapeutic uses of radioisotopes within the institution.(see Appendix B)

The physicians named on the institution's license conduct their programs with the approval of the Radiation Safety Committee (Radioisotope, or Medical Isotopes Committee). Institutional licenses provide a means whereby non-approved physicians under the supervision of physicians named on the license may obtain basic and clinical radioisotope training and experience which may enable them to qualify as individual users. Training and experience criteria for physicians are outlined in Appendix A.

- d. Specific licenses of broad scope for medical use, i.e., licenses authorizing multiple quantities and types of radioactive material for unspecified users, are issued to institutions that (1) have had previous experience operating under a specific institutional license of limited scope and (2) are engaged in medical research as well as routine diagnosis and therapy using radioisotopes. Such programs operate under the supervision of a Radiation Safety Committee (Radioisotope, or Medical Isotopes Committee).

Individual users are not named on the license nor are radioisotopes limited to specified uses. Individual users and procedures are approved by the institution's Radiation Safety Committee (Radioisotope, or Medical Isotopes Committee). Physicians may obtain basic and clinical radioisotope training and experience in the use of radiopharmaceuticals in such programs. A broad scope type of license is not appropriate for most institutions using radioactive material in medical programs.

- e. Licensees may also be private practice, institutional limited scope "group" licenses which means the isotopes and uses authorized are listed by groups in 28-35-135g.

## 2.0 Filing An Application

A license application for specific licenses for human use should be submitted on Form RH-10 "Application For Radioactive Materials License -Medical". All items on the application form should be completed in sufficient detail for the Radiation Control Program licensing staff to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on Form RH-10 is limited, the applicant should append additional sheets for Items 7-23 listed in the Form. Each separate sheet should contain the item number and the application date at the bottom right-hand corner of each page.

The application should be completed in duplicate. The original copy should be mailed to: Kansas Department of Health and Environment, Bureau of Air and Radiation, Radiation Control Program, 1000 SW Jackson, Suite 310, Topeka, KS 66612-1366. 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.

### 3.0 Contents Of An Application

#### Item 1.a.

Enter the name, mailing address and telephone number of applicant. If the request is for a private license, enter the name of the physician or partnership and Kansas Medical Certificate Number and medical specialty for each physician.

#### Item 1.b.

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

#### Item 2

Enter the name, telephone number (including area code) an e-mail address of the individual to be contacted regarding the application.

#### Item 3

Indicate whether the application is for a new license, amendment or renewal and provide the license number if the application is for a renewal or amendment.

#### Item 4

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

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

- a. The approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources.
- b. The prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered.

- c. The determination of the route of administration.
- d. The interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

The responsibility for a diagnostic or therapeutic procedure may not be delegated to technicians, technologists or other paramedical personnel, however, properly trained technicians, technologists, or other paramedical personnel under a user's supervision may be delegated the following activities:

- a. Preparation and quality control testing of radiopharmaceuticals and sources of radiation.
- b. Measurement of radiopharmaceutical doses prior to administration.
- c. Use of appropriate instrumentation for the collection of data to be used by the physician.
- d. Administration of radiopharmaceuticals and radiation from radioisotope sources to patients, within limits otherwise permitted under applicable federal, state or local laws.

### Training and Experience

- a. Authorized User(s)

If the physician has been previously authorized to use the radioactive material requested in this application, it is necessary to submit the previous license number (issued by the NRC (AEC) or an Agreement State) and a copy of the license should be included.

If the physician has not been previously authorized to use the radioactive material being requested, state where they are licensed to practice medicine and submit a complete description of the training and experience. Criteria for acceptable training and experience are contained in Appendix A.

The Training and Experience and Preceptor Attestation forms may be used for the description of the physician's training and experience.

- b. Onsite Physician

An onsite physician is required for each location where mobile nuclear medicine procedures are performed. Each location shall be listed as a location of use and shall have an onsite physician or authorized user who will be responsible in the event difficulties arise involving the patient. Criteria for acceptable training and experience are contained in Appendix A.

### Item 5

State the name and title of the person designated by, and responsible to, the institutions management for the coordination of the institution's radiation protection program (sometimes designated the "Radiation Safety Officer").

A statement should be included with the application outlining the named individual's duties and responsibilities. The radiation protection officer is expected to coordinate the safe use of the radioactive material and ensure compliance with the requirements of the Kansas Radiation Protection Regulations.

If the radiation safety officer is not one of the physicians named in Item 4, submit a complete description of the training and experience.

The Training and Experience and Preceptor Attestation forms may be used for the description of the radiation safety officer's training and experience.

Appendix C describes acceptable duties and responsibilities of the RSO and also contains an example letter for delegation of authority to administer the radiation safety program. In response to Item 5, you may state that the duties and responsibilities will be as described in Appendix C to this guide or submit a complete description of your Radiation Safety Officer duties and responsibilities.

#### Item 6.a.

For routine human use you may select the 10 CFR 35 use for which you are requesting a license. 10 CFR 35.100 and 10 CFR 35.200 consist of the more commonly used diagnostic procedures that involve radiopharmaceuticals for imaging or function studies; 10 CFR 35.300 consist of therapeutic procedures that involve radiopharmaceuticals and require a written directive; and 10 CFR 35.400 consist of therapeutic procedures that involve the use of sealed sources or devices and require a written directive.

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

The requested possession limit for Group VI and any radioactive material listed separately from Groups I-V should be stated. The possession limit for each radionuclide includes material held as radioactive waste and material in transit from the radiopharmacy.

#### Item 6.b.

For human use not described above and for non-human use, list each radionuclide to be used, the chemical and physical form, and the maximum quantity (in millicuries) required.

List the manufacturer's name, model number, and activity (in millicuries) for all sealed sources and devices containing radioactive material. Include remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

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

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

### Item 7 - Radiation Safety Committee (Radioisotopes, or Medical Isotopes Committee)

In accordance with K.A.R.28-35-181a, an institution applying for a radioactive materials license for human use shall establish a Radiation Safety Committee (Radioisotopes, or Medical Isotopes Committee). This committee should contain at least three (3) members to evaluate all proposals for research, diagnosis and therapeutic use of radioisotopes. Membership of the committee should include:

- a. Physicians expert in internal medicine, hematology, therapeutic radiology,
- b. A person with special competence in radiation safety, and
- c. A representative of the institution's management.

The following information should be submitted:

- a. The responsibility and duties of the committee,
- b. The meeting frequency of the committee (at least quarterly), and
- c. The name, specialty, and curriculum vitae of each member of the committee.

Appendix B contains an example of typical responsibilities and duties for a Radiation Safety Committee (Radioisotopes, or Medical Isotopes Committee). In response to Item 7, you may state that the responsibilities, duties and meeting frequency will be as described in Appendix B to this guide or submit a complete description of your Radiation Safety Committee.

### Item 8 - Instrumentation

Instruments required in a typical nuclear medicine laboratory are:

- a. Survey Instruments
  - (1) A low level survey meter capable of detecting 0.1 milliroentgen per hour to perform contamination surveys. Such a survey meter would be adequate for locating contamination or other routine uses provided the instrument is properly calibrated for the tasks undertaken. Such tasks can also be performed using swipes and the counting systems already available for patient and/or sample counting.
  - (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. This type of instrumentation is necessary to conduct surveys of and around therapy patients and/or generators larger than 50 millicuries.
- b. Dose calibrators and other instruments to assay radiopharmaceuticals.
- c. Diagnostic instruments for all procedures (e.g., gamma camera, well counter, thyroid probe).
- d. Other pertinent instrumentation (e.g., liquid scintillation counter, area monitor).

Appendix D contains a form that may be used to describe your instruments. If you do not use this form, attach equivalent information.

### Item 9 - Calibration of Instruments

#### a. Survey Instruments

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

Daily constancy checks of survey instruments should be supplemented every 12 months with a two-point calibration on each scale of the instrument such that (1) one point is in each half of the scale, and (2) the two points are separated by 35-50 percent of full scale. Survey instruments should also be calibrated after repair.

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

If you propose to calibrate your own radiation survey and monitoring instruments, you should submit a detailed description of your planned calibration procedures. The description of calibration procedures should include, as a minimum:

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

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

Appendix E contains an acceptable instrument calibration procedure. In response to Item 9, you may state that the survey instruments will be calibrated as described in Appendix E to this guide or submit an equivalent procedure.

#### b. Dose Calibrator

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

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

- (1) The manufacturer's name and model number of any sealed sources to be used,
- (2) The nuclide and activity (in millicuries) of radioactive material in the standards,
- (3) The accuracy of the standard. Traceability of the source to a primary standard should be provided, and
- (4) Step-by-step procedures used for calibration.

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

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

Appendix E contains an acceptable dose calibrator calibration procedure. In response to Item 9, you may state that the dose assay instruments will be calibrated as described in Appendix E to this guide or submit an equivalent procedure.

c. Diagnostic Instruments

Manufacturer's directions should be followed for calibration and maintenance of diagnostic instrumentation.

Item 10 - Facilities And Equipment

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

Describe the storage of radioactive material, including security of the radioactive material to prevent unauthorized use and access, include any administrative measures (log in/out sheets, key controls, authorized personnel, security personnel) and physical devices (locked rooms, locked storage safes).

A diagram should be submitted showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. Any wall shielding, special storage area shielding, or movable shielding around storage areas, generators, kit preparation areas, etc. should be indicated. Diagrams should be drawn to a specified scale, North and dimensions should be indicated.

For facilities in which radioactive material may become airborne, the diagrams should also include schematic descriptions of the ventilation system, with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments.

### Item 11 - Personnel Training Program

Submit a description of training required for all personnel who work with or in the vicinity of radioactive materials. The description should include the form of training (e.g., formal course work, lectures), the duration of training and the subject matter included. The training program should be of sufficient scope to ensure that all personnel, including clerical, nursing, housekeeping, and security personnel, receive proper instruction in the items specified in K.A.R. 28-35-333.

Appendix R describes an acceptable training program and course agenda to meet the requirements of K.A.R.28-35-333. In response to Item 11, you may state that you will follow the program described in Appendix R to this guide or submit an equivalent program.

### Item 12 - Ordering And Receiving Radioactive Materials

Submit a copy of written procedures for ordering radioactive materials, for receipt of materials during off-duty hours, and for notification of responsible persons upon receipt of radioactive materials. These procedures should be adequate to ensure that possession limits are not exceeded, that radioactive materials are secured at all times against unauthorized removal and that radiation levels in uncontrolled areas do not exceed the limits specified in K.A.R. 28-35-214a.

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

Appendix F contains an acceptable procedure and instructions for ordering and receiving packages containing radioactive material. In response to Item 12, you may state that you will follow the procedure described in Appendix F to this guide or submit an equivalent procedure.

### Item 13 - Safely Opening Packages Containing Radioactive Material

Describe your procedures for examining incoming packages for leakage, contamination or damage, and for safely opening packages in accordance with K.A.R.28-35-221a. The monitoring should be performed as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending on the quantity of radioactive material received, but should, at a minimum include instructions for surveying packages, wearing gloves while opening packages and checking packing material for contamination after opening. Even though K.A.R.28-35-221a exempts certain packages from immediate monitoring, procedures must be established for safely opening all packages containing radioactive material.

Appendix G contains an acceptable procedure for safely opening packages. In response to Item 13, you may state that you will follow the procedure described in Appendix G to this guide or submit an equivalent procedure.

### Item 14 - General Rules For The Safe Use Of Radioactive Material

Submit a copy of general instructions to be followed by physicians and technologists or technicians while working with radioactive materials. The instruction should:

- a. Outline control procedures for obtaining permission to use radioactive material at the institution,
- b. Explain what laboratory apparel to wear and what equipment to use, e.g., wearing of lab coats, the use of disposable gloves, trays, etc.,
- c. Prescribe limitations and conditions relative to handling liquid or loose radioactive materials and what laboratory equipment to use in working with them. For example, explain which materials and operations should be confined to radiochemical fume hoods or glove boxes,
- d. Explain what shielding or remote handling equipment is to be used when hard beta and/or gamma emitting materials are handled. Preparation of radiopharmaceuticals from reagent kits should be done behind shielding. Syringe shields should be used for the preparation and administration of patient doses,
- e. Give instructions for preparation and assay of patient doses,
- f. Give instructions concerning movement of material between rooms, halls, or in corridors if applicable,
- g. Explain requirements for storage of materials, labeling of containers, and identification of areas where radioactive materials are used. You should describe the shielding used for areas where large amounts of radioactive material are stored,
- h. Specify personnel monitoring devices to be used, where to obtain them, and instructions for recording exposure results or properly turning in personnel monitoring devices for processing at appropriate intervals,
- i. Describe waste disposal procedures to be followed for each type of waste, (e.g., liquids, gases, solids, long-lived, short-lived), and
- j. Describe contamination control procedures including prohibitions against smoking, eating or the consumption of beverages in controlled areas and instruction for individuals who prepare doses and radiopharmaceuticals to monitor their hands after each procedure and at the end of the day.

Appendix H contains an acceptable set of general laboratory rules for the safe use of radioactive material. In response to Item 14, you may state that you will follow the laboratory rules described in Appendix H to this guide or submit equivalent rules.

#### Item 15 - Emergency Procedures

Submit a copy of emergency instructions to be posted in all laboratory areas where radioactive materials are used. These instructions should (1) describe immediate action to be taken in order to prevent contamination of personnel and work areas (e.g., turning off ventilation, evacuation of the area, containment of the spill), (2) state the names and telephone numbers of the responsible persons to be notified in case of an emergency, and (3) instruct personnel on appropriate methods of reentering, decontamination, and recovering facilities that may have been accidentally contaminated.

Appendix I contains an acceptable set of Emergency Procedures. In response to Item 15, you may state that you will follow the Emergency Procedure in Appendix I to this guide or submit an equivalent procedure.

## Item 16 - Radiation Safety Procedures

Submit a description of the Radiation Safety Procedures.

- a. Bioassays may be required when individuals work with millicurie quantities of hydrogen-3, iodine-125 or iodine-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that the radioactive material will be ingested, inhaled or absorbed into the body. The applicant should show in his application that the need for bioassays has been thoroughly considered and that the proposed bioassay program is appropriate for his intended use of radioactive material, (i.e., hydrogen-3 (urinalysis), iodine-125 or 131 (thyroid counting determinations etc.).

Bioassay sampling procedures should include trigger level and frequency for performing bioassay sampling, type of sample to be collected, method of analysis, levels at which increased oversight or investigations will be performed to ensure personnel exposures are ALARA and include the considerations or actions to be taken when the levels are exceeded to prevent reoccurrence.

- b. Describe the procedures for testing for leakage and/or contamination of sealed sources (i.e., cobalt-57 flood sources, simulated liquid (epoxy resin) etc). Sealed sources containing more than 100 microcuries of a beta or gamma emitter or more than 10 microcuries of an alpha emitter must be leak tested at six-month intervals. Leak testing of alpha-particle-emitting sources containing more than 10 microcuries of an alpha emitter is required at three-month intervals.

If a commercial firm is to perform the leak tests, the name, address, and license number of the firm should be submitted. If the tests are to be performed using a commercial "kit" the name of the kit manufacturer or distributor and the kit model designation should be given. If the applicant intends to perform his own leak tests without the use of a commercial kit, the following information should be submitted:

- (1) Qualifications of personnel who will perform the leak test,
- (2) Procedures and materials to be used in taking test samples,
- (3) The type, manufacturer's name, model number, and radiation detection and measurement characteristics of the instrument to be used for assay of test samples,
- (4) Instrument calibration procedures, including calibration source characteristics, make, and model number, and
- (5) The method, including a sample calculation, to be used to convert instrument readings to units of activity, e.g., microcuries.

Appendix P contains an acceptable sealed source leak test procedure. In response to Item 16b for leak testing sealed sources, you may state that you will follow the procedure described in Appendix P to this guide or submit an equivalent procedure.

- c. Describe the ALARA Program and how the facility will maintain exposure to radiation and radioactive material as low as reasonably achievable.

Appendix S describes an acceptable ALARA Program. In response to Item 16c for ALARA Program description, you may state that you will follow the program described in Appendix S to this guide or you may submit an equivalent program.

- d. Describe the determination of Molybdenum-99 breakthrough when using Mo-99/Tc-99m generators.

Appendix Q contains an acceptable Molybdenum-99 breakthrough procedure. In response to Item 16d for Molybdenum-99 breakthrough determination, you may state that you will follow the procedure described in Appendix Q to this guide or submit an equivalent procedure.

- e. Describe the use of Positron Emission Tomography (P.E.T.) radiopharmaceuticals. The addition of P.E.T. to the radiopharmaceuticals available for use by a nuclear imaging program brings increased risk and, therefore, the need for increased awareness and radiological controls. If the applicant intends to use P.E.T. radiopharmaceuticals, the following information should be submitted:

- (1) Fluorine-18 in the form of Fluorodeoxyglucose (FDG), carbon-11 acetate, nitrogen-13 ammonia or oxygen-15 water are only allowed as specific line items in Item 6.b. of the application and are not covered by the medical groups. Possession limits and requested use.
- (2) Describe the procurement of shielded equipment designed for the high energy 511 KeV gamma. L-block shields, syringe shields, dose calibrator well.
- (3) Describe an increased awareness in training which should include:
  - Technologists and staff minimizing patient contact time after dose administration, maximizing distance from high radiation sources, and the proper use of available shielding.
  - Technologists should practice PET receiving, calibrating, and injecting procedures with saline prior to handling PET radiopharmaceuticals.
  - Stress the wearing of hand and body dosimetry badges
- (4) Describe shielding evaluations performed for storage location for sources, dose receiving and storage areas, dose calibration area, radioactive waste storage area, patient waiting area, injection and uptake area, scanner area and adjacent unrestricted areas.

- f. Describe the procedures to be followed on the mobile nuclear medicine coach, the following information should be submitted:

- (1) Equipment checks,
- (2) Base location, radioactive material receipt only when occupied by licensee personnel, security while parked, exposure to members of the general public, shielding, surveys,
- (3) Procedures for patient voiding prior to imaging, patient instructions, and
- (4) Provide copies of contract or agreement between the mobile service and each client authorizing the use of radioactive material at the client facility.

Appendix T contains an acceptable mobile nuclear medicine procedure. In response to Item 16f for mobile nuclear medicine, you may state that you will follow the procedure described in Appendix T to this guide or submit an equivalent procedure.

#### Item 17 - Area Survey Procedures

Describe the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable and provisions for maintaining records of surveys.

If the application is to cover multiple users and areas of use, the individual user should supplement the surveys performed by the radiation safety staff.

Appendix J describes an acceptable procedure for performing routine area surveys. In response to Item 17, you may state that you will follow the survey procedure described in Appendix J to this guide or submit an equivalent procedure.

#### Item 18 - Waste Disposal

Describe specific methods used for disposal of waste radioactive material. A licensee may dispose of waste by:

- a. Transfer to a person properly licensed to receive such waste, e.g., commercial waste disposal firms. (See K.A.R.28-35-223a.) Submit the name and NRC or Agreement State license number of the commercial firm selected,
- b. Release into a sanitary sewer in conformance with K.A.R.28-35-224a. You should describe your methods for controlling the sewage disposal of radioactive wastes in order to ensure that disposals do not exceed the limits specified in Appendix B, Appendices to Part 4, Standards for Protection Against Radiation,
- c. Burial in soil in conformance with K.A.R.28-35-225a,
- d. Release into the air in conformance with K.A.R.28-35-214b, and
- e. Other methods specifically approved by the Bureau pursuant to K.A.R.28-35-223(b).

Note: No licensee may dispose of radioactive material waste by incineration unless specifically authorized by the Bureau. (See K.A.R.28-35-226a.)

Appendix K contains a form that may be used to supply the information required in Item 18 of the application form. If you do not use this form, attach equivalent information.

#### Item 19 - Therapeutic Use Of Radiopharmaceuticals (Written Directive Required)

Describe special precautions for patients treated with radioactive material permitted by 10 CFR 35.300. Although some procedures are often performed on an out patient basis, patients likely to expose other individuals in excess of 500 mrem and should be hospitalized until the exposure other individuals will receive will be less than 500 mrem.

Appropriate procedures should be established for all patients treated with radioactive material and should include:

- a. Method for preparation and administration of therapeutic doses of iodine-131. Instruct personnel to wear gloves and to open containers of iodine-131 in a fume hood with adequate airflow or to take other precautionary measures to prevent contamination of themselves and surrounding areas.
- b. Methods for contamination control:
  - (1) Assignment to private room, and
  - (2) Use of disposable items (e.g., dishes, utensils, etc.)
- c. Procedures for surveys of:
  - (1) Uncontrolled areas,
  - (2) Linens and other items removed from patient's room, and
  - (3) Patient's room before it is reassigned to another patient.

Licensees should also perform surveys (e.g., measurement of iodine-131 in air; measurement of iodine-131 in the thyroid gland of laboratory personnel; contamination surveys of personnel, equipment, and facilities) to determine compliance with K.A.R.28-35-217a and K.A.R.28-35-218a.

- d. Instructions to nursing staff.
- e. Procedures for disposal of waste:
  - (1) Patient excreta,
  - (2) Surgical dressings, and
  - (3) Disposable items.
- f. Procedures to be followed in case of emergency surgery or death.
- g. Procedures for release of patients:
  - (1) Criteria for release of patients, and
  - (2) Instructions to patient and family.
- h. Procedures for bioassay of personnel.

Significant thyroid uptakes have been detected in individuals who open and prepare oral solutions of iodine-131 for therapeutic doses.

Guidance for the management of therapy patients can be found in National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," (NCRP Reports are available from: NCRP Publications, P.O. Box 30175, Washington, D.C. 20014).

Appendix L contains a description of precautions to be followed for patients treated with iodine-131, gold-198 and phosphorus-32. In response to Item 19, you may state that you will follow the procedure described in Appendix L to this guide or submit an equivalent procedure.

#### Item 20 - Therapeutic Use Of Sealed Sources (Written Directive Required)

Describe special procedures for patients treated with radioactive materials permitted by 10 CFR 35.400. These procedures should include descriptions of:

- a. Special precautions to be used while handling sealed sources,
- b. Your method for maintaining source accountability at all times. This should include a description of your sign-in and sign-out procedures, periodic inventory, and your method for determining that all sources are accounted for and returned to storage following treatment,
- c. Special instructions for nursing care of patients who are treated with sealed sources, and
- d. Surveys to be performed during the course of treatment and at the conclusion of treatment. Your dismissal survey should be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied.

Appendix M contains a description of precautions to be followed for patients treated with sealed sources. In response to Item 20, you may either state that you will follow procedure described in Appendix M to this guide or submit an equivalent procedure.

#### Item 21 - Use Of Radioactive Gases and Aerosols

The use of radioactive gases (e.g., xenon-133 gas or gas in saline) requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive gas in controlled and uncontrolled areas. The Radiation Control Program requires that each applicant make such determinations for his own unique situation and submit sufficient evidence to the Bureau in support of his request.

Appendix N contains sample procedures and instructions for submitting an application to use radioactive gases or aerosols.

#### Item 22 - Personnel Monitoring Devices

State the name of the organization providing the personnel monitoring service. Specify the frequency with which the badges are changed and evaluated, and give a description of the type, e.g., whole body, wrist, or finger badge. Where wrist badges are worn to monitor extremity exposures and exposures to fingertips are likely to be greater than the wrist exposures, describe how fingertip exposures will be estimated from the wrist badge data in lieu of fingertip monitors, and provide any backup data used to perform or verify these estimates.

#### Item 23 - Certificate

Items 23 a. and b. provide the signature of an individual authorized by management to represent an applicant institution or the signature of an individual physician, in the case of private practice, with the date of signature.

## Procedures And Precautions For Use Of Radioactive Material In Animals

Describe procedures to be followed if radioisotopes will be used in animals including (1) a description of the animal housing facilities, (2) a copy of instructions provided to animal caretakers for the handling of animals, animal waste and carcasses, (3) instructions for cleaning and decontaminating animal cages, and (4) procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

### 4.0 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 type of monitoring and survey instruments), procedures, personnel, or radioactive material to be used.

Applications for license amendments may be filed either on the application Form RH-10 or in a letter. 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.

### 5.0 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 Radiation Control Program as provided for in K.A.R. 28-35-186a.

Renewal applications should be filed on Form RH-10 appropriately supplemented if there are major program changes, and should contain complete and up-to-date information about the applicant's current program.

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

- a. The reference is made in response to a particular item of required information (e.g., bioassay procedures).
- b. The reference is clear and specific (e.g., title of document, date of submission, page, and paragraph).
- c. The referenced document contains all information required for a particular item at the time of renewal.

The application should be completed in duplicate. The original copy should be mailed to: Kansas Department of Health and Environment, Bureau of Air and Radiation, Radiation Control Program, 1000 SW Jackson, Suite 310, Topeka, KS 66612-1366. One copy of the application, with all attachments, should be retained by the applicant, since 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.

## APPENDICES ORDER

<u>Appendix</u>	<u>Title</u>
A	Acceptable Training And Experience For Medical Uses Of Radioactive Material
B	Radiation Safety Committee (Medical Isotopes Committee)
C	Radiation Safety Officer and Sample Delegation of Authority
D	Instrumentation
E	Calibration of Instruments
F	Ordering And Receiving Radioactive Material
G	Safely Opening Packages Containing Radioactive Material
H	General Rules For The Safe Use Of Radioactive Material
I	Emergency Procedures
J	Area Survey Procedures
K	Radioactive Waste Disposal Procedures
L	Therapeutic Use of Radiopharmaceuticals Exceeding Patient Release Criteria of 500 millirem
M	Therapeutic Use Of Sealed Sources For Treatment Of Patients
N	Use of Radioactive Gases And Aerosols
O	Use of Intravascular Brachytherapy Systems
P	Leak Test Procedure
Q	Molybdenum-99 Breakthrough Calculations
R	Training Program
S	ALARA Program
T	Mobile Nuclear Medicine Service
U	Positron Emission Tomography – PET

## APPENDIX A

### ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF RADIOACTIVE MATERIAL

K.A.R. 28-35-180a and K.A.R. 28-35-181a provides that the Radiation Control Program will approve a license application by an institution for medical use of radioactive material if it determines, among other things, that the physician designated as the individual user is adequately trained and experienced in (a) basic radioisotope handling techniques and (b) the clinical use of radioactive material proposed in the application. Similar criteria are established in K.A.R.28-35-181(b) for approval of licenses for medical use of radiopharmaceuticals by individual physicians. Outlined below are training and experience criteria that the Radiation Control Program, with the assistance of its Advisory Committee on the Medical Uses of Isotopes, has found acceptable for physicians who use radiopharmaceuticals. Each physician's training and experience are examined on a case-by-case basis. If a physician wishes to use radiopharmaceuticals but does not have the training and experience described, he must submit an application listing his specific qualifications and this will be reviewed by the Radiation Control Program with the assistance of the Medical Advisory Committee.

#### I. Training Requirements For Diagnostic Procedures Involving Radiopharmaceuticals

A. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group I, K.A.R. 28-35-135g (10 CFR 35.100) a physician has completed 60 hours of training and experience in basic radioisotope handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution and excretion studies including a minimum of 8 hours classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation Protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology;
5. Radiopharmaceutical chemistry; and

Work experience, under the supervision of an authorized user (52 hours) involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages of radioactive drugs to patients or human research subjects; and

Has obtained written attestation, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Group I.

Note A: The requirements specified in Sections A and B may be satisfied concurrently in a three month training program IF all areas are integrated into the program.

Note B: For each physician named in Item 4 of Form RH-10, complete The Training and Experience and Preceptor Attestation forms for the description of the physician's training and experience. (Preceptor Statement and the statement of training in basic radioisotope handling techniques). For each subject covered in basic training, state where the training was obtained, the dates, total number of hours and type of training (e.g., lectures, laboratory sessions).

Alternative: Certification by specialty board recognized by the NRC and written attestation, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements will be accepted as evidence that a physician has had adequate training and experience to use Group I or provide a copy of a radioactive material license naming the physician as an authorized user for Group I.

B. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Groups II and III, K.A.R. 28-35-135g (10 CFR 35.200) a physician has completed 700 hours of training and experience in basic radioisotope handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies including a minimum of 80 hours classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation Protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology;
5. Radiopharmaceutical chemistry; and

Work experience, under the supervision of an authorized user (620 hours) involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
6. Administering dosages of radioactive drugs to patients or human research subjects; and
7. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

Has obtained written attestation, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Groups II and III.

Note A: The requirements specified in Sections A and B may be satisfied concurrently in a three month training program IF all areas are integrated into the program.

Note B: For each physician named in Item 4 of Form RH-10, complete The Training and Experience and Preceptor Attestation forms for the description of the physician's training and experience. (Preceptor Statement and the statement of training in basic radioisotope handling techniques). For each subject covered in basic training, state where the training was obtained, the dates, total number of hours and type of training (e.g., lectures, laboratory sessions).

Alternative: Certification by specialty board recognized by the NRC and written attestation, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements will be accepted as evidence that a physician has had adequate training and experience to use Groups II and III or provide a copy of a radioactive material license naming the physician as an authorized user for Groups II and III.

## II. Training Requirements For Specific Diagnostic Procedures

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of radioactive material being requested. Such requests will be examined on a case-by-case basis by the Radiation Control Program with the assistance of the Advisory Committee on the Medical Uses of Isotopes.

## III. Training Requirements For Therapy Procedures Involving Radiopharmaceuticals

A. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Groups IV and V, K.A.R. 28-35-135g (10 CFR 35.300) a physician has completed 700 hours of training and experience in basic radioisotope handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive including a minimum of 200 hours classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation Protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology;
5. Radiopharmaceutical chemistry, and

Work experience, under the supervision of an authorized user (500 hours) involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
6. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—
  - (a) Oral administration of sodium iodide I-131, which the patient can be released pursuant

- to 10 CFR 35.75, for which a written directive is required;
- (b) Oral administration of sodium iodide I-131 which the patient can not be released pursuant to 10 CFR 35.75, for which a written directive is required (Experience with at least 3 cases also satisfies the requirement in 6(a) above);
  - (c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or
  - (d) Parenteral administration of any other radionuclide, for which a written directive is required; and

Has obtained written attestation, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Groups IV and V.

Note A: The requirements specified in Sections A and B may be satisfied concurrently in a three month training program IF all areas are integrated into the program.

Note B: For each physician named in Item 4 of Form RH-10, complete The Training and Experience and Preceptor Attestation forms for the description of the physician's training and experience. (Preceptor Statement and the statement of training in basic radioisotope handling techniques). For each subject covered in basic training, state where the training was obtained, the dates, total number of hours and type of training (e.g., lectures, laboratory sessions).

Alternative: Certification by a specialty board recognized by the NRC and written attestation, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements will be accepted as evidence that a physician has had adequate training and experience to use Groups IV and V or provide a copy of a radioactive material license naming the physician as an authorized user for Groups IV and V.

(The following requirements are in lieu of, not in addition to, those specified in Section III.A., above.)

B. Training requirements for oral administration of iodine-131 (Group IV – Iodine-131 only), which the patient can be released pursuant to 10 CFR 35.75, a physician has completed 80 hours of training and experience in basic radioisotope handling techniques applicable to the medical use of unsealed sodium iodide I-131 requiring a written directive including classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation Protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology;
5. Radiopharmaceutical chemistry; and

Work experience, under the supervision of an authorized user involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
6. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases for the oral administration of sodium iodide I-131, which the patient can be released pursuant to 10 CFR 35.75, for which a written directive is required, and

Has obtained written attestation, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Group IV for iodine-131 only or provide a copy of a radioactive material license naming the physician as an authorized user for Group IV iodine-131 only.

- C. Training requirements for oral administration of iodine-131, which the patient can not be released pursuant to 10 CFR 35.75, (Group V – Iodine-131 only) a physician has completed 80 hours of training and experience in basic radioisotope handling techniques applicable to the medical use of unsealed sodium iodide I-131 requiring a written directive including classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation Protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology;
5. Radiopharmaceutical chemistry; and

Work experience, under the supervision of an authorized user involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
6. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases for the oral administration of iodide I-131, which the patient can not be released pursuant to 10 CFR 35.75, for which a written directive is required (Experience with at least three cases also satisfies the requirement in B(6) above), and

Has obtained written attestation, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Group V for iodine-131 only or provide a copy of a radioactive material license naming the physician as an authorized user for Group V iodine-131 only.

#### IV. Training Requirements For Therapy Procedures Involving Sealed Sources- Group VI

To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group VI, K.A.R. 28-35-135g (10 CFR 35.400) a physician has completed three years of training and experience in residency training in an approved radiation oncology program including a minimum of 200 hours classroom

and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and

Work experience, under the supervision of an authorized user (500 hours) involving:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Checking survey meters for proper operation;
3. Preparing, implanting, and removing brachytherapy sources;
4. Maintaining running inventories of material on hand;
5. Using administrative controls to prevent a medical event involving the use of byproduct material;
6. Using emergency procedures to control byproduct material; and

Has obtained written attestation, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Group VI.

Alternative: Certification by a specialty board recognized by the NRC and written attestation, signed by a preceptor authorized user, that the individual has satisfactorily completed the requirements will be accepted as evidence that a physician has had adequate training and experience to use Group VI or provide a copy of a radioactive material license naming the physician as an authorized user for Group VI.

#### V. Training requirements for the Onsite Physician

To qualify as adequately trained to be named as an Onsite Physician, a physician has completed 30 hours of training and experience in basic radioisotope handling techniques in the following areas:

- |   |           |
|---|-----------|
| 1. Radiation physics and instrumentation                              | (4 hours) |
| 2. Radiation protection   | (4 hours) |
| 3. Mathematics pertaining to the use and measurement of radioactivity | (4 hours) |
| 4. Radiation biology  | (2 hours) |
| 5. Survey techniques  | (3 hours) |
| 6. Decontamination techniques   | (3 hours) |
| 7. Prenatal instruction   | (2 hours) |
| 8. Kansas Radiation Protection Regulations                            | (4 hours) |
| 9. Responsibilities of Onsite physician                               | (4 hours) |

Alternative: An authorized user named on a Kansas medical radioactive materials license or an on call Authorized User of the mobile service with a Certified Nuclear Medical Technician on the mobile unit.

#### VI. Training requirements for the Mobile Nuclear Medicine Technologist

A. Certified Nuclear Medicine Technologist (CNMT) or,

- B. Registered Nuclear Medicine Technologist or,
- C. Registry eligible Nuclear Medicine Technologist or,
- D. Registered Radiologic Technologist with a minimum of 2000 hours on the job nuclear medicine training with an associates degree in science (RT(N)) or,
- E. 2000 hours clinical or academic training in radiologic technology and 2000 hours on the job training in nuclear medicine and approved in writing by the RSO or,
- F. Registered Radiologic Technologist with a minimum of 320 hours on the job Positron Emission Tomography training with an associates degree in science (Mobile PET only).

## APPENDIX B

### RADIATION SAFETY COMMITTEE (MEDICAL ISOTOPES COMMITTEE)

#### Responsibility:

The committee is responsible for:

- A. Ensuring that all individuals who work with or in the vicinity of radioactive material or radiation producing devices have sufficient training and experience to enable them to perform their duties safely and in accordance with Radiation Control Program regulations and the conditions of the license.
- B. Ensuring that all use of radioactive material and radiation producing devices are conducted in a safe manner and in accordance with Radiation Control Program regulations and the conditions of the license.

#### II Duties:

The committee shall:

- A. Be familiar with all pertinent Radiation Control Program regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.
- B. Review the training and experience of any individual who uses radioactive material or radiation producing devices (including physicians, technologists, physicists, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with Radiation Control Program regulations and the conditions of the license.
- C. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material or radiation producing devices (e.g., nursing, security and housekeeping personnel) are properly instructed as required by K.A.R. 28-35-333a.
- D. Review and approve all requests for use of radioactive material within the institution.
- E. 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.
- F. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with Radiation Control Program regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of Radiation Control Program inspection, written safety procedures and management control system.
- G. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

- H. Maintain written records of all committee meetings, actions, recommendations, and decisions.
- I. Ensure that the radioactive material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

III Meeting Frequency:

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

IV Membership:

The Radiation Safety Committee shall consist of at least three members to oversee the use of licensed radioactive material and radiation producing devices throughout the institution and to review the institution's radiation safety program. Membership of the committee shall include at least the following: an authorized user for each type of use permitted by the license, a representative of the nursing staff, a representative of the institution's management, and a radiation safety officer.

## APPENDIX C

### RADIATION SAFETY OFFICER AND SAMPLE DELEGATION OF AUTHORITY

The RSO's duties and responsibilities include ensuring radiological safety and compliance with Radiation Control Program regulations and the conditions of the license.

These duties and responsibilities include the following:

- A. Stopping unsafe activities involving licensed material;
- B. Radiation exposures are ALARA;
- C. Up-to-date radiation protection procedures in the daily operation of the licensee's radiation safety program are developed, distributed, and implemented;
- D. Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations and the manufacturer's recommendations and instructions;
- E. Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- F. Personnel training is conducted and is commensurate with the individuals duties regarding licensed material;
- G. Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- H. Personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained and promptly reviewed;
- I. Licensed material is properly secured;
- J. Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- K. Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- L. Medical events and precursor events are investigated and reported to the Kansas Radiation Control Program, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- M. Audits of the radiation protection program are performed at least annually and documented;
- N. If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;

- O. Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- P. Licensed material is disposed of properly;
- Q. Appropriate records are maintained and promptly reviewed (for example, routine area radiation and removable contamination surveys, radioactive material receipt, radioactive material transport, personnel exposure, ALARA investigation, mis-administration) and
- R. An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

Memo To: Radiation Safety Officer  
From: Chief Executive Officer  
Subject: Delegation of Authority

You, \_\_\_\_\_, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of licensed material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the regulatory authorities at any time. It is estimated that you will spend 2 hours per week conducting radiation protection activities.

I accept the above responsibilities,

\_\_\_\_\_  
Signature of Management Representative

\_\_\_\_\_  
Signature of Radiation Safety Officer

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

cc: Affected department heads

## APPENDIX D

### Instrument Selection

Low-energy beta emitters, such as carbon-14 and sulfur-35, are difficult to detect with Geiger-Mueller (GM) probes. The detection efficiency generally is about 2% for low-energy beta emitters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys. Additionally, wipes should be taken and counted on a liquid scintillation counter to verify potential contamination.

Medium- to high-energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges from 15% to 40%, depending on the beta energy.

Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower (approximately 1%) and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.

Medium- to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.

#### Portable Instruments Used for Contamination and Ambient Radiation Surveys

Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-ray	mR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate

#### Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples

Detectors	Radiation	Energy Range	Efficiency
Liquid Scintillation Counter	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

INSTRUMENTATION

1. Radiation Survey Meter

Manufacturer's name: \_\_\_\_\_

Manufacturer's model number: \_\_\_\_\_

Number of instruments available: \_\_\_\_\_

Range: \_\_\_\_\_ mr/hr to \_\_\_\_\_ mr/hr

Window thickness: \_\_\_\_\_

Detector type/model number: \_\_\_\_\_

2. Contamination Survey Meter

Manufacturer's name: \_\_\_\_\_

Manufacturer's model number: \_\_\_\_\_

Number of instruments available: \_\_\_\_\_

Range: \_\_\_\_\_ cpm to \_\_\_\_\_ cpm

Window thickness: \_\_\_\_\_

Detector type/model number: \_\_\_\_\_

3. Instrument used to analyze wipes/leak checks

Manufacturer's name: \_\_\_\_\_

Manufacturer's model number: \_\_\_\_\_

Number of instruments available: \_\_\_\_\_

Minimum detectable activity\*: \_\_\_\_\_

4. Dose calibrator

Manufacturer's name: \_\_\_\_\_

Manufacturer's model number: \_\_\_\_\_

Number of instruments available: \_\_\_\_\_

## APPENDIX E

### CALIBRATION OF INSTRUMENTS

#### I Methods For Calibration Of Survey Meters, Including Procedures, Standards And Frequency

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

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

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

##### B. A reference check source of long half-life, e.g. greater than 5 years, shall also be read at the time of the above calibration. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:

1. Before each use to ensure that the instrument is operational,
2. After each maintenance and/or battery change, and
3. At least quarterly.

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

##### C. The instrument must be calibrated at lower energies if its response is energy dependent and it is to be used to measure in the I-125, Xe-133, or Tc-99m energy ranges.

This calibration may be done either:

1. As in A. above with calibrated standards of radionuclides at or near the desired energies, or

2. As a relative intercomparison with an energy independent instrument and uncalibrated radionuclides.

D. Records of the above, A, B-2, B-3, and C must be maintained. Attach a calibration sticker or tag to the instrument. The following information should be included on the sticker or tag:

1. Date of calibration and the next calibration due date
2. Reading from the reference check source.
3. Special use conditions (such as any scales checked for function but not calibrated)

E. Use of Inverse Square Law and Radioactive Decay Law.

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

2. Inverse Square Law

$$S \left( \frac{R_1}{P_1} \right) = \left( \frac{R_2}{P_2} \right)$$

Exposure rate at P<sub>2</sub>:

where:

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

- (a) S is the point source
- (b) R<sub>1</sub> and R<sub>2</sub> are in same units (mR/h or R/hr)
- (c) P<sub>1</sub> and P<sub>2</sub> are in the same units (cm, meter, feet etc.)

3. Radioactive Decay Law:

Exposure rate t units of time after specified calibration date:

where:

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

- (a) R<sub>o</sub> and R<sub>t</sub> are in the units (mR/hr or R/hr)
- (b) R<sub>o</sub> is exposure rate on specified calibration date
- (c) R<sub>t</sub> is exposure rate t unit of time later
- (d) T<sub>1/2</sub> and t are in the same units (years, months, days etc.)
- (e) T<sub>1/2</sub> is radionuclide half-life
- (f) t is time elapsed between calibration and present

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

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

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

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

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

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

## II Methods For Calibrating A Dose Calibrator

All radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

1. Test for the following:
  - (a) Instrument constancy (daily or prior to use), reproducibility in measuring a constant source over a long period of time.
  - (b) Instrument linearity (at installation and quarterly), the calibrator is able to indicate the correct activity over the range of use of that calibrator from 30 microcuries to the maximum activity normally assayed.
  - (c) Geometrical variation (at installation), the indicated activity does not change with volume or configuration.
  - (d) Instrument accuracy (at installation and annually), for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST.
2. After repair, adjustment or relocation of the dose calibrator, repeat the above tests as appropriate (dependent upon the nature of the repairs if proper function of the electronics is in doubt).
3. Assay at least one long lived reference source using a reproducible geometry each day before assaying patient doses.

### A. Instrument constancy

1. Assay a reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
2. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background circuit if it is used. Higher than normal background levels should be investigated to determine their origin and eliminated if possible by decontamination, relocation, etc.
3. For each source used either plot or log (i.e., record in the dose calibrator log book) the background level for each setting checked and the net activity of each constancy source.
4. Using the constancy source determined during the accuracy test, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
5. Variations greater than  $\pm 10$  percent from the activity determined during the accuracy test indicate the need for instrument repair, replacement or adjustment of the dose calibrator.

### B. Instrument Linearity

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

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

<u>Assay Time (Hrs.)</u>	<u>Correction Factor</u>
0	32
6	16
24	2
30	1
48	0.125

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

4. Plot both the measured net activity and the calculated activity versus time on semi-log graph paper.
5. The activities plotted should be within  $\pm 5$  percent of the predicted curve if the instrument is linear and functioning properly. Errors greater than  $\pm 10$  percent indicate the need for repair, replacement or adjustment of the dose calibrator.
6. If instrument linearity cannot be corrected, it will be necessary in routine assays to either assay an aliquot of the eluate that can be accurately measured, or to use the graph constructed in step 4 to relate measured activities to true activities.

### C. Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than  $\pm 2$  percent (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

1. In a small beaker or vial, mix 2 cc of a solution of technetium-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline or tap water.
2. Draw 0.5 cc of the technetium-99m solution into the syringe and assay it. Record the volume and millicuries.
3. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
4. Repeat the process until a volume of 2.0-cc has been assayed. The entire process must be completed within 10 minutes.

5. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed, with horizontal 10% error lines drawn above and below the chosen "standard volume".
6. If any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the error lines, it will be necessary to make a correction table or graph that will allow a conversion 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 and serial number of the calibrator.
7. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the technetium-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
8. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
9. Repeat the process until a volume of 19.0-cc has been assayed. The entire process must be completed within 10 minutes.
10. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed, with horizontal 10% error lines drawn above and below the chosen "standard volume".
11. If any correction factors are greater than 1.0, or less than 0.9, or if any data points lie outside the error lines, it will be necessary to make a correction table or graph that will allow conversion 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.

#### D. Instrument Accuracy

The accuracy of the dose calibrator should be checked for several radionuclides using appropriate reference standards whose activity is traceable to NIST. At least two sources with different principal photon energies (such as cobalt-57, cobalt-60, cesium-137) should be used. One source should have a principal photon energy between 100 keV and 500 keV. If a radium-226 source is used, it should be at least 10 microcuries; other sources should be at least 50 microcuries. Consider using at least one reference source with an activity that is within the range of activities normally assayed, giving adequate attention to source configuration. The lower energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting (e.g., use the cobalt-57 setting to assay cobalt-57) and subtract the background level to obtain the net activity. Repeat for a total of 3 determinations.
2. The average activity should agree with the certified activity of the reference source within  $\pm 5$  percent after decay corrections.
3. Repeat the procedure for other calibrated reference sources.

4. Calibration checks which do not agree within  $\pm 10$  percent indicate that the instrument will be repaired replaced or adjusted. If this is not possible a calibration factor should be calculated for use during routine assays of radionuclides.
5. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.
6. Put a sticker on the dose calibrator noting when the next accuracy test is due.
7. The individual performing the tests will sign or initial the records of all geometry, linearity, and accuracy tests.



CALIBRATION OF DOSE CALIBRATOR - ACCURACY

Dose Calibrator  
Manufacturer \_\_\_\_\_  
Model # \_\_\_\_\_  
Serial # \_\_\_\_\_

Calibration Sources:	1	2	3
Manufacturer	_____	_____	_____
Model No.	_____	_____	_____
Serial No.	_____	_____	_____
Isotope	_____	_____	_____
Activity	_____	_____	_____
Assay Date	_____	_____	_____
Half-life (days)	_____	_____	_____

Calibration Readings:			
Setting	_____	_____	_____
Reading 1	_____	_____	_____
Reading 2	_____	_____	_____
Reading 3	_____	_____	_____
Average Reading	_____	_____	_____
Background activity	_____	_____	_____
Net Average activity	_____	_____	_____
Expected activity	_____	_____	_____
% Accuracy	_____	_____	_____

Comment: \_\_\_\_\_

$$\text{Accuracy} = \frac{\text{Average} - \text{Activity}}{\text{Activity}} \times 100$$

Acceptable if within +/- 10%

Signature \_\_\_\_\_ Date \_\_\_\_\_ Cal Due \_\_\_\_\_

RSO Review \_\_\_\_\_ Date \_\_\_\_\_

CALIBRATION OF DOSE CALIBRATOR - LINEARITY

Certificate of Calibration

Dose Calibrator  
Manufacturer \_\_\_\_\_  
Model # \_\_\_\_\_  
Serial # \_\_\_\_\_

Source  
Isotope \_\_\_\_\_  
Half-life \_\_\_\_\_

Calibration Readings:

Date	Time	Time from Reference pt	Measured activity	Expected activity	Percent error

$$\% \text{ error} = \frac{\text{Measured} - \text{Expected}}{\text{Expected}} \times 100$$

Acceptable if within +/- 10%

Maximum error: \_\_\_\_\_%

Acceptable:    Yes    No

Comment: \_\_\_\_\_  
\_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_ Cal Due \_\_\_\_\_

RSO Review \_\_\_\_\_ Date \_\_\_\_\_



## SAMPLE MINIMUM DETECTABLE ACTIVITY CALCULATIONS

Several references contain discussions of counting statistics for radiation measurements. For purposes of this guide, the discussion contained in NCRP Report No. 58 appear to be the simplest to use. The formula recommended is the one for determining a measurement at the 95% confidence level. The formula for this level is:

$$LLD = \frac{2.71 + 4.65\sqrt{B}}{EFF}$$

where:

LLD = Lower Limit of Detection (dpm, divide by 2.2 E+6 for  $\mu\text{Ci}$ )

B = Background counting rate (counts/time) and

EFF = Counting efficiency.

The sample counting time and background counting time must be equal (typically 1 minute). The counting efficiency must be determined by using a standard source of known activity that emits photons of approximately the same energy as the contaminant to be detected. The counting rate for the standard is divided by the standard activity to determine the counting efficiency. When dividing, the two values must be in compatible units. A standard activity in  $\mu\text{Ci}$  must be converted to dpm by multiplying by a factor of 2.2E+6.

For a copy of the full discussion of the theory and limitations of this test, refer to pages 307-311 in NCRP Report No. 58, A Handbook of Radioactivity Measurement Procedures, issued February 1, 1985 by the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Bethesda, MD 20814.

## **APPENDIX F**

### ORDERING AND RECEIVING RADIOACTIVE MATERIAL

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

MEMORANDUM FOR: Security Personnel  
FROM: John Jones, Administrator  
SUBJECT: Receipt of Packages Containing Radioactive Material

Any packages containing radioactive material that arrive between 4:30 P.M. and 7:00 A.M. or on Sundays shall be signed for by the security officer on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately inside the door, and relock the door.

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

Radiation Safety Officer: \_\_\_\_\_

Office Phone: \_\_\_\_\_

Home Phone: \_\_\_\_\_



## APPENDIX G

### SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

This procedure applies to packages containing radioactive material with a Radioactive White I, Radioactive Yellow II or Radioactive Yellow III label and the package does not contain radioactive material in the form of gas or special form.

Monitoring is required within 3 hours of receipt (if received during working hours) or no later than 3 hours from the beginning of the next working day (if received after working hours).

An appropriate instrument with sufficient sensitivity will be used to assay the wipes. For example, a NaI(Tl) crystal and rate meter, a liquid scintillation counter, a proportional flow counter, or a thin-window G-M survey meter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute. *Note: a dose calibrator is not sufficiently sensitive for this measurement.* Take precautions against the potential spread of contamination. The wipes will be counted in a low background area.

KDHE and the final delivery carrier must be notified if the following conditions apply:

Removable radioactive surface contamination exceeds 2200 dpm/100 cm<sup>2</sup>; or

Surface radiation levels exceed 200 mrem/hr at any point of the package surface.

1. Put on gloves to prevent hand contamination.
2. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
3. Wipe external surface of the package with moistened cotton swab, filter paper or other suitable material applying moderate pressure; assay the wipe and record.
4. Survey external surface of the package for radiation levels if the package contains radioactive material in excess of the Type A quantity. (See below)
5. Monitor all packages known to contain radioactive material for removable contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged; assay the wipe and record.
6. Remove the packing slip.
7. Open the outer package, following any instructions that may be provided by the supplier.
8. Open the inner package and verify that the contents agree with the packing slip. Check also that shipment does not exceed possession limits.
9. Check the integrity of the final source container. Notify the radiation safety officer of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
10. If there is any reason to suspect contamination, wipe the external surface of the final source container; assay the wipe and record.

11. Check the user request to ensure that the material received is the material that was ordered.
12. Monitor the packing material and packages for contamination before discarding:
  - a. If contaminated, treat as radioactive waste.
  - b. If not contaminated, obliterate radiation labels before discarding in regular trash.
13. Make a record of the receipt.

Type A Quantities

Mo-99	20 curies (domestic use)	Cs-137	13.5 curies
Tc-99m	216 curies	Ir-192	13.5 curies
I-125	54.1 curies		
I-131	13.5 curies		
Xe-133	541 curies		

## APPENDIX H

### GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats, or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Monitor hands and clothing for contamination after each procedure or before leaving the area.
4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances, such as pediatric cases, where their use would compromise the patient's well-being.
5. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.
6. Determine the activity of each patient dose prior to administration. Do not use any doses that differ from the prescribed dose by more than 20 percent unless authorized by the authorized user.
7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist level.
8. Wear TLD finger badges during elution of generator and preparation, assay and injection of radiopharmaceuticals.
9. Dispose of radioactive waste only in specially designated receptacles.
10. Never pipette by mouth.
11. Survey generator, kit preparation and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.
12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity and radiation level, if applicable.
13. Always transport radioactive material in shielded containers.

## APPENDIX I

### EMERGENCY PROCEDURES

#### Minor Spills:

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wearing gloves and protective clothing as necessary clean up the spill, using absorbent paper. Carefully fold absorbent paper with the clean side out and place in a plastic bag and dispose of in the radioactive waste container. Include all other contaminated materials such as disposable gloves.
4. With a low-range, thin-window G.M. survey meter, check the area around the spill, your hands and clothing for contamination.
5. Report incident to the Radiation Safety Officer.

#### Major Spills:

1. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread of contamination
3. Shield the spill, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. Close the room and secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred;
5. Notify the Radiation Safety Officer immediately.
6. Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap;
7. Follow the instructions of the RSO.

Radiation Safety Officer: \_\_\_\_\_

Office Phone: \_\_\_\_\_

Home Phone: \_\_\_\_\_

## **APPENDIX J**

### **AREA SURVEY PROCEDURES**

Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 mR per hour.

Use methods to perform removable contamination surveys sufficiently sensitive to detect 200 dpm/100 cm<sup>2</sup>.

Removable contamination sample wipe tests are typically cloth or paper material wiped on the surface in an “S” pattern approximately 16 inches long, which should be analyzed using an appropriate counting instrument. Fixed contamination may be measured directly at the surface of the contamination with the appropriate instrument detector held at close proximity to the surface without direct contact. Removable contamination samples will be measured in a low background area.

Perform radiation level and removable contamination surveys in unrestricted areas at least monthly to demonstrate compliance of general public exposure to radioactive material.

Action levels for unrestricted areas - radiation level 0.1 mR/hr, removable contamination 200 dpm/100 cm<sup>2</sup>.

Action levels for restricted areas - radiation level 2 mR/hr, removable contamination 2000 dpm/100 cm<sup>2</sup> (200 dpm/100 cm<sup>2</sup> for iodine-131).

Area will be cleaned if the contamination level exceeds 2000 dpm/100 cm<sup>2</sup> (200 dpm/100 cm<sup>2</sup> for iodine-131) in restricted areas and 200 dpm/100 cm<sup>2</sup> in unrestricted areas.

A permanent record will be kept of all survey results, including negative results. The record will include:

1. Location, date, and type of equipment used,
2. Name of person performing the survey,
3. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.,
4. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action),
5. Measured contamination levels, keyed to locations on drawing, and
6. Corrective action taken to reduce elevated readings, record contamination levels or exposure rates after corrective action, and any appropriate comments.

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

### **AMBIENT RADIATION LEVEL SURVEYS**

- A. All elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy) when using radiopharmaceuticals requiring written directive will be surveyed each day of use.
- B. Unrestricted areas and laboratory areas where only small quantities of radioactive material are used (less than 200 microcuries) will be surveyed monthly.

- C. All radionuclide use, radioactive material storage and radioactive waste storage areas will be surveyed weekly. Patient rooms used for diagnostic administration need not be surveyed if care is taken to remove all paraphernalia.
- D. All sealed source and brachytherapy source storage areas will be surveyed quarterly.

**REMOVABLE CONTAMINATION SURVEYS**

Removable contamination surveys are performed in areas where unsealed forms of radioactive material are used.

- A. All elution, preparation, assay and administration areas, radioactive material storage and radioactive waste storage areas will be surveyed weekly. Patient rooms used for diagnostic administration need not be surveyed if care is taken to remove all paraphernalia.
- B. Unrestricted areas and laboratory areas where only small quantities of radioactive material are used (less than 200 microcuries) will be surveyed monthly.
- C. Any area where a spill or contamination event has occurred.

**TRIGGER LEVELS**

If a trigger level is exceeded, the area will be decontaminated or shielded, posted and access restricted from use. An investigation will be performed to determine the cause of the contamination.

Ambient dose rate:	Unrestricted area	0.1 mr/hr
	Restricted area	5 mr/hr

Surface contamination:

Unrestricted Areas:

Nuclide	Fixed	Removable
I-125, I-126, I-131, I-133, Sr-90	1000 dpm/100cm <sup>2</sup> (0.2 mrad/hr @ 1 cm)	200 dpm/100cm <sup>2</sup>

All other beta/ gamma emitters	5000 dpm/100cm <sup>2</sup> (0.2 mrad/hr @ 1 cm)	1000 dpm/100cm <sup>2</sup>
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Restricted Areas:

Nuclide	
P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	2000 dpm/100cm <sup>2</sup>

Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201	20000 dpm/100cm <sup>2</sup>
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## APPENDIX K

### RADIOACTIVE WASTE DISPOSAL PROCEDURES

1. Liquid waste disposal: (Check as appropriate)

By commercial waste disposal service, NRC/Agreement State License Number:

Name and address \_\_\_\_\_

In the sanitary sewer system in accordance with K.A.R. 28-35-224a.

Radioactive material with less than 120 day half-life will be held for decay until radiation levels as measured from the unshielded material, with an appropriate survey meter set on the most sensitive scale, are not distinguishable from background. All radiation labels will be removed or obliterated and the waste will be disposed in normal trash.

Other (specify):

2. Mo-99/Tc-99m generators disposal: (Check as appropriate)

Returned to the manufacturer for disposal.

Radioactive material with less than 120 day half-life will be held for decay until radiation levels as measured from the unshielded material, with an appropriate survey meter set on the most sensitive scale, are not distinguishable from background. All radiation labels will be removed or obliterated and the waste will be disposed in normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants.)

By commercial waste disposal service, NRC/Agreement State License Number:

Name and address \_\_\_\_\_

Mo-99/Tc-99m generators will not be used on this license.

Other (specify):

3. Other solid waste disposal: (Check as appropriate)

Radioactive material with less than 120 day half-life will be held for decay until radiation levels as measured from the unshielded material, with an appropriate survey meter set on the most sensitive scale, are not distinguishable from background. All radiation labels will be removed or obliterated and the waste will be disposed in normal trash.

By commercial waste disposal service NRC/Agreement State License Number:

Name and address \_\_\_\_\_

Other (specify):

## **APPENDIX L**

### **THERAPEUTIC USE OF RADIOPHARMACEUTICALS EXCEEDING PATIENT RELEASE CRITERIA OF 500 MILIREM**

1. Patients will be placed in a private room with a toilet. The room and toilet areas more likely to be contaminated will be covered with protective material as appropriate to the amounts of contamination to be expected.  
  
Particular attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate.
2. The patient's room will be properly posted in accordance with K.A.R. 28-35-219a.
3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, three feet (or 1 meter) away, and at the entrance to the room. The Radiation Safety Officer or designate will then determine how long a person may remain at these positions and will post these times in the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted stay times and will be posted on the patient's chart and on his door.
4. The form, Nursing Instructions for Patients Treated with phosphorus-32, gold-198, or iodine-131, will be completed immediately after administration of the treatment dose. A copy will be posted in the patient's chart.
5. Radiation levels in uncontrolled areas will be maintained less than the limits specified in K.A.R. 28-35-214a.
6. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.
7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer (or his designate) checked for contamination, and disposed of as normal or radioactive waste, as appropriate.
8. Non-disposable items used for these patients will be held in plastic bags in the patient's room, and checked for contamination by the Radiation Safety Officer or his designate. Items may be returned for normal use, held for decay or decontaminated, as appropriate.
9. Urine and vomitus, from iodine-131 therapy patients will be stored for decay in our radioactive waste storage area. When it has reached background levels as measured with a low-level survey meter, it may be released to the sanitary sewer system.
10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed.

11. Nursing Instructions:

- a. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet in the patient's chart. Nurses should read these instructions before administering to the patients. Call the Nuclear Medicine Department with any questions about the care of these patients.
- b. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precaution sheet in the patient's chart.
- c. Patients must remain in bed while visitors are in the room and visitors should remain at least three feet from the patient.
- d. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.
- e. No nurse, visitor or attendant who is pregnant will be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.
- f. Attending personnel will wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.
- g. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer or his designate for proper disposal of the contents of the designated waste container.
- h. All clothes and bed linens used by the patient will be placed in a laundry bag and left in the patient's room to be checked by the Radiation Safety Officer or his designate.
- i. All non-disposable items will be placed in a plastic bag and left in the patient's room to be checked by the Radiation Safety Officer or his designate.
- j. Surgical dressings should be changed only as directed by the physician. Gold-198 leaking from a puncture will stain the dressings dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designate. Handle these dressings only with tongs or tweezers. Wear disposable gloves.
- k. For iodine-131 patients:
  - (1) Urine from iodine-131 patients will be collected in special containers provided by the Radiation Safety Officer or his designate. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bedpan should be provided. The urinal or bedpan should be flushed several times with hot soapy water after use.

- (2) If the nurse helps to collect the excreta, disposal gloves should be worn. Afterwards, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste containers for disposal by the Radiation Safety Officer or his designate.
  - (3) Disposable plates, cups, and eating utensils will be used by patients who are treated with iodine-131.
  - (4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and/or floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Office or his designate, Ext. \_\_\_\_\_. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.
  - (5) All vomitus must also be kept in the patient's room for disposal by the Radiation Safety Officer or his designate. Feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times).
- l. Utmost precautions must be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer or his designate.
  - m. If a nurse, attendant or anyone else knows or suspects that his or her skin, or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designate immediately. This person should remain in the patient's room and not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.
  - n. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.
  - o. When the patient is discharged call the Radiation Safety Officer or his designate or the Nuclear Medicine Department, and request that the room be surveyed for contamination before remaking the room.

Date \_\_\_\_\_

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

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

Room No.: \_\_\_\_\_ Physician's Name: \_\_\_\_\_

Radioisotope Administered: \_\_\_\_\_

Date and Time of Administration: \_\_\_\_\_

Dose Received: \_\_\_\_\_ Method of Administration: \_\_\_\_\_

Exposure Rates in mR/hr

Date	3 feet from bed	Door
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

(Comply with all Checked Items)

- \_\_\_ 1. Visiting time permitted:
- \_\_\_ 2. Visitors must remain \_\_\_\_\_ from patient
- \_\_\_ 3. Patient may not leave room.
- \_\_\_ 4. Visitors under 18 are not permitted.
- \_\_\_ 5. Pregnant visitors are not permitted.
- \_\_\_ 6. Film badges must be worn.
- \_\_\_ 7. Tag the following objects and fill out the tag:  
\_\_\_ door    \_\_\_ chart    \_\_\_ bed    \_\_\_ wrist

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH  
PHOSPHORUS-32, GOLD-198, OR IODINE-131 (continued)

- \_\_\_ 8. Gloves must be worn while attending patient.
- \_\_\_ 9. Patient must use disposable utensils.
- \_\_\_ 10. All items must remain in the room until approved by Radiation Safety Officer or his designate.
- \_\_\_ 11. Smoking is not permitted.
- \_\_\_ 12. The room is not to be released to the admitting office until approved by the Radiation Safety Officer or his designate.
- \_\_\_ 13. Other instructions:

In case of an emergency contact:

RSO \_\_\_\_\_  
Name

\_\_\_\_\_/\_\_\_\_\_  
On Duty Off Duty  
Telephone Number

## APPENDIX M

### THERAPEUTIC USE OF SEALED SOURCES FOR TREATMENT OF PATIENTS

1. All patients treated with brachytherapy sources will be placed in a private room with toilet away from the nurses station and high traffic hallways.
2. The patient's room will be properly posted in accordance with K.A.R. 28-35-219a.
3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, three feet (or 1 meter) from the patient, three feet (or 1 meter) from the bed, and at the entrance to the room. The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these times and the exposure rate at three feet (or 1 meter) from the patient's chart.
4. Immediately after sources are implanted, the form, Nursing Instructions For Patients Treated With Brachytherapy Sources, will be completed and placed in the patient's chart.
5. Radiation levels in uncontrolled areas will be maintained less than the limits specified in K.A.R. 28-35-214a.
6. Nurses caring for brachytherapy patients will be assigned film badges. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient.
7. Prior to release of a patient receiving temporary implant therapy, perform a radiation survey of the patient and a source count to ensure that all sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time all radiation signs will be removed and all film and TLD badges assigned to nurses will be collected.
8. Prior to release of a patient receiving permanent implant therapy, perform a radiation survey of the patient. The patient may be released if the exposure rate is less than 5 mR/hr at 1 meter. Measure this exposure rate with a radiation measurement survey meter at a distance of 1 meter from the abdomen with the patient standing.
9. Instructions to Nurses
  - a. Special restrictions may be noted on the precaution sheet in the patient's chart. Nurses should read these instructions before administering to the patient. Call the Radiation Safety Officer or his designate with any questions about the care of these patients in regard to radiation safety precautions.
  - b. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Nurses must obtain and wear a film badge.
  - c. When a nurse receives an assignment to a therapy patient, a film or TLD badge should be obtained immediately from the Radiation Safety Officer or his designate. The badge shall be worn only by the nurse to whom it is issued and shall not be exchange between nurses.
  - d. Pregnant nurses should not be assigned to the personal care of these patients.

- e. Never touch needles, capsules or containers holding brachytherapy sources. If a source becomes dislodged use long forceps and put it in the corner of the room or in the shielded container provided; contact the Radiation Safety Officer, or the Nuclear Medicine Department at once.
- f. Bed bath given by the nurse should be omitted while the sources are in place.
- g. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary, unless orders to the contrary have been written.
- h. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist, and **MAY NOT BE DISCARDED** until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Safety Officer or his designate.

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

- i. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered. These items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into these items.
- j. All bed linens must be checked with a radiation survey meter before being removed from the patient's room to ensure that no dislodged sources are inadvertently removed.
- k. These patients must stay in bed unless orders to the contrary are written. In any event, patients will remain in their assigned rooms during the treatment period.
- l. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precaution sheet in the patient's chart.
- m. Visitors should sit at least three feet (or 1 meter) from the patient and should remain no longer than the times specified on the form posted on the patient's door and in the patient's chart.
- n. No nurse, visitor or attendant who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.
- o. Emergency Procedures
  - (1) If an implanted source becomes loose or separated from the patient, or
  - (2) If the patient dies, or
  - (3) If the patient requires emergency surgery, immediately call \_\_\_\_\_.  
Phone Number (days) \_\_\_\_\_, (nights) \_\_\_\_\_.
- p. At the conclusion of treatment, call the Radiation Safety Officer to (1) survey the patient and room and (2) count the radiation sources to be sure all temporary implants have been removed prior to discharging the patient.

Date \_\_\_\_\_

NURSING INSTRUCTIONS FOR PATIENTS TREATED  
WITH BRACHYTHERAPY SOURCES

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

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

Prescribed dose: \_\_\_\_\_ mCi of \_\_\_\_\_ as \_\_\_\_\_ individual sources.  
(Radionuclide) (Source count)

Date and Time of Administration: \_\_\_\_\_

Date and Time Sources are to be removed: \_\_\_\_\_ Number of sources removed: \_\_\_\_\_

Exposure Rates in mR/hr

Bedside	3 feet from bed	Door
_____	_____	_____

(Comply with all checked items)

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

RSO \_\_\_\_\_  
Name

\_\_\_\_\_/\_\_\_\_\_  
On Duty / Off Duty  
Telephone Number

## APPENDIX N

### USE OF RADIOACTIVE GASES AND AEROSOLS (e.g., Xenon-133 or Technetium-99m DTPA)

Submit the following information in support of requests to use xenon-133 or technetium-99m DTPA:

A. Quantities to be used:

1. Number of studies expected per week
2. Average activity per patient
3. The desired possession limit. This should be sufficient to provide for shipments whose calibration date is several days after receipt.

B. Equipment and areas of use:

1. Describe the area(s) in which you plan to use gases or aerosols. Include a diagram indicating the availability of shielding materials and the proximity to uncontrolled areas.
2. Describe the ventilation in all areas where are used and stored. The location of supply and exhaust vents, the measured airflow rates for each vent and the fraction of air that is recirculated by the system should be indicated.
3. All areas where xenon is used should be under negative pressure. State how you will ensure that all airflow rates are maintained as specified in this application.
4. Describe any special apparatus for administration and collection of gases or aerosols, specify the manufacturer's name and model number and include a description of its design characteristics and associated equipment. (Inclusion of a brochure would be helpful)

C. Procedures for routine use:

1. Describe the procedures to be followed for routine use of gases or aerosols, giving particular attention to radiological safety factors, patient preparation and delivery flow rates.
2. Describe any special procedures to be employed to reduce leakage, e.g., use of nose clamps or special enclosures.
3. Describe control of contaminated equipment, personnel protection and area surveys to be employed.

D. Emergency Procedures

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

E. Air concentrations of gases or aerosols in controlled areas:

No licensee shall permit any individual in a controlled area to inhale a quantity of radioactive material in any period of one calendar year greater than the quantity that would result from inhalation for 40 hours per week for 50 weeks at uniform concentrations of radioactive material.

Monitoring of internal exposure is required if an individual is likely to receive an intake in excess of 10 percent of the applicable ALI(DAC). You may evaluate your situation by making actual measurements of concentrations or by means of calculations. If you choose the latter approach, you may make simplifying assumptions, PROVIDING they are reasonable, conservative and stated explicitly in your request.

In actual use and storage, some gases or aerosols will be released into the room from storage and administration devices, rebreathing apparatus, collection systems, and escape from the patient. All sources of loss must be considered when estimating the fraction of gases or aerosols that is lost.

The following procedures may be used to calculate the air concentration of gases or aerosols in controlled areas:

1. Estimate the maximum amount of activity (A) to be used per week
2. Estimate the fraction of gases or aerosols that is lost during use and storage (f). This fractional loss must include ALL sources of loss, e.g., during patient administration, storage, and disposal.
3. Determine the measured airflow rate (V) in the area(s) of interest and calculate the volume of air available per week for dilution of the gases or aerosols.
4. For controlled areas, K.A.R. 28-35-217a provides that no monitoring is required if the exposure to airborne radioactive material is kept below 10 percent of the applicable ALI(DAC).

$$\text{DAC}_{\text{Xe-133}} = 1 \times 10^4 \text{ uCi/ml}$$

$$\frac{A \times f}{V} < 1 \times 10^{-5} \text{ uCi/ml for Xe-133}$$

5. Sample Problem

A nuclear medicine laboratory plans to use 10 mCi xenon-133 per patient and will perform a maximum of 10 studies per week. What ventilation rate is required to ensure compliance with K.A.R. 28-35-217a of Part 4 KRPR?

- (a) Maximum activity used per week:  
$$A = \frac{10 \text{ mCi}}{\text{patient}} \times \frac{10 \text{ patients}}{\text{week}} \times \frac{1000 \text{ uCi}}{\text{mCi}} = 1 \times 10^5 \frac{\text{uCi}}{\text{week}}$$
- (b)  $f = 0.2$  Assume a loss of 20%
- (c) 
$$V = \frac{A \times f}{1 \times 10^{-5} \text{ uCi/ml}}$$
$$= \frac{1 \times 10^5 \text{ uCi/week} \times 0.20}{1 \times 10^{-5} \text{ uCi/ml}}$$
$$= 2.0 \times 10^9 \text{ ml/week}$$

The required ventilation rate to demonstrate compliance is:

$$\frac{2.0 \times 10^9 \text{ ml/week}}{40 \text{ hrs/week}} \times \frac{\text{cfm}}{1.7 \times 10^6 \text{ ml/hr}} = 30 \text{ cfm}$$

The answer shows that, in order to meet the requirements of K.A.R. 28-35-217a, the imaging room (CONTROLLED AREA) must have a ventilation rate of at least 30 cfm with no recirculation of air. Where practical, the ventilation rate should be greater than that shown necessary by the calculations. Consider every alternative in order to maintain the air concentration of gases or aerosols as low as reasonably achievable in accordance with K.A.R. 28-35-217a. If the ventilation rate is inadequate to meet the requirements of K.A.R. 28-35-217a, consider methods of increasing ventilation or reducing the patient load.

The following table gives the amount of gases or aerosols that can be released per week without exceeding the permissible levels for gases or aerosols in controlled areas.

<u>Ventilation Rate (cfm)</u>	<u>Maximum Released</u>	
	<u>per 40 hour-week (mCi <sup>133</sup>Xe)</u>	<u>per 40 hour-week (mCi <sup>99m</sup>Tc)</u>
100	340	204
500	1700	1020
1,000	3400	2040

F. Methods of gases or aerosol disposal

1. Dilution through Exhaust Systems (least desirable)

Licensees are required to perform surveys (measurements or calculations) to ensure that they are in compliance with K.A.R. 28-35-214a. K.A.R 28-35-214a and 28-35-214b requires that the concentrations of gases or aerosols in effluents to uncontrolled areas be as low as is reasonable achievable by the current state of technology, and K.A.R 28-35-214b requires that the concentrations, averaged over a period of one (1) year, shall not exceed Appendix B Table II values for the appropriate radionuclide.

Many facilities do not have sufficient airflow to achieve the necessary dilution. The following procedure may be used to estimate the concentrations of gases or aerosols in effluents to uncontrolled areas.

- (a) Estimate the maximum amount of gases or aerosols to be released per year (A). This should include all anticipated losses during administration, storage and disposal.
- (b) Determine the flow rate of the exhaust system and describe the methods and equipment used for measuring the airflow rates.
- (c) Calculate the airflow per year (V).
- (d) Calculate the average concentrations for uncontrolled areas. K.A.R 28-35-214b of Part 4 KRPR for Xe-133 requires that:

$$C = \frac{A}{V} < 5 \times 10^{-7} \text{ uCi/ml}$$

(e) Sample problem:

A nuclear medicine laboratory plans to use 10 mCi per patient and will perform a maximum of 10 studies per week. A fume hood is available for disposal of  $^{133}\text{Xe}$ , and has a measured airflow of 168 ft/min with an opening of 8 ft<sup>2</sup>. What is the average concentration of xenon-133 at the point of release from the fume hood exhaust? (NOTE: All xenon that has been released, e.g., collection bags, filters, must be considered.)

$$A = \frac{10 \text{ patients}}{\text{week}} \times \frac{10 \text{ mCi}}{\text{patient}} \times \frac{1000 \text{ uCi}}{\text{mCi}} \times \frac{52 \text{ weeks}}{\text{year}} = 5.2 \times 10^6 \text{ uCi/year}$$

$$V = 168 \frac{\text{ft}}{\text{min}} \times 8 \text{ ft}^2 \times 1.49 \times 10^{10} \frac{\text{ml/year}}{\text{ft}^3/\text{min}} = 2.0 \times 10^{13} \text{ ml/year}$$

$$C = \frac{5.2 \times 10^6 \text{ uCi/year}}{2.0 \times 10^{13} \text{ ml/year}} = 2.6 \times 10^{-7} \text{ uCi/ml}$$

The following table gives the amount of gases or aerosols that can be released per week without exceeding an average concentration of Appendix B Table II values.

<u>Exhaust rate (cfm)</u>	<u>Average release of</u>	
	<u><math>^{133}\text{Xe}</math> per week (mCi)</u>	<u><math>^{99\text{m}}\text{Tc}</math> per week (mCi)</u>
100	14.3	5.7
500	71.6	28.7
1,000	143.3	57.3
1,500	214.9	86.0

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

2. Adsorption onto Charcoal Traps or filters

This is the disposal method of choice. The advantage of this disposal method is the gas or aerosol is trapped onto charcoal or other adsorbing medium. Filters containing gases or aerosols are then stored for decay.

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

- (a) Describe how you will handle the problem of leakage from such trapping devices. If the exhaust is vented to the outdoors (UNCONTROLLED AREA), show that air concentrations of xenon-133, averaged over one (1) year, do not exceed  $5 \times 10^{-7}$  uCi/ml. (See example in Item F-1)
- (b) Describe how you will ensure that collection and trapping devices are performing according to specifications, both initially and on a continuing basis. Include in your description how you will monitor traps to determine when saturation occurs and filter must be replaced.

- (c) Describe your procedures for handling saturated filters. Your discussion should include a description of the area (a diagram would be useful), available shielding, proximity to controlled areas, ventilation and an evaluation of average concentrations of xenon-133 in air. (See example in Item e(5)).

#### USEFUL CONVERSIONS

$$1 \text{ mCi} = 10^3 \text{ uCi}$$

$$1 \text{ ft}^3 = 2.832 \times 10^{-2} \text{ m}^3 = 2.832 \times 10^4 \text{ ml}$$

$$1 \text{ ft}^3/\text{min} = 1.699 \times 10^6 \text{ ml/hr} = 6.797 \times 10^7 \text{ ml/40-hr week} = 1.484 \times 10^{10} \text{ ml/yr}$$

$$1 \text{ week} = 168 \text{ hr}$$

#### REFERENCES

1. Blatz, Hanson, Radiation Hygiene Handbook, McGraw-Hill (New York, 1959) pp. 22-7.
2. Cember, Herman, Introduction to Health Physics, Pergamon Press (New York, 1969) pp. 334-9.
3. Fuchs, N.A., The Mechanics of Aerosols, Macmillan, New York (1964).

## APPENDIX O

### USE OF INTRAVASCULAR BRACHYTHERAPY SYSTEMS

The following information should be submitted in support of requests to use Intravascular Brachytherapy Systems

A. Requirements for all systems:

1. Provide a commitment to perform radiation surveys of patient and treatment catheter following the source retraction or removal to confirm complete retraction of the source
2. Provide procedures for using a written directive that shall specify the radioisotope, treatment site, and total radiation exposure for the procedure including exposure received during fluoroscopy
3. Documented training and experience for the authorized user(s) shall be that set forth in Appendix A part IV of this document "Training Requirements For Therapy Procedures Involving Sealed Sources"
4. Documentation of satisfactory completion of the vendor training for the treatment team
5. Provide a commitment that the treatment team composition shall consist, at a minimum, of an interventional cardiologist, an oncologist, and a medical physicist and the physical presence of the oncologist or medical physicist during all treatments
6. Provide a commitment that independent measurement of the source output will be performed describing the instrumentation used and provide documentation of instrumentation calibration
7. Provide written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures
8. The sources shall be leak tested at intervals not to exceed six months and a physical inventory shall be performed quarterly
9. Review the Quality Management Program and revise as appropriate
10. Treatment of multiple lesions separated by more than 3mm apart may be considered separate procedures provided the source is retracted and the catheter is repositioned prior to re-insertion of the source.

B. Unique requirements for the Cordis Checkmate system:

1. Provide procedures which disallow the use of source trains after the "use before" date
2. Provide the source manufacturer and model number. Request the possession limit to read: "No single seed to exceed 35 millicuries, in a three-ribbon set containing 6, 10 or 14 seeds per ribbon; no single set to exceed 1100 millicuries"

3. Request the use to be: “To be used for intravascular brachytherapy in the Cordis Checkmate Catheter System.”
4. Provide procedures, calculations and/or measurements demonstrating estimated radiation fields.

C. Unique requirements for the Novoste Beta-Cath system:

1. Consider to use the Arrow introducer sheath to prevent source transport blockages during treatment leading to misadministrations (a proven cause of multiple misadministrations during the clinical trials)
2. Consider to use the dual syringe system to avoid misadministrations due to premature depletion of the source transport fluid
3. Provide procedures for locked storage of the storage container in a secure location
4. Provide the source manufacturer and model number. Request the possession limit to read: “No single source to exceed 5 millicuries, 60 millicuries total” (Model A1732); “No single source to exceed 5 millicuries, 80 millicuries total” (Model A1733); “No single source to exceed 5 millicuries, 120 millicuries total” (Model A1730 and Model A1767)
5. Request the use to be: “To be used for intravascular brachytherapy in the Novoste Beta-Cath System Model A1000 series.”
6. Provide procedures for and frequency that the device shall be inspected and serviced; and, that maintenance and repair shall be performed only by the manufacturer or persons specifically authorized by the Commission or an Agreement State to perform such services
7. Provide procedures that demonstrate instances where source train separations occur during treatment will be evaluated as possible misadministrations
8. Novoste personnel shall be present for the first three clinical procedures performed by each treatment team to confirm competence with the Beta-Cath System has been achieved
9. Provide procedures that prior to each use of the Beta-Cath System on a human subject, a catheter integrity evaluation (“dummy” run) shall be conducted outside of the subject’s body to allow the clinician to simulate a clinical procedure with non-radioactive sources.

D. Unique requirements for the Guidant Galileo system:

1. Provide procedures for locked storage Request the use to be: “To be used for intravascular brachytherapy in the Guidant Model Galileo High Dose Rate Afterloader system.”
2. Provide procedures for the operation, operational checks of console, indicator lamps, source status indicators, catheter centering, source positioning and connectors, locked storage of the delivery device and source assembly and positive key control for the console key.
3. Provide the source manufacturer and model number. Request the possession limit to read: “No single source assembly to exceed 600 millicuries, 1200 millicuries total.”

4. Provide procedures for tests performed at source exchange prior to patient treatment, weld radiographs, source uniformity radiograph, source positioning accuracy, battery backup for emergency source retraction, source transit time, timer and linearity to meet manufacturer specifications.
5. Provide procedures demonstrating the source assembly will not be used longer than 60 days or 650 cycles whichever comes first, the device will be inspected and serviced at intervals recommended by the manufacturer and the maintenance or repair shall be performed by the manufacturer or persons specifically authorized to perform such services.
6. A single step or pullback procedure, where the proximal position of the first treatment site is coincident with the distal position of the second treatment site in the center of the stent is allowed by a commitment to follow the manufacturer's instructions.

## APPENDIX P

### LEAK TEST PROCEDURE

#### I Facilities and Equipment

- A. Leak tests will be analyzed in a low-background area.
- B. Instrumentation used to analyze leak test samples will be capable of detecting 185 Bq (0.005  $\mu$ Ci) of radioactivity.

#### II Procedure for Performing Leak Testing and Analysis

- A. For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- B. Use a separate wipe (e.g., cotton swab or filter paper) for each source.
- C. Number each wipe to correlate identifying information for each source.
- D. Wear gloves.
- E. Using moderate pressure, wipe the surface at the most accessible area where contamination would accumulate if the sealed source were leaking.
- F. Measure the background count rate and record.
- G. Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within 5% of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.
- H. Calculate efficiency of the instrument.

$$\text{Eff} = \frac{(\text{cpm}_{\text{STD}} - \text{cpm}_{\text{BKG}})}{\text{Activity of standard in microcuries}}$$

where: Eff = efficiency, in cpm/microcurie,  
 $\text{cpm}_{\text{STD}}$  = counts per minute of the standard  
 $\text{cpm}_{\text{BKG}}$  = counts per minute of the background.

- I. Analyze each wipe to determine net count rate.
- J. For each wipe, calculate the activity in microcurie and record.

$$\text{Activity microcuries} = \frac{(\text{cpm}_{\text{wipe}} - \text{cpm}_{\text{BKG}})}{\text{Eff}}$$

- K. Licensees should include the following in records:
  - 1. The model number and serial number (if assigned) of each source tested;

2. The identity of each source radionuclide and its estimated activity;
  3. The measured activity of each test sample expressed in microcurie;
  4. A description of the method used to measure each test sample;
  5. The date of the test; and
  6. The name of the individual who performed the test.
- L. If the wipe test reveals 185 Bq (0.005  $\mu$ Ci) or greater:
1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired.
  2. Report to the Kansas Radiation Control Program within 5 days of the leak test in accordance with the regulations.

## APPENDIX Q

### MOLYBDENUM-99 BREAKTHROUGH CALCULATIONS

Limit - 0.15 microcuries of Molybdenum-99 per millicurie of Technetium-99m.

$$\frac{\mu\text{Ci Mo99}}{\text{mCi Tc99m}} \leq 0.15 - \text{ at any time from elution to expiration time.}$$

Note: Must allow for decay.

$$\frac{\mu\text{Ci Mo99} * e^{-0.693 * t / T_{1/2} \text{ Mo99}}}{\text{mCi Tc99m} * e^{-0.693 * t / T_{1/2} \text{ Tc99m}} + (\mu\text{Ci Mo99}/1000 * (1 - e^{-0.693 * t / T_{1/2} \text{ Mo99}}))}$$

t<sub>1/2</sub> Mo 99 is 66 hours

t<sub>1/2</sub> Tc 99m is 6.02 hours

t- is 12 hours (eluate expires 12 hours after elution per the generator manufacturer)

$$(\mu\text{Ci Mo99}/1000 * (1 - e^{-0.693 * t / T_{1/2} \text{ Mo99}})) \quad \text{allows for the in growth of Tc-99m as the Mo99 decays - for practical purposes} = 0$$

$$\frac{e^{-0.693 * t / T_{1/2} \text{ Mo99}}}{e^{-0.693 * t / T_{1/2} \text{ Tc99m}}} = \text{decay constant} = 3.51 \text{ for } t = 12 \text{ hours}$$

$$= 1.1103 \text{ for } t = 1 \text{ hour}$$

if  $\mu\text{Ci Mo99}/\text{mCi Tc99m} * 3.51 \leq 0.15$  the elution will be good for 12 hours

$0.15/3.51 = 0.0427$  if the  $\mu\text{Ci Mo99}/\text{mCi Tc99m}$  ratio at elution  $\leq 0.0427$  then the ratio will be  $\leq 0.15$  at the 12 hour expiration time

If the  $\mu\text{Ci Mo99}/\text{mCi Tc99m}$  ratio at elution  $> 0.0427$  a new expiration time is calculated based on when the ratio will exceed 0.15 as follows:

decay constant for any time  $t = 1.1103^t$

$$\frac{\ln(0.15/\text{ratio})}{\ln(1.1103)} = t \text{ the new expiration time in hours}$$

$$\ln(1.1103) = 0.1046$$

$$\frac{\ln(0.15/\text{ratio})}{0.1046} = t \text{ the new expiration time in hours}$$

## TOTAL MOLYBDENUM-99 PER DOSE CALCULATION

Limit is  $\leq 5$  uCi of Mo-99 per dose of Tc-99m

$$\frac{5 \text{ uCi Mo } 99}{0.15 \frac{\text{uCi Mo } 99}{\text{mCi Tc } 99\text{m}}} = 33.3 \text{ mCi of Tc-99m}$$

Note: If a dose of Tc-99m is less than 33 mCi then total amount of Mo-99 will be less than 5 uCi.

## MOLYBDENUM-99 BREAKTHROUGH PROCEDURE

1. Elute the Mo-99/Tc-99m generator.
2. Determine the total microcuries molybdenum-99 and millicuries technetium-99m in the eluate following the manufacturers instructions.
3. Calculate the ratio of microcuries of molybdenum-99 per millicurie of technetium-99m.
4. To be conservative, if the ratio is more than 0.04 stop and notify the RSO. The state and manufacturer must be notified. Further evaluation is required to determine if the eluate may be used safely.
5. Record the date and time of the elution, microcuries of molybdenum-99, millicuries of technetium-99m, ratio, initials of person making the record.

## **APPENDIX R**

### **TRAINING PROGRAM**

The training program is required for all personnel who work with or in the vicinity of radioactive materials.

The training program will be of sufficient scope to ensure that all personnel, including clerical, nursing, housekeeping, and security personnel, receive instruction in the items specified in K.A.R. 28-35-333 appropriate to their job duties.

Personnel will be instructed:

- a. Before assuming their duties with or in the vicinity of radioactive materials,
- b. During annual refresher training, and
- c. Whenever there is a significant change in duties, regulations, or the terms of the license.

The training may be in the form of lectures, video tape, self study or electronic media and cover the subject matter including:

- a. Areas where radioactive material is used or stored,
- b. Potential hazards associated with radioactive material,
- c. Radiological safety procedures appropriate to their respective duties,
- d. Pertinent Kansas Radiation Control regulations,
- e. The rules and regulations of the licensee,
- f. The pertinent terms of the license,
- g. Their obligation to report unsafe conditions,
- h. Appropriate response to emergencies or unsafe conditions, and
- i. Their right to be informed of their radiation exposure and bioassay results.

## APPENDIX S

### ALARA PROGRAM

Monitoring the exposure to ionizing radiation is required if an individual is likely to receive more than 10% of the annual dose limits. This includes monitoring the dose, maintaining records of the dose, and, on at least an annual basis, to inform the individual of his/her dose.

Individual monitoring devices are required for personnel likely to receive, in one year, from sources external to the body, a dose in excess of 10 percent of the occupational dose limits as stated in the regulations. The whole body monitoring device is typically worn on the front of the upper torso. Monitoring devices are accordingly required for individuals with an annual dose in excess of:

- 0.5 rem (0.005 Sv) DDE
- 1.5 rem (0.015 Sv) eye dose equivalent
- 5.0 rem (0.05 Sv) shallow-dose equivalent to the skin
- 5.0 rem (0.05 Sv) shallow-dose equivalent to any extremity.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return monitoring devices on time. Delays in processing a monitoring device can result in the loss of the stored information. Reasonable attempts will be made to recover any missing monitoring devices.

In order to demonstrate compliance with occupational dose limits, the RSO will perform and document an evaluation of the dose the individual received, if an individual's monitoring device is lost. The radiation safety committee and KDHE must approve any estimated dose included in the employee's dose record.

#### I. Exposure Monitoring Program

- A. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low.
- B. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a whole body monitor that will be processed by a NVLAP accredited laboratory.
- C. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a finger monitor that will be processed by a NVLAP accredited laboratory.
- D. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for such patients.
- E. 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.

## II. Investigational Levels B External Dose Monitoring

- A. When the cumulative annual exposure to a radiation worker exceeds Investigational Level I (i.e., 10% of the annual limit for occupational exposure), the RSO or the RSO's designee should evaluate the exposure and review the actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds Investigational Level II (i.e., 30% of the annual limit for occupational exposure), the RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and report to the radiation safety committee the actions to be taken to reduce the probability of occurrence.

### Investigational Levels

Part of Body	Investigational Level I (mrem per year)	Investigational Level II (mrem per year)
whole body; head; trunk including male gonads; arms above the elbow; or legs above the knee	500 (5 mSv)	1500 (15 mSv)
hands; elbows; arms below the elbow; feet; knee; leg below the knee; or skin	5000 (50 mSv)	15,000 (150 mSv)
lens of the eye	1500 (15 mSv)	4500 (45 mSv)

- B. Take the actions listed below when the investigation levels are reached:

1. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO or the RSO's designee, no further action will be taken if an individual's annual dose is less than values for the Investigational Level I.

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

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

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

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

4. Re-establishment of Investigational Level II to a level above that listed.

In cases where an individual or a groups' annual doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented. The radiation safety committee will review the justification for and must approve or disapprove all revisions of investigational levels.

III. Declared Pregnancy and Dose to Embryo/Fetus

- A. This facility shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The facility shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo/fetus shall be taken as the sum of:
- B. The deep-dose equivalent to the declared pregnant woman; and
- C. The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

IV. Internal Exposure

- A. This facility will monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10% of the annual limit on intake (ALI) from intakes in 1 year.
- B. The DAC for each class of radionuclide is the concentration of airborne radioactivity in  $\mu\text{Ci}/\text{ml}$  that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a CEDE of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in Appendices to Part 4: Standards for Protection Against Radiation, Appendix B.
- C. For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, again, with no consideration for the contribution of external dose.
- D. The total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The ALI and DAC numbers reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (WT), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." When an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

- E. The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities require particular caution. To monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers will be established if necessary.
  
- F. If the facility determines that a program for performing thyroid uptake bioassay measurements is necessary, a program will be established. The program will include:
  - 1. adequate equipment to perform bioassay measurements,
  - 2. procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units,
  - 3. the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),
  - 4. trigger level and the interval between bioassays,
  - 5. action levels, and
  - 6. the actions to be taken at those levels.

V. Summation of External and Internal Doses

The external and internal doses must be summed if required to monitor both.

## APPENDIX T

### MOBILE NUCLEAR MEDICINE SERVICE

- I. Equipment checks
  - A. Check the survey meter with the dedicated check source at each location of use. Radioactive material may not be used if the survey meter is not working.
  - B. Camera
    1. Perform the following checks at each location of use before administering radioactive material:
      - (a) Peak each camera according to the manufacturer's instructions.
      - (b) Using either Tc-99m or Co-57, perform an extrinsic flood field with a frequently used collimator in place, or perform an intrinsic flood field test. Accumulate at least 1,000,000 counts for small-field-of-view cameras and 3,000,000 counts for large-field-of-view cameras. Process the image as if it were an image of a patient.
      - (c) Center of rotation test if SPECT procedures will be performed.
      - (d) Do not administer radioactive material until an authorized user or a designated technologist approves the camera for use.
    2. Perform the following checks weekly:
      - (a) With the same frequently used collimator in place, image a flood source and either a parallel-line-equal-space (PLES), bar, orthogonal-hole (OH) or resolution-quadrant phantom with the flood field as a source.
      - (b) If a PLES or bar phantom is used, rotate it 90° so that the camera is tested for both vertical and horizontal geometric linearity.
      - (c) If a resolution-quadrant phantom is used, rotate it so that each quadrant is imaged in each quadrant of the crystal. Then turn it over and again image it four more times. This procedure will check both resolution and horizontal and vertical geometric linearity in each quadrant of the crystal.
      - (d) Process the images as if they were images of a patient. Mark them clearly to indicate image orientation, source activity, and date.
    3. Perform the following safety checks after repairs and quarterly:
      - (a) Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 3.b.

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

4. Set the equipment in the same manner each time checks are run. Make a record of all these checks.

C. Perform a constancy test on the Dose Calibrator at each location of use before administering radioactive material.

## II. Base location

A. The coach will be located at a secure off-street parking area

B. Radioactive material will be secured inside a locked storage compartment within the coach.

C. Radioactive material will be delivered (if necessary) directly to the coach only when the coach is occupied by licensee personnel at the time of delivery.

D. The coach will not contain residential living quarters in the restricted area.

E. Unrestricted areas outside the coach will not exceed 100 mrem in a year and 2 mrem in any one hour. In the event these values are exceeded, the area will be barricaded and posted to prevent unauthorized access.

## III. Patient voiding

A. Identify the restroom within the facility to be used by the mobile service patients. This restroom should be locked and posted "Not Available For Public Use".

B. Prior to imaging, escort the patient to the designated restroom.

C. To prevent the spread of contamination, provide the following instructions to each patient:

1. Each patient should sit while voiding.

2. Flush the toilet at least 2 times after use.

3. Wash hands thoroughly with soap and warm water.

D. Prior to departure, survey the restroom for contamination.

E. If contamination is detected (any reading above background activity), make a note in the patient log or other suitable location and decontaminate the area.

F. Remove all cleanup materials and place on the coach to be decayed in storage.

G. Remove any postings from the restroom door and release the room back to the facility for general use.

If background levels are not achieved, notify the facility contact the sign is to remain in place until 10 half-lives of the material has elapsed (24 hours for PET and 2.5 days for Tc-99m) since the last patient and no access is granted to anyone until the time has passed. At that time the facility contact person may unlock the door, remove the sign and allow normal public restroom usage.

IN THE EVENT A PATIENT WHO HAS RECEIVED A NUCLEAR MEDICINE SCAN REQUIRES EMERGENCY CARE WITHIN 24 HOURS OF THE STUDY PLEASE CONTACT THE ON CALL AUTHORIZED USER AT:

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FOR INFORMATION REGARDING RADIATION SAFETY AND PATIENT CARE

BODY FLUID PRECAUTIONS

All nuclear medicine patients are given a radiopharmaceutical intravenously or orally before or during their nuclear medicine procedure. Therefore they are emitting minimal amounts of radiation and will have trace amounts of radioactivity in their blood, urine, feces and/or saliva for a period of time after they receive the radiopharmaceutical. Precautions should be taken when handling these substances. Routine Body Substance Isolation (BSI) policies are ideal for handling these fluids from patients. If your institution does not have a BSI policy, routine precautions for handling body substances containing diagnostic doses of radiopharmaceuticals are listed below.

NUCLEAR MEDICINE PRECAUTIONS

Use rubber gloves when handling, measuring, cleaning or disposing of patients' body substances.  
Flush urine, feces and emesis with copious amounts of water.  
Instruct patients to flush the toilet 2-3 times after each use for 12-24 hours after the radiopharmaceutical has been administered.

## APPENDIX U

### Positron Emission Tomography – PET

#### RADIATION

FDG is an abbreviated name for Fluorodeoxyglucose (2-deoxy-2-[18F]fluoro-D-glucose), a sugar compound that is labeled with radioactive fluoride. FDG is a radiopharmaceutical or tracer, used in two nuclear medicine imaging modalities: Positron Emission Tomography (PET) and Single Photon Emission Tomography (SPECT). FDG is administered intravenously and is used to determine how certain organs and tissues in the body are functioning at the cellular level by measuring glucose metabolism. It is widely used for functional studies in neurology, cardiology and oncology.

FDG is manufactured in an automated synthesis unit from Fluorine-18. Fluorine-18 is a radioactive isotope that is produced in a cyclotron by proton bombardment of enriched water (O-18). FDG is a time-sensitive product, having a half-life of 110 minutes. Its radioactivity is measured in millicuries and a typical dose is 5 - 10 millicuries at time of injection.

#### LICENSING REQUIREMENTS FOR POSITRON IMAGING

Prior to ordering your first PET radiopharmaceutical dose, Kansas Radiation Control Program will require a Radioactive Materials License amendment to possess and use PET radionuclides. This guidance is primarily intended to provide assistance to those planning on using PET radioisotopes/FDG in their imaging programs.

Kansas Radiation Control Program will require a specific line item in the license application for Fluorine-18 PET radiopharmaceuticals, the possession request should be worded:

Nuclide: Fluorine-18

Form: Fluorodeoxyglucose (FDG)

Possession Limit: The usual patient dose is 1 to 10 millicuries, allow for usage through patient loading and radioactive decay from the time of shipment to time of administration.

Add sealed sources and possession limits as may be necessary for the operation and calibration of your scanner.

Include a description of the equipment you will be using including the name and address of the equipment manufacturer.

Kansas Radiation Control Program will also want to know specific details regarding the equipment placement in your facility and radiation safety precautions for the use of positron emitting radionuclides. Review guidance in each of these areas prior to preparing your licensing request. Include a description or drawing of the facility and modifications that will be made to accommodate the high energy (511 keV) products. The description should include any changes as outlined in the Radiation Safety Requirements Section.

## RADIATION SAFETY REQUIREMENTS FOR POSITRON IMAGING

Precautions that must be planned or completed prior to applying for your amendment to your Radioactive Materials License. Most standard nuclear medicine dose shields offer little protection from the high energy gammas but will shield direct exposure to positrons. Nuclear medicine accessory suppliers have shields specifically designed for use with PET radionuclides.

Additional radiation safety precautions must be taken considering the high energy gammas (511 keV) emitted by positron radionuclides. It is important to remember that the exposure rate of 10 millicuries of Fluorine-18 is approximately six times greater than that of 10 millicuries of Technetium-99m at a distance of approximately 8 inches. In general, barriers, partitions, and shielding must be designed to protect operations personnel, other equipment, and public areas from sources of radioactivity. Sources of radioactivity to be considered are patient syringes (before and after injection), storage areas for sealed sources and waste, and patients after injection during radionuclides uptake.

The syringe shields will be transported in containers that contain an additional 1" of lead shielding. The individual patient syringe shield should be left in the transport container until just prior to calibration for patient use. The dose calibration area should have at least 2 inches of lead around the calibration well and L-block shield. Any leaded glass shields used in the dose calibrator area should have the equivalent of 2 inches of lead shielding.

After calibration, the patient syringe should be placed in a dose shield prior to patient injection. Using a long handled tongs to transfer the syringe to the dose calibrator and then to the injection shield can significantly decrease technologist exposure. Increasing the distance between the source and the technologist will decrease the exposure rate by the square of the distance.

Additional training should be given for technologists and staff in minimizing patient contact time after dose administration, maximizing distance from high radiation sources, and the proper use of available shielding. Technologists should practice PET receiving, calibrating, and injecting procedures with saline prior to handling PET radionuclides. Wearing of hand and body dosimetry badges should be stressed. Training should be provided and documented by your facility Radiation Safety Officer or qualified Health Physicist.

Other areas of potential high radiation activity are the storage area for phantoms, sources, patient dose receiving and storage areas, and the radioactive waste storage area. At least two inches of lead is recommended for shielding these areas. Measured activity rates from a patient injected with 10 millicuries of Fluorine-18 are approximately 1.5 millirem/hr at 1.5 meters. A reassessment of patient waiting areas, injection and uptake areas, and surrounding public areas should be made to determine if the controlled vs non-controlled area designation is still adequate. The current maximum dose rate for a non-controlled area is 2 millirem in any one hour and 100 millirem/year.

If other scanners are located close by, the high energy photons may interfere with other scans. This means injected patients should remain approximately 5 to 6 meters from other scanning equipment to minimize scanner interference. A shielded area may be necessary for the scanner and patient holding areas for radiopharmaceutical uptake. A qualified health physicist should assess requirements specific to your facility.