

Cyclotron/Radiochemistry Laboratory

PURPOSE

This procedure provides general instructions for developing, maintaining, and documenting, radiation safety procedures for the Cyclotron/Radiochemistry Laboratory at the Huntsman Cancer Institute on the University of Utah campus. The radiation safety procedures are to be followed by the laboratory in the preparation and distribution of radiopharmaceutical doses.

POLICY

The **Radiation Safety Committee (RSC)** is responsible for assuring that each individual who operates the cyclotron or prepares radiotracers or radiopharmaceuticals for use on humans, is properly qualified through training and experience. Training and experience must meet 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 and 48).

The Cyclotron/Radiopharmacy Laboratory 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 Cyclotron/Radiochemistry Laboratory, implemented and supervised by the **Cyclotron Laboratory Director (CLD)**. The CLD submits a copy of all new or revised 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 CLD for action. The RSO reports on the status and acceptability of the procedures to the RSC at least annually.

The CLD is designated by the RSO to be the on-site radiation safety officer for the Cyclotron/Radiochemistry Laboratory.

The handling of all radioactive materials at Cyclotron/Radiochemistry Laboratory 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. Distribution of bulk doses shall be conducted in accordance with URC Rules, Department Of Transportation (DOT) regulations, Utah State Board of Pharmacy and Nuclear Regulatory Commission (NRC), regulations.

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

SPECIFIC PROCEDURES

Additional requirements related to the safe handling of PET(Positron Emission Tomography) radiopharmaceuticals are included in the following procedures:

Training

The CLD shall ensure that all personnel involved in the preparation and/or distribution of PET radiopharmaceuticals 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 CLD shall ensure that all personnel and students have received appropriate spill and emergency training. Documentation of spill and emergency training shall be maintained by the CLD.

Unit Dosage and Multidose Vial Records

The Cyclotron/Radiochemistry Laboratory's safe use of radiopharmaceuticals will be based on methods in Appendix

I of Guide DRC-Medical Addendum dated 7-96. Records will be retained for a minimum period of three years.

file at the Cyclotron/Radiochemistry Laboratory and the Radiological Health Department.

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.

Area Survey Procedures

Contamination surveys will be completed in the Cyclotron facility when more than one reference quantity (i.e. 1 mCi of F-18) has been handled. All contaminated areas found to exceed 2,000 DPM/100cm² of removable activity will be decontaminated. (Note that our philosophy is to resolve contamination levels well below this limit.)

Personnel contamination surveys will be performed upon exiting the Cyclotron Laboratory Area. Action levels for personnel surveys will be no greater than twice the minimum detectable activity.

Radiation exposures will be monitored to ensure radiation exposure to the adjoining unrestricted 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 the cyclotron/radiochemistry laboratory will be conducted in accordance with applicable DOT regulations (49 CFR).

Transportation

PET radiopharmaceuticals are delivered to licensed clients in accordance with DOT regulations (49 CFR).

The PET radiopharmaceuticals are transported in containers which have been tested and certified as DOT Type A shipping containers. Test results are on

Waste Management

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 in accordance with RPR 13. All short half-life radioisotope waste disposal and surveys will be recorded in the "Radioactive Waste Disposal Log" or on an equivalent form.

All long life radioisotope waste will be disposed of in accordance with all applicable state and federal regulations.

ALARA Program

The Cyclotron/Radiochemistry will use the ALARA "Investigation" procedures outlined in RPR # 46 as the basis for its program.

SUPPORT SERVICES

The Radiological Health Department shall be responsible for radiological evaluation and calibration of portable survey instruments in accordance with Radiological Laboratory Evaluations (RPR 50) and Calibration and Use of Portable Survey Instruments (RPR 52). The RSO shall also be responsible for the evaluation of leak tests performed at the Cyclotron/Radiochemistry Laboratory.

REFERENCES

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.

Utah State Board of Pharmacy

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

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

Building: _____ **Room(s):** _____

EVALUATION CRITERIA	YES	NO
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Surveys:

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|--|-----|-----|
| 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 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 | | |

- Waste Disposal:** YES NO
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 (CLD)
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 (CLD)

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 required data? () ()
 radiopharmaceutical name

Calibration and Reference Sources:	YES	NO
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 (CLD)		

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) 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	()	()
2. Stack Monitor Files reviewed daily (on days of operation) by Cyclotron staff. Radiological Health notified immediately of any unexpected results.	()	()
3. Stack Monitor files reviewed quarterly by Radiological Health.	()	()