

Chapter I: Application for Radioactive Protocol

Policy

Each principal investigator or faculty group is required to have an approved protocol by the University Radiation Safety Committee (URSC) to order, possess and use radioactive material at the University of Chicago. The URSC approves protocols for the use of radioactive material for research, except for the use of radioactive material in human subjects based upon the principal investigators training and experience, safety evaluation of the proposed use, adequacy of facilities and equipment. The radioactive material protocol will expire after two years unless a renewal application is submitted before the expiration date.

Authority and Responsibility

University of Chicago Radiation Safety Committee is responsible for:

- 1 Review and approve the training and experience for all applicants.
- 2 Review on the basis of safety and approve or disapprove each proposed method of radioactive material use.
- 3 Review and approve or disapprove applications for the possession and use of radioactive materials.
- 4 Review the radiation safety program and institute corrective actions as the committee deems necessary.

Radiation Safety Officer is responsible for:

- 1 Review the application form, principal investigator training and experience form and associated forms to completeness and accuracy.
- 2 Work with the applicant to correct any deficiencies in the application.
- 3 Prepare the ballot and distribute the forms to the University Radiation Safety Committee.
- 4 Approve amendments and renewal applications as described in the institutional license issued by the Illinois Emergency Management Agency (IEMA), Division Nuclear Safety.
- 5 Notify principal investigators of the upcoming expiration of their protocol to assist with timely renewal.

Principal Investigator is responsible for:

- 1 Completing and signing protocol application for initial protocol submittal, renewal submittal and amendment submittal.
- 2 Submitting training and experience for new protocol applications.
- 3 Submitting an account authorization request form to provide an account number for recharge activities.
- 4 Conducting activities described in the application and in accordance with the University radiation safety policies and procedures or representations made by the applicant and any conditions added to the authorization.

Application Process

This information is intended to provide the research community with guidance in applying and maintaining an active protocol for ordering and using radioactive material at the University of Chicago. The three types of applications that may be submitted during the course of a protocol are:

- Initial application to possess an use radioactive materials,
- Renewal application to continue an existing protocol; or
- Amendment application to make changes to an existing protocol.

The application forms and other associated forms can be downloaded from our website.

The following provides general information to assist you in completing and submitting the proper application form:

- 1 The original application with the signature of the principal investigator must be submitted to the Office of Radiation Safety at MC 2106 or delivered to AMB M-031A. We do not accept faxed applications.
- 2 All applications must be typed. (Hand written applications will not be accepted.)
- 3 Each application must stand alone. Do not refer to previous applications.
- 4 If you are submitting an initial application, you must provide a statement of training and experience.
- 5 An application may be used for multiple radionuclides' you wish to be authorized to possess and use.
- 6 The long application form will be required for each new radionuclide to be added to an existing protocol.
- 7 Principal investigators desiring to increase or decrease the maximum activity to be ordered in a month, change the location of use or storage, or chemical/physical form of previously authorized radionuclide's may submit the shorter application form.
- 8 The University's license does not permit the use of radioactive material in human subjects. Note: Administration to human subjects is conducted under the University Medical Center license. Contact the Office of Radiation Safety if you have questions.

Initial Application for Non-Human Use of Radioactive Material

If a principal investigator has not submitted an Application for Non-human Use of radioactive material within the past two years, they will be required to complete a new Application for Non-Human Use of radioactive material and submit the application to the Office of Radiation Safety. The application shall include radioactive material the applicant wishes to acquire during the two year period the license will be active. (Please note: In the event that a change to the protocol is needed prior to the two year renewal process, an amendment may be filed at any time as noted below.) The Office of Radiation Safety will review the application forms, work with the applicant to correct any deficiencies, and distribute the application to the University Radiation Safety Committee (URSC) for approval. A majority approval of the voting members is required for applications needing committee approval.

The following forms must be completed and submitted for the initial application process:

- 1 Application for Non-human Use of radioactive material (ORS Form A1). Follow the item by item instructions below for completing the application form. **Please note:** The application must be typewritten. Submit the original application form, faxes will not be accepted.
- 2 Principal Investigator's, PI Training and Experience Form (ORS Form A4).
- 3 Account Authorization Form ORS Form A5.
- 4 New User Amendment and Training Certification form (ORS Form A3) for all new RAM users or RAM users transferring from other labs. Please note: See the training requirements below for initial and annual radiation safety training for RAM users (e.g. new radioactive material users must attend the radioactive material user training session provided by the Office of Radiation Safety)

Amendment Application for Non-Human Use of Radioactive Material

Laboratories that have been granted approval for use of radioactive material may need to amend their authorization. Amendments are considered changes in laboratory locations, radiochemical, radiochemical order limits, proposed uses, and laboratory personnel, who work with radioactive material.

The following changes require an amendment to an authorization:

- 1 Notifications for room changes (adding new lab or discontinuing use in a lab).
Radioactive material may only be used in laboratories, cold rooms, etc. approved by the University Radiation Safety Committee. In order to amend your areas of use, submit an Application to Amend Protocol for non-human use of radioactive material (ORS Form A2) listing the change (building, room number, type of room and indicate to add or delete). If the room change involves the termination of radioactive material work in that lab, the Office of Radiation Safety will perform a closeout survey certifying that no radiological hazards exist in the space. **Please note:** If your lab is moving or leaving the University, the Office of Radiation Safety requires advance notification (minimum 1 week) to schedule the radiological survey, radioactive waste removal, and cancellation of all radiation safety related services. Submit an email to the Office of Radiation Safety at radsafety@uchicago.edu. Surveys of lab equipment used in radioactive material experiments are required prior to packaging by a moving company. In addition, a close-out survey is conducted after the movers have removed all equipment.
- 2 Notification for changes in monthly order limits and changes in physical or chemical form.
 - To increase the monthly order limit: Complete and submit an Application to Amend Protocol for non-human use of radioactive material (ORS Form A2) listing the change to the Office of Radiation Safety.
 - To add a new radiochemical: Complete and submit an Application for Non-Human Use of radioactive material (ORS Form A1) listing the new radiochemical and radiation safety practices to the Office of Radiation Safety.
- 3 Adding laboratory personnel who will work with radioactive material. Laboratory personnel who work with radioactive material are required to be listed on the application. In order to update the laboratory personnel list, a New User

Amendment and Training Certification Form (ORS Form A3) must be submitted to the Office of Radiation Safety. Please note: New RAM users must attend the RAM user training presented by the Office of Radiation Safety. In addition, labs are required to update their Annual Refresher Radiation Safety (Training Certificate Form) or the list of users that is posted in their lab reflecting the addition of lab personnel. **Please note:** See initial and annual refresher radiation safety training requirements below.

- 4 Adding or modifying survey instruments. In order to add a new survey instrument, add a new probe, or discontinue use of a survey instrument, you are to submit a memo or email to the Office of Radiation Safety outlining the change including the instrument's model and serial number. A member of the Radiation Safety staff will contact the lab designee to conduct the change. **Please note:** If you have purchased a new instrument, the Office of Radiation Safety will affix a sealed source to the instrument to be used for its operational checks. A copy of the calibration certificate must be submitted to the Office of Radiation Safety. If you are unable to locate the calibration certification, the Office of Radiation Safety will be required to recalibrate the instrument.

Renewal Application for Non-Human Use of Radioactive Material

Each application for non-human use of radioactive material expires two years from the initial application approval date. If you are unaware of the expiration of your authorization, please contact the Office of Radiation Safety at 773-702-6299.

Approximately 30 days prior to the expiration, the Office of Radiation Safety will send notification to each Principal Investigator (PI) and their lab designee instructing the lab to submit the renewal application, if they wish to continue their authorized use of radioactive material. If a renewal application is not received in the Office of Radiation Safety prior to the expiration date, the laboratory will not be allowed to order radioactive material until a renewal application has been submitted to ORS and approved by the University Radiation Safety Committee.

If you need a copy of your previous application and/or amendments to complete the renewal application please call our office to obtain a copy.

The following forms must be completed and submitted for the renewal application process:

- 1 Application for Non-Human Use of radioactive material (ORS Form A1).
- 2 New User Amendment and Training Certification form (ORS Form A3) for those individuals new to the lab, who were not listed under the previous application as users of radioactive material. In addition, new radioactive material users must attend the new radioactive material user training, if they have not yet attended.
- 3 Updated Account Authorization Form (ORS Form A5), if your account will soon expire or if the previous account number has changed.

Please notify the Office of Radiation Safety by email at radsafety@uchicago.edu or memo if you do not wish to renew your protocol to possess and use radioactive materials. If you decide not to renew, our office will call to schedule a time to close-out your laboratory, if needed.

Radiation Safety Training

RAM User Training

Each individual using radioactive material must complete initial radioactive material user training and annual refresher training, thereafter.

RAM User Initial Training

- All new & current employees being added as RAM users to a protocol must attend the Office of Radiation Safety training course for RAM users prior to any use of radioactive material.
- The ORS RAM User training course is offered weekly. Refer to the Safety Training Academy for the course schedule and to register.
- Course duration is approximately 2.5 hours.
- A knowledge assessment will be provided to attendee's, so ORS can determine the effectiveness of the information provided and ensure all attendee's understand the information.

PI submittal of the [New User Amendment and Training](#) Certification form to ORS (fax no. 2-4008, mail MC2106 or deliver to AMB M-031A) is required to add a user to the protocol!

RAM User Annual Refresher Training Requirement

The Principal Investigator and all RAM users must complete the annual training requirement by one of the following methods:

- Attend one of the RAM user training course presented by ORS; or
- Complete the RAM User Refresher training module on the University Chalk Site and complete the knowledge assessment.

Laboratory Designee Training

Each laboratory must assign two individuals as laboratory designees to assist the PI with the radiation safety oversight in the laboratory.

Lab Designee Initial Training

- Each individual assigned the lab designee responsibilities must first attend the RAM user training course and then the laboratory designee training course presented by ORS.
- The RAM user course is presented weekly as noted above and the lab designee course is presented once a month.
- The lab designee course duration will be approximately 90 minutes.
- A knowledge assessment will be provided, so ORS can determine the effectiveness of the information provided and ensure the attendee's understand the information.

Lab Designee Annual Refresher Training

- The laboratory designee must complete annual refresher radiation safety training.
- The annual training for laboratory designee's shall be one of the RAM user refresher training methods as noted above.