



ENVIRONMENTAL HEALTH & SAFETY | RADIATION SAFETY

and

COMMITTEE ON IONIZING RADIATION

OFFICE OF THE ASSISTANT VICE CHANCELLOR FOR REGULATORY COMPLIANCE

RAM Application for Medical Research (Authorized User)

FOR EHS USE ONLY

HuCIR application no.

This form is for **new** applications. For renewals and minor amendments, contact radapphu@ucdenver.edu.

Submit completed form – *typed only, not handwritten* – to radapphu@ucdenver.edu.

Submit with this application copies of approved authorizations from the following:

- Colorado Multiple Institutional Review Board (COMIRB)
- Radioactive Drug Research Committee (RDRC)
- University of Colorado Hospital Radiation Safety Committee
- Clinical Trials Research Committee (CTRC)

This application will be rejected if any of the above is omitted. For any that are not required, attach signed correspondence from the relevant committee stating why it is non-applicable.

I. PI Information Refer to EHS [Radiation Safety Manual](#), Sec. 2.4.2, 2.4.11, and 2.4.14

PI: _____ Phone: _____

Faculty position: _____ Department: _____

Co-investigator: _____ Phone: _____

Faculty position: _____ Department: _____

II. Location of Use

Use on UCHHealth property requires application to the University of Colorado Hospital Radiation Safety Committee.

Building: _____ Room no(s): _____ Fume hood room no.: _____

BSC #: _____ Certification date: _____ Serial no.: _____

III. Radiation Workers Refer to EHS [Radiation Safety Manual](#), Sec. 2.4.8, 2.4.10, and 2.4.13.

Name: _____ Name: _____

Name: _____ Name: _____

Name: _____ Name: _____

Name: _____ Name: _____

IV. Radioactive Material and Amounts

Isotope: _____ Half-life: _____ Maximum radiation energy (MeV): _____

Type of decay: _____ Compounds: _____

Radioactivity to be used per patient: _____ mCi

Estimated no. of patients per month: _____

Radioactivity used per month: _____ mCi

Estimated no. of patients per year: _____

Possession limit (~2 x monthly use): _____ mCi

Yearly limit (~12 x monthly use): _____ mCi

V. PI Training and Experience

A. Presently authorized as PI with other radioisotopes: Yes No

If **yes**, complete below:

Authorization no.: _____ Isotope: _____ Possession limit: _____ mCi Yearly limit: _____ mCi

Authorization no.: _____ Isotope: _____ Possession limit: _____ mCi Yearly limit: _____ mCi

Authorization no.: _____ Isotope: _____ Possession limit: _____ mCi Yearly limit: _____ mCi

If **no**, complete EHS [RAM PI Training](#) and enter date of certification: _____

B. State of Colorado medical license number: _____

C. Certification / Attestation / Experience

1. Board Certification

a. Is applicant board certified?

Yes (Attach certificate.) Date of certification: _____

No

List of specialty boards: <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

b. Has applicant provided written attestation(s), signed by a preceptor authorized user, confirming the level of competency of the applicant sufficient to function independently as an authorized user for the medical uses detailed in this application?

Yes (Attach signed attestation letter.)

Date of letter (must be within 7 years of date of this application): _____

No

EHS USE ONLY	Does the preceptor meet the requirements of Appendix 7E, or Appendix 7F, and the requirements specified in 7E3.1(2)(g), or equivalent Agreement State or NRC requirements?	Yes
		No

2. Attestation Letter (classroom, laboratory and work experience)

- a.** Has applicant provided written attestation(s), signed by a preceptor authorized user, affirming that the applicant has satisfactorily completed 700 hours in basic radionuclide handling techniques applicable to medical use of unsealed radioactive materials for imaging and localization studies, and affirming a level of competency sufficient to function independently as an authorized user for the medical uses detailed in this application?

Yes (Attach signed attestation letter.)

Date of letter (must be within 7 years of date of this application): _____

No

- b.** Training must include at least 80 hours of classroom and laboratory training in the following:

		Hours
Formal instruction	Radiation physics and instrumentation	
	Radiation protection	
	Mathematics pertaining to the use and measurement of radioactivity	
	Chemistry of radioactive material for medical use	
	Radiation biology	
Work experience	Ordering, receiving, and unpacking radioactive material safety, and performing related radiation surveys	
	Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters	
	Calculating, measuring, and safety preparing patient or human research subject dosages	
	Using administrative controls to prevent a misadministration involving unsealed radioactive material	
	Using procedures to contain spilled radioactive material safety, and using proper decontamination procedures	
	Administering dosages to patients or human research subjects	
	Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	

3. Adequate Prior Experience

- a.** Is applicant currently identified as an authorized user on a facility license or permit under Appendix 7F {also meeting the requirements specified in 7E3.1(2)(g)}, or under the equivalent Agreement State or NRC requirements?

Yes; license or permit number: _____

No

B. Will the compound ever be in volatile or unbound form? Y N

If yes, describe the precautions taken to control and reduce exposure from a release.

C. Methods and precautions to be used to protect radiation workers from internal/external radiation exposure.

Refer to EHS [Radiation Safety Manual](#), Sec. 3.4.3, 3.4.4, 3.4.5, pgs. 42-60.

Example:

1. Workers will maintain their exposure as low as practical.
2. Dosimeters will be worn on the appropriate body part when working with radioactive materials.
3. No food or drink will be allowed in the laboratory.
4. Hands, shoes, clothing and skin will be surveyed before a worker leaves the laboratory.
5. When using radioactive materials, workers will wear goggles, lab coats, eye protection, close-toed shoes and long pants.

D. Precautions to be taken to ensure security of all radioactive materials, including waste and stock.

Example:

1. Refrigerators and freezers storing radioactive materials will be locked.
2. Waste containers will be stored in a locked cabinet.
3. The door to the laboratory will be closed and locked when no one is present.
4. Laboratory personnel will notice and challenge everyone who enters the laboratory who is not associated with the laboratory.

VIII. Radiation Monitoring

Refer to EHS [Radiation Safety Manual](#), Sec. 2.4.8, 2.4.10, and 2.4.13.

A. Portable survey instrument(s)

Each PI must **own** a portable survey instrument, except those using **only H-3**.

Make: _____ Model: _____ Serial no.: _____

Calibration due: _____ Probe model: _____ Probe serial no.: _____

Make: _____ Model: _____ Serial no.: _____

Calibration due: _____ Probe model: _____ Probe serial no.: _____

B. Liquid scintillation counter

Make: _____ Model: _____ Serial no.: _____

Calibration due: _____ Location: _____

C. Gamma counter

Make: _____ Model: _____ Serial no.: _____

Calibration due: _____ Location: _____

D. Frequency of contamination surveys (swipes tests, portable instrument sweeps)

Documented surveys must be performed in accordance with the Laboratory Hazard Classification requirements. Refer to EHS [Radiation Safety Manual](#), Appendix XV.

Daily Weekly Monthly

Location where survey records will be stored: _____

IX. Radioactive Waste Handling and Disposal

A. Describe the waste handling steps of the experiment.

Be explicit and detailed. EHS recommends attaching a flow chart showing the waste-handling steps.

Example:

All Eppendorf tips and tubes are deposited into a plastic container used exclusively for 32P waste, kept behind an acrylic shield. This container is periodically emptied into the bulk dry radioactive waste. Used buffer and gel soaking solutions are collected in the liquid radioactive waste. The wrapped, discarded gel, elution membranes and Spin-X cartridges, and elution tips are disposed as solid waste. Organic solutions, such as ethanol, are collected as mixed waste. Vials containing organic solutions will be collect in vial trays and labeled as "Mixed Waste."

B. Will chemical/radioactive mixed wastes be produced?

Refer to EHS [Radioactive Waste Disposal Manual](#), Sec. II G and IV C, E and K for classification of mixed wastes.

Y N

If **yes**, provide justification for production of these wastes here, and complete the "Organic" row in Table D.

C. Will infectious radioactive wastes be produced, requiring disinfection and collect as biological non-carcass material?

Refer to EHS [Radioactive Waste Disposal Manual](#), Sec. II G, and IV G and I for classification of biological non-carcass waste.

Y N

If **yes**, describe the method for disinfection here, and complete "Biological (non-carcass)" in Table D.

D. Anticipated waste forms, volumes, and percentages of total radioactivity

Refer to EHS [Radioactive Waste Disposal Manual](#), Sec. II G, and IV G and I for classification of biological non-carcass waste.

Waste Type	Volume Generated Monthly	Percent of Total Radioactivity	Disinfection Required (as indicated in C, above)	
			Yes	No
Dry solids	cubic feet			
Aqueous	gallons			
Scintillation vials Cocktail manufacturer: Product name:	(# of trays)			
Biological non-carcass	cubic feet			
Organic (see item IX, section B, above)	gallons			
Other				

By my signature, below, I agree that all radioactive materials procured as a result of this application will be used only as specified above, and in accordance with the guidelines of the EHS Radiation Safety Manual, as well as all other applicable university policies and procedures, the University Radioactive Materials License, and state and federal regulations.

PI signature: _____ Date: _____

Co-Investigator signature: _____ Date: _____