

UNIVERSITY OF TOLEDO

SUBJECT: Non-Clinical Authorized Users

Procedure No: HM-08-052

PROCEDURE STATEMENT

The Radiation Safety Committee shall oversee the approval of all Non-Clinical Authorized Users

PURPOSE OF PROCEDURE

To work within the Radiation Safety Committee (RSC) to approve or deny applications for use of radioactive material in non-clinical research settings through established guidelines and ensure the safe use of radioactive material within the scope of ODH regulations and University of Toledo policies and procedures to ensure the safety of staff and students.

DEFINITION

Non-Clinical Authorized Users (AU) are generally the principal investigators in laboratories using radioactive materials. They are responsible for supervising the proper purchasing, storing, using, and disposing of radioactive materials within their individual laboratories. They are also responsible, along with the RSO, for the training of all others using radioactive materials within their individual laboratories. Authorized Users are subject to directives of the Ohio Department of Health, Radiation Safety Committee, RSO, and all University of Toledo policies and procedures. Authorized Users will take action to restrict exposure to radioactive materials, this is in keeping with the need to limit exposure to as low as reasonable achievable.

PROCEDURE

1. To become an AU in a Non-Clinical Research Setting, an individual must:
 - a. Be a faculty member.
 - b. Have a Ph.D. in biological, chemical, or engineering sciences.
 - c. Have formal training or supervised laboratory experience of no less than 40 hours with the use of radioactive material.
 - d. Have formal or supervised laboratory training with the hazards associated with the use of radioactive material.
 - e. Attend the University of Toledo 3-hour Radiation Safety Seminar.
 - f. Complete the form "Application for Use of Radioactive Materials"
 - g. Request and receive approval to become an AU from the University of Toledo Radiation Safety Committee.
2. If the request to become an AU in a Non-Clinical Research Setting is approved by the Radiation Safety Committee, a Certificate of Use will be created listing:
 - a. Radionuclides permitted
 - b. Physical form of radionuclide permitted
 - c. Chemical form of radionuclide permitted
 - d. Maximum activity of each radionuclide permitted per order
 - e. Maximum total activity of each radionuclide that the AU may possess at one time.
 - f. The assigned Certificate of Use number
 - g. The expiration date of the Certificate of Use (5 yrs. from date of approval)
3. If the request to become an AU in a Non-Clinical Research is denied by the Radiation Safety Committee the applicant will be informed of the reason.

RENEWAL OF NON-CLINICAL AU CERTIFICATE OF USE

Certificates of Use are issued for a period of five years. Six months prior of the Certificate of Use expiration date, to allow sufficient time to satisfy renewal requirements, the Non-Clinical AU's will be contacted by the RSO to see if they wish to renew the Certificate of Use and if they desire any changes to the Certificate of Use.

1. If the Non-Clinical AU would like to renew the Certificate of Use for an additional 5 year period **with no changes** and **has used radioactive material in the previous 5 years**, the request will be presented to the RSC for approval or denial. Approval or denial of the request will be based primarily on the Non-Clinical AU's history of compliance with ODH regulations, University of Toledo Radiation Safety policies and procedures, and compliance with annual Radiation Safety Training requirements.
2. If the Non-Clinical AU would like to renew the Certificate of Use for an additional 5 year period **to include changes**, and **has used radioactive material in the previous 5 years**, the Non-Clinical AU must complete and submit the Radioisotope Amendment Request form to the RSO. The request and amendment form will be presented to the RSC for approval or denial based on the Radioisotope Amendment Request and the Non-Clinical AU's history of compliance with all ODH regulations, University of Toledo Radiation Safety policies and procedures, and compliance with annual Radiation Safety Training requirements.
3. If the Non-Clinical AU would like to renew the Certificate of Use for an additional 5 year period **with or without changes** and **has not used radioactive material in the previous 5 years**, the Non-Clinical AU must first repeat the 3-hour Radiation Safety Seminar. After completion of the Radiation Safety Seminar, the request will be presented to the RSC for approval or denial based primarily on the Non-Clinical AU's history of compliance with ODH regulations, University of Toledo Radiation Safety policies and procedures, and compliance with annual Radiation Safety Training requirements.
4. If the Non-Clinical AU would like to renew the Certificate of Use for an additional 5 year period **with or without changes and has radioisotope inventory but has not used the inventory in the previous 5 years**, the Non-Clinical AU must first repeat the 3-hour Radiation Safety Seminar. After completion of the Radiation Safety Seminar, the request will be presented to the RSC for approval or denial based primarily on the Non-Clinical AU's history of compliance with ODH regulations, University of Toledo Radiation Safety policies and procedures, and compliance with annual Radiation Safety Training requirements.
5. If the Non-Clinical AU does not wish to renew the Certificate of Use for an additional 5 year period the RSC will be informed that the individual is no longer a Non-Clinical AU.
6. If any Non-Clinical AU's request to renew the Certificate of Use is denied by the RSC, the applicant will be informed of the reason and may appeal the decision to the RSC in writing. A Non-Clinical AU may be present at the next RSC meeting when the appeal is presented to the Committee.