

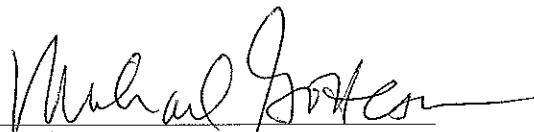
STATEMENT OF AUTHORITY AND RESPONSIBILITY

RADIATION SAFETY OFFICER
AND
RADIATION SAFETY COMMITTEE

CHARTER

RADIATION SAFETY COMMITTEE
NATIONAL INSTITUTES OF HEALTH

APPROVED:


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National Institutes of Health

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Date

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Mission Statement

The Radiation Safety Committee (RSC) is responsible to the Director, NIH for oversight of the NIH Radiation Safety Program to ensure the safe use of radioactive materials and all sources of ionizing radiation throughout NIH and those NIH-occupied buildings included in the NIH Radiation Safety Program. The RSC is responsible for formulating policy with regard to radiation protection matters in the intramural research program that involve NIH employees and members of the general public, routine clinical and clinical research programs, and protection of the environment to ensure compliance with Federal regulations, including those of the U.S. Nuclear Regulatory Commission and the Occupational Safety and Health Administration. The Radioactive Drug Research Committee is a subcommittee of the NIH Radiation Safety Committee. The Radiation Safety Officer (RSO) is responsible to the Director, NIH, for management and operation of the Radiation Safety Program as well as policy directives of the RSC. The RSO and RSC shall be provided sufficient authority, organizational freedom, and management prerogative to accomplish these goals. These responsibilities and authorities are limited to the NIH's intramural research program and client agencies served under USNRC licenses 19-00296-10, 19-00296-21, and 19-00296-17.

Duties of the Committee

1. Ensures the safe use of all radioactive materials and sources of ionizing radiation throughout NIH and those NIH-occupied buildings included within the NIH Radiation Safety Program, for the Director, NIH.
2. Delegates to the NIH Radiation Safety Officer the authority to implement the Radiation Safety Program and enforce applicable Federal regulations and NIH radiation safety policies and procedures to ensure the radiation safety of persons and protection of the environment.
3. Provides technical advice, assistance, and management-level support to the Radiation Safety Officer in implementing the Radiation Safety Program and the NIH program for maintaining radiation exposures to employees, patients, and research subjects as low as reasonably achievable (ALARA).
4. Reviews the Radiation Safety Program at least annually to determine that all activities involving radioactive materials and sources of ionizing radiation are being conducted safely and in accordance with applicable Federal regulations and NIH radiation safety policies.
5. Reviews the qualifications of licensed physicians and grants approval for the use of radioactive materials in human subjects. If a Committee member is an investigator who may participate in the research being proposed in an application to the Committee, he or she shall abstain from voting on the approval or disapproval of the application.
6. Performs functions of the Radioactive Drug Research Committee in accordance with applicable regulations of the Food and Drug Administration, PHS, DHHS.
7. Reviews and approves a subset of clinical research studies involving exposure of human subjects to ionizing radiation. Criteria for protocols requiring RSC review are delineated in RSC policies and procedures. Note: the review and approval of clinical research studies do not constitute official business of the RSC.
8. The Radiation Safety Officer acts for the Director, NIH, in all matters relating to Federal or State radioactive material or radiation source licensing, with the concurrence of the RSC and the NIH Executive Management.
9. Establishes and revises radiation safety policies, consulting with the Office of the Director through the Management Representative on issues that require involvement of upper level management, e.g., in cases when there is significant potential for impact on the NIH mission.
10. Establishes working groups and appoints ad hoc members to the Committee, as the Committee deems necessary.

Membership and Organization of the Committee

The membership of the Committee shall include the following: The RSO; a representative of NIH management who is neither an Authorized User nor RSO (this person typically hails from the Office of the Deputy Director for Intramural Research); a physician who is Authorized by the RSC for clinical use of radioactive materials; a person who is Authorized by the RSC for the use of radioactive materials in laboratory research; and a representative of the nursing service. The Deputy Chair is selected by the RSC Chair and other members are selected by the RSC Chair or Deputy Chair. The Medical Board may be consulted to identify nominees for membership on the RSC to represent clinical care areas; the Board of Scientific Directors may be consulted to identify nominees for other positions. Membership shall include representation of the various types of users of radioactive materials and radiation sources at NIH. Additional members may be added to the RSC, upon recommendation of its Chair to enable effective action by the Committee. The following are highly recommended: the Chair of the RDRC; a health or medical physicist with training and experience in radiation dosimetry of radioactive materials administered to humans; a radiopharmacist; a representative of cyclotron operations, and physicians with expertise in diagnostic radiology, nuclear medicine, and radiation therapy. Individuals with these qualifications in the list of mandatory members may serve the RSC in these areas of expertise. Members terms are effective until they resign their membership. The Chairperson's appointment shall be effective until the Chairperson resigns or until another Chairperson is appointed by the Director, NIH. When members are replaced, new appointees shall be chosen to maintain the balance of members required under 10 CFR 35.

The Division of Radiation Safety shall provide administrative support to the Committee and shall maintain the official Committee files.

Meetings shall be conducted at a frequency sufficient to meet the commitments of the license which are quarterly. The following conditions shall constitute a quorum for the conduct of official Committee business:

- Attendance of at least half of the total number of Committee members;
- At least one of the following individuals: the RSC Chair, Deputy Chair, RSO, or Deputy RSO;
- Management Representative or backup; and
- Members who have the necessary expertise for the issues being discussed.

If the Chair is absent from the meeting, the Deputy Chair shall preside over the meeting. If both the Chair and Deputy Chair are absent, then the RSO shall preside over the meeting.