

Charter

University Radiation Safety Committee

Iowa State University
March 2021

I. INTRODUCTION

The policy of the University is to control and facilitate the use of radioactive materials and radiation-producing devices on campus for purposes of research and teaching. In this process, the University is committed to ensuring that all uses of these materials and devices are in compliance with regulatory requirements and that any resulting radiation exposures are as low as is reasonably achievable (ALARA). Toward this end, the University has established specific administrative entities with responsibilities for controlling the use of radioactive material and radiation-producing devices on campus.

The Iowa State University Radiation Safety Committee (RSC) is appointed by the Vice President for Research (VPR) as one of the standing committees of the University. The RSC shall have the responsibility to provide general review and audit functions of the radiation safety programs at Iowa State University to determine compliance with regulations and licenses issued on the local, state, and federal level. The RSC shall likewise have the authority to require program changes, including termination of unsafe projects, to assure compliance with regulations and the maintenance of reasonable standards of health and safety.

The University Radiation Safety Officer (RSO) will normally carry out the directives of the RSC. The RSO operates out of the Department of Environmental Health and Safety (EH&S) which has broad responsibilities for all safety and occupational health programs on the Iowa State University campus.

This Charter covers the responsibilities of the RSC regarding radiation safety at Iowa State University.

II. GENERAL COMMITTEE REQUIREMENTS

A. Composition of the Committee

The RSC is required to be composed of:

- the radiation safety officer (RSO)
- a representative from University management, and
- persons trained in the safe use of radioactive material.

Additionally, the committee will include the Director of the Office of Research Ethics (DORE), who may serve as the representative of University management, and the RSO from Ames Laboratory.

The committee will include individuals representing various departments from whom radioactive use requests originate. Every effort will be made to find representatives from each College who have prior education or experience using radioactive material. The administrative members of the committee do not need to have a background in radiation safety.

The committee may use an alternate member system when sufficient membership is available to have alternates. When both the primary and alternate member attend the RSC meeting, only one will be counted as a voting member.

One voting member of the committee will be appointed as vice chair and will serve in the capacity of chair if the chair is unavailable or has a conflict of interest. If both the chair and vice chair attend the RSC meeting, the chair will lead the meeting and the vice chair will serve as a voting member.

The committee, including the chair and vice chair, shall be appointed by the VPR. The terms on the committee for the RSO, the Ames Laboratory RSO, and the DORE are indefinite. All other terms are for three years with reappointments being determined by the VPR.

B. Frequency of Meetings

The RSC meets at least once during the spring and fall academic semesters, at a time arranged by the chair for maximum attendance. Additional meetings may be called if circumstances dictate the need for them.

C. Quorum Requirements

The minimum committee members required to be present for quorum are:

- the chairperson,
- the RSO,
- management representative, and
- two members.

D. Committee Reporting

Recommendations and minutes of the RSC meetings are sent to the VPR. Any recommendations, comments or questions in the minutes regarding a specific project or program are sent to the person in charge of the project, and to the person having administrative authority for the department involved, when such action appears appropriate.

E. Relationship of the RSC and the RSO

The RSO is responsible for keeping the RSC apprised of all major actions taken to implement and enforce radiation safety rules and regulations on campus. The RSO shall implement and

enforce directives of the RSC and coordinate the total radiation safety program to ensure proper and timely response to current problems.

F. Environmental Health and Safety

The RSC's function of assuring the day-to-day implementation of the radiation safety program is delegated to the Department of Environmental Health and Safety. This department provides monitoring services for personnel, receives and handles shipments of radioactive material, collects radioactive waste and performs other health physics functions.

III. RSC ACTIONS RELATIVE TO GENERAL USE OF RADIOACTIVE MATERIALS AND RADIATION-PRODUCING EQUIPMENT AT IOWA STATE UNIVERSITY

A. Approval of Projects involving Radioactive Materials or Ionizing Radiation

Before an individual may use radioisotopes or ionizing radiation in experimental or routine procedures, approval must be obtained from the Radiation Safety Committee. This must include approval of the following:

1. The project itself on the basis of radiation protection only.
2. The facility for the amounts and types of radioisotopes or other radiation sources which will be used.
3. The training and background of the individual to handle the radioactive material or radiation which he or she intends to use.

This information shall be submitted to the RSC through the RSO. All projects and major additions or changes in projects, shall be reviewed by the RSO and the RSC chair. The RSC chair or the RSO will determine if further committee review is necessary and act accordingly. All approvals for projects shall be granted by the chair of the RSC or his/her designated alternate. Minor additions or changes to projects will be reviewed and approved by the RSO or a designated alternate.

NOTE: A complete outline of information necessary to submit for approval for projects involving radiation can be found in the Radioactive Materials Safety Manual.

B. Suspension or Changes in Radiation Projects

The RSC shall have the authority to enforce changes in any radiation project in order to comply with regulations and to meet reasonable standards of safety and health.

In the event that any radiation project presents an imminent danger to the health or safety of any individual, or presents an imminent threat to the safety of property, the RSO shall have the authority to suspend such projects or operations. Upon taking such action, the RSO must immediately notify the chair of the RSC and the chairs of the involved departments, college dean, and VPR. The RSO will also notify the RSC of such action and work closely with the committee during the process.

C. Noncompliance/Complaint Process

Whenever possible, the following process will be followed when a complaint is received or possible noncompliance is suspected.

Upon notification to the Office of Research Ethics of potential noncompliance or complaint:

1. The DORE, the RSC chair, and the RSO will determine if immediate suspension of the project in question is required, while the issue is addressed, in consultation with the VPR. This initial decision will be based on preliminary information and the seriousness of the situation. If applicable, the sponsor contract or grant award notice will be reviewed to determine requirements for notifying the sponsor. Reports to the sponsor are made by the DORE.
2. The DORE will lead the investigation of the incident with the assistance from any combination of the following as appropriate: the RSC chair, the RSO, and the RSC members.
3. It may be necessary to perform an audit of study records. In that case, the principal investigator will be required to produce all data related to the study projects, applications for approval from the RSC, and any study-related documentation including monitoring logs, etc.
4. Following completion of the investigation, a meeting will be called with the RSO, the RSC chair, and DORE to discuss the nature of the situation and may include the principal investigator and/or the principal investigator's department chair.
5. The RSC chair will present the matter to the members of the RSC when a quorum of the committee is present. The RSC will determine if (1) suspension is not merited or (2) suspension is merited. In order to suspend a study, a majority of the quorum of members present must vote in favor of the suspension:
 - a. **Suspension is not merited:** If suspension is not merited, the issue will be resolved among the DORE, RSC chair, RSO, and may include the principal investigator and/or principal investigator's department chair. These actions will be based on recommendations from the RSC members and in communication with the VPR. All communications will be documented.
 - b. **Suspension is merited:** *Notice of suspension effective immediately will be sent to:* the principal investigator, co-principal investigators, the department chair, the associate dean for research, and the VPR. If applicable, the Office of Sponsored Programs Administration, and/or Sponsored Programs Accounting will also be notified. The RSO will notify the Iowa Department of Public Health if needed. If applicable, the sponsor contract or grant award notice will be reviewed to

determine requirements for notifying the sponsor. Reports to the sponsor are made by the DORE.

6. In cases involving noncompliance, the RSC makes a determination regarding noncompliance, whether the situation merits a designation of serious or continuing noncompliance, and any corrective actions:
 - a. **Serious noncompliance:** Noncompliance that compromises the safe use of radioisotopes or ionizing radiation in experimental or routine procedures. Acts that are determined by the RSC to be flagrant or an intentional violation of RSC requirements may also constitute serious noncompliance.
 - b. **Continuing noncompliance:** Repeated acts of noncompliance in the use of radioisotopes or ionizing radiation in experimental or routine procedures suggesting a pattern indicative of a lack of understanding or attention to adequate safeguards or of University policies and/or non-University regulatory requirements for the use of radioisotopes or ionizing radiation. Continuing noncompliance is characterized by the frequency rather than the magnitude of the noncompliance.

The possible actions that may be taken as corrective measures include:

- Suspension or termination of Radiation Safety Committee approval of protocols that are found to be noncompliant with institutional policies and procedures, state laws, and/or federal laws or regulations;
- Compliance audits;
- Letters of reprimand (i.e., formal letters from the VPR to PI which remain on file with Human Resources);
- Restrictions on serving as an investigator on radiation safety protocols;
- Modification to research protocols;
- Removal of data related to noncompliance from any data collection/pool so it will not be used for analysis and publication
- Requests for more information prior to making final decision;
- Referral of the issue to other organizational entities such as legal counsel, risk management, or the research integrity officer;
- Requiring continuing education;
- Other actions as appropriate,

A report from the DORE to the principal investigator describing a summary of the investigation and outcomes will be written. The committee's determinations regarding noncompliance and their recommendations regarding corrective actions are forwarded to the VPR for review. The VPR may not reverse a committee determination of noncompliance, but the VPR may make his or her own determination that a study is in noncompliance. Upon VPR review, a copy of the final report will be sent to the principal investigator, principal investigator's department chair, chair of the RSC, RSO, and VPR.

For cases of serious noncompliance, the RSO will notify the Iowa Department of Public Health regarding the final outcome if needed. If applicable, the sponsor contract or grant award notice will be reviewed to determine requirements for notifying the sponsor. Reports to the sponsor are made by the DORE.

D. Appeals

Any individual may appeal the actions of the RSO through the RSC. Additionally, an individual may appeal the decision of the RSC, to the RSC. Appeals must be done in writing and the investigator must provide rationale for the appeal and any other relevant supporting documentation.

An individual may also appeal to the VPR, after first appealing to the RSC. Grounds for appeal to the VPR are limited to 1) a violation of University rules, regulations, policies; or 2) a specific act by the University that was arbitrary or capricious. Such appeals must be filed within 10 business days of the RSC issuing their decision. The VPR will respond in writing within 30 business days of receiving the appeal, unless, in the opinion of the vice president, that is insufficient time to appropriately investigate and consider the substance of the appeal. If additional time is needed, the vice president shall contact parties to provide a new date by which the decision shall be made.

E. RSO Review of Radiological Safety Programs and RSC Audit

1. Annual RSO Review

The RSC shall assure itself through reports from the RSO, and through actual audits when necessary, that control of the radiation safety program is being maintained. This will include the following items and records maintained by the RSO:

1. Procurement and possession of radioactive material.
2. Transfer and shipment of radioactive material on and off campus.
3. Inventory lists to assure compliance with local possession limits, and with Iowa Department of Public Health licenses and regulations.
4. Appropriate surveys, leak tests, and monitoring of radiation projects to assure worker safety and compliance with regulations.
5. Personnel dosimetry records including bioassay results.
6. Disposal of radioactive waste materials.
7. Instruments and calibration records.
8. Renewal and changes in any federal, state, or other licenses held by Iowa State University that pertain to the use of radiation or radioactive materials.
9. Any other important records that may be required or deemed appropriate.
10. ALARA program.


The RSO reviews will be available for review and audit by the Iowa Department of Public Health.

2. RSC Member Audit Function

The audit function shall include selective (but comprehensive) examination of operating records, logs, and other documents. Where necessary, discussion with cognizant personnel shall take place. In no case shall an individual perform the audit of an area for which he or she has operational responsibility. Deficiencies uncovered that affect safety shall be reported immediately to the RSO. A written report of the findings of audit shall be submitted to the RSC by the spring meetings.

Reviewed and approved by the RSC: April 13, 2021

Approved by:



Peter Dorhout, Ph.D.
Vice President for Research

14 April 2021

Date