

Radiation Safety Committee Policy on Minor Modifications to an Existing Protocol

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Applies To: Radiation Safety Committee, Radiation Safety Officer

For More Information contact: EHS, Radiation Safety Officer at 860-486-3613

Glossary of Terms

Environmental Health and Safety (EHS)

Licensed Investigator (LI)

Nuclear Regulatory Commission (NRC)

Radiation Safety Committee (RSC)

Radiation Safety Officer (RSO)

I. PURPOSE

To establish and define minor modifications to radioactive materials protocols which may be approved by the RSO and do not require full RSC review.

II. SCOPE

The RSC must review and approve initial protocol applications. In addition, major modifications to previously approved radioactive material and sealed source research protocols must be approved prior to implementation. However, some requested protocol modifications may be relatively minor. These minor modifications require review and approval by the RSO only and do not require submission and review by the full RSC. Some minor modifications will require review by the RSO and also at a minimum, the RSC Chair or Vice Chair. Modifications the RSC considers minor are defined in this policy. All modifications not listed are considered to be substantive in nature and must be submitted to the full RSC and RSO for review and approval prior to implementation.

III. POLICY STATEMENT

This minor modification policy was established by the RSC. It is a University specific policy governing radioactive materials that incorporates Federal and State regulations and the University's NRC license conditions. Compliance with all requirements and procedures in this policy is required.

IV. ENFORCEMENT

Violations of this policy may result in appropriate disciplinary measures in accordance with University Laws and By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, and the University of Connecticut Student Conduct Code.

V. DEFINITIONS

Minor modifications: modifications to a radionuclide usage protocol that are within NRC license limits and conditions and the requirements of the Radiation Safety Manual and do not require a change in monitoring requirements or procedure changes. These modifications, identified in this policy, require RSO approval only and do not require RSC review and approval.

Substantive modifications: modifications that are not minor as defined by this policy and may include a request that would require an amendment to the University's NRC license or would require a change in monitoring requirements or procedure changes. Such modifications must be submitted to the RSC for review and approval by the majority and by the RSO prior to implementation.

VI. RESPONSIBILITIES

The Radiation Safety Manual contains the responsibilities of the Radiation Safety Committee, the Radiation Safety Office, Licensed Investigators and individual users of licensed radioactive material.

VII. PROCEDURES

A. Licensing Procedures

The Radiation Safety Manual includes specific procedures regarding application for a radionuclide usage protocol, permissible radionuclides, and review and approval. New protocols are circulated to the RSC for review and, when approved, a radioactive materials usage license is signed by the RSO and issued to the LI. The RSC's approval of any protocol will expire 24 months from the date of formal approval. Renewals and amendments can be made on the same protocol form.

B. Minor Modifications to Approved Protocols

The RSO may approve a minor modification to an approved protocol requested in an application for an amendment or a protocol renewal without RSC approval. There may be instances where the RSO may request approval from the RSC Chair or Vice Chair for a minor change if it is a change covered by this policy but is considered to be non-routine by the RSO. The Chair or Vice Chair may advise the RSO to bring the request before the full RSC. The minor modifications may only be approved by the RSO for renewals which are submitted prior to the expiration date. If a LI allows their protocol to expire, the Radiation Safety Office will remove radioactive material from the laboratory and the LI must submit a new protocol application that shall require review and approval by the RSC and RSO. The following are considered minor modifications to a protocol:

- a. Lab personnel changes.
- b. Adding or removing a location of use that does not require additional security or modifications affecting safety or security.
- c. Adding detail or information to a protocol, which is consistent with the Radiation Safety Manual.
- d. Increasing the allowed amount of activity for a radionuclide for a current protocol approved by the RSC. Increases in activity shall be within NRC license limits and for the same procedure initially approved by the RSC. Requests for authorization to increase allowable activity limits shall be evaluated by the RSO and approved at the discretion of RSO in consultation with the RSC as needed. The RSO shall consult the RSC prior to denial of a request.
- e. Addition of a radionuclide to a current protocol approved by the RSC, which is on the NRC license if the additional radionuclide does not require a change in monitoring or protocol procedures. Procedures for use must be consistent with the Radiation Safety Manual.
- f. Transfers of radioactive material from one LI currently authorized by the RSC for the radionuclide and amount to another LI also authorized by the RSC for the radionuclide and amount, with prior permission by the RSO in accordance with the Radiation Safety Manual.
- g. Editorial changes to include corrections of grammar and language to increase understanding.

C. MINOR MODIFICATIONS REPORTS

The RSO shall report minor modifications to the RSC during each Radiation Safety Committee meeting, if applicable. The RSO is not required to report editorial changes to protocol renewals or lab personnel changes as these changes are understood to occur routinely.