

TENNESSEE DIVISION OF RADIOLOGICAL HEALTH
MEDICAL LICENSE APPLICATION GUIDE

(revised May 2012)

The following paragraphs explain the information requested on Form RHS 8-5 “Application for Radioactive Material License.” SRPAR is the acronym for “State Regulations for Protection Against Radiation.” SRPAR is available for review at <http://www.tn.gov/sos/rules/0400/0400-20/0400-20.htm> See Chapters 0400-20-04, 0400-20-05, 0400-20-07, and 0400-20-10. Medical use as defined in SRPAR means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

Item 1.(a) Enter the name, mailing address, and contact information of the applicant as they are authorized to do business in Tennessee.

Item 1.(b) List the street addresses of 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.

A license that authorizes more than one address where licensed material is used or stored is assessed at a higher fee than a single site license. It may be financially advantageous to apply for a separate license for each site. Different addresses that are part of the same contiguous facility may be judged as a single site by the Department.

If applying for a license for mobile medical services, submit the additional information requested in Appendix L.

Item 2. Enter the Department to use radioactive material.

Item 3. Indicate if this is an application for a license renewal and give number.

Item 4. List the full names of all physicians who will use or supervise the use of licensed material and the category of use for which authorization is requested, or confirm that physicians designated as authorized users will meet the appropriate training requirements and be approved as required by licensee management. Categories of medical use are specified in SRPAR 0400-20-07-.38, .40, .44, .51, .61, .63, and .81. See Appendix A. See .05(5), .13 (1)(b), and .17(1)(b) for Authorized Users. Supervision is described in 0400-20-07-.19.

These physicians must meet the appropriate training and experience requirements as defined in SRPAR 0400-20-07-.26, .27, .39, .43, .47, .48, .49., .50, .59, .60, .62, and .80. Physicians who only interpret diagnostic scans/studies or the results of therapeutic procedures involving the administration of licensed material to individuals do not need to meet the training and experience requirements of SRPAR, and are not required to be named as authorized users on the license.

Item 5. State the name of the individual designated by, and responsible to, the proposed licensee’s management for the day-to-day oversight and coordination of the radiation safety program. If not a full-time employee of the licensed facility, this person shall be on site periodically to conduct person-to-person interactions with licensed staff. The licensee shall require an individual fulfilling the responsibility of the radiation safety officer to be an individual who meets the training requirements of SRPAR 0400-20-07-

.23. See Appendix E for typical duties of a Radiation Safety Officer.

Item 6.(a)

Specify the category or categories of use of radioactive material in SRPAR 0400-20-07-.38, .40, .44, .51, .61, .63, and .81 for which you wish to be authorized. For .63 specify which modality is requested. For .81 specify the radionuclide for each use. Request depleted uranium if needed for shielding. Note that Technetium 99m for sentinel lymph node biopsy is authorized as part 0400-20-07-.40.

To request licensure of Yttrium 90 microspheres for brachytherapy or Strontium 90 for intraocular use, please contact the Division.

Calibration, transmission, and reference sources will be authorized by SRPAR 0400-20-07-.31. Identify any sources installed within an imaging device (scanner), and provide the manufacturer and model number of the device as it is approved in the Sealed Source and Device Registry defined in 0400-20-07-.05(33).

Item 6.(b)

For 0400-20-07-.38, .40, and .44 the division will license the chemical and/or physical form as "Any." For .51, .61, .63, and .81 the applicant shall specify the manufacturer and model number for sealed sources as listed in the Sealed Source and Device Registry. Other uses for .81 shall specify the manufacturer and chemical and/or physical form. The division will license depleted uranium as metal.

For .38 and .40 the division will license the maximum amount of radioactivity to be possessed as "As needed." For .44 the applicant needs to request the maximum activity to be possessed. For sealed sources except seeds the applicant needs to specify the maximum activity per source. For all sealed sources specify the total amount of activity to be possessed. For other uses for .81 the applicant needs to request the maximum activity to be possessed. The division will authorize 999 kilograms for depleted uranium.

The possession of a sealed source or sources in accordance with the criteria in Table 1: Radionuclides of Concern (See Appendix C) will require the implementation of Increased Controls for security before licensure. It is recommended that the licensee avoid these requirements if possible and submit its application accordingly. If needed, contact the division for more information.

Any individual sealed source with the radioactive material listed in SRPAR 0400-20-05-.164 and a radioactivity that equals or exceeds those activities found in Category 1 or 2 of SRPAR 0400-20-05-.164 will require the tracking of sealed sources as required by SRPAR 0400-20-05-163.

Item 7.

The division will authorize the purpose of use as stated in 0400-20-07-.38, .40, .44, .51, and .61. For .63 and .81 the applicant should provide a specific purpose of use. The division will authorize depleted uranium for shielding.

Items 8. and 9. Training and Experience. Provide information as requested below rather than completing Items 8 and 9 on the license application. See SRPAR 0400-20-07-.23, .24, .26, .27, .39, .43, .47, .48, .49, .50, .59, .60, .62, and .80 for applicable requirements.

- a. Authorized User(s). If the physician has been previously authorized to use the radioactive material requested in this application, it is necessary to submit only the previous license number (if issued by the State of Tennessee) or a copy of the license (if issued by the Nuclear Regulatory Commission or another Agreement State).

Certifications by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State may be submitted to qualify an authorized user for approval of applicable radioactive materials. Recognized boards may be found at the NRC webpage at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

If the physician has not been previously authorized to use the radioactive material being requested, confirm he/she is licensed to practice medicine in Tennessee, and submit the applicable Authorized User Training and Experience and Preceptor Attestation forms with the required information. See Appendix B.

- b. Radiation Safety Officer. If the radiation safety officer is not one of the physicians named in Item 4, submit a completed Radiation Safety Officer Training and Experience (See Appendix B) and Preceptor Attestation form. If previously named as a Radiation Safety Officer on another license, it is necessary to submit only the previous license number (if issued by the State of Tennessee) or a copy of the license (if issued by the Nuclear Regulatory Commission or another Agreement State).
- c. Authorized Medical Physicist. To name an Authorized Medical Physicist submit a completed Training and Experience (See Appendix B) and Preceptor Attestation form. If previously named as an Authorized Medical Physicist on another license, it is necessary to submit only the previous license number (if issued by the State of Tennessee) or a copy of the license (if issued by the Nuclear Regulatory Commission or another Agreement State).

Item 10. Instrumentation. Provide a description of survey instruments that will meet the following capabilities:

- a. Survey Instruments
 - (1) A survey meter capable of detecting 0.1 mr/hr to perform contamination surveys and capable of reading radiation exposure rates required to show compliance.
 - (2) For those wishing to dispose of empty radioactive material containers, or materials, items, etc., once contaminated with radioactive isotopes, to the normal trash, a survey meter capable of detecting 0.01 mr/hr to measure at background levels.
- b. Dose calibrators or other instruments to assay radiopharmaceuticals.

SRPAR 0400-20-07-.30 does not require a dose calibrator for all measurements, but they are recommended by the division to be used.

Item 11. Calibration of Instruments

- a. Survey Instruments. Calibration of survey instruments shall be performed in accordance with 0400-20-07-.29. 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 shall be supplemented at least every 12 months with a battery check and two-point calibration on each scale of the instrument. Survey instruments shall also be calibrated after repair.

A survey instrument may be considered properly calibrated at one point when the indicated exposure rate measured by the instrument differs from the calculated exposure rate by less than 20% of full scale.

If you propose to calibrate your own radiation survey and monitoring instruments, submit a detailed description of your planned calibration procedures that meet Appendix D.1 or equivalent.

If a consultant or outside firm will perform the calibration of your radiation survey and monitoring instruments, confirm that radiation monitoring instruments will be calibrated by a person authorized by the Nuclear Regulatory Commission or an Agreement State to perform survey meter calibrations.

Appendix D.1 to this Guide contains an acceptable procedure for calibrating survey meters. Indicate that the procedures contained in Appendix D.1 will be followed or submit equivalent procedures.

- b. Equipment Used To Measure Doses The activity of dosages of unsealed radioactive material shall be determined and recorded before medical use in accordance with SRPAR 0400-20-07-.30. The usual method for performing assays is with a dose calibrator. Upon installation, after repair, 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 constancy and proper operation at the beginning of each day of use.

Confirm that equipment used by the licensee to measure the activity of unsealed radioactive material will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions. See Appendix D.2 (referenced below), or American National Standards Institute standards [ANSI N42.13-1986 (R1993)].

Appendix D.2 to this Guide contains a description of an acceptable procedure for calibrating dose calibrators.

Item 12. Personnel Dosimetry

SRPAR 0400-20-05.-71 requires that occupational exposures to radiation be monitored for individuals who are likely to receive an external dose or intake of radioactive material in excess of certain levels. Records of personnel monitoring are required to be maintained. You may evaluate the exposure of occupational workers to determine if personnel monitoring is required. These evaluations should be maintained to justify any determinations made. Confirm that you will perform these evaluations of exposure or will provide appropriate personnel monitoring.

Personnel monitors, except for extremity monitors and pocket ionization chambers, shall be processed and evaluated by a dosimetry processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP may be reviewed at <http://ts.nist.gov/Standards/scopes/dosim.htm> Confirm that if required to use a personnel dosimetry processor, it will be NVLAP accredited.

If it is necessary to monitor the intake of radioactive material, the licensee may use Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program." Regulatory Guide 8.9 may be reviewed at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/occupational-health/active/8-09>.

Item 13. Facilities and Equipment

Submit a diagram with access points of all room(s) where radioactive material is used and/or stored including surrounding areas. Also, include in this diagram a description of the area(s) assigned for the receipt, storage, waste storage, preparation, administration, and measurement of radioactive material. This does not include patient rooms where radiopharmaceuticals are used. Describe any facility or portable shielding that may be necessary in order for the licensee to be able to conduct operations so that the annual dose limit to the public as required by SRPAR 0400-20-05-.60 is not exceeded. This may be most

appropriate for Positron Emission Tomography, High Dose-Rate Afterloader Units (HDR), or certain therapy operations.

Describe the safety equipment to be employed in the use of licensed material. For nuclear medicine this shall include storage shielding, preparation shielding (L-block), syringe shields, transport shields, waste shielding, Xenon dispenser, Xenon trap, and fume hood, if applicable. For brachytherapy this shall include shielding for storage (shielded safe required for Cs-137), preparation shielding (L-block), transport shields, and portable shields for patients.

Additionally, for HDR provide a description of the warning system and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room, area radiation monitoring equipment, viewing and intercom systems, steps that will be taken to ensure that no two units can be operate simultaneously (e.g., linear accelerator, X-ray machine) are in the treatment room, methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons, and emergency response equipment.

For facilities in which radioactive material may become airborne, e.g., Xenon 133, Appendix M to this guide contains information for the safe use of these radioactive materials and to demonstrate compliance with SRPAR.

Item 14. Radiation Protection Program

1. Radiation Safety Committee In accordance with SRPAR 0400-20-07-.17(6) licensees that are authorized for two or more types of use of radioactive material under 0400-20-07-.44, .51, .63, and 81, or two or more types of units under 0400-20-07-.63 shall establish a radiation safety to oversee all uses of radioactive material permitted by the license. Membership of the committee must include:
 - a. An authorized user of each type of use permitted by the license.
 - b. A representative of the nursing service.
 - c. A representative of management who is neither an authorized user nor a radiation safety officer.
 - d. The radiation safety officer.
2. Safety Instruction for Individuals Working in or Frequenting Restricted Areas All individuals working with or around licensed materials should receive safety instructions commensurate with their assigned duties. This should be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, housekeeping, and security personnel, receive proper instruction. This instruction should be given before assuming duties with or in the vicinity of radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, or the terms of the license.

Individuals who in the course of their employment are likely to receive in a year an occupational dose in excess of 100 mrem must receive instruction in accordance with SRPAR 0400-20-04-.12. Personnel caring for hospitalized patients or human research subjects undergoing radiopharmaceutical or implant therapy shall be provided with safety instructions in accordance with SRPAR 0400-20-07-.45 and .54. Operators of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units shall be provided instruction in accordance with SRPAR 0400-20-07-.66(4). Individuals working with licensed material under the supervision of an authorized user, or individuals preparing radioactive material for medical use under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, must receive instruction in accordance with 0400-20-07-.19.

Appendix K to this guide contains acceptable general items of instruction.

3. Procedures for Safely Opening Packages In Which Radioactive Material Is Received, and Receipt of Packages Procedures for examining incoming packages for leakage, contamination, or damage, and for safely opening packages are required by SRPAR 0400-20-05-.115. 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.

Appendix F to this guide contains acceptable procedures for receiving radioactive material. Appendix G to this guide contains acceptable procedures for safely opening packages containing radioactive material.

4. Safety Rules Appendix H to this guide contains an acceptable set of rules for the safe use of radioactive material. Indicate if Appendix H rules will be followed, or attach equivalent procedures.
5. Leak Tests of Sealed Sources Submit sealed source leak testing and analysis procedures if you wish to be authorized to perform leak tests for your licensed sealed sources. If not, confirm that sealed source leak tests will be analyzed by persons authorized by the Nuclear Regulatory Commission or an Agreement State.
6. Emergency Procedures for Spills Describe the emergency instructions to be posted in all areas where radioactive materials are used. These instructions should (a) describe immediate action to be taken in order to prevent contamination of personnel and work areas, (b) state the names and telephone numbers of the responsible persons to be notified in case of an emergency.

An acceptable set of emergency procedures for spills is contained in Appendix I to this Guide. Indicate that emergency procedures in Appendix I will be followed or submit a copy of equivalent procedures with your application.

7. Area Survey Procedures Describe the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable, and provision for maintaining records of surveys.

Acceptable procedures and frequencies for routine surveys are described in Appendix J to this guide. Indicate that you will follow the survey procedures in Appendix J or submit equivalent procedures.

8. Therapeutic Use of Radiopharmaceuticals Although therapeutic procedures in 0400-20-07-.44 and .81 may be performed on an outpatient basis, hospitalization is sometimes required. If patients are to be hospitalized, see 0400-20-07-.45 and .46. In addition confirm that you will commit to the following:

- a. Method for preparation and administration of therapeutic doses of Iodine 131. This would include a commitment to open containers of liquid Iodine 131 in a containment system with adequate airflow to prevent contamination of themselves and surrounding areas.
- b. Significant thyroid uptakes have been detected in individuals who open and prepare oral solutions of Iodine 131 for therapeutic doses. The use of capsules does not normally require bioassay of personnel except for a crushed capsule, etc. In these situations, a bioassay may be necessary. A bioassay is a determination of the kind, quantity or concentration, and location of radioactive material in the human body. In the case of iodine, this would involve in vivo measurement of the gamma radiation emitted from the thyroid gland, or in vivo analysis of the iodine present in a urine sample. If it is necessary to monitor the intake of radioactive material, the licensee may use Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program." Regulatory Guide 8.9 may be reviewed at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/occupational-health/active/8-09>.

9. Therapeutic Use of Sealed Sources Describe special procedures for patients treated with byproduct materials listed in 0400-20-07-.51, .63, or .81.

These procedures should include descriptions of:

- a. The areas where sealed sources will be stored, including (1) placement and thickness of shielding, and (2) proximity of the storage area to unrestricted areas.
 - b. Special precautions to be used while handling sealed sources.
 - c. Your method for determining the radiation doses to the extremities of personnel handling sealed sources.
 - d. The equipment and shielding available for transporting sources from storage sites to the place of use.
 - e. Your method for maintaining source accountability at all times. This should include a description of sign-in and sign-out procedures, periodic inventory, and the method for determining that all sources are accounted for and returned to storage following treatment.
 - f. Surveys to be performed during the course of treatment and at the conclusion of treatment. The patient and room should be surveyed with a radiation survey instrument after the end of treatment and before dismissal. Your dismissal survey should include a source count and should be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied.
10. Release of Patients or Human Research Subjects Licensees may release from confinement patients or human research subjects who have been administered licensed material if the Total Effective Dose Equivalent to any other individual from exposure to the released patient is not likely to exceed 500 mrem. Licensees must provide radiation safety instructions to patients released in accordance with 0400-20-07-.35.

Appendix U of NUREG-1556 Vol. 9 issued by the U.S. Nuclear Regulatory Commission found at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/> contains acceptable procedures for the release of patients administered radioactive materials in accordance with 0400-20-07-.35. Indicate that these procedures will be followed, or attach equivalent procedures.

11. If you are requesting the licensure of a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit, submit a copy of the safety procedures for responding to an abnormal situation as required to be developed by 0400-20-07-.66(1)(d). Submit the written procedures for performing spot check measurements of the above as required to be developed by 0400-20-07-.72(2), .73(2), and .74(2)(a).
12. If you wish one of your employees to be authorized to install, maintain, adjust, or repair a therapy device containing sealed sources as discussed in 0400-20-07-.62, you should submit the name of the employee and the types of activities requested, a description of their training and experience demonstrating that they are qualified for the use requested, a copy of the manufacturer's training certification for the employee in the requested activities, and an outline of the training in procedures to be followed.

Item 15. Waste Disposal

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

- a. Decay in storage as authorized in SRPAR 0400-20-07-.37.
- b. Transfer to a person properly licensed by the NRC or Agreement State to receive such waste, e.g., commercial waste disposal firms.
- c. Release into a sanitary sewer in conformance with SRPAR 0400-20-05-.122.
- d. Release into the air in conformance with SRPAR 0400-20-05-.61.
- e. Other methods specifically approved by the Division pursuant to SRPAR 0400-20-05-.121.

Note: No licensee may dispose of byproduct material waste by incineration unless specifically approved by the Division. [See SRPAR 0400-20-05-.123]

Appendix N to this guide contains acceptable procedures for waste disposal. Indicate that you will dispose of wastes as specified in Appendix N or attach equivalent procedures.

Item 16. Signature of Certifying Official

As required by SRPAR 0400-20-07-.11, the application must be signed by the applicant's management defined in 0400-20-07-.05(14) as the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or that person's delegate or delegates.

AMENDMENT TO LICENSES

Licensees are required to conduct their programs in accordance with Items and Conditions in their license and 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 as outlined in SRPAR 0400-20-07-.14. See also 0400-20-07-.18.

Requests for license amendments may be submitted in letter form by management as defined in 0400-20-07-.05(14). Requests 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. An original and two copies of the request for amendment should be prepared; the original and one copy should be submitted, as in the cases for new or renewal applications.

LIST OF APPENDICES

- A Medical Uses of Radioactive Material
- B Training for Authorized Users, Radiation Safety Officer, and Authorized Medical Physicist
- C Table 1: Radionuclides of Concern
- D Methods of Calibration of Survey Meters and Dose Calibrators
- E Radiation Safety Officer Duties
- F Procedures for Receiving Radioactive Material
- G Procedures for Opening Packages Containing Radioactive Material
- H Rules for the Use of Radioactive Material
- I Emergency Procedures for Spills
- J Area Survey Procedures
- K General Instructions
- L Mobile Medical Services
- M Procedures and Precautions for use of Radioactive Gases (e.g., Xenon 133)
- N Waste Disposal Procedures

APPENDIX A

MEDICAL USES OF RADIOACTIVE MATERIAL

0400-20-07-.38 USE OF UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION, AND EXCRETION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED.

- (1) Except for quantities that require a written directive under 0400-20-07-.20(2), a licensee may use any unsealed radioactive material, prepared for medical use for uptake, dilution, or excretion that is:
 - (a) Obtained from:
 1. A manufacturer or preparer licensed under Rule 0400-20-10-.13(10) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or
 2. A PET radioactive drug producer licensed under Rule 0400-20-10-.11(8) or equivalent Agreement State requirements; or
 - (b) Excluding production of PET radionuclides, prepared by:
 1. An authorized nuclear pharmacist;
 2. A physician who is an authorized user and who meets the requirements specified in Rule 0400-20-07-.43, or Rule 0400-20-07-.47 and Rule 0400-20-07-.43 (1)(c)1(ii)(VII); or
 3. An individual under the supervision, as specified in Rule 0400-20-07-.19, of the authorized nuclear pharmacist in part 1 of this subparagraph or the physician who is an authorized user in part 2 of this subparagraph; or
 - (c) Obtained from and prepared by an Agreement State or U.S. Nuclear Regulatory Commission licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug (IND) protocol accepted by Food and Drug Administration (FDA); or
 - (d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee approved application or an Investigational New Drug (IND) protocol accepted by Food and Drug Administration (FDA) for use in research.

0400-20-07-.40 USE OF UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED.

- (1) A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in Rule 0400-20-07-.20
- (2) that is:
 - (a) Obtained from:
 1. A manufacturer or preparer licensed under Chapter 0400-20-10-.13(10) or equivalent regulations of another Agreement State or U.S. Nuclear Regulatory Commission requirements; or
 2. A PET radioactive drug producer licensed under Rule 0400-20-10-.11(8) or equivalent Agreement State requirements; or

- (b) Excluding production of PET radionuclides prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule 0400-20-07-.43, or Rule 0400-20-07-.47 and Rule 0400-20-07-.43(1)(c)1(ii)(VII), or an individual under the supervision of either as specified in 0400-20-07-.19; or
- (c) Obtained from and prepared by an Agreement State or U.S. Nuclear Regulatory Commission licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug (IND) protocol accepted by Food and Drug Administration(FDA);or
- (d) Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug (IND) protocol accepted by Food and Drug Administration (FDA).

0400-20-07-.44 USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED.

- (1) A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:
 - (a) Obtained from:
 - 1. A manufacturer or preparer licensed under 0400-20-07-10-.13(10) or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or
 - 2. A PET radioactive drug producer licensed under Rule 0400-20-10-.11(8) or equivalent Agreement State requirements; or
 - (b) Excluding production of PET radionuclides prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule 0400-20-07-.43,Rule 0400-20-07-.47, or an individual under the supervision of either as specified in Rule 0400-20-07-.19; or
 - (c) Obtained from and prepared by an Agreement State or U.S. Nuclear Regulatory Commission licensee for use in research in accordance with an investigational new drug (IND) protocol accepted by Food and Drug Administration (FDA) for use in research; or
 - (d) Prepared by the licensee for use in research in accordance with an investigational new drug (IND) protocol accepted by Food and Drug Administration (FDA).

0400-20-07-.51 USE OF SEALED SOURCES FOR MANUAL BRACHYTHERAPY.

- (1) A licensee shall use only brachytherapy sources for therapeutic medical uses:
 - (a) As approved in the Sealed Source and Device Registry; or
 - (b) In research in accordance with an active investigational device exemption (IDE) application accepted by the Food and Drug Administration (FDA) provided the requirements of 0400-20-07-.22 are met.

0400-20-07-.61 USE OF SEALED SOURCES FOR DIAGNOSIS.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the sealed source and device registry.

0400-20-07-.63 USE OF SEALED SOURCE IN REMOTE AFTERLOADER UNIT, TELE THERAPY UNIT, OR GAMMA STEREOSTACTIC RADIOSURGERY UNIT.

- (1) A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:
 - (a) As approved in the sealed source and device registry; or
 - (b) In research in accordance with an active investigational device exemption (IDE) application accepted by the Food and Drug Administration (FDA) provided the requirements of 0400-20-07-.22(1) are met.

0400-20-07-.81 OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL.

- (1) A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in this rule if:
 - (a) The applicant or licensee has submitted the information required by 0400-20-07-.11(2), 0400-20-07-.11(3), and 0400-20-07-.11(4); and
 - (b) The applicant or licensee has received written approval from the Division in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Division considers necessary for the medical use of the material.

APPENDIX B

0400-20-07-.23 TRAINING FOR RADIATION SAFETY OFFICER

Except as provided in 0400-20-07-.26, the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer under 0400-20-07-.17 to be an individual who:

- (1) Is certified by a specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State, and who meets the requirements of paragraphs (4) and (5) of this rule. (Specialty boards whose certification processes have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.) To be recognized, a specialty board shall require all candidates for certification to:
 - (a)
 1. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of twenty college credits in physical science;
 2. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and
 3. Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or
 - (b)
 1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
 2. Have two years of full-time practical training and/or supervised experience in medical physics:
 - (i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the U.S. Nuclear Regulatory Commission or an Agreement State; or
 - (ii) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users under Rule 0400-20-07-.26, 0400-20-07-.43 or 0400-20-07-.47; and
 3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or
- (2) (a) Has completed a structured educational program consisting of both:
 1. Two hundred hours of classroom and laboratory training in the following areas:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;

- (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiation biology; and
 - (v) Radiation dosimetry; and
2. One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a Division, U.S. NRC or Agreement State license or a permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:
- (i) Shipping, receiving, and performing related radiation surveys;
 - (ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
 - (iii) Securing and controlling radioactive material;
 - (iv) Using administrative controls to avoid mistakes in the administration of radioactive material;
 - (v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
 - (vi) Using emergency procedures to control radioactive material; and
 - (vii) Disposing of radioactive material; or
- (3) (a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State under 0400-20-07-.24(1) and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as radiation safety officer and who meets the requirements in paragraphs (4) and (5) of this rule; or
- (b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and
- (4) Has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in paragraph (5) of this rule, and in subparagraph (1)(a), (1)(b), (2)(a), (3)(a) or (3)(b) of this rule, and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and
- (5) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by an authorized medical physicist, authorized user, authorized nuclear pharmacist, or radiation safety officer, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

0400-20-07-.24 TRAINING FOR AN AUTHORIZED MEDICAL PHYSICIST

Except as provided in 0400-20-07-.26, the licensee shall require the authorized medical physicist to be an individual who:

- (1) Is certified by a specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in subparagraph (2)(b) and paragraph (3) of this rule. To be recognized, a specialty board shall require all candidates for certification to:
 - (a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
 - (b) Have two years of full-time practical training and/or supervised experience in medical physics:
 1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the U.S. Nuclear Regulatory Commission or an Agreement State; or
 2. In clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in Rule 0400-20-07-.26, 0400-20-07-.59 or 0400-20-07-.80; and
 - (c) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or
- (2) (a) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use modalities for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy and brachytherapy services and must include:
 1. Performing sealed source leak tests and inventories;
 2. Performing decay corrections;
 3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
 4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
- (b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraphs (1)(a) and (b) and paragraph (3), or subparagraph (2)(a) and paragraph (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is

requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in Rule 0400-20-07-.24, Rule 0400-20-07-.26 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

- (3) Has training for the type(s) of use in the modalities for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

0400-20-07-.26 TRAINING FOR EXPERIENCED RADIATION SAFETY OFFICER, TELE THERAPY OR MEDICAL PHYSICIST, AUTHORIZED USER, AND NUCLEAR PHARMACIST

- (1) An individual identified as a radiation safety officer, a teletherapy physicist or medical physicist, an authorized medical physicist, or a nuclear pharmacist or authorized nuclear pharmacist on a Division, U.S. Nuclear Regulatory Commission, or Agreement State license, or a permit issued by the Division, U.S. Nuclear Regulatory Commission, or an Agreement State broad scope licensee or master material license permit, or by a master material license permittee of broad scope before effective date of these rules, need not comply with the training requirements of 0400-20-07-.23, 0400-20-07-.24, or 0400-20-07-.25, respectively.
- (2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Division, U.S. Nuclear Regulatory Commission, an Agreement State, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by the Division, U.S. Nuclear Regulatory Commission, or Agreement State broad scope licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee issued before the effective date of these rules, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of 0400-20-07-.39, 0400-20-07-.43, 0400-20-07-.47, 0400-20-07-.48, 0400-20-07-.49, 0400-20-07-.59, 0400-20-07-.60, 0400-20-07-.62 and 0400-20-07-.80.

0400-20-07-.27 RECENTNESS OF TRAINING

The training and experience specified in 0400-20-07-.17 through 0400-20-07-.27 and 0400-20-07-.38 through 0400-20-07-.80 must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

0400-20-07-.39 TRAINING FOR UPTAKE, DILUTION, AND EXCRETION STUDIES

- (1) Except as provided in 0400-20-07-.26, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 0400-20-07-.38 to be a physician who:
 - (a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements of part (1)(c)2 of this rule. To be recognized, a specialty board shall require all candidates for certification to:
 1. Has completed 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive

- material for uptake, dilution, and excretion studies as described in subparts (1)(c)1(i) and (ii) of this rule; and
2. Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or
- (b) Is an authorized user under 0400-20-07-.43 or 0400-20-07-.47 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or
- (c) 1. Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:
- (i) Classroom and laboratory training in the following areas:
 - (I) Radiation physics and instrumentation;
 - (II) Radiation protection;
 - (III) Mathematics pertaining to the use and measurement of radioactivity;
 - (IV) Chemistry of radioactive material for medical use; and
 - (V) Radiation biology; and
 - (ii) Work experience, under the supervision of an authorized user who meets the requirements in 0400-20-07-.39, 0400-20-07-.43, or 0400-20-07-.47 or equivalent U.S. Nuclear Regulatory Commission or agreement State requirements, involving:
 - (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (III) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
 - (V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (VI) Administering dosages of radioactive drugs to patients or human research subjects; and
2. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, 0400-20-07-.39, 0400-20-07-.43, or 0400-20-07-.47 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in parts (1)(a)1 or (1)(c)1 of

this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 0400-20-07-.38.

0400-20-07-.43 TRAINING FOR IMAGING AND LOCALIZATION STUDIES

- (1) Except as provided in 0400-20-07-.26, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 0400-20-07-.40 to be a physician who:
 - (a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in part (c)2 of this paragraph. To be recognized, a specialty board shall require all candidates for certification to:
 1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in subparts (c)1(i) and (ii) of this paragraph; and
 2. Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or
 - (b) Is an authorized user under 0400-20-07-.47 and meets the requirements in item (c)1(ii)(VII) of this paragraph or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or
 - (c) 1. Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:
 - (i) Classroom and laboratory training in the following areas:
 - (I) Radiation physics and instrumentation;
 - (II) Radiation protection;
 - (III) Mathematics pertaining to the use and measurement of radioactivity;
 - (IV) Chemistry of radioactive material for medical use;
 - (V) Radiation biology; and
 - (ii) Work experience, under the supervision of an authorized user, who meets the requirements in this rule, Rule 0400-20-07-.26, or item (VII) of this subpart and Rule 0400-20-07-.47 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, involving:
 - (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- (II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (III) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
 - (V) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
 - (VI) Administering dosages of radioactive drugs to patients or human research subjects; and
 - (VII) 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
2. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule, Rule 0400-20-07-.26, or Rule 0400-20-07-.47 and item 1(ii)(VII) of this subparagraph or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in parts (a)1 or (c)1 of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 0400-20-07-.38 and 0400-20-07-.40.

0400-20-07-.47 TRAINING FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED

- (1) Except as provided in 0400-20-07-.26, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 0400-20-07-.44 to be a physician who:
- (a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission an Agreement State and who meets the requirements in item (1)(b)1(ii)(VI) and part (1)(b)2 of this rule. (Specialty boards whose certification processes have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.) To be recognized, a specialty board shall require all candidates for certification to:
 - 1. Successfully complete a residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in subpart (b)1(i) through item (b)1(ii)(V) of this paragraph. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postgraduate Training of the American Osteopathic Association; and
 - 2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed by-product material; or

- (b) 1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:
- (i) Classroom and laboratory training in the following areas:
 - (I) Radiation physics and instrumentation;
 - (II) Radiation protection;
 - (III) Mathematics pertaining to the use and measurement of radioactivity;
 - (IV) Chemistry of radioactive material for medical use; and
 - (V) Radiation biology; and
 - (ii) Work experience, under the supervision of an authorized user who meets the requirements of this rule, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in this subparagraph, must also have experience in administering dosages in the same dosage category or categories (i.e., item (VI) of this subpart) as the individual requesting authorized user status. The work experience must involve:
 - (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (III) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
 - (V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (VI) 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:
 - I. Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;
 - II. Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131. Experience with at least three cases in this also satisfies the requirement in subitem I of this item;

III. 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

IV. Parenteral administration of any other radionuclide for which a written directive is required; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraph (a) and item (b)1(ii)(VI) of this paragraph or subparagraph (b) of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 0400-20-07-.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule, Rule 0400-20-07-.26, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements in this subparagraph, must have experience in administering dosages in the same dosage category or categories (i.e., item 1(ii)(VI) of this subparagraph) as the individual requesting authorized user status.

0400-20-07-.48 TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODINE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES LESS THAN OR EQUAL TO 1.22 GIGABECQUERELS (33 MILLICURRIES)

(1) Except as provided in 0400-20-07-.26, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in subparagraph (c) of this paragraph and whose certification has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State; (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.); or

(b) Is an authorized user under 0400-20-07-.47 for uses listed in 0400-20-07-.47(1)(b)1(ii)(VI)I or II, 0400-20-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(c) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule 0400-20-07-.26, 0400-20-07-.47, 0400-20-07-.48, 0400-20-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A

supervising authorized user who meets the requirements in 0400-20-07-.47(1)(b), must also have experience in administering dosages as specified in 0400-20-07-.47(1)(b)1(ii)(VI)I or II. The work experience must involve:

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;
 - (v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and
3. Has obtained written attestation that the individual has satisfactorily completed the requirements in parts 1 and 2 of this subparagraph and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 0400-20-07-.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, 0400-20-07-.47, 0400-20-07-.48, 0400-20-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirement in 0400-20-07-.47(1)(b), must also have experience in administering dosages as specified in 0400-20-07-.47(1)(b)1(ii)(VI)I or II.

0400-20-07-.49 TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODINE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES GREATER THAN 1.22 GIGABECQUERELS (33 MILLICURRIES)

- (1) Except as provided in 0400-20-07-.26, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:
 - (a) Is certified by a medical specialty board whose certification process includes all of the requirements in parts (c)1 and 2 of this paragraph and whose certification has been recognized by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in part (1)(c)3 of this rule. (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.); or
 - (b) Is an authorized user under 0400-20-07-.47 for uses listed in 0400-20-07-.47(1)(b)1(ii)(VI)II, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

- (c) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:
- (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Chemistry of radioactive material for medical use; and
 - (v) Radiation biology; and
2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule 0400-20-07-.26, 0400-20-07-.47, 0400-20-07-.49 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements in 0400-20-07-.47(1)(b), must have experience in administering dosages as specified in 0400-20-07-.47(1)(b)1(ii)(VI)II. The work experience must involve:
- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;
 - (v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and
3. Has obtained written attestation that the individual has satisfactorily completed the requirements in parts 1 and 2 of this subparagraph and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 0400-20-07-.44. The written attestation must be signed by a preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, 0400-20-07-.47, 0400-20-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in 0400-20-07-.47(1)(b), must have experience in administering dosages as specified in 0400-20-07-.47(1)(b)1(ii)(VI)II.

0400-20-07-.50 TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE

- (1) Except as provided in Rule 0400-20-07-.26, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:
 - (a) Is an authorized user under Rule 0400-20-07-.47 for uses listed in 0400-20-07-.47(1)(b)1(ii)(VI)III or 0400-20-07-.47(1)(b)1(ii)(VI)IV, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or
 - (b) Is an authorized user under Rule 0400-20-07-.59 or 0400-20-07-.80, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements and who meets the requirements in subparagraph (d) of this paragraph; or
 - (c) Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State under Rule 0400-20-07-.59 or 0400-20-07-.80, and who meets the requirements in subparagraph (d) of this paragraph.
 - (d)
 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Chemistry of radioactive material for medical use; and
 - (v) Radiation biology; and
 2. Has work experience, under the supervision of an authorized user who meets the requirements in Rule 0400-20-07-.26, 0400-20-07-.47 or 0400-20-07-.50, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 0400-20-07-.47 must have experience in administering dosages as specified in Rule 0400-20-07-.47(1)(b)1(ii)(VI)III and/or IV. The work experience must involve:
 - (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
 - (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
 - (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

- (v) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
 - (vi) Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and
- (e) Has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraphs (b) or (c) of this paragraph, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, 0400-20-07-.47, 0400-20-07-.50, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A preceptor authorized user, who meets the requirements in Rule 0400-20-07-.47 must have experience in administering doses as specified in Rule 0400-20-07-.47(1)(b)1(ii)(VI)III and/or IV.

0400-20-07-.59 TRAINING FOR USE OF MANUAL BRACHYTHERAPY SOURCES

- (1) Except as provided in 0400-20-07-.26, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 0400-20-07-.51 to be a physician who:
- (a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State, and who meets the requirements in part (1)(b)3 of this rule. (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.) To be recognized, a specialty board shall require all candidates for certification to:
 1. Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postgraduate Training of the American Osteopathic Association; and
 2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or
 - (b) 1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
 - (i) 200 hours of classroom and laboratory training in the following areas:
 - (I) Radiation physics and instrumentation;
 - (II) Radiation protection;
 - (III) Mathematics pertaining to the use and measurement of radioactivity; and
 - (IV) Radiation biology; and

- (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this rule or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements at a medical institution, involving:
 - (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (II) Checking survey meters for proper operation;
 - (III) Preparing, implanting, and removing brachytherapy sources;
 - (IV) Maintaining running inventories of material on hand;
 - (V) Using administrative controls to prevent a misadministration involving the use of radioactive material;
 - (VI) Using emergency procedures to control radioactive material; and
- 2. Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this rule or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subpart 1(ii) of this subparagraph; and
- 3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this rule, Rule 0400-20-07-.26, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in part (a)1, or parts (b)1 and 2 of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 0400-20-07-.51.

0400-20-07-.60 TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90

- (1) Except as provided in 0400-20-07-.26, the licensee shall require the authorized user of strontium-90 for ophthalmic uses authorized under 0400-20-07-.51 to be a physician who:
 - (a) Is an authorized user under 0400-20-07-.59 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or
 - (b) 1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:
 - (i) Examination of each individual to be treated;
 - (ii) Calculation of the dose to be administered;
 - (iii) Administration of the dose; and
 - (iv) Follow up and review of each individual's case history; and
3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, 0400-20-07-.59, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in subparagraphs (a) and (b) of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

0400-20-07-.62 TRAINING FOR USE OF SEALED SOURCES FOR DIAGNOSIS

- (1) Except as provided in 0400-20-07-.26, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under 0400-20-07-.61 to be a physician, dentist, or podiatrist who:
 - (a) Is certified by a specialty board whose certification process includes all of the requirements in subparagraphs (b) and (c) of this paragraph and whose certification has been recognized by the Division, the U.S Nuclear Regulatory Commission, or an Agreement State (The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State will be posted on the U.S. Nuclear Regulatory Commission's Web page.); or
 - (b) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:
 1. Radiation physics and instrumentation;
 2. Radiation protection;
 3. Mathematics pertaining to the use and measurement of radioactivity;
 4. Radiation biology; and
 - (c) Has completed training in the use of the device for the uses requested.

0400-20-07-.80 TRAINING FOR USE OF REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

- (1) Except as provided in 0400-20-07-.26, the licensee shall require an authorized user of a sealed source for a use authorized under 0400-20-07-.63 to be a physician who:

- (a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in part (b)3 and subparagraph (c) of this paragraph. To be recognized, a specialty board shall require all candidates for certification to:
1. Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
 2. Pass an examination administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or
- (b) 1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
- (i) 200 hours of classroom and laboratory training in the following areas:
 - (I) Radiation physics and instrumentation;
 - (II) Radiation protection;
 - (III) Mathematics pertaining to the use and measurement of radioactivity; and
 - (IV) Radiation biology; and
 - (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this rule or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements at a medical institution, involving:
 - (I) Reviewing full calibration measurements and periodic spot-checks;
 - (II) Preparing treatment plans and calculating treatment doses and times;
 - (III) Using administrative controls to prevent a misadministration involving the use of radioactive material;
 - (IV) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
 - (V) Checking and using survey meters; and
 - (VI) Selecting the proper dose and how it is to be administered; and
2. Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this rule or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subpart 1(ii) of this subparagraph; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in part (a)1 of this paragraph or part 1 of this subparagraph, and part 2 of this subparagraph and subparagraph (c) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in this rule, Rule 0400-20-07-.26, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and
- (c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

APPENDIX C

Table 1: Radionuclides of Concern

Radionuclide	Quantity of Concern ¹ (TBq)	Quantity of Concern ² (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Ra-226 ⁵	0.4	11
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above ³	See Footnote Below ⁴	

¹ The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

² The primary values used for compliance with this Order are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

³ Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

⁴ If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n , $A_{i(n)}$, to the quantity of concern for radionuclide n , $Q_{(n)}$, listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... ≥ 1

⁵ On August 31, 2005, the NRC issued a waiver, in accordance to Section 651(e) of the Energy Policy Act of 2005, for the continued use and/or regulatory authority of Naturally Occurring and Accelerator-Produced Material (NARM), which includes Ra-226. The NRC plans to terminate the waiver in phases, beginning November 30, 2007, and ending on August 7, 2009. The NRC has authority to regulate discrete sources of Ra-226, but has refrained from exercising that authority until the date of an entity's waiver termination. For entities that possess Ra-226 in quantities of concern, this Order becomes effective upon waiver termination. For information on the schedule for an entity's waiver termination, please refer to the NARM Toolbox website at <http://nrc-stp.ornl.gov/narmtoolbox.html>.

APPENDIX D.1

METHODS FOR CALIBRATION OF SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY

1. Calibration of survey meters shall be performed with radionuclide sources.
 - A. The sources shall be approximate point sources.
 - B. The source activities shall be NIST traceable within 5% accuracy.
 - C. The frequency shall be at least annually and following repair.
 - D. Calibrate all required scale readings up to 10 millisieverts (1000 millirems) per hour.
 - E. Calibrate two separate readings on each scale or decade that will be used to show compliance.
 - F. The indicated exposure rate measured by the instrument shall differ from the calculated exposure rate by less than 20%. (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration).
 - G. Conspicuously note on the instrument the date of calibration.

NOTE: Sources of Cs-137 or Co-60 are appropriate for the performance of calibration. The activity of the calibration standard should be sufficient to calibrate the survey meters on all ranges required to show compliance.

2. A reference check source of long half-life, e.g. Cs-137, shall also be read at the time of the above calibration. The reading 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:
 - A. Before each day of use.
 - B. After each maintenance and/or battery change

If any reading with the same geometry is not within $\pm 20\%$ of the reading measured immediately after calibration, the instrument should be recalibrated (see Step 1).

3. Records of 1, and 2.B. above must be maintained.
4. Use of Inverse Square Law and Radioactive Decay Law
 - A. 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.
 - (1) The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.
 - (2) The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

B. INVERSE SQUARE LAW

Exposure rate at P_2 :

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

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

(2) P_1 and P_2 are in the same units (cm, meter, feet, etc.)

C. RADIOACTIVE DECAY LAW:

Exposure rate t units of time after specified calibration date:

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

(1) $T^{1/2}$ is radionuclide half-life

(2) t is number time elapse calibration time of units of time between and present time

(3) R_o and R_t are in the units (mr/hr or R/hr):

(4) R_o is exposure rate on specified calibration date

(5) R_t is exposure rate t unit of time later

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

APPENDIX D.2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR

1. Test for the following
 - A. Instrument constancy (daily prior to assay of patient doses)
 - B. Instrument accuracy (at installation and annually thereafter)
 - C. Instrument linearity (at installation and quarterly thereafter)
 - D. Geometrical variation (at installation)
2. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above. (Dependent upon the nature of the repairs.)
3. Test for Instrument Constancy

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

 - A. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
 - B. Measure background level at same instrument setting or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.
 - C. Calculate net activity of each source subtracting out background level.
 - D. For each source, plot net activity versus the day of the year on semilog graph paper.
 - E. Log the background levels.
 - F. Indicate the predicted activity of each source based on decay calculations and the ± 10 percent limits on the graph.
 - G. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
 - H. Variations greater than ± 10 percent from the predicted activity indicate the need for instrument repair or adjustment.
 - I. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.
4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set. (See manufacturer's instructions)
5. Test of Instrument Linearity

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

- A. Assay the Tc-99m vial in the dose calibrator and subtract background level to obtain net activity in millicuries.
- B. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
- C. 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:

<i>Assay, Time* (hr)</i>	<i>Correction Factor</i>
0	31.633
6	15.853
24	1.995
30	1
48	0.126

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

- D. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).
- E. The activities plotted should be within ± 10 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ± 10 percent indicate the need for repair or adjustment of the instrument.
- F. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.
- G. The licensee may choose to use a shield method for performance of instrument linearity. If the licensee chooses this method, a copy of the manufacturer's procedures shall be maintained for inspection by the Department.

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

6. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ± 10 percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

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

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

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

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

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

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

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

- F. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.
- G. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower- energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

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

7. Test for Instrument Accuracy

Check the accuracy of the dose calibrator with a source(s) which energy falls between 100 and 500 KeV, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. 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.

- A. Assay the reference standard in the dose calibrator at the appropriate setting, and subtract the background level to obtain the net activity.
- B. Repeat step 1 for a total of 3 determinations, and average results.

- C. The average activity determined in step 2 should agree with the certified activity of the reference source within ± 10 percent after decay corrections.
- D. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.
- E. Keep a log of these calibration checks.
- F. Calibration checks that do not agree within ± 10 percent indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.
- G. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

APPENDIX E

RADIATION SAFETY OFFICER DUTIES

Typically, these duties and responsibilities include ensuring the following:

Unsafe activities involving licensed material are stopped;

Radiation exposures are ALARA;

Up-to-date radiation protection procedures in the daily operation of the licensee's radioactive material program are developed, distributed, and implemented;

Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;

Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;

Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;

Documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;

When necessary, personnel monitoring devices are used and exchanged at proper intervals, and records of the results of such monitoring are maintained;

Licensed material is properly secured;

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;

Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;

Misadministrations and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;

Audits of the radiation protection program are performed at least annually and documented;

If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;

Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;

Licensed Material is disposed of properly;

Appropriate records are maintained; and

An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

APPENDIX F

PROCEDURES FOR RECEIVING RADIOACTIVE MATERIAL

1. During normal working hours carriers will be instructed to deliver radioactive material packages directly to the Nuclear Medicine Department.
2. For packages delivered after normal working hours, you may develop procedures in accordance with those outlined in the attached memorandum.

MEMORANDUM FOR: Security Personnel

FROM: _____, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive before or after normal working hours, or on Sundays, shall be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

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

RADIATION SAFETY OFFICER: _____

OFFICE PHONE: _____

HOME PHONE: _____

APPENDIX G

PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted stop procedure and notify Radiation Safety Officer.
2. Monitor the package for radioactive contamination and radiation levels as required in SRPAR 0400-20-05-.115
3. Put on gloves.
4. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slips, and label on bottle) check integrity of final source container (inspect for breakage of seals or vials, loss of liquid, discoloration of packing material). Check also that shipment does not exceed possession limits.
5. If there is any reason to suspect external contamination, wipe external surface of final source container with moistened cotton swab or filter paper held with forceps, assay, and record.
6. Monitor the packing material and packages for contamination before discarding:
 - A. If contaminated, treat as radioactive waste.
 - B. If not, obliterate radiation labels before discarding in regular trash.

APPENDIX H

RULES FOR THE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats, or other protective clothing at all times in areas where radioactive material are used.
2. Wear disposable gloves at all times while handling primary containers of 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 when their use is contraindicated, such as pediatric cases, where their use would compromise the patient's well-being.
5. Do not eat, drink, smoke, store food or drink, or apply cosmetics in any area where radioactive material is stored or used.
6. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 20% except as approved by an authorized user.
7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist level.
8. Wear finger badges during elution of generator and preparation, assay, injection of radiopharmaceuticals, or handling of brachytherapy sources.
9. Dispose of radioactive waste only in specially designated receptacles.
10. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.
11. Always transport radioactive material in shielded containers.
12. Syringes, vials, and shields containing radioactive must be labeled in accordance with SRPAR 0400-20-07-.33 and 0400-20-05-.113.
13. Check the patient's name and identification number, and the prescribed radionuclide, chemical form, and dosage before administering.
14. Secure all licensed materials when not under the constant surveillance and immediate control of an individual authorized under the license.

APPENDIX I

EMERGENCY PROCEDURES FOR SPILLS

MINOR SPILLS

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

MAJOR SPILLS

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.
5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.
6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: _____

EMERGENCY CONTACT NUMBER: _____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RSO:

APPENDIX J

AREA SURVEY PROCEDURES

1. Perform periodic surveys of ambient radiation dose rates in unrestricted and restricted areas as needed to ensure that regulatory dose limits to the public and occupational workers are met. Suggested trigger levels for investigation and response are 0.1 m^r/hr and 5 m^r/hr for unrestricted and restricted areas, respectively.
2. All radiopharmaceutical elution, preparation, assay, and patient administration areas will be surveyed at the end of each day for contamination with a survey meter and decontaminated if necessary. Patient rooms where diagnostic administrations are made need not be surveyed if special care is taken to remove all potentially contaminated items and no contamination is suspected.
3. Patient radiopharmaceutical therapy rooms shall be surveyed for ambient radiation levels and contamination at the end of therapy.
4. Laboratory areas where only small quantities of radioactive material are used (less than 200 μCi) will be surveyed monthly for contamination.
5. Radionuclide storage and radioactive waste storage areas will be surveyed weekly for contamination.
6. Sealed source and brachytherapy source storage areas shall be surveyed quarterly for ambient radiation dose rates.
7. The surveys in Items 1 through 6 will consist of a measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 m^r/hr and capable of measuring dose rates that will be used to show compliance.
8. Surveys in Items 3 through 5 shall include a series of smear tests to measure removable contamination levels. The method for measuring smear tests will be sufficiently sensitive to detect contamination trigger levels as listed below.

Removable surface contamination trigger levels for decontamination of restricted areas are 2,000 dpm/100 cm² for beta-gamma radionuclides except for only Technetium 99m, Thallium 201, Gallium 67, Mercury 197, Cobalt 57, and Chromium 51 which are 20,000 dpm/100 cm².

Trigger levels for unrestricted areas are 1000 dpm/100 cm² for beta-gamma radionuclides and 200 dpm/100 cm² for radioiodine.

9. A record will be maintained for three years of all survey results, including negative results. The record must include:
 - A. The date of the survey.
 - B. The results of the survey.
 - C. The instrument used to make the survey.
 - D. The name of the individual who performed the survey.

APPENDIX K

General Instructions

- 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 State Regulations.
- e. Pertinent terms of the license.
- f. Their obligation to report unsafe conditions.
- g. Appropriate response to emergencies or unsafe conditions.
- h. Their right to be informed of their radiation exposure and bioassay results.
- i. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 0400-20-04-.11(1) of SRPAR.

APPENDIX L

MOBILE MEDICAL SERVICES

1. In general, there are two types of mobile medical services in which radioactive material is used. One type is transportation and use within a transport vehicle. A second type is transportation to a client's facility and use within that facility. The provider of these mobile services will need to obtain a radioactive material license for use within Tennessee. Licensed operations shall be performed under the supervision of an authorized user physician who takes responsibility for the client locations.
2. The licensee shall obtain a letter signed by the management of each of its clients for which services are rendered. The letter will permit the use of licensed material at the client's address and will clearly delineate the authority and responsibility of each entity. A copy of this letter shall be submitted with the license application or amendment.
3. The licensee shall ensure that all licensed material including radiopharmaceuticals, sealed sources, and all associated radioactive wastes shall be removed before leaving the client's address.
4. If the licensee will maintain a base location in Tennessee, specify its location. Provide a description and diagram of this facility and associated equipment including adjacent areas. Describe how the facility will be secured from unauthorized access. If the base location is to be in a mobile van, it shall be in secured off-street parking under licensee control not on a public right-of-way. Surveys shall be performed as necessary to show that dose to the public radiation levels do not exceed 2 millirems in any one hour and 100 millirems in a year.
5. The licensee will need to provide a list of the name and address of each client for which licensed activities will be performed. A diagram of the location of use at the client facility including adjacent areas shall be submitted. Instruments used to measure the activity of licensed material and transported imaging cameras shall be checked for proper operation at each client's address or on each day of use, whichever is more frequent. Licensed material may be delivered to a van only if licensed personnel are present, or to a client facility if licensed.
6. Provide assurance that individuals administered radioactive material under this license may be released following treatment in accordance with 0400-20-07-.35.
7. The licensee shall develop emergency procedures to be implemented in the case of an accident. They shall contain the following:
 - A. 24-hour emergency contact telephone number for the licensee's responsible individual(s) and The Tennessee Emergency Management Agency at 1-800-262-3300 or 615-741-0001.
 - B. Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazard exists.
 - C. Procedures for retrieving and securing any radioactive material.
 - D. Decontamination procedures.
 - E. The provision for a calibrated, operational survey meter to be maintained in the cab of the transporting vehicle.

APPENDIX M

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

Information for the use of radioactive gases (e.g., Xenon 133):

1. Maintain a diagram of the area(s) in which you plan to use and store Xenon 133.
2. Ensure that negative pressure will be maintained in all areas where Xenon 133 is used, and that the negative pressure will be verified annually.
3. Calculations for air concentrations of Xenon 133 in Restricted and Unrestricted Areas.

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

- a. Estimate the maximum amount of activity to be used per week (A).
- b. Estimate the fraction of Xenon 133 that is lost during use and storage (f). This fractional loss must include ALL sources of loss, e.g., during patient administration, storage, and disposal.
- c. Determine the measured airflow rate in the area(s) of interest, and calculate the volume of air available per week for dilution of the Xenon 133 (V).
- d. Calculate the concentration (C) for the restricted area(s) where

$$C = \frac{A \times f}{V}$$

SRPAR 0400-20-05-.51 requires that C be equal to or less than 1×10^{-4} $\mu\text{Ci/ml}$.

The following procedure may be used to estimate the concentrations of Xenon 133 in effluents to unrestricted areas.

- a. Estimate the maximum amount of Xenon 133 to be released per year (A).
- b. Estimate the fraction of Xenon 133 to be released per year (f). This should include all anticipated losses during administration, storage, and disposal.
- c. Determine the measured airflow rate of the exhaust system and calculate the airflow quantity per year (V).
- d. Calculate the Concentrations (C) for unrestricted areas where:

$$C = \frac{A \times f}{V}$$

SRPAR 0400-20-06-.61 requires that C be equal to or less than 5×10^{-7} $\mu\text{Ci/ml}$.

4. Develop the emergency procedures to be used in case of accidental release of Xenon 133. This should include such considerations as temporary evacuation of the area or increasing the ventilation of the

area. Perform a calculation that shows Restricted Area concentrations are acceptable for reentry into the room. An acceptable formula is:

$$\text{Evacuation time (t)} = \frac{-V}{Q} \times \ln(C \times V/A)$$

V = volume of air in milliliters

Q = total room air exhaust in milliliters per minute

C = maximum permissible air concentrations in restricted and unrestricted areas

A = highest activity of gas in a single container, in microcuries

5. Employ charcoal traps or other absorbing medium in your exhaust ventilation system.
6. Ensure collection and trapping devices are performing according to specification, both initially and on a continuing basis (at least monthly).

USEFUL CONVERSIONS

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

APPENDIX N

WASTE DISPOSAL PROCEDURES

1. Decay-in -Storage

A licensee may hold radioactive material with a half-life of 120 days or less for decay-in-storage for disposal without regard to its radioactivity. The radioactive material shall be monitored in a low background area (less than 0.05 mr/hr) at the container surface to determine that the radioactivity cannot be distinguished from the background level with an appropriate radiation detection instrument set on its most sensitive scale with no interposed shielding. This should be an instrument capable of detecting 0.01 mr/hr. All radiation labels shall be obliterated or removed except for those that are within containers that will be treated as biomedical waste after release by the licensee. Records of each disposal shall be maintained.

2. Return of Licensed Material to Authorized Recipients

Licensed material including used Mo99/TC99m generators may be returned to the manufacturer or authorized recipient in accordance with DOT regulations. A DOT 7A Specification package or strong, tight package shall be assembled in accordance with the manufacturer's instructions, if applicable. Dose rate and removable contamination surveys shall be performed. Proper labels and shipping papers shall be prepared, if applicable. Records of transfer shall be maintained.

3. Liquid Waste

License liquid waste may be disposed of by release into the sanitary sewerage in accordance with SRPAR 0400-20-05-.122