I. Organization and Responsibilities

A. Management Policy Statement

The Medical College of Wisconsin (MCW) is licensed by the State of Wisconsin for radioactive materials (RAM) for clinical and research applications at facilities located at MCW and Froedtert Hospital (FH). The license is of broad scope for the use of sealed and unsealed radioactive sources. The Administration of MCW is responsible for the maintenance of the license and the activities governed by the State. FH and MCW are jointly responsible for the implementation and review of the Radiation Safety Program to ensure that it conforms to specific license conditions and any other applicable local, state or federal regulations.

The Radiation Safety Program is directed and monitored by the Radiation Safety Committee (RSC). The RSC is an administrative committee responsible for the oversight of RAM under the license. The day-to-day operation of the Radiation Safety Program is provided by the Office of Radiation Safety

D. Authorized User

An Authorized User is an individual who has been approved by the RSC for use of RAM or ionizing radiation from RA

II. Authorization for the Use of Radioactive Material

The use of RAM or ionizing radiation from RAM is only permitted with the approval of the RSC.

A. Application Process

Applicants to become Authorized Users must complete the following forms, available from ORS or the ORS website:

- x Radioactive Materials Use Application (Non-Human Research)
- x Statement of Training and Experience

Instructions for completing these forms are also available from ORS.

Completed forms must be returned to ORS. Upon receipt of the forms, ORS will perform a preliminary review of the application for completeness. The application is then sent to the RSC for review. The RSC meets the second Wednesday of the second month of each calendar quarter (February, May, August and November). Applicants who wish to be considered for approval must provide completed application forms to ORS at least two weeks prior to the RSC meeting date. Requests for an expedited review can be made by contacting the ORS. Applications, whether reviewed by the RSC at a regular meeting date, or by expedited review, must receive signatures from a quorum of the RSC before becoming effective.

B. Authorization Requirements

The applicant Must be authorized to submit applications as a PI based on MCW policy. Training and experience requirements depend on the type of laboratory being established. Laboratory types are classified one through four. The Laboratory Classification Scheme is presented in Section V (G), Laboratory Classification. Minimum training and experience requirements for each lab type are:

1. Laboratory Type 1 & 2 Training and Experience Requirements

    a. A college degree at the bachelor level, or equivalent training and experience, in such areas as physical, chemical, biological, biomedical, veterinarian or engineering sciences.

    b. At least 40 hours of training and experience in the safe handling of RAM, the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and the biological effects of radiation exposure appropriate to the types and forms of radioactive material used.

2. Laboratory Type 3 Training and Experience Requirements

c. Same as for Types 1 & 2 except a total of 80 hours of training and/or experience for quantities of radionuclides, or similar radionuclides, proposed for use or an additional 10 hours of advanced formal training including type three quantities.

3. Laboratory Type 4 Training and Experience Requirements

d. Same as for Type 3 except a total of 120 hours of training and/or experience for quantities of radionuclides, or similar radionuclides, proposed for use.

Applicants who can provide documentation showing that they were an Authorized User on another Agreement State/NRC license for substantially similar uses and quantities may provide such documentation in lieu of the Statement of Training and Experience form.

C. Authorization Amendments

Any changes in RAM use, possession or order limits, rooms where RAM is used or stored, and the addition of radionuclides to an existing authorization, shall only be permitted with approval of the RSC. Request to Amend Radioactive Material Authorization forms are available from the ORS. The ORS staff will provide assistance in completing the application upon request. The review process is the same as for new applications. The RSO may give interim approval to an amendment request for minor changes, such as:

- Increase of possession limit for previously approved isotope.
- Change of isotope or chemical form for previously authorized use.
- Change of location of use or storage (excluding the BSL-3 facility, see Section F, below).

All amendment requests given interim approval will be submitted at the next RSC meeting for review, comments, and approval.

D. Authorization Termination

When an authorization is terminated the laboratory shall be surveyed for contamination and decontaminated where necessary. Remaining RAM shall be removed by transfer to another Authorized User on this license, transfer to another license, or release as radioactive waste. No RAM is to leave MCW or FMLH without prior approval by the ORS. Procedures for the transfer of RAM are outlined in Section XIII, Ordering and Transferring RAM.

E. Inactive Status

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inactive status, an amendment request must be sent to the RSC. Active status will be

III. Training of Radiation Workers

A. Definition of a Radiation Worker

For the purposes of the Radiation Safety Program at MCW, a radiation worker is an individual who is likely to receive an occupational dose in excess of 1 mSv (100 mrem) in a calendar year.

Occupational dose, as defined by the State in DHS 157.03, "means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation, or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee, registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under s. DHS 157.62 (8), from voluntary participation in medical research programs or as a member of the public."

B. Instruction

Radiation workers shall be given all of the following information annually:

1. The proper storage, transfer and use of sources of radiation in the workplace.
2. Health risks to the individual and potential offspring associated with exposure to radiation and radioactive material, precautions and procedures the individual should use in the workplace to protect themselves and minimize exposure to radiation and radioactive material, and the purposes and functions of protective devices.
3. A worker's responsibility to report promptly to the ORS or MCW management any condition which may constitute, lead to or cause a violation of the regulations or a condition of the license.
4. How to respond in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material.
5. Radiation exposure reports provided to workers.

The extent of the instructions provided shall be commensurate with potential radiological health protection problems present in the workplace and shall take into consideration assigned activities during normal and abnormal situations involving exposure to radiation or radioactive material that can be reasonably be expected to occur.

The form Training and Instruction Checklist must be completed for each radiation worker as soon as practical after starting to work with RAM in the lab. Upon completion, the form must be signed by both the radiation worker and the Authorized User and the completed form sent to the ORS.

Training of radiation workers may be accomplished in several different ways:

Direct Training by the Authorized User – In all cases some direct training by the Authorized User or designee is mandatory. The specifics of how and where RAM and RAM records are stored, what precautions should be taken in specific laboratory procedures, authorized use and possession limits, are unique to each lab.

Classroom Training – ORS periodically offers a classroom-based course in radiation safety for laboratory workers. This course is designed to cover training requirements not unique to individual laboratories. All radiation workers should attend this course for initial training.

Computer or Video-based Training – Training materials approved by ORS may be used as a substitute for the classroom training listed above. Contact ORS for approved content.

employee, a statement that she is pregnant, her estimated date of conception (month and year only) and the department/service of employment.

The Declaration may be sent to the employee's immediate supervisor, or to ORS. If the immediate supervisor is notified, the supervisor must promptly notify ORS.

ORS will provide information to the Declared Pregnant Woman concerning the health effects/risks associated with exposure of the fetus during pregnancy, and methods of maintaining radiation exposure within the dose limits, and As Low As Reasonably Achievable. ORS will evaluate the working conditions to determine compliance with fetus/embryo radiation exposure limits.

C. Dosimeters

Types

Dosimeters are devices worn by radiation workers to measure actual occupational dose. Three types of dosimeters are commonly available through commercial vendors that meet State accreditation requirements:

- Film badges
- Thermoluminescent Dosimeters (TLD's)
- Optically-Stimulated Luminescent (OSL) Dosimeters

The use of other dosimeter devices for measurement of occupational dose must be approved on a case-by-case basis by ORS.

Requirements

ORS assigns dosimeters, at a minimum, according to the following criteria:

1. Adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the radiation dose limits.
2. Minors who are at risk of receiving over 10% of the radiation dose limits.
3. Declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of 1 mSv (100 mrem).
4. An individual entering a high or very high radiation area.
5. An individual working within 6 feet of operating medical fluoroscopic equipment.

Monitoring devices shall be individually assigned and not shared.

Recommendation

ORS recommends that dosimeters be worn by radiation workers who handle beta-emitting isotopes, where the maximum beta energy is greater than 1 MeV, and more than 1 mCi is used per process.

Obtaining a Dosimeter

To request a dosimeter, complete and forward a Personnel Dosimetry Application to ORS. Forms are available at ORS or the ORS website.

General Instruction

The requirement for bioassays is as follows:

1. Adults likely to receive, in one year, an intake in excess of 10% of the applicable Annual Limit on Intake (ALI) in DFS 157 (excerpt in Appendix B).
2. Minors likely to receive, in one year, a committed effective dose equivalent in excess of 10% of the ALI.
3. Declared pregnant women likely to receive, during the entire pregnancy, a committed dose equivalent in excess of 1 mSv (100 mrem).

To determine when bioassays are necessary, based on the quantity of RAM and the process involved, the methodology describeALI) in D

V. Radioactive Work Areas

Restricted Areas – Locations where RAM is used are defined as restricted areas, areas, access to which is limited for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials (DHS 157.03). Eating, drinking, the application of cosmetics, and smoking are prohibited in restricted areas. Any items relating to the above are also prohibited from these areas (e.g., cups, lunch bags, cigarettes).

Controlled Areas – A controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited for reasons of of cos stricte bited from these areas (e.g., cup
cigarettes).

Controlled Areas

Radioactive work areas that contain self-shielded irradiators, or other sealed sources, are not required to be posted if the external radiation at 30 cm from the housing is less than 5 mR/hr.

B. Radioactive Cold Zones

A radioactive cold zone is an area inside

VI. General Radioactive Material Use

A. Operating Considerations

1. Before any procedure is performed, consideration should be given to the amount and type of RAM being used to determine the need for additional precautions, such as remote handling, hoods, air sampling devices or special working surfaces. Consideration should also be taken for the volume and type of waste generated. ORS will be available for assistance on initial or unusual operations.
2. Determine if an individual will be required to have a personal monitoring device or participate in a bioassay or in vivo counting program. This depends on the radionuclide, quantity, frequency of use, chemical form, and type of work being performed. Refer to Section IV, Exposure Monitoring.
3. Transferring of RAM from one Authorized User to another user under our State license (MCW and FH) may be made only with PRIOR approval from ORS.
4. Gamma emitting radionuclides are to be used and stored in such a way so that the total dose equivalent to individual members of the public does not exceed 1 mSv (100 mrem) in a year or in excess of 0.02 mSv (2 mrem) in any one hour in unrestricted areas.

B. Safety Rules for Working with RAM

1. Wear appropriate protective clothing (e.g., lab coat, gloves, closed-toe shoes).
2. Use remote handling tools, as appropriate.
3. Wash hands and monitor clothing, as appropriate, for contamination after each procedure and before leaving the area.
4. Do not eat, drink, smoke, or apply cosmetics in a restricted room or area where RAM is used.
5. Do not store food, drink, or

3. Unbreakable containers are recommended for storage of RAM. Radioactive liquids shall not be stored in open containers.
4. Freezers used for storage of RAM shall be kept reasonably free of frost. When defrosting a freezer, caution shall be used to prevent the spread of possible contamination.
5. Radioactive gases and volatile radionuclides shall be stored in a negative pressure airflow hood.
6. Equipment or containers known or suspected to be contaminated with RAM should be marked with an appropriate sign or tape until such contamination is

F. Irradiators

Use of irradiators is limited to individuals whose training and credentials have been reviewed and approved by the RSO. Operators are required to pass a written exam for each type of use and for each irradiator they wish to operate. Contact ORS for specific details and forms.

G. High Energy Beta-Emitter Use

Individual users of high-energy beta-emitters (E_{max} > 1 MeV) in quantities greater than 1 mCi shall:

1. Use low atomic number materials, such as plastic or wood for shielding.
2. Use remote handling devices when appropriate.
3. Wear a TLD ring badge to monitor extremity exposure. Wear the ring so that the TLD chips are on the palm side of the hand.
4. Perform a GM and/or a wipe test survey after each use, but at least at the end of each day of use. The survey is to include, but not limited to, lab bench tops, floors around work area, drawer handles, utensils/equipment, lab coats and bottoms of shoes.

H. Radioiodination

Due to radioactive iodine's radiotoxicity, special safety precautions must be taken. Since free iodine has the ability to volatilize then be inhaled and concentrate in the thyroid, radioiodination procedures shall only be performed in facilities approved by the ORS and by individuals approved by the RSC.

Thyroid scans are required for workers iodinating or observing the iodination if greater than one millicurie is used.

Normally protein is only stable for a few weeks after the iodine is bound. This time duration varies depending on the nature of the protein. After a period of time, the protein is broken down by the radiation, liberating free iodine. Therefore, workers should be cautious when handling old iodinated proteins.

I. Radioactive Material in Animals

Procedures involving the use of RAM in animals may only be done with the knowledge and approval of the Institutional Animal Care and Use Committee (IACUC) and the RSC. Applications for the use of RAM in animals shall be submitted to ORS. Approval by the IACUC and the RSC shall be obtained before any work may begin.

In addition to the Biological Resource Center (BRC) rules and procedures, the following rules and procedures apply to experiments involving RAM in animals in areas under the jurisdiction of MCW or FH.

1. No radioactive animals, tissues or animal wastes may be disposed as normal trash.
2. Cages containing radioactive animals shall be labeled by the investigator bearing the “Caution Radioactive Materials” symbol and stating the identity of the radionuclide(s), the activity, time and date originally given to the animal(s).
3. Personnel having physical contact with such animals, the animal's waste, or the equipment they may have been in contact with shall wear disposable gloves. These gloves are to be disposed in the designated radioactive waste container.
4. Personnel exposed to radioactive animals, wastes, areas, or equipment may require exposure monitoring. Refer to Section IV, “Exposure Monitoring”.
5. Wastes swept up from the floor of any room housing radioactive animals shall be monitored for radiation. If found to be contaminated, the waste shall be disposed in the designated containers in the room.
6. BRC shall inform the ORS of any activity involving RAM which appear to deviate from the approved project's guidelines.
7. Rooms housing radioactive animals shall have the room or area labeled with a "Caution Radioactive Materials" or "Caution Radiation Area" sign, as appropriate. Refer to Section V, “Radioactive Work Areas”.

J. Contamination Surveys

Surveys for contamination must be performed routinely in and around areas where RAM is used and stored. The type and frequency of surveys is dependent on the specific isotope and the quantity in use.

Daily Use of Survey Meters

When a procedure using RAM is performed, a portable survey meter should be available and in use for detecting the presence of contamination during and immediately after completion (for all procedures except those involving H-3). Selection of the proper survey instrument is important; see the table below for a guide to survey instrument selection:

Isotope	Portable Survey Meter
H-3	None*
C-14, S-35, P-32, P-33 (beta or beta-gamma emitters)	Thin-window or pancake Geiger-Muller meter
Cr-51, I-125 (gamma or x-ray emitters)	NaI scintillation detector

* For procedures using > 10 mCi of H-3 per process, monitoring should be performed immediately using liquid scintillation counting.

The proper use of portable survey meters during and immediately following a RAM procedure can reduce the spread of contamination. The use of portable survey meters as described above is for the detection of contamination only, and such surveys are not intended to demonstrate compliance with laboratory contamination limits.

Periodic Laboratory Surveys

Routine, documented surveys for contamination shall be performed to verify that the use of RAM has been contained and will not present an exposure hazard to staff or members

VII. Possession Limits

A. Kits for *In Vitro* Testing

The State has issued a general license to MCW and FH for the use of certain prepackaged kits, such as those used for radioimmunoassay (RIA). Strict activity limits apply to the following isotopes:

^{3}

VIII. Ordering and Transferring Radioactive Material

A. Unsealed Radioactive Material

All orders for RAM must be approved by ORS before the vendor is contacted. To ensure that RAM orders are handled in a timely manner, the following procedure is provided:

Place RAM orders through Central Purchasing. **Orders arriving after 2:00 pm will not be processed until the following business day.** Be sure to include:

- Authorized User Name
- Vendor
- Catalog Number
- Isotope
- Chemical Form
- Quantity (PCi, mCi or MBq)
- Ship To Address as "Radiation Safety"

Standing Orders- When the same product is purchased frequently, or needed on a recurring schedule, set up a standing order with Central Purchasing. DO NOT PHONE IN YOUR OWN ORDERS! Individual orders on the same purchase order number must still be approved by ORS and phoned in by Central Purchasing.

Once a RAM order reaches central purchasing, the order is reviewed by ORS prior to placement. The order is then approved or disapproved according to the Authorized User's current inventory and RAM limits. If disapproved, the Authorized User will be notified as to the reason for disapproval.

If a laboratory is planning on receiving a special shipment (e.g., replacement, gratis material from a vendor, labeled items from a fellow investigator at a different institution), the ORS must be informed and approval granted before the item is shipped.

B. Sealed Sources, Irradiators

Sealed sources used in instruments (e.g., electron capture detectors) or irradiator sources must be purchased with approval from ORS. As the requirements for these sources are highly varied, check with ORS before considering purchasing such sources.

C. Calibration and Check Sources

Sealed check sources that are of exempt quantities to be used in conjunction with counters and survey equipment may be ordered without the approval of the ORS. The ORS is available to provide guidance or assistance in which sources and activities are best for your equipment.

- The material is readily soluble, or is readily dispersible biological material, in water.
- Radioactive liquids must be disposed in designated sinks only.
- A record must be kept of all disposals.
- The activity does not exceed the following limits:

Isotope	Activity
^{3}H	5,000 PCi
^{14}C	1,000 PCi
All Others Combined	1,000 PCi

Authorized Users may choose to transfer liquids to ORS for disposal. Such liquids must be stored in approved containers.

E. Dry, Solid RAM Waste

Lab waste contaminated with RAM that contains only dry solids, paper, plastic, gloves, glass and some metal shall be prepared for disposal and transfer to ORS.

HAZARDOUS MATERIALS, LEAD SHIELDING AND UNDEFACED RADIATION STICKERS OR LABELS ARE NOT PERMITTED IN RADIOACTIVE WASTE.

ORS provides semi-transparent yellow bags with the radiation symbol printed on the outside. Put the waste in the bag, fill out a waste tag, tie-wrap the bag closed and place it in one of the designated RAM waste lockers. ORS performs laboratory pickup of radioactive waste upon request by submitting a waste request using the online data base "EHSA".
H-3 and C-14 – These are the only two isotopes that may be combined in a single bag.

All Other Isotopes – Waste from any isotopes other than H-3 and C-14 must be placed in separate bags.

Sharps – Contaminated sharps must be stored in approved sharps containers. Contaminated sharps must be segregated according to isotope, the same as for other dry, solid waste.

F. Biological Waste

Animal carcasses or tissue containing RAM must be disposed of through transfer to ORS. Waste must be bagged, tagged, and kept frozen.

- Animal tissue containing H-3 or C-14 in quantities less than 0.05 PCi/gram, averaged over the weight of the entire tissue or carcass may be combined into the same bag.

- All other isotopes or H-3 and C-14 concentration above 0.05 PCi/gram must be bagged separately.

Due to freezer space constraints, the Authorized User should consult with ORS before starting any projects involving biological waste containing RAM. The cost of storing biological waste may be passed on to the Authorized User.

G. Mixed Hazardous and Radioactive Waste

Projects that generate hazardous waste mixed with radioactive contamination must be declared on the Application for Authorization and approved by the RSC. Contact EHS for hazardous waste criteria.

H. Waste Tags

A waste tag must be completed for every item

- All shipping labels or other markings or symbols indicating “Radioactive” or references to activity have been clearly defaced, so that a member of the public would not confuse the package for one containing radioactivity,
- All lead has been removed.

Stock Vials– When stock vials are emptied, deface the label and put the vial in with the dry, solid radioactive waste.

X. Emergencies

Emergency procedures are posted in areas where RAM is used. Radiation workers and other personnel who frequent areas where RAM is used should know where these are posted, and familiarize themselves with the procedures. The following general procedures apply to emergencies involving RAM.

A. General Instruction

1. Medical attention to an injured individual will take precedence over all other concerns. If a life or death situation occurs, a rescuer may chose to receive a maximum dose of 0.25 Sv (25 rem). Such an exposure should only be considered to save a life.
2. Do not risk radiation exposure to save

XI. Records

A. Training Records

Radiation workers training records are to be kept by each Authorized User and a copy of the training form must be sent to ORS. If a radiation worker transfers to another Authorized User, the training record will follow the worker, with the new Authorized User responsible for the training of the worker in areas specific to the new job duties. This new training must also be documented with a copy furnished to the ORS. Training documentation forms can be obtained from ORS.

B. Inventory Records

The Materials Possession transfer shall be returned to OR upon depletion... [illegible]

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5. Any items not in compliance with the authorization, institutional policy, state and federal regulations.
6. Other items based on current compliance trends and issues.