

# **RPR 29**

## **CYCLOTRON RADIOCHEMISTRY LABORATORY**

### **PURPOSE**

This procedure provides instructions for developing, maintaining, and documenting, radiation safety procedures conducted at the Cyclotron Radiochemistry Laboratory located at the Huntsman Cancer Institute at the University of Utah. The radiation safety procedures shall be followed by laboratory personnel preparing and distributing radiopharmaceutical Positron Emission Tomography (PET) doses.

### **POLICY**

The Radiation Safety Committee (RSC) has the responsibility to assure that every individual operating the cyclotron, or who prepares radiopharmaceuticals for use in human beings is properly qualified through suitable training and experience and must, at a minimum, be equivalent to appropriate regulatory requirements. Research or experimental applications of radiopharmaceuticals to human beings must be reviewed and approved by the Human Use Subcommittee or the Radioactive Drug Research Committee of the RSC as described in RPR 48. The Cyclotron Radiochemistry Laboratory program shall be audited by the RSC through coordination with the University of Utah Radiation Safety Officer (RSO).

Radiation safety procedures should be implemented and supervised by the Authorized User named as the onsite Radiation Safety Officer (AURSO). The AURSO submits a copy of all new or revised procedures involving any aspect of radiation protection to the RSO for review and documentation. After review, the RSO submits comments, suggestions, or proposed changes to the AURSO for action. The RSO reports on the status and acceptability of the procedures to the RSC at least annually.

Cyclotron operation is to be conducted only by or under the supervision of an approved Cyclotron Operator. Cyclotron Operators must be individuals who have received requisite training, have demonstrated competence, and are approved by both the Cyclotron Onsite Radiation Safety Officer, and the Radiation Safety Committee using criteria found in appropriate volumes of NUREG 1556.

Transportation, use, and storage of radioactive materials shall be conducted in compliance with the Radiation Safety Policy Manual, applicable RPR's, the Utah Division of Radiation Control (DRC) Rules, and recommendations from appropriate DRC NUREG-1556 guidance documents. Transportation and distribution of radioactive material patient doses shall only be conducted in accordance with DRC Rules, Department of Transportation (DOT) regulations, Utah State Board of Pharmacy regulations and Nuclear Regulatory Commission (NRC) regulations, as applicable.

Clinical uses of radionuclides for therapeutic or diagnostic use are under the authority of qualified physicians and are not subject to review or approval by the RSC.

## **SPECIFIC PROCEDURES**

Guidance and requirements related to the safe operation of the facility is included in the following sections:

### **Training**

The AURSO shall ensure that all University personnel involved in the transportation, use, or storage of radioactive material have received appropriate radiation safety training. Documentation of all radiation safety training should be maintained at the laboratory and copies shall be provided to and maintained by the Radiological Health Department (RHD).

### **Emergency Procedures**

Procedures shall be established to ensure an appropriate response to spills and other emergencies. These procedures must, at a minimum, be in accordance with guidance described in RPR 45 "Radiation Emergency Notification and Response". The AURSO should ensure that all personnel transporting, using, or storing radioactive material have received appropriate spill and emergency training. Documentation of spill and emergency training shall be maintained at the laboratory by the AURSO.

### **Unit Dosage and Multidose Vial Records**

Safe use and preparation of radiopharmaceuticals should be based on the best available pharmaceutical guidance as well as applicable sections of the DRC NUREG-1556 guidance documents. Documentation of all records related to the use, preparation, and transportation of radiopharmaceuticals shall be retained for a minimum period of three years.

### **Dose Calibrator: Calibration and Testing**

Calibration of equipment (including dose calibrators) must be in accordance with nationally recognized standards or the manufacturer's instructions and shall be performed in compliance with DRC Rule R313-32 incorporating 10 CFR 35.60 and 35.63 by reference. Calibration procedures should be based on applicable sections of the DRC NUREG-1556 guidance documents.

### **Area Survey Procedures**

Contamination surveys are to be completed in the laboratory when more than one reference quantity has been handled. Any contaminated areas found should be decontaminated to background levels or appropriately shielded for decay. Personnel contamination surveys will be performed upon exiting the active radioactive material use area. Action levels for personnel surveys will be no greater than twice the minimum detectable activity. Radiation exposures shall be monitored to ensure that radiation exposure rates in the laboratory and in adjoining unrestricted areas is maintained below the regulatory limits proscribed by the DRC.

### **Shipping, Receiving and Transportation**

All shipping, receiving and transportation of radioactive materials and PET radiopharmaceuticals to and from the laboratory shall only be conducted in accordance with applicable DOT

regulations R313-19-100 incorporating 49 CFR by reference. A copy of the radioactive material license for each client receiving licensed radioactive material is to be maintained by laboratory staff. PET radiopharmaceuticals shall only be transported in containers which have been tested and certified as DOT Type A shipping containers. Container certification results shall be kept on file at the laboratory and at the RHD.

#### **Waste Management**

Any waste containing radioactive material with a half-life of less than 120 days may be stored until decay periods of ten half-lives have passed. After decay, this waste material may be disposed of as non-radioactive in accordance with RPR 13 "Radioisotope Acquisition and Disposition", provided a documented survey with low-energy gamma and beta survey meters indicates no radiation level above background. Each disposal of all short half-life radioactive waste material is to be documented using form RPR 13D "Radioactive Disposal Log" or equivalent. Any waste containing radioactive material with a half-life of greater than 120 days is to be disposed of in accordance with RPR 13, RPR 54 "Radioactive Waste Management" and applicable regulatory requirements.

#### **ALARA Program**

The Cyclotron radiochemistry Laboratory will use radiation safety practices that follow "As Low As Reasonably Achievable" (ALARA) principles and procedures. Overexposure investigations and guidelines, along with ALARA investigation levels, are found in RPR 46 "Personal Exposure Investigations and Reporting".

#### **Pneumatic Tube System**

A pneumatic tube relay system is maintained to facilitate delivery of PET radiopharmaceuticals from the Cyclotron laboratory to the Huntsman Cancer Hospital Nuclear Medicine Clinic. This system is a dedicated loop with only two entry/exit points. Personnel using this system shall first receive appropriate training on the use and emergency procedures. A record of this training is maintained at the laboratory by the AURSO.

### **SUPPORT SERVICES**

Representatives of the RHD shall conduct radiological evaluation monthly in accordance with RPR 50 "Radioisotope Laboratory Evaluations" and RPR 29. Appropriate contamination and dose rate calibrations of portable survey instruments shall be performed by representatives of RHD in accordance with RPR 52 "Portable Radiation Survey Instruments". The RHD shall maintain appropriate inventory and leak test records on all sealed sources located in the laboratory.

### **REFERENCES**

National Council on Radiation Protection and Measurements:

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

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

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

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

U.S. Nuclear Regulatory Commission:

NUREG 1556, Volumes 9, 13 and 21

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

Utah Radioactive Material License UT1800001

RPR 48-1 "Human use Subcommittee Radiation Safety Committee"

RPR 48-2 "Radioactive Drug Research Committee Radiation safety Committee"

**RPR 29A CYCLOTRON RADIOCHEMISTRY LABORATORY EVALUATION CHECK LIST**  
**(Use in addition to RPR 50A.)**

**RU Name:** \_\_\_\_\_ **RU #:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Building:** \_\_\_\_\_ **Rooms:** \_\_\_\_\_

<b>EVALUATION CRITERIA</b>		<b>YES</b>	<b>NO</b>
<b>Surveys:</b>			
1.	Daily contamination surveys performed?	( )	( )
2.	Daily surveys of lab area?	( )	( )
	a. Exposure rates measured?	( )	( )
	b. Wipe surveys performed?	( )	( )
3.	Unrestricted areas included during weekly surveys?	( )	( )
4.	Records maintained and contain required information? (Date of survey, plan of areas surveyed, action levels, detected dose rate in mrem/hr or removable contamination in dpm/100 cm <sup>2</sup> , survey instrument used, serial number, calibration date, surveyor initials.)	( )	( )
5.	Areas decontaminated if 2000 dpm/100 cm <sup>2</sup> ?	( )	( )
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 <sup>2</sup> ), 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 (m R/hr) at package surface, contamination measurement (cpm based on 6600 dpm/300 cm <sup>2</sup> ), scaler used with calibration date, count rates, surveyor signature.)	( )	( )

**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?	( )	( )

## EVALUATION CRITERIA

YES NO

- (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.)
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.)

### Radiopharmaceutical Use:

1. Unit dosage (prescription) records maintained and contain required data? ( ) ( )  
(Supplier, 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.)
2. 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.)
3. Syringe and vial shields used when dosages prepared? ( ) ( )
4. Syringes and syringe shields containing radiopharmaceuticals labeled with required data? ( ) ( )  
(Radiopharmaceutical name, name of nuclear medicine procedure to be performed.)
5. Vial radiation shield containing a vial labeled with 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 onsite RSO.)

### Interlock/Emergency Power off: (tested at least once quarterly)

1. Shield interlock tested twice annually by Cyclotron Staff ( ) ( )  
(Will be tested twice a year during quarters not serviced by GE)  
Last Date of Interlock test: \_\_\_\_\_
2. Emergency Power Off interlocks tested twice annually by GE Service Reps ( ) ( )  
(Will be tested twice a year during regular bi-annual service)

## EVALUATION CRITERIA

YES NO

Last Date of Interlock test: \_\_\_\_\_

### Radiation Area Monitors: (tested at least once quarterly)

- |   |     |     |
|---|-----|-----|
| 1. Audible alarms work properly on all area radiation monitors? | ( ) | ( ) |
| 2. Visual alarms work properly on all area radiation monitors?  | ( ) | ( ) |

### Stack Radiation Monitor: (calibrated annually)

- |   |     |     |
|---|-----|-----|
| 1. Calibrated annually? [Date of calibration: _____ ]   | ( ) | ( ) |
| 2. Stack Monitor Files reviewed daily (on days of operation) by Cyclotron staff.<br>(Radiological Health notified immediately of any unexpected results.) | ( ) | ( ) |
| 3. Stack Monitor files reviewed quarterly by Radiological Health.   | ( ) | ( ) |