

RPR 60

NUCLEAR MEDICINE AT SATELLITE HEALTH CENTERS

PURPOSE

Information related to the use of radioactive material in the Nuclear Medicine Clinics located at University of Utah Satellite Health Centers is provided. This includes documents and directions for developing, maintaining and recording radiation protection procedures related to the safe use of radionuclides. Instruction is given about the following topics:

- Preparation, calibration and administration of radio-pharmaceutical doses.
- Control of radiation exposures to patients, visitors and staff members.
- Control of radioactive material.
- Safe use and possible mitigation of contaminated material or objects.

POLICY

The Radiation Safety Committee (RSC) is responsible for assuring that every individual who prescribes or administers ionizing radiation in, or on, human beings, is properly qualified by meeting all regulatory requirements for such administration, including appropriate training and experience. Note that routine clinical uses of radionuclides are individually controlled by the approved Authorized Users (AU) and are not typically reviewed or approved by the RSC. Research, or experimental, applications of ionizing radiation to human beings are reviewed and approved by the Human Use or Radioactive Drug Research subcommittees of the Radiation Safety Committee following protocol found in RPR 40, 48-1, and 48-2 as appropriate.

Radiation safety procedures for the use of radionuclides in each Nuclear Medicine Clinic are prepared, implemented, and supervised by the Nuclear Medicine Technical Coordinator (NMTC) with the concurrence of the Nuclear Medicine Director (NMD). The NMTC submits a copy of all new or revised nuclear medicine procedures involving any aspect of radiation protection to the Radiation Safety Officer (RSO) for review and documentation. The RSO submits comments, suggestions, or proposed changes to the NMTC for action. The RSO reports on the status and acceptability of the procedures to the RSC at least annually.

The NMD designates an AU as the onsite radiation safety officer for each Nuclear Medicine Clinic at University of Utah Satellite Health Centers, with the concurrence of the RSO and RSC.

TRAINING AND RECORDS

The NMTC and the NMD shall ensure that all Nuclear Medicine personnel involved in the care of patients who are injected with radioactive material have received appropriate radiation safety training. Records of worker training should include date, topics covered, name(s) of individual(s) providing training, and attendees. All records should be maintained for at least three years.

All staff radiologists must meet the training requirements in chapter R313-32(incorporating 10 CFR 35 by reference) of the Utah Division of Radiation Control (UDRC) Rules.

Nuclear medicine technologists who independently prepare or administer doses to patients must be Certified Nuclear Medicine Technologists or have equivalent training and experience.

MEDICAL EVENT

Procedures for medical events shall be in accordance with UDRC Rules in R313-32 (incorporating 10 CFR 35 by reference) and license commitments made following guidance in U.S. NRC, NUREG 1556 Vol. 9, Revision 2 “Program-Specific Guidance About Medical Use Licenses”.

RPR 22 “MEDICAL EVENTS” contains instructions for developing, maintaining, and documenting programs for the prevention of medical events as well as instructions for notifications, reports, and records of medical events.

RADIONUCLIDE HANDLING

All procedures for radionuclide handling and emergency response shall be performed according to procedures in the University of Utah Radiation Safety Manual and Procedures, in compliance with UDRC Rules, and based on license commitments made following guidance in the applicable sections of U.S. NRC, NUREG 1556.

PACKAGE RECEIPT AND OPENING

Packages containing radioactive material shall be handled in accordance with UDRC rules, and University policy as found in the Radiation Procedures and Records (RPR). RPR 13 “RADIOISOTOPE ACQUISITION AND DISPOSITION” contains information specific to safe package receipt and opening. Tracking of radioactive material used for diagnostic and therapeutic purposes at Satellite Health Clinics, are typically tracked in accordance with accepted Nuclear Medicine software.

UNIT DOSE RECORDS

Unit dosage records will be kept in accordance with UDRC Rules in R313-32 (incorporating 10 CFR 35 by reference) and license commitments made following guidance in U.S. NRC, NUREG 1556 Vol. 9, Revision 2 “Program-Specific Guidance About Medical Use Licenses”.

CALIBRATION OF DOSE CALIBRATOR

Calibration of dose calibrators shall be performed in accordance with UDRC Rules in R313-32 (incorporating 10 CFR 35 by reference) and license commitments made following guidance in U.S. NRC, NUREG 1556 Vol. 9, Revision 2 “Program-Specific Guidance About Medical Use Licenses”, and NUREG 1556 Vol. 13, Revision 1 “Program-Specific Guidance About Commercial

Radiopharmacy Licenses”. Note that equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

DECAY IN STORAGE

Radioactive material disposition shall be conducted in accordance with RPR 13 “Radioisotope Acquisition and Disposition”. Radioactive waste material with a half-life shorter than 120 days, may be disposed of in appropriate non-radioactive waste streams, provided the material has been held for a minimum of ten half-lives, and an appropriate survey has been conducted to determine that radiation levels are indistinguishable from background. All radioactive material labels must be removed or obliterated before transfer. A record of the disposal shall be kept and maintained.

SUPPORT SERVICES

The RSO shall ensure that radiological evaluations, leak testing of sealed sources, and calibration of portable survey instruments are all performed in accordance with UDRC rules and University Policy as found in RPR 50 “RADIOLOGICAL LABORATORY EVALUATIONS”, RPR 51 “LEAK TESTING OF SEALED SOURCES”, and RPR 52 “CALIBRATION AND USE OF PORTABLE SURVEY INSTRUMENTS”. Form RPR 60A “NUCLEAR MEDICINE EVALUATION CHECK LIST” is included and is intended to be used by RSO staff during routine audits of the satellite facilities.

REFERENCES

Davis, D.A. et al, "Dose Calibrator Activity Linearity Evaluations with ALARA Exposures," Journal of Nuclear Medicine Technology, Vol. 9, No. 4, 188-190, 1981.

International Commission on Radiological Protection:

Radiation Dose to Patients from Radiopharmaceuticals, ICRP Publication 53, 1987.

National Council on Radiation Protection and Measurements:

The Experimental Basis for Absorbed-Dose Calculations in Medical Uses of Radio-nuclides, 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.

US Nuclear Regulatory Commission:

Consolidated Guidance about Materials Licenses: Program Specific Guidance About Commercial Radiopharmacy Licenses. NUREG-1556 Vol. 13 1999

Consolidated Guidance about Materials Licenses: Program Specific Guidance about Licenses of Broad Scope. NUREG-1556 Vol.11, 1999

Consolidated Guidance about Materials Licenses: Program Specific Guidance About Medical Use Licenses. NUREG-1556 Vol. 9, Revision 2, 2008

Guide for the Preparation of Applications for Medical Use Programs, Reg. Guide 10.8, Rev. 2, 1987.

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.

University of Utah, Radiation Safety Manual and Procedures, Radiation Procedures and Records.

International Commission on Radiological Protection, Recommendations of the ICRP, Publ. No. 26, 1977

State of Utah Department of Environmental Quality, Division of Radiation Control, Utah Radiation Control Rules (R313)

U.S. Environmental Protection Agency, Limiting of Radionuclide Intake and Air Concentration, and Dose Conversion Factors for Dose Conversion Factors for Inhalation, Submersion, and Ingestion, Federal Guidance Report No. 11, EPA-520/1-88-020, September 1988

U.S. Nuclear Regulatory Commission Chapter 10, Code of Federal Regulations

U.S. Nuclear Regulatory Commission Regulatory Guide 8.23 Radiation Safety Surveys at Medical Institutions, Rev 1, Jan. 1981

Utah Radioactive Material License UT1800001, UT1800145, UT1800458, UT1800461, and UT1800559

RPR 60A. NUCLEAR MEDICINE EVALUATION CHECK LIST

(Use in addition to RPR 50A.)

Date of Evaluation: _____

Permit#: _____ Responsible User: _____

Building: _____ Rooms: _____

YES NO

SURVEYS:

1. Contamination surveys performed each day of use? () ()
2. Lab and storage areas surveyed each week of use? () ()
 - a. Exposure rates measured? () ()
 - b. Wipe surveys performed? () ()
3. Survey records maintained up to date and contain required data? () ()
Date, plan of areas surveyed, trigger levels, dose rate in mrem/hr and removable contamination in dpm/100 cm², instruments used (make, model, serial#, calibration date), initials or signature.
4. Any areas of contamination have been appropriately cleaned or shielded? () ()

WASTE DISPOSAL:

1. Radioactive waste held for a minimum of 10 half-lives? () ()
2. Disposal records maintained up to date and contain required data? () ()
Date of disposal, storage date, radionuclides disposed, instruments used (make, model, serial#, calibration date), background measured, surface readings taken, name and signature of disposer.

DOSE CALIBRATOR:

1. Constancy check performed each day of use? () ()
 - a. Records maintained and contain required data? () ()
Date, dose calibrator model and serial#, radionuclide in check source, activity measured, initials or signature.
2. Linearity test performed at least quarterly? Date: _____ () ()
 - a. Records maintained and contain required data? () ()
Date, dose calibrator model and serial#, calculated activities, measured activities, signature of onsite RSO (NMTC)
3. Accuracy test performed at least annually? Date: _____ () ()
 - a. Records maintained and contain required data? () ()
Date, dose calibrator model and serial#, check source serial#, radionuclide activity, results, signature of onsite RSO (NMTC)
4. Patient doses measured prior to administration? () ()
 - a. Records maintained and contain required data? () ()
Date and time, radiopharmaceutical name, prescription#, radionuclide, patient name, measured activity, initials or signature.

YES NO

CALIBRATION AND REFERENCE SOURCES:

- 1. Have sealed sources been leak tested within the last 6 months, if required? () ()
Date of last leak test: _____
- 2. Have all sealed sources been inventoried within the last 6 months? () ()
Date of last inventory: _____
 - a. Records maintained and contain required data? () ()
Date, source information (make, model and serial#), radionuclide and activity, location,
signature of onsite RSO (NMTC)

RECORDS:

- 1. Training records available onsite? () ()
(Authorized Users, Nuclear Med Technicians, Ancillary Staff)
- 2. Nuclear Medicine procedures available? () ()
- 3. Dosimetry records available onsite? () ()
- 4. Instrumentation calibration records available onsite? () ()
- 5. Radiation Safety Committee Minutes available onsite? () ()
- 6. Current license available onsite? () ()