RAD-14-21-Rev/sept/21

RESET FORM

APPLICATION FOR THE USE OF RADIOACTIVE MATERIAL NUCLEAR MEDICINE DEPARTMENT

Revised June 14, 2021

1. Submit original and two copies to the Radiation Safety Office.
2. Each approved application is valid for one year.
3. The Authorized User (AU) is required to submit renewal 30 days before the expiration date of current license.

1. Name of Chief Department:

2. Department and Lab Number:

3. Telephone and extension number:

4. E-mail address of the Authorize User:

Please indicate:

New Application: _____
Renewal Application: _____
If any changes occurred, detail in item #14

5 List training and previous experience of Chief Department in the handling of radioactive material.

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

8. List personnel to be handling radioactive material under Authorize User's supervision and date of training. Please include residents and students under the Nuclear Medicine Technologist Program.	9. ☐ MSC Employee / Job title

Radioisotopes for clinical use (therapeutic and diagnostic) and Possession limit of isotope requested (specific amount per isotope in mCi or uCi):

10. Isotopes	***11. Amount***	***12. Commercial Vendor***
☐ Tc^{99M} (Sodium Pertechnetate)		
☐ Ga^{67} (Gallium Cytrate)		
☐ Tl^{201} (Thallium Chloride)		
☐ I^{131} (Iodine 131)		
☐ I^{123} (Iodine 123)		
☐ I^{125} (Iodine 125)		
☐ In^{111} (Pentatate Indium Disodium)		
☐ Sr^{89} (Strontium 89 Chloride)		
☐ Sm^{153} (Samarium 153 EDTMP)		
☐ C^{14} (Carbon 14)		
☐ P^{32} (Phophurous 32)		
☐ R^{223} (Radium 223)		
☐ Co^{57} (Cobalt 57)		
☐ Cs^{137} (Cesium 137)		
☐ Ba^{133} (Barium 133)		
☐ F^{18} (Fluorine 18)		

13. Other Potential Hazards:

14. For Renewal Applications. Please indicate if there has 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 or reorganization:	☐	☐	

15. Description of protocols used for Nuclear Medicine and experimental procedures with radioactive material. Nuclear Medicine Clinical Protocols are available upon request in the Nuclear Medicine Procedures Manual: ☐ Yes or ☐ No

16. Will the project or procedure involve administration of radioactive material?

To animals: ☐ Yes ☐ No

To humans: ☐ Yes ☐ No

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

18. Radiation Survey Instruments available in the immediate area:

a. Radiation Survey Instruments b. Radioactivity Instruments

Radiation Survey Instruments	Geiger Counter Instrument		Geiger Counter Instrument		Well Counter Instrument
	Instrument	Probe	Instrument	Probe	
Manufacturer:					
Model:					
Series Number:					

19. Signature of Chief Department: _____ Date: _____

20. Print Name: _____ Signature of user: _____
Print Name: _____ Signature of user: _____
Print Name: _____ Signature of user: _____
Print Name: _____ Signature of user: _____
Print Name: _____ Signature of user: _____
Print Name: _____ Signature of user: _____

FOR THE USE OF THE RADIATION SAFETY COMMITTE

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

22. Signature of RSO: _____ Approved Date: _____

23. Expiration date: _____

Note: The clinical user must present evidence of Radiation Safety Training for all personnel to be handling radioactive material. Remember, all personnel must take an annual refresher course. For further information, please contact us at phone number (787) 758-2525 ext. 1687 or 1688.

INSTRUCTIONS ON COMPLETING APPLICATION FOR THE USE OF RADIOACTIVE MATERIAL FOR NUCLEAR MEDICINE LABORATORY (Revised June 15, 2018)

This form can be found at the following website (http://committees.rcm.upr.edu/radiation.html)

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 required to present evidence of adequate training in radiation protection and experience handling the types and quantities of licensed material that is propose to use. It is required to take the Radiation Safety Training offered by the Office of Laboratory Safety in Research and the annual refresher course.

Renewals: If you are renewing your license, indicate if there have been any changes and provide details on item 14. It is required to take the annual Radiation Safety refresher course offered by the Office of Laboratory Safety in Research.

All applicants should submit two copies of the application and documents to the Radiation Safety Office 30 days before the 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, requested radioisotope, location and equipment. New applicants for the use of radioactive materials should submit an application to the Radiation Safety 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).

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

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

3. Write the laboratory 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 they were 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, residents and students of who will be handling radioisotopes. Give a brief description of radioisotope experience of individuals using the produced radioisotope under applicant's supervision. Include the Radiation Safety training certificate from the MSC. This personnel list should be periodically updated. You may use additional pages if required.

   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 instructions as specified in 10 CFR-19.12. The Radiation Safety Committee and RSO will make certain that the authorized user and personnel supervisor certifies 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.

9. Please indicate if the technical personnel and students are MSC employees. Clarify their position.

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

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

11. 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.

    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 micro curie (uCi).

    Please note that the quantities requested must have the correct activity unit in terms of mille-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.

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

13. Is radioisotope a gamma or hard beta emitter? Is radioactive gas generated? Other hazards?

14. 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

15. 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.

16. Indicate if experiment will involve humans or animals.

Before allowing an individual to care for animals used in studies 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 instrument usage.
- 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 of the experiment proposal for evaluation of the applicant request.

17. 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 handled, describe the procedure used for receiving radioactive materials in your laboratory, describe the survey contamination methods used in your laboratory after each experiment, indicate the survey instruments used for this purpose, what type 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 investigator's supervision. (Consult the RSO for assistance, if necessary). May use additional pages if required.

18. List instruments available; 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.

19 The chief department signature and date submitted.

20 Write the names of all personnel handling radioactive material under the Authorize User or the Principal Investigator supervision. All personnel to be handling radioactive material must read and sign the application.

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

22 The signature of Radiation Safety Officer and date approved.

23 Expiration date.