RESET FORM

APPLICATION FOR THE USE OF RADIOACTIVE MATERIAL BIOMEDICAL RESEARCH

HPO-FORM 001(a)) Revised June 14, 2021

1. Submit original and two copies to the Radiation Safety Office.
2. Each approved application is valid only for the user, request radioisotope, location and for one year.
3. The AU user is required to submit a renewal application 30 days before expiration date of current license.
4. New applicants should submit an application form and should comply with all the requirements of the RSC/RSO

1. Name of Principal Investigator:

2. Department and Lab Number:

3. Telephone and extension number:

4. E-mail of Principal Investigator:

Please indicate:
New Application: _____
Renewal Application: _____
If any changes, please detail in item # 17

5. Brief past experience and training of above named individual in the use of radioisotopes

6. Title of experiment proposal	7. Funding Source(s)

8. Name of Authorized Personnel Handling Radioisotopes under applicant supervision.	9. ☐ Undergraduate ☐ Graduate student ID number required	10. ☐ MSC Employee Position required

11. Brief past experience and dates of radiation safety training of authorized personnel handling radioisotopes under applicant supervision.

12. Radioisotope(s) requested: ☐ ^{14}C ☐ ^{3}H ☐ ^{32}P ☐ ^{35}S ☐ ^{125}I ☐ ^{99M}Tc

13. Name(s) of radioactive compound(s) (Physical and Chemical forms):

14. Maximum amount that licensee may order per fiscal year under this license (specific amount per radioisotope in mCi or uCi):

Activity limits (amount / isotope mCi or uCi)	☐ ^{14}C	☐ ^{3}H	☐ ^{32}P	☐ ^{35}S	☐ ^{125}I	☐ ^{99M}Tc
Amount requested per year:						
Renewals: Indicate current amount in freezer:						
Renewals: Indicate current amount of waste:						
Amount approved by RSC / isotope:						

Reporting Small Quantity Protocol Radioactive Material Balance in grams:

Radioactive Material	Amount Received (Grams)	Date Received	Amount Removed (Grams)	Date Removed	Amount Remains (Grams)	Date Reported	Amount Radioactive Waste
Uranyl Acetate							
Uranyl Nitrate							
Uranyl Formate							
Uranyl Oxalate							
Magnesium Uranyl Acetate,							
Other							

15. Other Potential Hazards:
16. Name and address of commercial vendor:
17. For Renewal Applications. Please indicated if there have been any changes in the following areas:

Any changes in the following areas?	Yes	No	If yes, please detail
Radioisotope:	☐	☐	
Protocol(s):	☐	☐	
Personnel:	☐	☐	
New Equipment:	☐	☐	
Decommission Equipment	☐	☐	
Facility, reorganization:	☐	☐	
New Small Quantity Protocol Radioactive Material	☐	☐	

18. Description of experimental procedure with radioactive material:

19. Will the project involve administration of radioactive material?

To animals: ☐ Yes ☐ No

To humans: ☐ Yes ☐ No

For Electronic Microscopy ☐ Yes ☐ No

20. Description of safety procedures while handling radioactive material:
May use additional pages if necessary

21. Instruments available in the immediate area:

a. Radiation Survey Instruments b. Radioactivity Instruments

Survey Instruments	☐ Geiger Counter Instrument (GM)		☐ Liquid Scintillation Counter
	Instrument	Probe	
Manufacturer:			
Model:			
Series Number:			

22. Signature of Principal Investigator: _____ Date: _____

23. Signature of users under AU supervision:

Print Name: _____ Signature: _____
Print Name: _____ Signature: _____
Print Name: _____ Signature: _____
Print Name: _____ Signature: _____
Print Name: _____ Signature: _____
Print Name: _____ Signature: _____

FOR THE USE OF THE RADIATION SAFETY COMMITTE

24. Radiation Safety Committee amount approved / isotope:

☐ ^{14}C	☐ ^{3}H	☐ ^{32}P	☐ ^{35}S	☐ ^{125}I	☐ ^{99M}Tc

Radioactive Material	Amount Approved (Grams)
Uranyl Acetate	
Uranyl Nitrate	
Uranyl Formate	
Uranyl Oxalate	
Magnesium Uranyl Acetate,	
Other	

25. Signature of RSC President: _____ Approved Date: _____

26. Signature of RSO: _____ Approved Date: _____

27. Expiration date: _____

Note: The principal investigator must present evidence of Radiation Safety Training of all personnel handling radioisotopes before summiting this application. Also they are required to take the Radiation Safety Training offered by the Office of Laboratory Safety in Research before beginning with their duties and an annual refresher course. For further information, please contact us at phone number (787) 758-2525 ext. 1687, 1688.

INSTRUCTIONS FOR APPLICATION OF RADIOISOTOPE PRINCIPAL INVESTIGATOR (HPO-FORM 001(a))

The HPO-Form 001(a) must be completed online, website (http://committees.rcm.upr.edu).

Eligibility: Only faculty members are allowed to apply for a radioisotope license. Students and laboratory technicians may use radioisotopes under the supervision of a licensed authorized user. By signing this application, the authorized user is agreeing that byproduct material will be used only by, or under the direct supervision of, individuals who have at least 40 hours of training and have experience in the safe handling of radioactive materials.

New users: Please indicate if you are applying for the first time. You are require to present evidence of adequate training in radiation protection and experience handling the types and quantities of licensed material that is propose to use. Also need to take the Radiation Safety Training offered by the Office of Laboratory Safety in Research and there after an annual refresher course

Renewals: If you are renewing your license, please indicate if there have been any changes and provide detail of changes on item 17. You and your lab personnel are require to take the Radiation Protection refresher course.

All applicants should submit two copies of the application and documents to the Radiation Protection Office (RPO) in 30 days before expiration date of the current license. Qualified individuals of the UPR- Medical Sciences Campus as authorized by the Radiation Safety Committee and engaged as principal investigators and/or have significant responsibility for administrative, medical, academic or experimental functions involving radioisotopes and can demonstrate an acceptable level of confidence in the safe handling of radioactive materials. Approved application is valid only for the authorize user, request radioisotope, location and equipment. New applicants for the use of radioactive materials should submit an application to the Radiation Protection Office for the RSC evaluation and approval. Please indicate if you are applying for the first time (New Application) or if you are renewing the application (Renewal Application). If you are renewing your application and there has been any changes, please detail it on item 17.

1. Name of applicant performing immediate supervision of laboratory operations.

2. Write the department and the laboratories number were radioisotopes are going to be handled.

3. Write the laboratories telephone and the extension number.

4. Write the principal investigator's e-mail address.

5. Applicant must submit a statement that byproduct material will be used only by, or under the direct supervision of, individuals who have received: at least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used (20 CFR 33.15 (b) (2)).

   Write a brief description of direct laboratory experience with radioisotopes university where used, type of protocol (e.g., in vivo, in vitro). Include the dates of any radiation safety

trainings in the use, management and disposal of radioisotopes. List radioisotope courses, where and when taken.

6. Write the title(s) of the experiment(s) proposal(s).

7. Indicate funding sources for the investigational proposal.

8. List all technical personnel and students who will be handling radioisotopes. Give a brief description of radioisotope experience of individuals using the produced radioisotope under applicant's supervision. Indicate if hold certificate from MSC training course. This personnel list should be periodically up-dated.
   Note: Only individuals Scientists, Program Directors, and/or investigators at staff positions may be authorized by the Radiation Safety Committee to use radioactive materials in research activities at the UPR-Medical Sciences Campus. Candidates should submit evidence of training and experience in accordance with the requirements of 20 CFR 33.15 (b) (2).

   Research activities, ancillary personnel and radiation workers must receive instruction as specified in 10 CFR-19.12. Then the radiation Safety Committee and RSO should provide that the authorized user and personnel supervisor verify that all laboratory personnel will be properly instructed before assuming duties and whenever there is a significant change in duties, regulations, or the terms of the Institutional License.

   It is required to present copies of certificates of training to courses with the application.

9. Indicate status of undergraduate or graduate students. Please write the students identification number.

10. Please indicate if the technical personnel and students are MSC employee. Write their position.

    Note: It is required to present a copy of the MSC employee's identification card and MSC students ID.

11. Write a brief past experience and dates of radiation safety training of authorized personnel handling radioactive materials under applicant's supervision. New candidates should submit evidence of training and experience in accordance with the requirements of 10 CFR 33.15 (b) (2) that justify the safety of handling radioactive material.

12. Indicate with an (X) the radioisotope to be used.

13. Please indicate the radioactive compound(s) including physical and chemical forms (i.e 1251 estradiol; 35S enkephalin).

14. The NRC license states precisely the quantity of each radioisotope that is permitted on the MSC at any one time. Amendments are possible, but must be justified. Consider your experimental protocol and answer the questions carefully. What is the maximum to be used in a single experiment? How much will be ordered in a single shipment? How much will be ordered per fiscal year? When selecting limits, take into consideration the price and size of the commercially available material of interest.

You should also indicate the amount of radioactive material stored in your laboratory freezer in millicuries (mCi) or microcurie (uCi). Also indicate the amount of radioactive waste generated in your laboratory in millicuries (mCi) or microcurie (uCi).

Please note that the quantities requested must have the correct activity unit in terms of milli-curies (mCi) or micro- curies (uCi). Requests for very large quantities of radioisotope should be fully justified on a continuation page. Failure to supply this information correctly is the most common reason that applications are returned to the originator for clarification.

15. Is radioisotope a gamma or hard beta emitter? Is radioactive gas generated? Other hazard?

16. Company from which radioactive material will be purchased. New suppliers may request from you a copy of the MSC-NRC license. (Consult the RSO).

17. If you are renewing your application indicate any changes in the following areas please detail:
    - Radioisotope(s)
    - Protocol(s)
    - Personnel
    - New equipment
    - Decommission Equipment
    - Facility or reorganization

18. Investigators or directors of research protocols involving the use of radioactive materials "in vitro" or animals will also have to provide the information requested in this form and fulfill the minimum experience and training. Applicant will submit a complete protocol describing his research plan to include its rationale, background, methods and a description of measures employed to minimize radiation exposure to the experimenter, any human subjects and the protection of the environment.

19. Indicate if experiment will involve humans or animals.

Before allowing an individual to care for animals used in studies with or treated with licensed material, the Radiation Safety Officer (RSO), Authorized User (AU), and/or veterinarian must ensure that he or she has sufficient training and experience to maintain doses ALARA, control contamination, handle waste appropriately, etc.
Classroom training may be in the form of lecture, video tape, or self-study and should cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training should consist of:
- Observing authorized personnel using survey equipment, using proper contamination control techniques, and proper disposal of radioactive material

- Using survey equipment, proper contamination control techniques, and proper disposal of radioactive material procedures under the supervision of, and in the physical presence of, an individual authorized to handle animals treated with licensed material or otherwise containing licensed material.

Note: It is also required by the Radiation Safety Committee to present a copy(s) of the experiment(s) proposal(s) for evaluation of the applicant request.

20. Present a brief description of safety procedures in the use, management and disposal of radioactive material. Indicate clearly how the radioisotope will be used (in vitro, in vivo, etc.,), what quantities will be utilized per experiment, what potential hazards (if any) are present in the experimental protocol, in which room and in which part of the room (table-top, hood, etc.) will the radioisotope be used. Also describe the procedure used for receiving and opening of radioactive materials packages in your laboratory, describe the survey contamination methods used in your laboratory after each experiment, indicate the survey instruments used for this purpose, what types of radioactive waste will be generated and how will they be disposed. How are you going to handle the radiation exposure of the personnel under the principal investigators supervision. (Consult the RSO for assistance, if necessary).

21. List instruments available and the following information must be included: manufacturer, model and series number for:

    a. radiation survey for leak and/or contamination, (Geiger counters GM) not instruments for analysis such as liquid scintillation counters or gamma counters.
    b. radioactivity measurements for analysis such as liquid scintillation counters or gamma counters.

22. The principal investigators signature and date submitted.

23. Write the names of all personnel handling radioactive material under the Authorize User or the Principal Investigator supervision.

    Note: All personnel to be handling radioactive material must read and sign the application.

24. Radiation Safety Committee amount approved / isotope

25. The signature of Chairperson of the Radiation Safety Committee and date approved.

26. The signature of Radiation Safety Officer and date approved.

27. Expiration date