

RADIATION SAFETY COMMITTEE

PURPOSE

This procedure defines the membership, authority, responsibilities and operating rules of the University's Radiation Safety Committee.

POLICY

The Radiation Safety Committee is the governing body for all aspects of radiation protection within the University, including all affiliated research, clinical, instructional and service units utilizing radiation sources in facilities owned or controlled by the University. The Committee will ensure that all possession, use and disposition of radiation sources by University personnel complies with pertinent federal and state regulations and with the specific conditions of licenses issued to the University, and that all concomitant radiation exposures are maintained ALARA.

DEFINITIONS

ALARA - one of the basic premises of radiation protection, i.e. that all radiation exposures should be kept as low as reasonably achievable, taking into consideration all social and economic factors.

Management - the chief executive officer or that person's delegate; the Vice President for Research (or Associate) is the principal representative of University management for radiation protection.

Radiation source - a general term that includes any radioactive material or radiation-generating machine that can emit ionizing radiation.

RESPONSIBILITIES AND AUTHORITY

The Committee is empowered and directed to promulgate policies, rules and procedures for the safe use of radiation sources. The Committee is responsible for assuring that only qualified individuals are permitted to use radiation sources, or to supervise such use by others. The Committee oversees, reviews and audits the activities of the

Radiation Safety Officer, the Radiological Health Department and all users of University radiation sources. The Committee reports to the Vice President for Research.

MEMBERSHIP

Membership shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer (RSO), a representative of Nursing Service, and a representative of management who is neither a responsible user nor the RSO. To fulfill this requirement, the RSO and the Alternate RSO, if there is one, and the Vice President for Research or Associate, are *ex-officio* members. The chairperson of the Radioactive Drug Research Committee is also an *ex officio* member.

The chairperson and other members of the Committee are appointed by the President for indefinite terms on the basis of professional qualifications. Appointments are made to provide representation from major academic, clinical and research areas that use radiation sources. Representatives of other groups or functions closely associated with the radiation safety program, e.g. purchasing, safety and maintenance may also be appointed. Categories of radiation use and suggested representation are attached (RPR 40B).

The membership of the Committee is reviewed at least annually, and additions or replacements are normally appointed at the beginning of the Third Calendar Quarter.

MEETINGS, AGENDA AND QUORUM

The Committee meets at least once during each calendar quarter, or more frequently at the call of the chairperson. A recommended standard agenda for Committee meetings is attached (RPR 40A). A quorum consists of at least one-half of the members appointed to represent various radiation uses, plus the RSO and the representative of management. All members present are entitled to vote. Between meetings, interim decisions may be made by established subcommittees or by a majority of all voting members *via* a mailed ballot, but such decisions shall not be considered final until ratified by vote at a called

meeting of the Committee. Parliamentary procedures shall be determined by *Robert's Rules of Order*.

RECORDS AND REPORTS

The Committee publishes its basic policies and rules in the form of a *Radiation Safety Policy Manual* and it authorizes and directs the RSO to develop and promulgate such procedures and records as are necessary for compliance with all federal and state radiation control regulations and for effective interpretation and implementation of the policies of the Committee.

The minutes of the Committee's meetings, together with all reports submitted to the Committee, serve as the primary documentation of the radiation protection program of the University. The minutes of each meeting must include the date of the meeting, the members present and absent, a summary of deliberations and discussions, recommended actions and the numerical results of all ballots, and ALARA program reviews.

A copy of the minutes of all Committee meetings, with all subcommittee reports and attachments, is submitted annually to the University Archivist for permanent storage in accordance with *University Policy and Procedures Manual* 1-3. The list of topics to be reported by or to the Committee, and filed with the Committee's records, is indicated in the recommended standard agenda (RPR 40A). Although not all of the listed topics are addressed at every meeting, the topical numbering system is retained to assure consistency in identifying all components of the annual record.

The Radiological Health Department provides the administrative support for all of the Committee's activities.

SUBCOMMITTEES

The Committee may establish subcommittees to perform specific functions. Each subcommittee must submit a written report of its activities and actions to the Committee for each calendar quarter in which it was active. Each subcommittee report accepted by the Committee becomes part of the record filed in the University Archives. The active subcommittees and their functions are:

The **User Authorization Subcommittee** reviews and evaluates all new applications for authorization to use radiation sources and all applications for revisions to previous authorizations that involve significant changes in conditions or radiation exposure potential as determined by the RSO. In addition to regular members, an alternate member is appointed to review applications if a regular member is not able to do so in a timely manner. Unanimous approval by the members of the subcommittee constitutes interim authorization to use a radiation source. Applications not receiving unanimous approval by the subcommittee are referred to the Committee for action. All authorizations approved by the RSO or by the subcommittee become final only when ratified by majority vote of the Committee at a called meeting.

The **Human Uses Subcommittee** evaluates and approves or disapproves all proposed uses of ionizing radiation sources on or in humans for investigational or non-routine clinical procedures. The review of the proposed protocol and of the investigator's qualifications to use radiation on human subjects is conducted by this subcommittee after the adequacy of facilities and general conditions for radiation protection have been verified by the RSO. Because of the professional qualifications and functions represented among its membership, the **Radioactive Drug Research Committee (RDRC)** (see RPR 48) also serves as the Human Uses Subcommittee. The chairperson of the RDRC is an *ex officio* member of the Radiation Safety Committee.

An **Audit Subcommittee** may be appointed by the chairperson to perform an audit of any or all aspects of the radiation safety program. Alternatively, the Committee may elect to hire an independent consultant to conduct an audit. A list of topics that should be audited periodically is attached (RPR 40C). The Committee may select the topics to be audited on the basis of their relative importance and the time that has elapsed since the last audit. Audits are to be preplanned and conducted to assess the performance of the RSO, the Radiological Health Department and of users of radiation sources.

Audits are conducted in four general steps:

1 determine the regulatory requirements, license conditions or other guidelines or commitments that the University must satisfy;

2 determine whether the University has a formal procedure for complying with each identified requirement;

3 determine whether compliance with each requirement can be demonstrated by objective documentation, and/or by conducting visits to a sample of active radioisotope laboratories; and

4 submit a written report of the audit findings and recommendations.

Utah Department of Environmental Quality, Division of Radiation Control, *Radiation Control Rules. Specific Licenses*, R313-22.

_____, *Radiation Control Rules. Medical Use of Radioactive Material*, R313-32.

REFERENCES

Food and Drug Administration, *Radioactive Drugs for Certain Research Uses*, 21 CFR 361.1, (functions and membership of the Radioactive Drug Research Committee).

National Council on Radiation Protection and Measurements, *Operational Radiation Safety Program*, Report No. 59, 1977.

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

Nuclear Regulatory Commission, Radiation Safety Committee, *Medical Use of Byproduct Material*, 10 CFR 35.22.

_____, *Guide for the Preparation of Applications for Type A Licenses of Broad Scope*, Regulatory Guide 10.5.

_____, *Guide for the Preparation of Applications for Medical Programs*, Reg. Guide 10.8, Appendix B, Medical isotopes committee, and Appendix O, Model program for maintaining occupational radiation exposures at medical institutions ALARA.

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

RPR 40A. RADIATION SAFETY COMMITTEE STANDARD AGENDA

I. Opening Business

- A. Attendance and agenda
- B. Approval of minutes
- C. Appointments and announcements

II. Subcommittee Reports

- A. User Authorizations
- B. Human Uses (RDRC)
- C. Audits

III. Radiation Safety Officer's Report

- A. Licensing, registration or regulatory actions
- B. Radiation policy, procedures and records
- C. Radiation safety training and user qualifications
- D. Occupational radiation exposures
- E. Misadministrations
- F. Radiation surveys and monitoring
- G. Radioactive material control and inventory
- H. Radioactive waste management
- I. Radioactive effluents and environmental releases
- J. Recordable Events
- K. Decommissioning
- L. Medical use Quality Management Program
- M. Other

IV. Recommendations & Responses

- A. Cumulative List of Open Action Items
- B. Responses to Recommendations

V. Table of Contents & Other Business

RPR 40B. RADIATION SAFETY COMMITTEE REPRESENTATION

The following types of radiation use and groups of radiation users and related functions should be represented on the Committee:

REQUIRED *EX OFFICIO* MEMBERS

Management representative

Vice President for Research or designee, or
University Hospital Administration or designee

Radiation Safety Officer or alternate

Chair, Radioactive Drug Research Committee

REPRESENTATIVE OF NURSING SERVICE

REPRESENTATIVES OF MAJOR CATEGORIES OF AUTHORIZED USES

(Approximate size of population from which to select.)

Clinical (Human) Use of Radioactive Materials

Radiation Oncology - **1 representative**

Experimental Oncology (4)

Radiation Therapy (3)

Radiopharmaceutical users - **1 representative**

Nuclear Medicine (2)

Radiopharmacy (3)

Medical Research (123) - 3 representatives

Anatomy (5)

Anesthesiology (1)

Biomedical Engineering (1)

Cardiology (7)

CVRTI (2)

Dermatology (3)

Endocrinology (5)

Gastroenterology (3)

Hematology (7)

Human Develop & Aging (1)

Infectious Disease (3)

Internal Medicine (2)

Medicinal Chemistry (3)

Metabolic Lab (1)

Nephrology (2)

Neurology (2)

Obstetrics (2)

Pathology (17)

Pediatrics (18)

Pharmaceutics (9)

Pharmacology (7)

Pharmacy Practice (1)
Physiology (5)
Psychiatry (3)
Pulmonary (2)
Rheumatology (2)
Surgery (9)

Basic Biological Research (66) - 2 representatives

Biochemical Pharmacology & Toxicology (10)
Biochemistry (9)
Biology Department (22)
CVM Biology (9)
Genetic Epidemiology (1)
Howard Hughes Medical Institute (2)
Human Genetics (5)
Radiobiology (8)

Physical Sciences & Engineering Research (27) - 1 representative

Bioengineering (3)
Chemistry (10)
Civil Engineering (1)
Material Science Engineering (2)
Mech & Indust Eng (Nuclear Reactor) (1)
Metallurgical Engineering (3)
Physics (7)

Medical Radiation-Generating Machines (7) - 1 representative

Diagnostic Radiology - Radiology Department (2)
Catheterization Lab - Cardiology (2)
Radiation Therapy - Radiology Department (3)

Non-medical Radiation-Generating Machines (8) - 1 representative

Chemistry (2)
Metallurgical Engineering (1)
Material Science Engineering (2)
Physics (2)
Research Institute (1)

REPRESENTATIVES OF ASSOCIATED FUNCTIONS - 1 representative each

Hospital Administration

Purchasing Department

Environmental Health Services

VA Medical Center Radiation Safety Officer

RPR 40C. RADIATION SAFETY COMMITTEE AUDIT TOPICS

<u>Subject of Audit</u>	<u>References</u>
1. Program Management, including:	FDA, 21 CFR 361 NRC, 10 CFR 33.13
a. Radiation Safety Committee and Radioactive Drug Research Committee, membership and operations;	NRC, Reg. Guide 10.5 NRC, Reg. Guide 10.8, App. F & G NCRP, Report No. 59 (2.2) UDRC, R313-15-10
b. Radiation Safety Officer, functions and performance;	UDRC, R313-22-50 UU, <i>Radiation Safety Manual</i> UU, RPR 40 - 42
c. ALARA policy and implementation.	
d. Record management; retrievability, security, and retention	NCRP, Report No. 114 NRC, 10 CFR 20.401, 30.51 UDRC, R313-12-51, 15-401 UU, <i>Policy and Procedures</i> , 1-3 UU, RPR 42
2. User Authorizations	
a. Non-medical use of radioisotopes and radiation generating machines;	NRC, Reg. Guide 10.9 UDRC, R313-22-50 UDRC, R313-40-60 UDRC, R313-44-30 UU, RPR 2, 30 - 32
b. Medical (human) use of radiation sources for diagnosis, treatment or research.	NRC, 10 CFR 35 NRC, Reg. Guide 10.8 UDRC, R313-22-50 UDRC, R313-32-900 - 972 UDRC, R313-40-60 UDRC, R313-44-30 UU, RPR 2, 20 - 28
3. Emergency Planning	
a. General	NCRP, Report No. 111 UU, RPR 45
b. Nuclear Engineering Laboratory Research Reactor	ANSI, ANS 15.16-1982 NRC, 10 CFR 50, App. E NRC, Reg. Guide 2.6 UU, RPR 45

4. Training
 - a. Normally exposed radiation users, including radioisotope and machine users
ANSI, N43.2-1977
NCRP, Report No. 71
NRC, 10 CFR 19.12
 - b. Emergency personnel, e.g. police, fire fighters, security, etc.
NRC, Reg. Guide 8.13
NRC, Reg. Guide 8.27
NRC, Reg. Guide 8.29
 - c. Minimally exposed (ancillary) personnel, e.g. nurses, maintenance, custodians, etc.
NRC, NUREG 0267, 3.4.1.6
UDRC, R313-18-12
UU, RPR 44

5. Radioactive Material Control
 - a. Procurement; package receiving; inventory records (broad license and radiopharmacy); user's disposal records.
NRC, 10 CFR 20.1906
UDRC, R313-15
UU, RPR 13
 - b. Waste handling, packaging and shipping; effluent and environmental releases.
NRC, 10 CFR 20.2001-2007
UDRC, R313-15-1001-1008

6. Individual Dosimetry Requirements and Records
 - a. External (badges) and internal (bioassays)
NCRP Report 116
NRC, 10 CFR 20.1201-1208
NRC, 10 CFR 20.1502
NRC, Reg. Guide 8.9
NRC, NUREG 0938
UDRC, R313-15-201-208
UDRC, R313-15-502
UU, *Radiation Safety Policy Manual*
UU, RPR 12

7. Radiation Exposure Control, Surveillance and Monitoring
 - a. Radioisotope Lab Surveys
NCRP, Report No. 59
NRC, 10 CFR 20.1501-1502, 1901-1905
NRC, Reg. Guide 8.21
UDRC, R313-15-501-501, 801-905
UU, RPR 11, 50

- | | | |
|----|-----------------------------------|---|
| b. | Radiation Machine Surveys | ANSI N43.2-1977
FDA, 21 CFR 1020
UDRC, R313-28 (all)
UDRC, R313-40 (all)
UU, RPR 23, 30, 32 |
| c. | Sealed Source Leak Test | UDRC, R313-15-401
UDRC, R313-32-59
UU, RPR 51 |
| d. | Radiation Oncology; Brachytherapy | NCRP Reports 37 and 40
NUREG 0267
UDRC, R313-32
UU, RPR 24 |
| e. | Nuclear Medicine | NCRP Reports 37, 48 and 73
NRC Reg. Guide 10.8
NUREG 0267
UU, RPR 27 |
| f. | Diagnostic Radiology | UDRC R313-32
UU, RPR 23 |
| h. | Radiopharmacy | Utah License # 18000145
UU, RPR 28 |
-
- | | | |
|----|---|---|
| 8. | Support Functions | |
| a. | Instrument Calibrations, including: survey meters, installed monitors, analytical instruments and direct-reading dosimeters | ANSI, N13.5-1972
ANSI, N323-1978
NCRP, Report No. 112 |