RADIATION SAFETY COMMITTEE

CHARTER

REVISION 1

AUGUST 24, 2021

The Charter has been reviewed and is endorsed by the Chief of Staff & Chief Administrative Officer of the Executive Office of the President & Provost and the Chair of the Radiation Safety Committee.

Kalpana Kanal

Kalpana Kanal, Ph.D., Radiation Safety Committee Chair

Margaret A. Shepherd, Chief of Staff & Chief Administrative Officer,

Executive Office of the President & Provost
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1. COMMITTEE ROLES AND RESPONSIBILITIES

1.1 Charge

The University of Washington (UW) Radiation Safety Committee (RSC) is given the following charge:

a. Ensure radioactive materials are being used safely and in accordance with applicable regulations and the University's radioactive material license (RML) requirements.

b. Ensure radiation producing devices are being used safely and in accordance with applicable regulations.

c. Make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable (ALARA). [WAC 246-220-007]

1.2 Responsibilities

Based on the above charge, the RSC has the following roles and responsibilities:

a. Establish policies, and oversee the implementation of those policies, to ensure the safe storage, use, and security of radioactive materials. [License line item 13]

b. Establish appropriate administrative procedures to assure: [WAC 246-235-090]
   - Control of procurement and use of radioactive material;
   - Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
   - The safety evaluation is reviewed, approved, and recorded prior to use of the radioactive material.

c. Independent review and approval authority for individual research projects and work involving the use of radioactive material or radiation producing machines, including:
   - Medical use of radioactive materials and radiation producing machines at both campuses of the University of Washington Medical Center (UWMC) and Harborview Medical Center (HMC);
   - Research and development, as defined in Washington Admimstrate Code (WAC) 246-220-010(126), involving the use of radioactive material or radiation producing devices;
• Research involving the use of radioactive material or radiation producing machines on human subjects as described in the Federal Policy for Protection of Human Subjects.

d. Advise the Executive Office of the President & Provost and the Senior Director of Environmental Health and Safety (EH&S) Department on all matters relating to the procurement, use, storage, transportation, and disposal of radioactive materials and radiation producing machines at the UW.

e. Evaluate the adequacy of University resources that are necessary to meet applicable regulations, especially those provided to EH&S. [License line item 13.D]

f. Rescind approval for further use of ionizing radiation for due cause.

g. Establish necessary administrative controls to assure that there is adequate surveillance over the University's radiation safety program.

h. Establish Committee procedures and bylaws necessary to function effectively.

1.3. Duties

Based on the above responsibilities, the RSC is assigned the following duties:

a. Develop operating policies, procedures, and criteria used in decisions involving approvals, disapprovals, standards, and objectives for an effective radiation safety program.

b. Develop procedures for the proper review of proposed uses of radioactive materials and radiation producing devices to include:

• A critical examination of the details of the proposed use including radiation exposure to individuals involved;

• The adequacy of training and experience of users;

• The adequacy of the equipment, facilities, and procedures.

c. Review and approval of requests to use ionizing radiation prior to:

• All uses of ionizing radiation on or within property that is owned by, rented, or leased to the University, and operated by UW personnel;

• All research or experimental programs supported by or through the University, which require approval by the University Human Subjects Review Committee (HSRAC) (or contracted review committees), that are conducted at locations supported by the UW radiation safety program, and involve intentional administration of radiation or radioactive materials to human experimental subjects;

d. Specify possession limits and general restrictions to define those uses of ionizing radiation, which are generally authorized without specific action by the RSC:
2. Authority

The requirement for and authority of the RSC is found in both the Washington Administrative Code and the University's radioactive materials license.

2.1 Radioactive Materials License (RML)

The University of Washington has been issued a Type A specific license of broad scope (WN-C001-1) by the Department of Health, Office of Radiation Protection. This license allows the University to store and use radioactive material at any property owned or leased by the University as well as some temporary job sites with the state of Washington. The license states:

A Radiation Safety Committee shall be appointed by the University Board of Regents, the President, or designee to set policies and oversee the
implementation of those policies to ensure the safe storage, use, and security of radioactive materials.

2.2 Washington Administrative Code (WAC)

a. The WAC that specifies the requirements for a Type A specific license of broad scope [WAC 246-235-090] states:

The department will approve an application for a Type A specific license of broad scope if... The applicant has established administrative controls and provisions to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including: The establishment of radiation safety committee composed of a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material...

b. The WAC that specifies the authority and responsibility for a radiation safety program involving the medical use of radioactive materials [WAC 246-240-051] states:

Licensees that are authorized for two or more different types of use of radioactive material under WAC 246-240-201, 246-240-251, or 246-240-351, shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license.

c. The WAC that specifies the requirements for the use of particle accelerators [WAC 246-229-0020] states:

If the particle accelerator is intended for human use...The registrant must appoint a radiation safety committee.

3. INSTITUTIONAL RESPONSIBILITIES

The general roles and responsibilities for health and safety programs at the UW are outlined in UW Presidential Order #55. In order to maintain a Type A specific license of broad scope, the University must have established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including the establishment of a radiation safety committee and appointment of a radiation safety officer [WAC 246-235-090].

As such the University has an institutional responsibility to support the RSC and its activities by providing equipment, facilities, and procedures that are adequate to minimize danger to public health and safety or property [WAC 246-235-020].
4. RADIATION SAFETY COMMITTEE MEMBERSHIP

4.1 Members

a. Required members of the RSC are specified in numerous documents.
   - Radioactive Materials License Line Item 13.A;
     
     *The Radiation Safety Committee shall consist of at least the President or designee, the Radiation Safety Officer, medical representation from the University of Washington Medical Center, Harborview Medical Center, and faculty authorized investigators representing major programs or modalities where radioactive materials are stored or used.*
   - WAC 246-235-090 (2)(c)(i) requirement for a Type A broad scope radioactive materials license;
     
     *The establishment of a radiation safety committee composed of a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material*
   - WAC 246-240-051 (6) for the medical use of radioactive materials.
     
     *The committee must include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. The committee may include other members the licensee considers appropriate.*

b. Additionally, major programs or modalities where radiation producing machines are used must be represented on the RSC.

c. Therefore the RSC shall include the following. A member may fill more than one required position, but the RSC shall consist of no less than ten members.
   - The UW President, or designee, as the management representative;
   - The UW Radiation Safety Officer (RSO);
   - The UW Associate Radiation Safety Officer (ARSO);
   - An Authorized User (AU) for each type of human use of radioactive material currently authorized under the UW RML;
   - A representative of the nursing service;
   - A representative for the human use of particle accelerators;
• A representative of major departments, programs or modalities where radioactive materials are stored or used. At a minimum this will include representation from:
  o Department of Radiology, Nuclear Medicine
  o Department of Radiation Oncology
  o Center for Experimental Physics and Astrophysics (CENPA);
• A representative of major departments, programs or modalities where radiation producing machines are used. At a minimum this will include representation from:
  o Department of Radiology, Diagnostic Physics
  o Department of Radiation Oncology, Physics
  o School of Dentistry; and
• Other members as deemed necessary by a majority vote of the committee.

4.2 Expected time commitment

The time commitment of service to this committee is expected to be 12 to 24 hours per year to attend and prepare for meetings. Additional time is anticipated for special projects or activities to support the committee.

4.3 Term appointments

a. The appointment of the RSO, ARSO and management representative will be permanent, as long as they remain in their current positions and are in good standing.

b. The appointment of the RSC Chair and RSC Vice Chair will be for a period of two years, concurrent with the member's term appointment. The Chair and Vice Chair appointments are made in accordance with Section 5 Committee Member Roles and Responsibilities. At the end of their membership term, the Chair or Vice Chair may choose to resign from their respective committee leadership role, while renewing their term as a member. There is no minimum or maximum term of appointment for the Chair and Vice Chair, who serve at the discretion of the appointing authority.

c. The appointment for all other members will be for a period of two years. Such appointments may be renewed at the discretion of the appointing authority and the member. Such appointments may be terminated prior to completion of a full term at the discretion of the appointing authority, in consultation with the Senior Director of the EH&S Department, the RSC Chair, and the RSO due to lack of constructive participation, or at the request of the members. There is no minimum or maximum term of appointment for committee members, who serve at the discretion of the appointing authority.
4.4 Resignation
Resignation of members should be tendered to the RSO by email. The resignation will be communicated to the RSC Chair and the Executive Office of the President & Provost.

5. COMMITTEE MEMBER ROLES AND RESPONSIBILITIES

5.1 Appointing authority
The Appointing Authority is the Executive Office of the President & Provost, and has the following responsibilities:

a. Appoint the RSC Chair, in consultation with the EH&S Senior Director and the RSO.
b. Appoint the RSC Vice Chair, in consultation with the EH&S Senior Director, the RSC Chair, and the RSO.
c. Appoint RSC members in consultation with the EH&S Senior Director, the RSC Chair, and the RSO.
d. Oversee priorities, progress, and success of the Committee.
e. Obtain institutional support for priorities and initiatives.
f. Assist the Chair.

5.2 Chair
The RSC Chair is selected from those members of the RSC with a faculty appointment and appointed by the Executive Office of the President & Provost.

The RSC Chair has the following duties:

a. Facilitate and conduct meetings.
b. Consult on membership appointments.
c. Maintain the RSC charter.

5.3 Vice Chair
The RSC Vice Chair is selected from those members of the RSC with a faculty appointment and appointed by the Executive Office of the President & Provost, in consultation with the EH&S Senior Director, the RSC Chair, and the RSO.

The RSC Vice Chair performs the duties of the RSC Chair in his or her absence or as delegated by the RSC Chair. In order to stay current on RSC operations, the RSC Vice Chair should be included in communications between the RSO and RSC Chair.

5.4 Radiation Safety Officer (RSO)
The RSO is appointed by the Executive Office of the President & Provost and must be qualified in training and experience in radiation protection as specified in WAC 246-240-
6. Meeting Policies

6.1 Open Public Meetings Act (OPMA)

Since the RSC is responsible for developing policy and procedure for the University, it therefore falls under the requirements of the OPMA. [RCW 42.30]

6.2 Meeting frequency

a. The RSC shall have regularly scheduled meetings four times per year.

b. Additional meetings may be called by the RSC Chair with at least one-week notice. Any member, with the endorsement of two additional members, may call for a special meeting by submitting the request and endorsements in writing to the RSC Chair.

6.3 Meeting announcements

a. RSC members shall be notified of regularly scheduled meetings of the RSC by email. This announcement will include the following information: date, time, location, draft agenda, and access to any available materials to be discussed or reviewed.
b. The public shall be notified of regularly scheduled and special meetings of the RSC at the time points required by the institution and Washington state OPMA [RCW 42.30]. Regularly scheduled meetings of the RSC are announced on the publicly accessible pages of the EH&S Radiation Safety website. This announcement shall include the following information: date, time, and location.

c. The RSC meeting agenda will be posted on the website at least 24 hours in advance of the published start time of meeting. [RCW 42.30.077]

d. When there is a change in date, time, and location of a meeting, it is considered a special meeting. A notice will be posted on the EH&S Radiation Safety website. A notice will be displayed at the principal location's meeting site if it is not held at the usual location. [RCW 42.30.080]

6.4 Meeting location

All in-person meetings shall be held at publicly accessible areas of the UW main campus or, when appropriate, other branches of the UW campus. When a meeting is held with all members attending remotely, members of the public must still be allowed to attend in accordance with the OPMA requirements.

6.5 Meeting attendance

Convened meetings of the RSC are open to the General Public, in accordance with Washington State OPMA except as otherwise provided in RCW 42.30.

It is important that RSC members attend all meetings. Remote attendance is possible, however the member must be able to communicate orally. In the event that a member cannot attend a meeting, the member is asked to send a delegate who has similar education and experience. Delegates serve as a member of the Committee for the meeting they attend. Their attendance counts towards the quorum and they are allowed to vote on committee actions and decisions

a. If a member is absent from two meetings per year without sending a delegate, the member can be removed from the Committee at the discretion of the RSC Chair. A vote is not required for the removal.

b. Even if a member has sent a delegate, if the member is absent from four consecutive meetings, the member will be removed from the Committee. A vote is not required for the removal.

c. In the event a member is removed from the Committee, arrangements will be made to appoint a new member representing the same department or discipline of clinical patient care as soon as practicable.
6.6 Voting procedures

a. If a decision by the Committee is required, the RSC Chair or RSO will call for a vote after the discussion is completed. Members vote to accept or reject a proposal by a show of hands.

b. Members attending remotely will communicate their votes orally or by using a voting mechanism included in the remote meeting software (such as yes/no indications). Members must ensure their votes are acknowledged.

c. Members may also abstain from voting if they wish.

d. Items will be approved by a simple majority vote.

e. If, during the course of the meeting the quorum is lost, members present may decide to continue the meeting or adjourn, but an official vote on official business mandated of the Committee cannot be conducted without a quorum or outside of a public meeting. If the meeting is adjourned, and such an action is required of the Committee before the next scheduled meeting of the RSC, a special meeting shall be convened. [RCW 42.30.090, RCW 42.30.080]

f. If, during the course of the meeting, a quorum is lost due to the ineligibility of a RSC member to vote on a particular application due to a conflict of interest, final deliberation on that application will be postponed until a quorum can again be established.

6.7 Referring actions to the full committee

A member may request to refer to the full committee any action that is normally delegated to the HSRAC, RSC Chair and/or the RSO. This request may be made at a meeting or in a written communication to the RSC Chair. At the discretion of the RSC Chair, the previous action may be stayed, pending the full committee’s action.

6.8 Meeting minutes

The topics discussed and decisions made at convened meetings shall be captured in the formal meeting minutes. These meeting minutes are made available to the Committee. An opportunity to solicit corrections to the previous meeting’s minutes will be made at each meeting.

6.9 Meeting materials

Materials to be the subject of review at a convened meeting will be made available to the committee prior to the meeting.
7. PROCEDURES FOR DEFINING A QUORUM

7.1 Quorum

For purposes of a convened meeting, a quorum of the RSC shall be defined as at least one half of the current membership, with at least one of the members being either the RSO or the RSC Chair. Remote attendance by a RSC member is counted towards a quorum, however the member must have the ability to communicate orally. Delegates count towards a quorum.

7.2 Lost quorum

If, during the course of the meeting, a quorum is lost, the members present may decide to continue the meeting or adjourn. If the meeting is adjourned, requirements in RCW 42.30.090 shall be met. A vote on any official business mandated of the committee cannot be conducted without a quorum, or outside of a public meeting. Refer to Section 6.6 Voting procedures.

8. CONFLICT OF INTEREST POLICY

8.1 Policy

Members of the RSC shall not participate in review and approval of applications by the RSC when a conflict of interest exists. This includes, but is not limited to, conflicts of interest as defined in institutional policy or Washington state law.

If, during the course of the meeting, a quorum is lost due to the ineligibility of a RSC member to vote on a particular application due to a conflict of interest, final deliberation on that application will be postponed until a quorum can again be established.

8.2 Examples

Examples of conflicts of interest include the following:

a. The RSC member is currently engaged, or expects to be engaged, in the research or clinical use under review.

b. The RSC member has a direct financial interest in the PI or the entity funding the research proposed by the PI, as defined by UW Financial Conflict of Interest Policy.

c. The RSC member and the PI of the application under consideration share a familial relationship.

d. The RSC member has other reasons to feel that he/she cannot render an independent assessment of an application.

8.3 Disclosure

The RSC member shall disclose the conflict of interest at the following times:
9. Delegation of Authority

9.1 Approval authority for radiation use

The responsibility of the RSC includes approval of many uses of ionizing radiation, which would be needlessly delayed by a requirement for action by the full committee. The Committee may delegate its approval authority to the RSO alone, or to the RSO and RSC Chair acting together for certain specific groups of uses.

Radiation use in human subjects research participants are authorized by the Human Subjects Radiation Approval Committee (HSRAC), a subcommittee of the UW and Seattle Cancer Care Alliance (SCCA) radiation safety committees.

a. Authorization of limited amounts of radioactive material for laboratory uses - RSO Only

The RSO may authorize limited amounts of radioactive material for laboratory uses. Excluded from this authority are the review and approval of the RSO's Radiation Use Authorization (RUA) and any uses in which radioactive material or the radiation from radioactive material is administered to humans. This delegated authority is consistent with state regulations that allow uses under a Type B broad license [WAC 246-235-090], which relates to quantities of radionuclides specified in Schedule B, Column I [WAC 246-235-140]. The specific limits for RSO authority are as follows:

- Except as noted below, the RSO may approve for any PI possession and use of quantities of each radionuclide not to exceed 10% of the quantities listed in Schedule B, Column I [WAC 246-235-140]. For radionuclides that are not listed in Schedule B, the RSO may approve for any PI possession and use of quantities not to exceed 100 times the calculated Annual Limit on Intake (ALI). Radionuclides that are not listed in Schedule B and do not have published ALIs will be brought to the RSC for review;

8.4 Recusal

An RSC member shall be recused from participating in the final decision vote on an application for which he or she has declared a conflict of interest. The RSC member shall nevertheless remain eligible to provide information related to the review of the project to the RSC.
9. Delegation of Authority

- The RSO may approve for any PI possession and use of Iodine-125 and/or Iodine 131 not to exceed 30 millicuries total possession of each isotope and separate orders of no more than 15 millicuries of each isotope; and possession and use of gallium-67 up to 1 curie;
- The RSO may approve for any PI possession and use of commercially manufactured sealed sources and contained sources of radioactive material not to exceed 5 curie for each individual source;
- The RSO may approve amendments to authorizations for laboratory uses, which were originally approved by the RSC. The circumstances for this approval are:
  o Changes in personnel
  o Changes in location of use
  o Increases in total possession of up to two times the amounts originally approved by the RSC
  o Renewal of authorization originally approved by the RSC (unless instructed otherwise)
  o Temporary assumption of PI status in absence of original PI;
- If the need arises, the RSC Chair may sign for the RSO in the circumstances listed above when the latter is not available.

b. Authorization of interim approval - RSO and RSC Chair joint approval

The RSO and RSC Chair are approved to expedite authorization of certain uses of radioactive material not specifically delegated to RSO.

- Laboratory Uses
  The RSO and RSC Chair, acting together, may approve on a single occasion (or on an interim basis not to exceed six months) the possession and use of radioactive material for laboratory use, quantities of each radionuclide not to exceed the quantities listed in Schedule B, Column I [WAC 246-235-140].

- Clinical Uses
  The RSO and RSC Chair, acting together, may approve on an interim basis not to exceed six months the possession and use of radioactive material for clinical use, quantities not to exceed the quantities listed in the University's radioactive material license.

c. Authorization of radiation in human subjects research participants – HSRAC

Prior to June 1, 2010, the RSC directly reviewed applications for uses of radiation in human subjects research participants and provided approvals on behalf of the UW Human Subjects Division (HSD). As of June 1, 2010, a joint SCCA and UW HSRAC
was commissioned at the direction of the UW Executive Director of Health Sciences Administration and the SCCA Medical Director. This avoids researchers needing to make dual applications for approval at two different institutions.

The HSRAC reviews and approves all research or experimental programs supported by or through the UW and SCCA, that require approval by the Cancer Consortium Institutional Review Board or UW Human Subjects Review Committee (or contracted review committees), that are conducted at locations supported by the UW and SCCA radiation safety programs and involve intentional administration of radiation or radioactive materials to human experimental subjects.

Most members of HSRAC are also members of either the UW or SCCA RSCs. Refer to Appendix B for more information on HSRAC membership and authority delegated to HSRAC staff.

It is recognized that Washington Administrative Code [WAC 246-240-070] places final approval of experimental investigation involving radiation exposure to human subjects with the Institutional Review Boards (IRBs). However, the IRBs typically lack members with radiation expertise and therefore SCCA and the UW defer to the HSRAC to provide appropriate professional attention, radiation risk analysis, advice, and protocol approval prior to final approval by the IRBs.

9.2 Reporting to Department of Health (DOH)

The RSO may correspond directly with DOH for routine matters, and is authorized to work directly with DOH on licensing issues including submitting license amendments. The RSO will inform the RSC of all actions involving DOH including license amendments and reports submitted.

For events that must be reported to DOH under WAC 246-221-240 Reports of stolen, lost or missing radiation sources, WAC 246-221-250 Notification of incidents, WAC 246-221-260 Reports of overexposures and excessive levels and concentrations, and WAC 246-221-265 Special reports to the department—Planned special exposures and leaking sources the RSO is authorized to conduct immediate and twenty-four hour notifications that are required by these regulations. However, all follow-up written reports will be reviewed by the RSC Chair and signed by both the RSO and the RSC Chair. If either the RSO or RSC Chair is not available, the Associate RSO and/or the Vice Chair will co-sign the written report as authorized by the radioactive materials license and section 5.3 of this charter, respectively.

9.3 Signature authority

Signatures signifying Committee action shall be according to the following schedule:

a. Radiation Use Authorizations (RUAs) that may be approved directly by the RSO shall be signed by the RSO.

b. All other RUAs shall be signed by the RSO and RSC Chair.
c. Applications for amendments to the UW RML of Broad Scope shall normally be signed by the RSO. Applications for amendment that involve significantly scientific issues or are not supported unanimously by the RSC shall be signed by the RSO and RSC Chair.

10. DEFINITIONS

ALARA: As low as reasonably achievable
ALI: Annual limit on intake
AU: Authorized User
DOH: Department of Health
EH&S: Environmental Health and Safety Department
HSD: Human Subjects Division
HSRAC: Human Subjects Radiation Approval Committee; a committee of radiation experts from the UW and SCCA that reviews research protocols in which human subjects are exposed to radiation
IRB: Institutional Review Board
PI: Principal Investigator, UW faculty member with overall project authority
RCW: Revised Code of Washington
RML: Radioactive Materials License
RSC: Radiation Safety Committee
RSO: Radiation Safety Officer
RUA: Radiation Use Authorization
SCCA: Seattle Cancer Care Alliance
UW: University of Washington
WAC: Washington Administrative Code

11. APPLICABLE REGULATIONS AND POLICIES

- University of Washington Radioactive Materials License (WN-C001-1)
- [WAC 246-220](#): Radiation Protection – General Provisions
- [WAC 246-229](#): Radiation Protection – Particle Accelerators
- [WAC 246-235](#): Radioactive Materials – Specific Licenses
- [WAC 246-240](#): Radiation Protection – Medical Use of Radioactive Material
• **RCW 42.30**: Open Public Meetings Act

• **UW Presidential Order #55**: University Health and Safety Programs: Policy and Responsibilities

**APPENDIX**

A. Membership Roster

B. Joint Seattle Cancer Care Alliance and University of Washington Human Subjects Radiation Approval Committee – General Information and Policy Statement