



ENVIRONMENTAL HEALTH AND SAFETY | RADIATION SAFETY

Radioactive Materials Application – Human Use

**Committee on Ionizing Radiation
Office of the Assistant Vice Chancellor for Regulatory Compliance**

CIR Application Number (For EHS Use Only)

Please submit copies of approved authorizations from the following:

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

NOTE: This application will be rejected if any one of the above is omitted. If one of the above is not required, you must attach signed correspondence from the respective committee which states why it is non-applicable.

This form is for **New Applications**. If your authorization needs renewal or minor amendments, please contact EHS for the applicable form (303-724-0345). Submit your completed application to RadAppHU@ucdenver.edu.

THIS APPLICATION MUST BE TYPED (available in Word format by contacting EHS at 303-724-0345)

I. PI Information

(Refer to EHS Radiation Safety Manual, Sec. 2.4.2, 2.4.11, and 2.4.14)

Principal Investigator	Faculty Position
Department	PI Phone

Co-Investigator	Faculty Position
Department	Co-Investigator Phone

II. Location of Use

(Use on University Hospital Property requires application to the University Hospital Radiation Safety Committee)

Building	Room Number(s)	Fume Hood Rm #
Biosafety Cabinet Rm # (If Applicable)	Make/Model:	S/N:

III. Radiation Workers

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

1.	2.
3.	4.
5.	6.
7.	8.

IV. Radioactive Material and Amounts

Isotope		Half-life of Isotope		Maximum Radiation Energy (MeV)	
Type of Decay (Alpha, Beta, Gamma)			Compounds		
A. Radioactivity to be used per experiment		mCi			
B. Estimated # of experiments/month					
C. Radioactivity used/month		mCi			
Possession Limit (~2x C)	mCi		Yearly Limit (~12x C)	mCi	

V. Principal Investigator Training and Experience

A. Are you presently authorized as a PI with other radioisotopes?		YES <input type="checkbox"/>	NO <input type="checkbox"/>
If YES, list your authorization numbers below			
Authorization #	Isotope:	Possession Limit	mCi Yearly Limit mCi
Authorization #	Isotope:	Possession Limit	mCi Yearly Limit mCi
Authorization #	Isotope:	Possession Limit	mCi Yearly Limit mCi
If NO, you must pass the university certification tests given by EHS for the PI Level.			
Date of certification:			

B. Training Received in Basic Handling Techniques for Radioactive Material

(Note: The CIR may not review this application if experience/training information is omitted. Below is NRC Form 313M Supplement A equivalent)

Field of Training	Location and Dates of Training	Lecture or Laboratory Courses (Hours)	Supervised Laboratory Experience (Hours)
	<i>For Example... CU Anschutz Medical Campus, Aurora, CO (Mod 1) 07-01-2010</i>	<i>1 Hour</i>	<i>5 Hours</i>
1. Radiation Physics and Instrumentation			
2. Radiation Protection			
3. Mathematics Pertaining to the Use and Measurement of Radioactivity			
4. Radiation Biology			
5. Radiopharmaceutical or Chemistry			

C. Experience with Radiation and Radioactive Materials

Radionuclide(s)	Maximum Amount (mCi), respectively	Where Experience Gained	Duration	Type of Use

<i>For Example... I-125, P-32</i>	<i>0.5, 1.0</i>	<i>Univ. of Washington</i>	<i>1980 – 1988</i>	<i>Labeling cells, DNA for biochemical and molecular analysis</i>

VI. Plan of Investigation

A. Study Classification (check one):

- Basic human research (tracer studies, etc., with a compound not being developed as a radiopharmaceutical.)
- IND (Investigational New Drug Application)
- Routine Nuclear Medicine Procedure being used for research purposes

B. Dose Scheme:

Dose administered (in mCi):	Number of Doses administered per subject:
Number of subjects per year:	
Chemical and physical form of dose:	
Route of administration (IV, oral, etc.):	

C. Dose Preparation:

(Describe the chemical and physical handling steps involved in preparing the dose, along with any radiation safety precautions that will be observed in preparing and transporting the dose).

VII. Exposure Control and Monitoring

A. Do you subscribe to the EHS dosimetry badge service?

(Note: badges are not required for pure beta emitters with maximum energies less than 0.5 MeV – e.g. H-3, C-14, S-35)

YES

NO

Comments

B. Describe the methods and precautions that will 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)

For Example:

- 1. Workers will maintain their exposure as low as practical.*
 - 2. Dosimetry badges, if applicable, will be worn on the appropriate location when working with radioactive materials.*
 - 3. No food or drink unrelated to the study is allowed in the laboratory.*
 - 4. Hands, shoes, coat, and skin will be surveyed before leaving the laboratory.*
 - 5. When working with radioactive materials, workers will wear goggles, lab coats, eye protection, closed toed shoes and long pants.*
- ETC...*

C. Describe the precautions that will be taken to ensure security of all radioactive materials, including waste and stock material

For 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 in the laboratory.
 4. Laboratory personnel will notice and challenge everyone who enters the laboratory who is not associated with the laboratory.
- ETC...

VIII. Radiation Monitoring

(Refer to EHS Radiation Safety Manual, Sec. 2.4.13 and 3.4.3)

A. Portable survey instrument(s)

(Each PI must OWN a portable survey instrument, except those using H-3 ONLY)

Make		Model		S/N	
Calibration Due Date:		Probe Model		Probe S/N	
Make		Model		S/N	
Calibration Due Date:		Probe Model		Probe S/N	

B. Liquid Scintillation Counter

Location		Make		Model		S/N	
Calibration Due Date:							

C. Gamma Counter

Location		Make		Model		S/N	
Calibration Due Date:							

D. Frequency of Contamination Surveys (swipe tests, portable instrument sweeps)

(Note: Documented surveys must be performed in accordance with the Laboratory Hazard Classification requirements, refer to EHS Radiation Safety Manual, Appendix XV)

Daily	<input type="checkbox"/>	Weekly	<input type="checkbox"/>	Monthly	<input type="checkbox"/>
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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 to include the waste handling steps)

For Example: All Eppendorf tips and tubes are deposited into a plastic container used exclusively for 32P waste kept behind a Plexiglas™ 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 collected in vial trays and labeled as "Mixed Waste".

B. Will you produce any chemical-radioactive mixed wastes?

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

YES

NO

If YES, please justify the production of these wastes here and complete the "Organic" row in the table "D." below.

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C. Will you produce any infectious radioactive wastes that require disinfection and collection 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)	YES <input type="checkbox"/>	NO <input type="checkbox"/>
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If YES, please describe the method for disinfection here and complete the "Biological (non-carcass)" row in the table "D." below.

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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 per Month	% of Total Radioactivity	Requires Disinfecting (as indicated in Item IX Section C above)
Dry Solids	(cubic feet)		YES <input type="checkbox"/> NO <input type="checkbox"/>
Aqueous	(gallons)		YES <input type="checkbox"/> NO <input type="checkbox"/>
Scintillation vials	(# of trays)		YES <input type="checkbox"/> NO <input type="checkbox"/>
Cocktail mfr/product name			
Biological (non-carcass)	(cubic feet)		YES <input type="checkbox"/> NO <input type="checkbox"/>
Organic (please justify in Item IX Section B above)	(gallons)		YES <input type="checkbox"/> NO <input type="checkbox"/>
Other			YES <input type="checkbox"/> NO <input type="checkbox"/>

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 University Radiation Safety Manual, as well as all other applicable university policies and procedures, the University Radioactive Materials License, and state and federal regulations.

Signature of PI	Date
Signature of Co-Investigator	Date