1. **Purpose:** The purpose of this SOP is to provide guidance on how to apply for Authorized User status or a RAM permit as well as amending a current RAM permit.

2. **Scope:** Authorized Users (AUs) and Permitted Individuals (PIs) should use this procedure to apply for AU status or a RAM permit. When applying, always refer to the Radiation Safety Manual (RSM) for additional information and requirements.

3. **Definitions:**

   **3.1** Authorized User (AU) – A physician, dentist, or podiatrist who meets the requirements laid out in §§35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), 35.690(a), or is identified as an authorized user on a commission or agreement state license or similar permit. AUs are only applicable for human medical use as described in 10 CFR 35; veterinarians cannot apply for AU status.

   **3.2** Mixed Waste – Waste that has more than one hazard, such as radioactive and flammable or radioactive and corrosive, as defined by the Resource Conservation and Recovery Act (RCRA).

   **3.3** Permitted Individual (PI) – A full-time MU faculty or staff member, or MU employee working part-time, who has primary responsibility for locations where hazardous materials are used. Full-time students are not eligible to apply as a PI.

4. **Procedure Details:**

   **4.1** To obtain a RAM permit, an individual must submit a permit application which will be reviewed and approved by the Radiation Safety Committee (RSC). Information requested during the application may vary and can include the following:

   4.1.1 Personal information and application type

   4.1.1.1 Information such as highest degree earned, department, job title, and contact information will be collected.

   4.1.1.2 The application type will be indicated. Types include new ram permit, amendment, renewal, inactivation, re-activation, and termination.

   4.1.1.3 A brief description of the reason for applying should be included. Detailed information will be provided in separate sections of the application, but the brief description provides an overview for all reviewers.

   4.1.1.4 PIs will need to sign an acknowledgment statement saying they understand the responsibilities of being a PI and maintaining a RAM permit.

   4.1.2 Supervisor Approval

4.1.2.1 The application will be reviewed by the direct supervisor of the applicant, so this individual must be listed on all applications, with a few exceptions.

4.1.2.2 All PIs must demonstrative administrative support for their RAM permit. The administrator responsible for the PI is based on the primary location of the PI's authorized work. This is typically the department chair and also the PI's direct supervisor. Administrators can refer to the RSM for a list of responsibilities.

4.1.2.3 If a PI is requesting the addition of a room for which their Direct Supervisor does not oversee, then the supervisor for the other area must submit their approval for the room's use.

4.1.3 Training and Experience

4.1.3.1 Each new PI must demonstrate that they have appropriate training and experience to oversee a RAM permit. The RSC will review the training and experience for new PIs, and the criteria for acceptable training and experience are based on the proposed uses and amounts of radioactive materials.

4.1.3.2 The type, date, and duration of formal classroom training and experience received must be documented on the initial RAM permit request. Training topics include: principles and practices of radiation protection, biological effects of radiation, basic calculations for radioactivity measurement and standardization, instrumentation and monitoring techniques, and other applicable training.

4.1.3.2.1 Note that the MU provided radiation safety training does not count towards hours required for formal classroom training.

4.1.3.2.2 If an applicant cannot fulfill the training and experience requirements, then they may be required to complete an additional formal training class outside of MU at their own cost.

4.1.3.3 The content of the training requirements is subject to change based on MU's Radioactive Materials License (RML), so always refer to the RSM for an accurate list of requirements.

4.1.3.4 The training and experience requirements for a PI who is also an AU will be different from non-medical PIs. These requirements can be found in 10 CFR 35 depending on the medical use types requested. Typically, an individual who is already an AU and is requesting to become a PI and obtain a RAM permit will have already met the training and experience requirements based on their AU status. However, this will be evaluated by the Radiation Safety Staff (RSS) during review.

4.1.3.5 The RSS will also request a copy of the applicant's CV or resume to evaluate the training and experience requirements.

4.1.3.6 If the applicant has held a RAM permit on another license, then a copy of that may be submitted as well for justification of training and experience.

4.1.3.7 For medical users, submission of board certificates and state medical licenses may be needed too.

4.1.4 Radionuclides

4.1.4.1 PIs must list requested radionuclides and associated hazards. Each radionuclide must be listed individually along with the following:

4.1.4.1.1 Shipping and possession limits (in mCi) – These limits must be different from each other. The two limits intend to prevent a PI from accidentally going over their possession limit by ordering too much in one shipment. Because of this, the RSS typically suggests that the shipping limit be approximately 80% of the possession limit.

4.1.4.1.2 Form – Each radionuclide needs to have a "form" associated with it. Common types are "Any," "Generator", or "Sealed Source". The applicant does not need to include detailed information about form such as chemical compound; in general, the RSS only needs to know if the radionuclide will be used in sealed or unsealed form.

4.1.4.1.3 Special Uses – If any special uses will be performed using the radionuclides request, descriptions of the additional controls and procedures for each condition must be included in the Standard Operating Procedure (SOP) or application. Refer to the "Protocols" section of this SOP for additional information on addressing special uses.

4.1.4.1.4 Activities used per experiment – To perform an appropriate assessment of the uses requested, the RSS requires an estimate of the amount of activity used per experiment or procedure and the typical frequency of each experiment or procedure. This information is not binding and does not have to be exact. It simply allows the RSS to perform dose estimates and evaluate if the MU NRC RML has sufficient activity space for each line item. PIs are encouraged to request only exactly what they need, both for radionuclides and for activity limits.

4.1.5 Protocols and Special Uses

4.1.5.1 Each RAM permit application must include an SOP on how RAM will be used. This SOP does not need to include step by step instructions of how to do each experiment or procedure (unless this is specifically requested by the RSS). Rather, the SOP should provide a description on how the RAM will be used and address each of the special uses indicated. Special uses may include:

4.1.5.1.1 Generic procedures – These would include standard experiments such as northern blots, hybridization, gas chromatography, etc. The SOP does not need to be extensive for these types of procedures, as they are common practice and typically present a low risk. The PI should address common radiation safety concerns such as shielding, contamination control, and waste.

4.1.5.1.2 Biohazards – If work will involve the use of biohazards, describe the safety procedures, special waste handling, and radiation safety procedures involving the biohazards. Because use of biohazards with RAM can generate mixed waste, be sure to indicate if mixed waste will be generated and describe how this will be handled.

4.1.5.1.3 Hazardous materials – If work will involve the use of hazardous or dangerous chemicals, describe the safety procedures and waste handling. It is important to be specific about the waste stream generated during experiments so the RSS can evaluate if a waste vendor has the capability to dispose of the waste.

4.1.5.1.4 Airborne hazards – If work will involve the powdery, volatile, or other airborne forms of RAM, describe the airborne safety procedures such as use of fume hood and glove box facilities.

4.1.5.1.5 High energy beta emitters – Describe procedures used to minimize and detect contamination, minimize exposure, maximum activity in any stock solution, maximum activity in any other container storing solutions or waste, proposed storage and usage in each area, etc.

4.1.5.1.6 Radioiodines – Describe the radionuclides involved, use procedure, radiation safety precautions, maximum activity involved with iodinations, proposed storage, usage or iodination in each room, maximum activity in any container storing solutions or waste, engineering controls to minimize internal exposure, etc.

4.1.5.1.7 H-3 > 10 mCi – Describe the maximum activity in any container storing solutions or waste, storage and usage in each area, engineering controls to minimize internal exposure, etc.

4.1.5.1.8 Sealed sources or foils – Describe locations of storage and use, source information (radionuclide, manufacturer, model), use procedures, etc. If using foil sources, describe procedures to minimize the spread of contamination and storage.

4.1.5.1.9 Food items or food container use – If you plan to use any food items or food containers, describe the specific food items and containers, purpose for use, locations of storage and use, and labeling precautions taken to ensure no consumption by humans occurs.

4.1.5.1.10 Animal Use – Describe if use will be clinical or research as well as the animal types, RAM used, procedures, locations of animals, individuals providing care, radiation safety procedures, waste management, etc.

4.1.5.1.11 Human use – Describe RAM use procedures including drug/source name and manufacturer, basic workflow, etc. Procedures should address all items in 10 CFR 35 and NUREG 1556 Volume 9, Revision 3, Appendix C.

4.1.5.1.12 Alpha emitters – Describe RAM safety procedures to minimize contamination, internal exposure, etc.

4.1.5.1.13 Direct receipt of packages – If any radionuclides will be received directly by the workers under a RAM permit and not through EHS, list which radionuclides will be directly received, which workers will perform the receipt, what vendors will be shipping the packages, and if there are other radionuclides that have been previously approved on the RAM permit for direct receipt.

4.1.5.1.14 Impurities – If any radionuclides received may contain impurities (co-produced radionuclides), then the PI must individually list all impurity radionuclides as individual line items on their permit with appropriate shipping and possession limits. The RSS will assess the hazards associated with the radionuclides requested and determine whether the addition should be an administrative, minor, or major amendment.

4.1.5.2 If a procedure or experiment is highly specialized, then the RSS may require the applicant to submit a separate protocol addressing the procedure. This is often the case for certain medical therapeutic procedures or complex RAM research experiments.

4.1.6 Locations of use

4.1.6.1 Each room where RAM may be used must be listed on the application with the following information:

4.1.6.1.1 Building and room number.

4.1.6.1.2 Level of security – This would include if the room is locked when unoccupied or if all RAM is locked up in cabinets when the room is unoccupied.

4.1.6.1.3 Room type – This would include if the room is a traditional radioactive work area, modified restricted area, common use area, storage only, transitory use only, or other.

4.1.6.1.4 Floor plan/survey map – each room added will need a simple layout of the floor plan that includes information pertinent to radiation safety such as radioactive work areas or storage areas. Predetermined swipe and survey locations are not necessary as part of the application. The applicant will use this simplified layout to develop documented survey maps.

4.1.6.2 Modified Restricted Areas (MRA)

4.1.6.2.1 An MRA is a restricted ram room that has a dedicated area where drinks and/or food are allowed. These rooms are not common and are only approved if a strong need arises. During the application to create an MRA, the applicant must provide justification for the request along with the following:

4.1.6.2.1.1 Provide a floor plan of the entire restricted area and surrounding areas. Identify all doors securing the area and mark which areas within the current restricted area will remain restricted and which will be non-restricted.

4.1.6.2.1.2 Describe how security to the modified restricted area will be maintained.

4.1.6.2.1.3 If food and drink are to be allowed in the non-restricted area, explain how the food and drink will be brought into that area, and how the food and drink will be kept completely out of the proposed restricted area.

4.1.6.2.1.4 Explain how all individuals having access to the MRA will be trained to know and understand their responsibilities about compliance with the special conditions governing the area.

4.1.6.2.1.5 MRAs may be reviewed by other groups within EHS to confirm there are no compliance issues outside of radiation safety (such as

industrial hygiene, biosafety, general safety). If compliance issues are identified, the application will not be supported.

4.1.6.2.1.6 Once an MRA is approved, any deficiency identified with compliance of the special conditions governing that area could result in the removal of the MRA.

4.1.6.3 Transitory Use Only (TUO) rooms are areas where RAM is used infrequently and for short periods that cannot exceed 8 hours [10 CFR 20.1903(a)]. Refer to the RSM for additional requirements of TUO rooms. Patient administration rooms in hospitals fall under this category provided the patient can be released per 10 CFR 35.75 [10 CFR 20.1903(b).

4.1.6.4 Temporarily posted spaces are rooms which do not need to be posted all the time but will contain RAM for periods >8 hours at a time and therefore do not meet the TUO definition. A temporarily posted space can be used for tasks such as inpatients or temporary storage of ram. At the conclusion of the ram use, the PI and designated Radiation Workers will be responsible for performing a documented close out of the room and ensuring that no contamination over the trigger levels exists. If this is performed and no issues are identified, then the PI can remove the postings and release the room. Prior to room release, the PI must submit a notification to the RSS which may include close out survey results.

4.1.6.5 If the applicant is not the primary individual responsible for the room, then the name of the PI responsible for maintaining compliance of the room should be listed in the application so the supervisor of that room can approve of the ram uses.

4.1.7 Survey Instrumentation

4.1.7.1 The applicant should have appropriate survey instrumentation available to detect both fixed and removable contamination. When submitting an application, include the survey instrument serial number, manufacturer, model number, detector type, detector probe model number, detector probe serial number, and any other pertinent information.

4.1.7.2 Most RAM permits utilize a Geiger-Meuller (GM) survey meter to perform the required area surveys. A NaI meter may be required if the permit includes radioisotopes of iodine. A ZnS meter may be required for alpha emitters.

4.1.7.3 A Liquid Scintillation Counter (LSC) is most commonly used for detection of removable contamination. Applicants do not need to own an LSC, however they must have easy access to one to perform the required removable contamination

surveys. In some instances, a well counter with a NaI detector may be more appropriate for identifying removable contamination than an LSC.

4.1.7.4 Refer to the Instrument Calibrations SOP as well as the RSM for additional information on instrument calibration procedures and requirements.

**4.2** The review process:

4.2.1 Once an application is submitted, the assigned Health Physicist (HP) will perform an in-depth review. If additional information is needed, the HP will follow up with the applicant. Items that may be reviewed during a RAM permit application could include:

4.2.1.1 A dose analysis if new radionuclides or increased possession limits are requested. This is to confirm that the public dose does not exceed 100 mrem a year and 2 mrem in any one hour [10 CFR 20.1301].

4.2.1.2 The applicant's inspection history.

4.2.1.3 The training status for the PI and any Radiation Workers listed under the permit.

4.2.1.4 The requested shipping and possession limits as compared to the MU NRC Radioactive Materials License.

4.2.1.5 If a sealed source is requested, the RSS may need proof that the source has a Sealed Source Device Registration (SSDR).

4.2.1.6 In certain cases, typically involving a major change, the RSS may need to submit an NRC amendment which takes upwards of six months.

4.2.2 Refer to the RSM for the level of review required based on the application type. The application type and level of review will be assessed by the assigned HP and verified by the RSO. In general, the types of applications are classified as follows:

4.2.2.1 Administrative – changes can be made automatically and require minimal review.

4.2.2.2 Minor – changes do not impact the PI's operation significantly, but some elevated review is required.

4.2.2.3 Major – changes impact the PI's operation significantly and require RSC review.

4.2.2.4 Interim – these changes do not occur often and are only allowed if the need is justified before the application can be reviewed and approved by all reviewers.

4.2.3 The applicant should be mindful of the timeliness of their submission. Sometimes, RAM permit applications require detailed review, and the RSS cannot guarantee a swift turnaround from the date of submission to approval.

4.2.4 Refer to the RSM for any additional requirements based on the type of amendment. In some cases, an amendment may need to be submitted within a certain timeframe for the applicant to continue normal operations, as is the case with renewals.

4.2.5 Once approved, an amendment will be signed by the Radiation Safety Officer and issued to the PI. The RSS will keep the official signed copy as a record.

**4.3** When becoming an Authorized User, an individual will not receive a RAM permit. Rather, the applicant will apply for AU status, and then be added to the special conditions of a medical RAM permit. To apply for AU status, refer to the Radiation Safety website.

## 5. References:

**5.1** 10 CFR 20.1903

**5.2** 10 CFR 35

**5.3** Radiation Safety Manual

**5.4** MU NRC Radioactive Materials License

## 6. Revisions

**6.1** Rev 01 – 2024-6-13 – New SOP. Supersedes RSM pages “RAM Permit Applications” and “How to Fill Out Permit Application Forms.”