

Section 4

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The Radioactive Materials License allows the Radiation Safety Office (RSO) to issue “authorizations” which define specific conditions of radioactive material use.

A. Authorized Investigator

The RSO authorizes investigators who are affiliated with the UW to operate under the UW Radioactive Materials License of Broad Scope; these are called Authorized Investigators (AUI).

1. Criteria

The Authorized Investigator is usually a faculty member. Such investigators are legally responsible for the handling of radioactive material under their jurisdiction.

2. Authorized Investigator versus Radiation Worker

An individual who wishes to use radioactive material may seek approval as either an Authorized Investigator (AUI) or as a radiation worker. The AUI directs and supervises a project, whereas a radiation worker works under the authorization of an Authorized Investigator.

3. Authorized Investigator Responsibilities

a. Planning Experiment/Program

- 1) Properly plan and organize an experiment or program, with appropriate consideration to the type and amount of radiation or radioactive material involved.
- 2) Provide necessary equipment and controls for the safe use of radiation or radioactive material by obtaining necessary funding, specifying equipment, and assuring that all equipment is properly used and functioning.

b. Personnel

- 1) Provide instruction for all personnel regarding specific radiation safety requirements for the laboratories in which they will be working.
 - a) Workers shall be instructed by the AUI or his/her designee in the health protection considerations associated with exposure to radiation. The extent of these instructions shall be commensurate with potential radiological health protection considerations present in their workplace.
 - b) Facilitate enrollment of new personnel in the UW Radiation Safety Training program.
- 2) Require personnel to follow safe laboratory practices as described in this manual.

c. Radiation Detection Instruments

- 1) Equip each laboratory suite with appropriate survey meters or arrange for use of liquid scintillation equipment capable of detecting the types of radiation that might be encountered in the area.

- 2) Arrange for repair or inspection of instruments suspected of operating erratically or incorrectly.
- 3) Calibrate instruments at appropriate intervals.
- 4) Notify the Radiation Safety Office of the acquisition of new instruments.

d. Posting

- 1) Work with the Radiation Safety Office to post all areas under AUI control with proper radiation warning signs and notices.
- 2) Maintain this posting.

e. Security

Require and foster security of radioactive materials.

- 1) Secure radiation-producing machines, sealed sources, and concentrated stock solutions of radioactive materials when not in use. Radioactive materials can be secured in locked storage containers, provided these containers cannot be easily removed from the premises.
- 2) Lock laboratories when unattended.

f. Program Changes

Contact the RSO whenever changes in operational procedures, facilities, personnel, or equipment occur that may lead to changes in personnel exposure.

B. Applications to Use Radioactive Materials

1. General Laboratory Use of Radioactive Materials

An investigator seeking to become an Authorized Investigator for non-human use of radioactive material should enroll in the RS Training Class; and request an application packet from the Radiation Safety Office.

a. Application Forms

The application packet will contain the following:

- 1) General

Form 10 – Description of overall proposed program.

2) Personnel

Form 20 – Description of personnel training and experience in radiation work. Each person who will be working under the proposed authorization must complete a separate form.

3) Laboratory Registration

Form 50 – Description of the laboratory or workspace and the facilities in which radiation and/or radioactive materials will be used. A separate form must be completed for each space.

4) Instrument Registration

Form 51 – Description of each radiation instrument used in the program and its location. Each instrument will require a separate form.

5) A set of miscellaneous attachments, as appropriate, that may include emergency procedures, inventory record forms, laboratory survey forms, package-opening procedures, and current Radiation Safety Updates.

b. Short-Term Authorization for Visiting Scientists

Certain specialized authorizations may be granted primarily to visiting scientists and scholars who plan to use radioactive materials for a limited period of time at UW facilities or on research vessels. Appropriate training must have been completed at the individual's home institution, and documentation that such training has been received will be required.

1) Friday Harbor Lab (FHL)

Form 13 – This application form is to be used by visiting scientists to Friday Harbor Laboratory (FHL), operated by the UW Zoology Department at Friday Harbor on San Juan Island. Form 13 should be obtained from FHL and returned to them. It will be reviewed by FHL staff and then forwarded to the RSO for review and final authorization.

2) Radioactive Materials Onboard Research Vessels

Form 13V – This application form is to be used by visiting scientists, who plan to use radioactive materials onboard research vessels that are owned, leased, and/or operated by the UW.

For work planned on the RV Clifford A. Barnes or the RV Thomas A. Thompson, the application should be obtained from the UW Oceanography Department and returned to them. It will be reviewed by Oceanography staff and then forwarded to the RSO for review and final authorization.

For work that is planned on other UW vessels, the application should be obtained directly from the Radiation Safety Office.

2. Clinical Use

a. Nuclear Medicine

The medical use of radioactive materials as diagnostic tracers or for therapy for certain medical conditions shall be covered under an authorization for Clinical Use in Nuclear Medicine, and the Director of that program shall be appointed the Authorized Investigator.

Form 100 – Application for Authorization to Use Radioactive Material in a Nuclear Medicine Clinic.

b. Radiation Oncology

The medical use of radioactive sources or radiation producing machines to treat cancer shall be covered under an authorization for Clinical Use in Radiation Oncology, and the Director of that program shall be the appointed Authorized Investigator.

Form 101 – Application for Authorization to Use Radioactive Material in Radiation Oncology.

3. Sealed Source Use

a. Definition

“Sealed source” means any device containing radioactive material to be used as a source of radiation, which has been constructed in such a manner as to prevent the escape of any radioactive material. For example, sealed sources may be used in irradiators, electron-capture detectors of gas chromatographs, static elimination devices, and many other applications.

b. Training

In many cases, the risks from small sealed sources may be very slight and workers would not be expected to get a measurable occupational dose. Personnel working with sealed sources need to have training commensurate with the risks of the materials they will be using or to which they may be exposed, but they may not always be required to take the UW Radiation Safety Training program. Consult with the RSO regarding appropriate instruction for sealed source use.

c. Application Forms

An investigator seeking to become an AUI for non-human use of radioactive sealed sources should request an application packet from the RSO. The packet will contain the following:

1) General

Form 11 – Description of overall proposed program.

2) Personnel

Form 20 – Description of personnel training and experience in radiation work. Each person who will be working under the proposed authorization must complete a separate form.

3) Depending on the program, other forms or attachments, as appropriate, may be required.

4. Broad Authorization

Under certain limited conditions, a Broad Authorization may be granted for programs in which the involved personnel have a high degree of knowledge, expertise, and training in the use of radioactive materials, and their program is wide-ranging in the use of those materials.

Once a Broad Authorization is in place, changes or additions to that program may be requested using either Form 12, Application for Individual Use under a Broad Authorization, or Form 14, Amendment to Use Additional Radionuclide(s).

C. Human Subjects Applications

Research involving human subject volunteers at the UW must be reviewed and approved by the Human Subjects Review Committee. If such research involves the exposure of subjects to radiation or radioactive materials, the UW Radiation Safety Committee (RSC) must also review each protocol, focusing on protecting and informing the subjects enrolling in the protocol. The RSC must be convinced that the radiation dose to the subjects is as low as possible (without compromising the outcome of the research or the quality of the medical care received by the subjects), and that the scientific merit of the proposal justifies the risk to the subjects.

1. Authorization Criteria for Human Subjects Research

A faculty member seeking to become an Authorized Investigator for research involving the use of radiation in human subjects must first meet certain criteria.

a. Health Care Practitioner

For human subjects work with radioactive materials, medical or dental diagnostic x-rays, or therapeutic radiation, the AUI/HS is usually a health care practitioner licensed by the State of Washington, and the proposed use of radiation must be within the scope of the practitioner's license.

b. Collaboration with a Health Care Practitioner

A person, who is the principal investigator in a research program, but not a licensed health care practitioner, may be approved as an AUI/HS if the actual administration of radiation is under the authorization of a licensed health care practitioner named in the application as a collaborator. The radiation use in these studies must be standard clinical procedures that are within the scope of the collaborator's licensed practice.

c. Authorization to Cover Use of Radioactive Materials

Either an active and appropriate Radioactive Materials Authorization or a Clinical Authorization must also be in effect to cover the use of radioactive materials used in the protocol. Such authorization should be in effect for the principal investigator or for a collaborator on the study.

2. Application Forms**a. General (Long Form)**

Form 30 – Application for Authorization to Use Radiation with Human Subjects at University of Washington Licensed Facilities. This is the general form that can be used for any protocol, and covers the use of radioactive materials, x-rays, and fluoroscopy.

b. Short Form

Form 31 – Short Form Application for Authorization to Use Radiation with Human Subjects at University of Washington Licensed Facilities. This form is to be used only when there are no subjects less than 18 years old involved in the study and when the radiation is only in the form of x-rays (this includes CT scans, but excludes fluoroscopy).

c. Renewal

Form 32 – Renewal Application for Authorization to Use Radiation with Human Subjects at University of Washington Licensed Facilities. This form is used to apply for annual review of studies that have been approved but will extend longer than one year.

3. Annual Review

As with the Human Subjects Review Committee, all human subjects research studies must be reviewed by the RSC on an annual basis.

D. Review of Initial Application

The completed application must be submitted to the RSO. Part of the review process is an evaluation of the appropriateness of the facilities and equipment to be used. The review includes an interview with the applicant to discuss various details of the project and radiation safety considerations.

E. Approval

Some experimental protocols involving large amounts of radioactive material or the use of radiation or radioactive material in humans may need to be presented to the RSC for full approval. However, a degree of latitude has been granted by the State of Washington Department of Health to allow the RSC to delegate some approvals of certain specific uses. For example, the Radiation Safety Officer acting alone may approve most laboratory use of radioactive materials in millicurie quantities or less. The Radiation Safety Officer and Scientific Executor acting together may approve some other specific uses of radioactive material and specific clinical applications of radiation. The entire RSC may still choose to review any authorization.

If an application is approved, the authorization form is signed and forwarded to the Authorized Investigator

F. Renewal

1. General Laboratory or Sealed Source Use

The Radiation Safety Officer and the Scientific Executor, acting together, may renew any authorization for laboratory work that was initially approved, according to current practices and criteria. At the discretion of the Radiation Safety Officer and Scientific Executor, the renewal may be referred to the full committee.

2. Human Subjects

The Radiation Safety Officer and the Scientific Executor, acting together, may renew four consecutive annual renewals of any authorization that involves the administration of radiation to human subjects. The Radiation Safety Officer, acting alone, may approve the renewal of any authorization for a research study that involves the administration of radiation to human subjects, in which no subjects have yet been enrolled.

G. Non-Approval of an Application

If approval of a project is not granted, a written notification, including an explanation for the decision, is forwarded to the applicant. The notification may contain a description of the possible modifications to the project that would be necessary for it to be approved.

1. Appeal Process

An appeal of any decision of the UW Radiation Safety Committee (UWRSC) or a decision of the Radiation Safety Officer and/or the Scientific Executor, which is made within the delegated authority of the UWRSC, can be made to the UWRSC.

a. Basis

An appeal of a UWRSC decision may be initiated for any of the following reasons:

- 1) The applicant considered the decision improper.
- 2) The decision was considered improper by a minority of the RSC.
- 3) Other persons who have a qualified interest in the decision considered the decision improper.

b. Submittal

An individual effected by a UWRSC decision, a UWRSC member, or a person who has a qualified interest in the decision, should present an appeal to the Chairman of the RSC. The appeal must be in writing and include additional supporting information or specific arguments in rebuttal to the Committee's explanation of the decision.

c. Processing

At the discretion of the Chairman, with the advice of the Scientific Executor, the Chairman must either return the matter to the UWRSC to be reheard or present the appeal to the Executive Director of Health Sciences Administration.

d. Second Hearing

If a second hearing by the UWRSC results in a continuing basis for appeal, the appellant should request that the Chairman present the issue to the Executive Director of Health Sciences Administration.

2. Limitation of Appeal

UWRSC action to deny use of radiation is normally final. However, the Executive Director of Health Sciences Administration may refer the action back to the committee if proper procedures were not followed.

H. Amendments

Requested changes will be subject to the same review and approval process as was the original application. The Authorized Investigator is notified of the approval of a change through an amendment to his or her authorization.

1. Major Changes

If an AUI wishes to make several major changes to his or her authorization, it may be necessary to conduct a review of the entire program. The decision as to whether or not a complete review is necessary will be made by the RSO.

2. Forms

An Authorized Investigator may request changes to his or her authorization by submitting the requested change in writing or by email. For many changes, the appropriate form should also be submitted.

a. Radionuclide

Form 14 – Used to request authorization for a new radionuclide, new physical/chemical form of a previously approved radionuclide, or an increase in the possession limit for a previously approved radionuclide.

Requests to delete a radionuclide from the list of allowed radionuclides, may be accomplished by memo or email.

b. Personnel

Form 20 – Used to add a participant to the authorization. The AUI may inform the RSO of personnel terminations via memo or email.

c. Laboratory Registration

1) New Lab

Form 50 – Used to request the addition of a new laboratory or work space. A separate form must be completed for each space.

2) Revision of Use within a Lab

Form 50R – Used to revise conditions of use within a previously certified laboratory. This form will also be required as part of any major review of an authorization.

3) Inactivation/Termination

Requests to inactivate or terminate laboratories may be accomplished by memo or email.

d. Instrument Registration

Form 51 – Used to add a new radiation detection instrument to the authorization. A separate form must be filled out for each instrument.

I. Termination/Inactivation of Authorization

Prior to closing a laboratory or other area where radionuclides have been used or stored, the Authorized Investigator must develop a plan for terminating or inactivating these areas. Termination refers to the decommissioning of laboratory space that will no longer be under the control of the Authorized Investigator or perhaps even the University. Inactivation means that the Authorized Investigator retains control of the laboratory space, yet does not have current need to use radioactive materials in his/her research program.

1. Notification

Prior to termination or inactivation, advance notification must be given to the Radiation Safety Office. RS staff needs to arrange for some coordination and oversight. This is especially important for facilities where UW possession of the property is being relinquished. In this situation, the State of Washington DOH will need to be involved with decommissioning activities. Other offices within UW Environmental Health and Safety Department also need advance notification for decommissioning activities, such as chemical disposal.

2. Transfer

The Authorized Investigator must arrange for the transfer of any remaining radioactive materials to another Authorized Investigator, or apply for the use of another space using RSO Form 50.

3. Decontamination

Decontaminate all laboratory surfaces to levels suitable for unrestricted release. See Section 1 - Emergencies Involving Radiation for acceptable residual contamination levels.

4. Termination Survey

A final termination survey must be done after all radiation use has ceased and decontamination has been completed. Records documenting the level of remaining contamination must be generated. RS staff will also do a confirmation survey after termination.

5. Financial Responsibility

The Department under which the Authorized Investigator is employed will be held responsible for any costs associated with additional decontamination or disposal of equipment and waste to facilitate unconditional release.

J. Radiation Worker

A radiation worker is a person listed on an authorization and who is allowed to work independently with radioactive materials under an Authorized Investigator.

1. Application

Any person who wishes to be approved as a radiation worker must submit a completed Form 20 to the Radiation Safety Office. Note that this application must be submitted only with the knowledge of the Authorized Investigator.

A Form 20 may be submitted for an individual at the time of the Authorized Investigator's initial application for project approval or at any time thereafter. The Authorized Investigator will be notified of the approval of personnel additions to his or her project through an amended authorization.

2. Training

Almost every radiation worker at the University of Washington must take the Radiation Safety Training Course given by the Radiation Safety Office. The exceptions are some users of sealed sources and certain individuals in clinical programs that have received extensive and specialized training in handling radioactive materials. This training is in addition to job specific training required to be given by the Authorized Investigator or his/her designee (see Section 5 - Training).

a. New Authorization

A new Authorized Investigator and the staff that will be put on the authorization must take the UW Radiation Safety Training Course before a new authorization will be approved.

b. Existing Authorization

Before being added to an authorization to use radioactive materials as a certified radiation worker, an individual must first complete the UW Radiation Safety Training Course.