

**UNIVERSITY OF PITTSBURGH
RADIATION SAFETY OFFICE
POLICY AND PROCEDURES**

SUBJECT:	RADIATION SAFETY PROGRAM ADMINISTRATIVE REQUIREMENTS	POLICY #:	101
		INDEX TITLE:	RADIATION SAFETY
		REVISION #:	0

POLICY

To establish administrative requirements for safely managing licensed radioactive material and ionizing radiation equipment under the Radiation Safety Committee's jurisdiction and ensuring compliance with federal, state, and institutional regulations.

SCOPE

This policy covers administrative requirements of the Radiation Safety Program, including the committee's responsibility for establishing a radiation safety program and promoting a philosophy for keeping radiation exposure As Low As Reasonably Achievable (ALARA). A list of the locations that this policy and the University of Pittsburgh Radiation Safety Committee oversee is detailed in Attachment A. This list will be periodically updated and reviewed as determined by the University Management.

MEMBERSHIP OF RADIATION SAFETY COMMITTEE

1. Appointments to the Radiation Safety Committee (RSC) are made by the Vice Chancellor for Research Protections.
2. A chairperson is appointed by the Vice Chancellor for Research Protections.
3. Formal appointment letters will be provided to the RSC Members by the Office of Research Protections. Appointment letters for sub-committees are not required.
4. There are no set term limits for membership.

A. Voting Membership

Voting membership of the RSC must include:

1. An Authorized User or representative for the major types of use of radioactive material or ionizing radiation generating devices (to include as a minimum: diagnostic radiology, nuclear medicine, radiation oncology, and PET).
2. Radiation Safety Officer
3. Representative of University Management

4. Representative of UPMC Management
5. Representative of Nursing Service

B. Non-voting Membership

Non-voting membership of the Radiation Safety Committee must include:

1. A representative of the University Office of General Counsel
2. A representative of UPMC Corporate Legal

STANDING COMMITTEES AND MEMBERSHIP

The following standing committees shall provide specialized authority and responsibility in support of the Radiation Safety Committee (RSC).

A. Executive Committee

1. RSC Chairperson
2. RSC Vice-Chairperson
3. HUSC Chairperson
4. Radiation Safety Officer
5. University Management Representative

B. Subcommittee on Human Research Use of Radioisotopes and X-ray Producing Equipment (HUSC)

1. Minimum of five members to include the following specialties:
 - Physician Board Certified in Nuclear Medicine
 - Nuclear Pharmacist
 - Physician Board Certified in Radiation Oncology
 - Physicist Board Certified by ABHP, ABR, or ABMP
 - Physician Board Certified in Radiology
2. The RSC Chair is responsible for appointing the chair of the HUSC, who in turn is responsible for appointing its members.

3. For efficiency, protocols needing review for the use of X-ray producing equipment and radiation therapy may be reviewed informally or as part of other committees as long as the review serves to meet the HUSC requirements by individuals with appropriate expertise (for example, physicist with appropriate certification or radiation oncologist).

C. Radioactive Drug Research Committee (RDRC)

1. Minimum of 5 members to include the following specialties:
 - A physician recognized as a specialist in nuclear medicine
 - A person qualified by training and experience to formulate radioactive drugs (i.e., a nuclear pharmacist or radiochemist)
 - A person with special competence in radiation safety and radiation dosimetry (i.e., a health physicist)
2. The RSC Chair is responsible for appointing the chair of the RDRC, who in turn is responsible for selecting its members. Additionally, the RDRC Chair is responsible for ensuring proper notification to the FDA is completed for changes to the committee roster and that approval from the FDA is received for RDRC membership.
3. The RDRC Chair, with administrative support from Office of Research Protections staff, is responsible for filing all required FDA reports related to the function of the RDRC.

D. Hospital Radiation Safety Subcommittees

1. Membership to include, at a minimum, the following specialties:
 - Chairperson
 - UPMC Management Representative
 - University RSO or Designee
 - Other Authorized Users or representatives from the hospital
2. The RSC Chair is responsible for appointing the Chair of each Hospital Subcommittee, who in turn is responsible for appointing its members.

AUTHORITIES AND RESPONSIBILITIES

A. Radiation Safety Committee

1. Set policy for the radiation safety program.
2. Review and approve program and procedural changes prior to implementation.
3. Conduct an annual review of the radiation safety program to ensure that all activities are being carried out in a safe manner, in compliance with NRC regulations and license

conditions.

4. Identify problems, recommend corrective actions, and provide support in the performance of the radiation safety program.
5. Perform quarterly assessments of all radiation safety incidents and violations, as well as review summaries of occupational radiation dose records, providing recommendations for maintaining radiation doses as low as reasonably achievable (ALARA).
6. Review reports and interim actions of the standing committees.
7. Address and respond to issues from the Hospital Radiation Safety Subcommittees
8. Provide final approval/disapproval of individuals applying to become an Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist
9. Provide final approval/disapproval of new types or modalities of use of radioactive materials and radiation producing equipment.
10. No committee member can participate in the review of an activity in which that member has a conflicting interest, except to provide information requested by the RSC.

B. Executive Committee

1. Review and grant initial approval/disapproval, on the basis of safety and with regard to training and experience, individuals applying to become an Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist.
2. Review and grant initial approval/disapproval, on the basis of safety, regulatory compliance, and the ALARA philosophy, all new types or modalities of uses of radioactive materials and radiation producing equipment.
3. Approve all radioactive materials licensing actions, as necessary.
4. Act on behalf of the University Radiation Safety Committee on issues requiring immediate action.

C. Subcommittee on Human Research Use of Radioisotopes and X-ray Producing Equipment (HUSC)

1. Review and approve/disapprove, on the basis of safety, regulatory compliance, and the ALARA philosophy, all proposed human research uses of radioactive material.
2. Review and approve/disapprove, on the basis of safety, regulatory compliance, and the ALARA philosophy, all proposed human research uses of X-ray producing equipment.
3. No committee member can participate in the review of a protocol or activity in which that member has a conflicting interest, except to provide information requested by the HUSC.

D. Radioactive Drug Research Committee (RDRC)

1. Review and approve the research use of radioactive drugs in accordance with FDA regulations at 21 CFR 361.1.
2. No RDRC member shall vote on a protocol in which he/she is an investigator or co-investigator [§ 361.1(c)(2)].
3. No committee member can participate in the review of a protocol or activity in which that member has a conflicting interest, except to provide information requested by the RDRC.

E. Hospital Radiation Safety Subcommittees

1. Review a summary of the RSO program activities for the hospital.
2. Identify problems, recommend corrective action, and provide support in the performance of the radiation safety program.
3. Set hospital radiation safety policy in coordination and accordance with the University program.
4. Report to the University RSC.
5. Address and respond to issues from the University RSC.

ADMINISTRATIVE REQUIREMENTS

A. Radiation Safety Committee

1. The University Radiation Safety Committee shall meet at least quarterly.
2. To establish a quorum, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer, the Chair (or designee) and the University Management representative (or designee).
3. The minutes of each RSC must include:
 - a. Date of meeting
 - b. Members present and absent
 - c. Summary of deliberations and discussions
 - d. Recommended actions and the numerical results of all votes taken
 - e. ALARA program reviews

4. Minutes from each RSC meeting shall not include patient identifying information.
5. The minutes from each meeting will be prepared and reviewed for approval at the next RSC meeting.
6. Ministerial changes: program and procedural changes will be documented to state the change, the reason for the change, a summary of radiation safety matters considered and the date of approval by the committee.

B. Executive Committee

1. The Executive committee shall meet at least monthly.
2. No minutes are required for the Executive Committee meetings, however, all decisions (e.g., approvals for Authorized Users, etc.) made by the Executive Committee in between full RSC meetings shall be brought to the RSC for official review and approval.

C. Subcommittee on Human Research Use of Radioisotopes and X-ray Producing Equipment (HUSC)

1. The HUSC shall meet at least once each quarter in which research activity had been authorized or conducted.
2. Minutes are required to be collected and maintained by the Chair of the HUSC. Such minutes shall include summaries of the protocol reviewed, comments collected from the committee and dispositions, including voting numbers, and abstentions.

D. Radioactive Drug Research Committee

1. The Radioactive Drug Research Committee shall meet at least once each quarter in which research activity has been authorized or conducted per 21 CFR 361.1c(2).
2. Minutes are required to be collected and maintained by the Chair of the RDRC. Such minutes shall include summaries of the protocol reviewed, comments collected from the committee and dispositions, including voting numbers, and abstentions.

E. Hospital Radiation Safety Subcommittees

1. The recommended frequency for Hospital Radiation Safety Subcommittees is quarterly.
2. Minutes are required to be collected and maintained by the Chair of the Subcommittee or a designee from the hospital administration. Such minutes shall include summaries of the discussions, incidents that have occurred since the last meeting, dosimetry reviews and a list of members who have attended.

3. Minutes from each Hospital Subcommittee meeting shall not include patient identifying information.

DELEGATION OF AUTHORITY TO THE RADIATION SAFETY OFFICER

1. The Radiation Safety Officer is responsible for managing the radiation safety program, identifying radiation safety problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, and insuring compliance with regulations and license conditions.
2. The Radiation Safety Officer is delegated the necessary authority from University management to perform those responsibilities.
3. The Radiation Safety Office supports the Radiation Safety Officer by developing and implementing the policies and procedures of the radiation safety program as approved by the Radiation Safety Committee. The office is directed by the Radiation Safety Officer and is staffed with personnel who possess the necessary training and experience to perform the required radiation safety duties.

POLICY APPROVALS

1. The Radiation Safety Officer is responsible for ensuring that content of all radiation safety policies meets regulatory requirements.
2. The Radiation Safety Committee shall review and approve all Radiation Safety policies before they become effective.
 - a. A majority vote will be needed to approve a policy by the RSC.
3. In a situation where guidance is needed before the RSC can meet or approve a final policy, the Executive Committee will be delegated the authority to provide temporary guidance for the institution to follow.
4. All policies will be managed by the Radiation Safety Office.
 - a. All policies revisions are required to be kept on file.
 - b. The Radiation Safety Office has the authority to number/renumber and format policies as need for professionalism as long as content is not changed. This includes the addition or removal of covered facilities in Attachment A as agreed upon within UPMC contractual relations.
 - c. All approved policies will be posted on the Radiation Safety website to be made available to all potential users.
5. UPMC facilities covered by the University of Pittsburgh Radiation Safety Office are required to

follow all policies approved by the RSC.

- a. Individual institutions may convert policy wording into their own policy format; however, changes may only be made related to format not content or policy expectations.
- b. Individual institutions may make additional requirements as UPMC management deems necessary, however, requirements approved by the RSC cannot be removed.

RADIATION SAFETY PROGRAM REVIEW

1. In accordance with 10 CFR 20.1101(c), the licensee shall review the radiation safety program at least annually.
2. It is the Radiation Safety Officer's responsibility to present this review to the RSC at one of the scheduled meetings.
3. Committee members should participate in the review by ensuring that regulations are upheld, regulatory violation are appropriately identified and corrected, and that growth of the radiation safety program is met with adequate support from the institution (staffing, resources, etc.).

Sponsor: Radiation Safety Office
Original: 11/2023

ATTACHMENT A: LIST OF LOCATIONS COVERED
(Last Updated November 2023)

Locations/Addresses where Licensed Material may be Used.
(Note: all sources of ionizing radiation at these sites are also covered)

1. Main Campus of the University of Pittsburgh, 4200 Fifth Ave, Pittsburgh, PA 15260
2. University of Pittsburgh Center for Biotechnology and Engineering, 300 Technology Drive, Pittsburgh, PA 15213
3. UPMC Children's Hospital of Pittsburgh, 45th Street and Penn Avenue, Pittsburgh PA 15224
4. Hill Building, 3434 Fifth Avenue, Pittsburgh, PA 15213
5. Kaufmann Medical Building, 3471 Fifth Avenue, Pittsburgh, PA 15213
6. UPMC Magee-Womens Hospital, Forbes and Halket Streets, Pittsburgh, PA 15213
7. Magee-Womens Research Institute, 204 Craft Avenue, Pittsburgh, PA 15213
8. UPMC Montefiore, 3459 Fifth Avenue, Pittsburgh, PA 15213
9. UPMC Presbyterian Hospital, 200 Lothrop Street, Pittsburgh, PA 15213
10. UPMC Shadyside Hospital, 5230 Centre Avenue, Pittsburgh, PA 15232
11. Shadyside Medical Center Building, 5200 Centre Avenue, Pittsburgh, Pa 15232
12. 110 McKee Place, Pittsburgh, PA 15213
13. UPMC Western Psychiatric Hospital, 3811 O'Hara Street, Pittsburgh, PA 15232
14. UPMC Hillman Cancer Center, 5115 Center Avenue, Pittsburgh, PA 15232
15. McGowan Institute for Regenerative Medicine, 3025 East Carson Street, Pittsburgh, PA 15203
16. Bridgeside Point, 100 Technology Drive, Pittsburgh, PA 15219
17. University Primate Research Laboratory, 709 New Texas Road, Plumboro, PA 15239
18. University of Pittsburgh Pymatuning Laboratory of Ecology, 13142 Hartstown Road, Linesville, PA 15904
19. University of Pittsburgh Branch Campus in Johnstown, 450 Schoolhouse Road, Johnstown, PA 15904
20. University of Pittsburgh Branch Campus in Bradford, 300 Campus Drive, Bradford, PA 16701
21. University of Pittsburgh Branch Campus in Titusville, 504 Main Street, Titusville, PA 16354
22. University of Pittsburgh Branch Campus in Greensburg, 150 Finoli Drive, Greensburg, PA 15601-5860
23. Bridgeside Point 2, 450 Technology Drive, Pittsburgh, PA 15219
24. UPMC South Surgery Center, 1300 Oxford Drive, Suite G100, Bethel Park, PA 15102
25. Magee Imaging South Hills, 1300 Oxford Drive, Suite 2100, Bethel Park, PA 15102
26. Magee-Womens Imaging-Monroeville, Corporate One Office Park, Building II, Suite 225, 4075 Monroeville Blvd, Monroeville, PA 15146
27. UPMC Children's Hospital of Pittsburgh, South, 205 Millers Run Road, Bridgeville, PA 15017
28. Hieber Building, 3500 Fifth Avenue, PA 15213
29. UPMC Outpatient Center, West Mifflin, 275 Clairton Boulevard, West Mifflin, PA 15122
30. The Assembly/Ford Building 5051 Centre Avenue Pittsburgh, PA 15232

ATTACHMENT A: LIST OF LOCATIONS COVERED
(Last Updated November 2023)

Locations Covered that do not use Radioactive Material (X-ray devices only)

1. Falk Medical Building
2. Shadyside Medical Center Building
3. UPMC Family Health Center (Shadyside)
4. Pain Management at Centre Commons (Shadyside)
5. UPMC Children's Hospital of Pittsburgh South
6. UPMC Children's Hospital of Pittsburgh East
7. UPMC Children's Hospital of Pittsburgh North
8. UPMC Children's Hospital of Pittsburgh Dental Hampton
9. Magee-Womancare North
10. UPMC West Mifflin Imaging
11. UPMC Lemieux Sports Complex
12. UPMC Center for Sports Medicine Clinic