RADIOPHARMACY

PURPOSE

This procedure provides general instructions for developing, maintaining, and documenting, radiation safety procedures for Intermountain Radiopharmacy, Radiology Department, University of Utah. The radiation safety procedures are to be followed by radiopharmacy in the preparation and distribution of radiopharmaceutical doses.

POLICY

The **Radiation Safety Committee (RSC)** is responsible for assuring that each individual who prepares for use, prescribes, or uses in any form ionizing radiation on humans, is properly qualified through training and experience. Training and experience must meets all regulatory requirements. Research or experimental applications of radiation to humans must be reviewed and approved by the Human Uses Sub Committee of the RSC (RPR 40).

Intermountain Radiopharmacy's Radiation Safety Program will be audited by a subcommittee of the RSC. The audits will be coordinated by the University Of Utah, Radiation Safety Officer (RSO).

Radiation safety procedures for the use of radionuclides in the Intermountain Radiopharmacy are prepared, implemented and supervised by the **Radiopharmacy Director (RPD)**. The RPD submits a copy of all new or revised radiopharmacy procedures involving any aspect of radiation protection to the University's **Radiation Safety Officer (RSO)** for review and documentation. The RSO submits comments, suggestions or proposed changes to the RPD for action. The RSO reports on the status and acceptability of the procedures to the RSC at least annually.

The RPD is designated by the RSO to be the on-site radiation safety officer for the Intermountain Radiopharmacy.

The handling of all radioactive materials at Intermountain Radiopharmacy will be in compliance with the University's *Radiation Safety Policy Manual* and applicable Radiation Procedures and Records (RPR's), the Utah Radiation Control (URC) Rules, and based on recommendations in the appropriate appendices of Guide DRC-Medical Addendum dated 07/96. Redistribution of reagent kits, used generators, reference (sealed) sources, and *in vitro* kits shall be conducted in accordance with URC Rules, Department Of Transportation (DOT) regulations and Nuclear Regulatory Commission (NRC), regulations.

Routine clinical uses of radionuclides for diagnosis or treatment are controlled by qualified physicians and are not subject to review or approval by the Radiation Safety Committee.

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SPECIFIC PROCEDURES

Additional requirements related to the safe handling of radiopharmaceuticals are included in the following procedures:

Training

All radiopharmacists staff must be certified by the Board of Pharmaceutical Specialties or have equivalent training and experience.

The RPD shall ensure that all Intermountain Radiopharmacy personnel and pharmacy students involved in the preparation and/or distribution of radiopharmaceuticals for therapy or diagnosis have received appropriate radiation safety training. Documentation of radiation safety training for these personnel shall be provided to and maintained by the Radiological Health Department.

Emergency Procedures

Spills and other emergencies will be responded to according to established procedures described in RPR #45. The RPD shall ensure that all Intermountain Radiopharmacy personnel and pharmacy students have received appropriate spill and

emergency training. Documentation of spill and emergency training shall be maintained by the RPD.

Unit Dosage Records

Radiopharmacy will follow the procedure for "Unit Dosage Records" described in Appendix I .7 of the Guide DRC-Medical Addendum dated 07/96

Multidose Vial Records

Radiopharmacy will follow the procedure for "Multidose Diagnostic Vial Records" described in Appendix I .15 of the Guide DRC-Medical Addendum dated 07/96. Records will be retained for a period of three years.

Molybdenum Concentration Records

Radiopharmacy will follow the procedure for "Measuring and Recording Molybdenum Concentration" as described in Appendix M.3 of the Guide DRC-Medical Addendum dated 07/96 with the following modifications:

Radiopharmacy will perform a test to detect and quantify the activity of Mo-99 concentration in each elution of Tc-99m from a Mo-99/Tc-99m generator and in each extraction or separation of Tc-99m from Mo-99 not contained in the generator. Radiopharmacy will not distribute for human use if the Tc-99m contains more than 5.55 KBq (0.15μCi) of Mo-99 per 37.0MBq (one mCi) of Tc-99m. Ratios may be computer verified.

Written procedures for testing Mo-99 concentrations (method, calculation, corrective actions) will be maintained and used in training personnel prior to their conducting the Mo-99 tests. Records of test results and personnel training will be maintained for three (3) years by the RPD.

Dose Calibrator: Calibration and Testing

Calibration of dose calibrators shall be performed in compliance with URC Rules in chapter R313-32. Calibration procedures will be based on methods in Appendix C of Guide DRC-Medical Addendum dated 07/96, with provisions that computer generated forms and graphs may be utilized and linearity tests may be performed by decay and/or a commercial sleeve method.

Radioactive Xenon Control

Xenon-133 is stored in an Xenon Dispenser in the fume hood located within the Radiopharmacy's restricted work area. The air is exhausted through an activated charcoal bed and released above the top of the building. The nearest unrestricted areas that are regularly occupied are offices in the western half of suite A and the suites south of suite A in building 391.

The efficiency of the charcoal filter in the fume hood shall be monitored and spill procedures shall be followed in accordance with URC Rules in chapter R313-32 and methods stated in Appendix O of Guide DRC Medical Addendum dated 07/96.

Area Survey Procedures

Radiopharmacy will follow the procedures for conducting area surveys as outline in the RPR's and in Appendix N of the Guide DRC-Medical Addendum dated 07/96.

Radiation exposures at the west (common) interior wall of suite A east (radiopharmacy), will be monitored to insure radiation exposure to the adjoining unrestricted office space is maintained below the limit set in URC Rules in chapter R313-32-302.

Shipping and Receiving

All shipping and receiving of radioactive materials at radiopharmacy will be conducted in accordance with RPR #13, Appendix L of Guide DRC-Medical Addendum dated 07/96 and with DOT regulations .

Transportation

Radiopharmaceuticals are delivered by the Intermountain Radiopharmacy to licensed clients in University of Utah vehicles marked with appropriate placards in accordance with DOT regulations (49 CFR).

The radiopharmaceuticals are transported in metal ammunition boxes which have been tested and certified as DOT Type A shipping containers. Test results are on file at the Intermountain Radiopharmacy and the Radiological Health Department.

Waste Management

Before it is placed in waste storage, each container of radioactive waste will be assigned a waste control number. The number will be entered in the "Radioactive Waste Disposal Log" along with the date and radioisotope.

Radioactive waste composed of short half-life radioisotopes are to be stored until they have decayed ten half-lives. After ten half-lives, the waste is to be surveyed with low-energy gamma and beta survey meters. If the survey readings are at background level, the waste may be disposed of in the ordinary trash. All short half-life radioisotope waste disposal and surveys will be recorded in the "Radioactive Waste Disposal Log".

All long life radioisotope waste will be disposed of following procedures contained in the appropriate RPR's.

Retrieving Radioactive Waste from Customers

The Radiopharmacy may accept back from its customers any unneeded radioactive sources previously provided. Such sources maybe disposed of as radioactive waste or returned to the manufacturer. Shipping and labeling of the unneeded sources will be according to the manufacturer's instruction, URC R313-19-100, and DOT regulations

ALARA Program

The Radiopharmacy Program will use the ALARA "Investigation " procedures outline in RPR # 46 as the basis for it's program.

SUPPORT SERVICES

The RSO shall be responsible for radiological evaluations, leak testing of sealed sources, and calibration of portable survey instruments in accordance with Radiological Laboratory Evaluations (RPR 50), Leak Testing of Sealed Sources (RPR 51), and Calibration and Use of Portable Survey Instruments (RPR 52).

REFERENCES

License Renewal Application dated 7/10/98, 1800145.

National Council on Radiation Protection and Measurements:

The Experimental Basis for Absorbed-Dose Calculations in Medical Uses of Radionuclides, NCRP Report No. 83, 1985.

General Concepts for the Dosimetry of Internally Deposited Radionuclides, NCRP Report No. 84, 1985.

Radiation Protection for Medical and Allied Health Personnel, NCRP Report No. 105, 1989.

University of Utah:

Radiation Safety Policy Manual.

Applicable Radiation Procedures and Records:

US Department of Transportation Regulations, Title 49 of Code of Federal Regulations.

US Nuclear Regulatory Commission:

Guide for the Preparation of Applications for Nuclear Pharmacy Licenses, Division 10, Task FC 410-4, 1985.

Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable, NUREG-0267, Rev. 1, 1982.

Radiation Protection Training for Personnel Employed in Medical Facilities, NUREG-1134, 1985.

Utah Department of Environmental Quality, Division of Radiation Control:

Guide DRC-Medical Addendum dated 07/96
Utah Radiation Control Rules, Standards for Protection against Radiation, Chapter R313-15.

Utah Radiation Control Rules, Medical Use of Radioactive Material, Chapter R313-32.

RPR 28A. RADIOPHARMACY EVALUATION CHECK LIST

(Use in addition to RPR 50A.)

Responsible User: _____ Group No.: _____ Date: _____

Building: _____ Room(s): _____

Completed By: _____

EVALUATION CRITERIA	YES	NO
Surveys:		
1. Daily contamination surveys performed (restricted areas A-R on IRP map)?	( )	( )
2. Daily surveys of lab area (restricted areas A-R on IRP map)?	( )	( )
a. Exposure rates measured?	( )	( )
b. Wipe surveys performed?	( )	( )
3. Weekly wipe surveys of unrestricted areas performed? (offices, lunchroom, vehicles)	( )	( )
4. Records maintained and contain required data? date of survey, plan of areas surveyed, action levels, detected dose rate in mrem/hr or removable contamination in dpm/100 cm^2, survey instrument used, serial number, calibration date, surveyor initials	( )	( )
5. Areas decontaminated if 2000 dpm/100 cm^2?	( )	( )
6. Incoming package surveys?	( )	( )
a. Exposure rates?	( )	( )
b. Wipe surveys?	( )	( )
c. Records maintained and contain required data? date of survey, survey meter used, radiopharmaceutical, activity received (mCi), exposure rate (mR/hr) at package surface and 1 meter, contamination measurement (dpm/100 cm^2), scaler used, count time, efficiency, counts, surveyor initials	( )	( )
7. Outgoing package surveys?	( )	( )
a. Exposure rates?	( )	( )
b. Wipe surveys?	( )	( )
c. Records maintained and contain required data? date of survey, survey meter used with calibration date, radiopharmaceutical, activity (mCi), exposure rate (mR/hr) at package surface, contamination measurement (cpm based on 6600 dpm/300 cm^2), scaler used with calibration date, count rates, surveyor signature	( )	( )
8. Hood and charcoal trap monitoring performed?	( )	( )
a. Records maintained and contain required data? posting of spill clearance time calculation and post-spill safety measures monthly collection system operation check and ventilation rate measurement every 6 mo.	( )	( )

RPR 28A. RADIOPHARMACY EVALUATION CHECK LIST (cont.)

(Use in addition to RPR 50A.)

Responsible User: _____ Group No.: _____ Date: _____

Waste Disposal:

1. Hold for decay methods adequate (decay of 10 half-lives)? ( ) ( )

2. Records of disposals maintained and contain required data? ( ) ( )
   date of disposal, date material was stored, radionuclides disposed, survey instrument used, serial number, calibration date, background dose rate, highest dose rate measured at surface, name of disposer

Dose Calibrator:

1. Daily constancy check performed? ( ) ( )
   a. Records maintained and contain required data? ( ) ( )
      dose calibrator model and serial number, identity of radionuclide in check source, date of check, activity measured, checker initials

2. Annual accuracy tests performed? ( ) ( )
   a. Records maintained and contain required data? ( ) ( )
      dose calibrator model and serial number, model and serial number of check source, identity of radionuclide in check source and its activity, date of test, results of test, signature of on-site RSO (RPD)

3. Quarterly linearity tests performed? ( ) ( )
   a. Records maintained and contain required data? ( ) ( )
      dose calibrator model and serial number, calculated activities, measured activities, date of test, signature of on-site RSO (RPD)

RADIOPHARMACEUTICAL USE:

1. Mo-99 breakthrough tests performed?
   a. Records maintained and contain required data? ( ) ( )
      measured activity of Tc-99m in mCi, measured activity of Mo-99 in µCi, ratio of measures expressed as µCi Mo-99 per mCi Tc-99m, time and date of measurement, measurer's initials

2. Unit dosage (prescription) records maintained and contain required data? ( ) ( )
   supplier (IRP), radiopharmaceutical name, lot number, expiration date, radionuclide, name of nuclear medicine procedure, prescribed dosage, activity of dosage, date and time of dose calibration, pharmacist's initials

3. Multidose vial records maintained and contain required data? ( ) ( )
   radionuclide, radiopharmaceutical name, date of receipt or preparation, date and time of initial assay, amount in mCi and ml, supplier or kit manufacturer, initials of preparer, disposal method and date (if discarded by IRP)

4. Syringe and vial shields used when dosages prepared? ( ) ( )

RPR 28A. RADIOPHARMACY EVALUATION CHECK LIST (cont.)

(Use in addition to RPR 50A.)

Responsible User: _____ Group No.: _____ Date: _____

5. Syringes and syringe shields containing radiopharmaceuticals labeled with required data? ( ) ( )
   radiopharmaceutical name, name of nuclear medicine procedure to be performed

6. Vial radiation shield containing a vial labeled with required data? ( ) ( )
   radiopharmaceutical name

Calibration and Reference Sources:

1. Sources requiring leak tests? ( ) ( )
   a. Additions? ( ) ( )
   b. Deletions? ( ) ( )

2. Other check sources? ( ) ( )
   a. Additions? ( ) ( )
   b. Deletions? ( ) ( )

3. Quarterly inventory performed? ( ) ( )
   a. Records maintained and contain required data? ( ) ( )
      model and serial number of source, radionuclide and its nominal activity, location of source, signature of on-site RSO (RPD)

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