OKLAHOMA STATE UNIVERSITY

RADIATION SAFETY PROGRAM: RAM SEALED SOURCES PI HANDBOOK

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Overview

Personnel on the Oklahoma State University (OSU) -Stillwater and OSU-Tulsa campuses who use sealed sources of radioactive materials (RAM) must adhere to applicable federal and state regulations and institutional policies. Refer to OSU's <u>Institutional Radiation Safety Policy</u> and the <u>Radiation Safety</u> website for specific regulatory links and additional guidance.

This handbook is designed to outline the responsibilities of RAM Principal Investigators (PIs) who use sealed sources and assist them in designing their projects and research activities while maintaining compliance with safety regulations and best practices.

For the purpose of this document, "sealed source" will be used to refer to any sealed source of RAM. While there are different regulatory and license requirements for different types and quantities of sealed sources, as noted later in this document, the vast majority of sealed sources fall under regulatory requirements. Pls should always consult with Radiation Safety personnel to determine which regulatory and license requirements he/she will need to follow. See the Generally Licensed Materials and Devices webpage for more information.

Radiation Safety personnel will periodically update this handbook and linked documents. <u>We strongly</u> recommend that you bookmark this handbook in your browser as opposed to printing it.

Section 1: Radiation Safety Program Oversight

RAM use, from ordering, procurement, transportation, storage, method of use, waste, to final disposal, is regulated. There are federal and state regulations that must be followed, as well as institutional polices that are in place to ensure that federal and state regulations are met.

1.a: Institutional Oversight

OSU's Radiation Safety Office works to ensure that all aspects of research and instructional activities that involve the use of sealed sources of RAM occurring on the OSU-Stillwater and OSU-Tulsa campuses are compliant with all applicable regulations and institutional policies. The Radiation Safety Office is located in the Office of <u>University Research Compliance</u> (URC). URC is under the purview of the Vice President for Research (VPR).

The Radiation Safety Office is managed by the Radiation Safety Officer (RSO), who is tasked with ensuring the safety of OSU faculty, staff, and students, as well as members of the general public, while enabling the use of sealed sources in a variety of research and instructional activities on the referenced OSU campuses.

Radiation Safety Office Personnel Contact Information can be found on OSU's Radiation Safety website.

1.b: State and Federal Oversight

Because Oklahoma is an agreement state¹, the RAM licenses held by OSU are issued by the Oklahoma Department of Environmental Quality (ODEQ). The ODEQ may incorporate by reference the federal Nuclear Regulatory Commission (NRC) regulations into Oklahoma Radiation Management Rules.

OSU currently holds two specific RAM licenses issued by ODEQ, a <u>type A broad scope license</u> and a <u>special nuclear material</u> license. While these licenses cover the majority of the regulated² sealed sources at OSU, there are some sources that fall under the general license for certain commonly-used devices (ask Radiation Safety personnel for more information).

In addition to the ODEQ, which regulates acquisition, use, and disposal of RAM, the Oklahoma Department of Transportation (ODOT) regulates the transporting of RAM on state roadways. ODOT follows the U.S. Department of Transportation's (USDOT) regulations.

ODEQ Regulations: Oklahoma Administrative Code (OAC) <u>252:410</u>

NRC Regulations: Code of Federal Regulations (CFR); <u>10 CFR</u> Parts 19, 20, and 30-33

USDOT Regulations: Code of Federal Regulations (CFR); <u>49 CFR Parts 100-177</u>

Section 2: Approval/Standard Operating Procedure (SOP)

The use of most¹ RAM sealed sources on the referenced OSU campuses requires current authorization for use to be on file in the Radiation Safety Office. In such cases, RAM PIs are required to submit a <u>RAM Use Application</u> to the Radiation Safety Office. Authorizations must be renewed every three years.

Information that is required to be in the application includes, but is not limited to:

- isotope and activity of the sealed source;
- how the sealed source will be used;
- how the sealed source will be shielded;
- how users will reduce their overall exposure; and
- security measures regarding the sealed source.

¹ An agreement state is defined by OAC as "any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274(b) of the Atomic Energy Act of 1954, as amended (73 Stat. 689; 42 USC §2021 et seq.)"

² The NRC, and by extension ODEQ, considers small quantities of some radioactive material to be exempt from regulation. The exempted quantity varies by radioisotope, and can be found in 10 CFR Part 30.71 Schedule B. Note that although these quantities of byproduct material may be exempted from NRC/ODEQ regulation, they are likely to be regulated with regard to transportation.

The application must be submitted to the Radiation Safety Office, where personnel will ensure that all required information is included before submitting it for review to the Radiation Safety Committee (RSC), which issues final approval. Under certain circumstances, the RSO may grant provisional approval until the RSC meets to review the application.

Upon RSC approval of an application, PIs will receive a copy of the application with all required signatures and a signed letter of approval *via* campus mail. The letter of approval will include:

- 1. your approval number, which is to be used on routings for grant proposals and other awards that will involve the use of the sealed source;
- 2. your approval date; and
- 3. your approval expiration date.

You should retain copies of both the signed application and the letter of approval with your records. Copies of the letter of approval will also be sent to your department head *via* campus mail.

¹ RAM sealed sources that are on a general license and are stationary (not portable), or sealed sources that are exempt from licensing altogether, will likely not require an SOP. However, you should always contact the RSO to verify whether or not these types of sealed sources will still require leak testing.

Section 3: Inventory

It is the PI's responsibility to ensure that the Radiation Safety Office has approved the purchase of RAM sealed sources prior to placing the order. Except for exempt sources (those that have activities less than those listed in 10 CFR Part 30.71 Schedule B) or generally licensed devices¹ (those that meet the criteria outlined in 10 CFR Part 31), manufacturers and distributors will not sell RAM sealed sources without verification that the purchasing organization has a license to possess the type and quantity of radioisotope being purchased.

Additionally, each PI must ensure that RAM sealed sources are properly removed from his/her inventory prior to transfer or disposal. It is important to note that even if a source is considered exempt from ODEQ and NRC regulations, it will likely not be exempt from ODOT or USDOT regulations. See Section 7 for more information.

Inventory verification by Radiation Safety Office personnel is part of each annual inspection. In addition, PIs are required to verify their inventory on a quarterly basis *via* the quarterly reports provided to them by the Radiation Safety Office. Leak tests on all non-exempt sealed sources will be performed by Radiation Safety Office personnel at quarterly or semi-annual intervals (see section 4: Leak Tests for more information).

¹See the <u>Generally Licensed Materials and Devices</u> webpage for more information.

3.a: Acquisition

The Radiation Safety Office should *always* be consulted before an order for radioactive materials is placed. Ordering sealed sources without prior approval¹ from the Radiation Safety Office is a violation of OSU's license agreement with ODEQ. Authorization for radioactive materials purchases must be obtained from the Radiation Safety Office at least one day prior to an order being placed. Any package that arrives without pre-approval will not be released to the PI unless the order was for particular exempt sources or generally licensed devices. If the possession of the sealed source requires that authorization and/or training requirements be met, Radiation Safety Office personnel will not release the package until appropriate corrective actions have been satisfied.

Approval is obtained by entering a request into the URC Assistant database² (contact Radiation Safety personnel for assistance with this process). Radiation Safety Office personnel will review requests and send an e-mail message to the PI to let him/her know if the request was approved. It is likely that, if you have not already spoken with Radiation Safety Office personnel about purchasing a new sealed source, you will be contacted by the RSO for more information.

Once the PI receives the e-mailed approval for the purchase, the order may be placed with the vendor. It is likely that the vendor will require verification that OSU has a material license and is authorized to possess the radioisotope and activity being purchased. Radiation Safety Office personnel will provide copies of the appropriate license upon request.

All RAM packages shipped to either of the referenced OSU campuses will be labeled, as required by USDOT and ODOT (49 CFR Parts 100-177), even if the sources they contain are exempt from ODEQ/NRC regulations. University Mailing Services (UMS) personnel will notify the Radiation Safety Office personnel of all packages labeled with RAM shipping labels and will only release these packages to Radiation Safety Office personnel. Radiation Safety personnel will then check in the package and perform the required survey to confirm that there has been no leakage of RAM during transport. Any sealed source that requires Radiation Safety Office authorization for use will remain in Radiation Safety Office storage until such time as the required paperwork has been received from the PI and has been approved.

When purchasing exempt or generally licensed devices, prior authorization for the purchase is not technically required. However, all packages must be checked in through the Radiation Safety Office before they can be delivered to the purchaser. Most generally licensed devices will still be required to have routine leak tests performed, and some will require that an approved RAM use application (see Section 2) be on file with the Radiation Safety Office. Notifying the Radiation Safety Office prior to initiating the purchase of these items will allow a PI to understand all requirements, expediting the process of checking the package in and receiving delivery of the RAM.

¹ Some sealed sources can be purchased on a general license or as exempt quantities. These do not require Radiation Safety Office approval. However, some of these sources may still require authorization for use, which is granted by the Radiation

Safety Committee. Therefore, a PI should always contact the Radiation Safety Office prior to purchasing a sealed source so that applicable paperwork and training requirements can be addressed before the sealed source arrives on campus.

3.b: Removal from Inventory

It is a license requirement that the Radiation Safety Office be aware of the storage location and, if the sealed source is portable, use locations. The Radiation Safety Office <u>must</u> be informed any time a RAM sealed source will be transferred to another PI, relocated, or disposed of. It is important to remember that transportation of RAM in a vehicle is regulated by ODOT/USDOT, regardless of whether or not the sealed source is regulated by ODEQ/NRC (see Section 7).

3.b.1: Transfer of sealed sources to another PI

In most cases, when PIs leave the university their sealed sources remain on campus. When this occurs, the Radiation Safety Office must be notified so that another PI can be identified to take possession of and responsibility for the sealed source. It is always best to notify the Radiation Safety Office of separations as soon as possible to give Radiation Safety Office personnel enough time to work with the new PI and ensure that all training and regulatory requirements are met. Any sealed source for which a trained PI has not been identified or for which an application of use has not been approved will be "locked out" by Radiation Safety Office personnel until all requirements have been met.

3.b.2: Sealed source is leaving campus

The PI must notify the Radiation Safety Office when his/her sealed source will leave either OSU campus for any reason. <u>Radiation Safety Office personnel may need to notify ODEQ when a sealed source is going to be removed from the campus' RAM license.</u>

Additionally, arrangements for transportation of the sealed source will need to be made, as every aspect of transportation; from shipping, transporting, delivering, and receiving is regulated by ODOT/USDOT (domestic shipping). If a PI plans to transport a RAM sealed source, or he/she intends to dispose of one, please refer to Section 7 of this handbook, which covers transportation. The PI should consider the following.

• When a PI is leaving OSU and taking a sealed source to a new location

 Radiation Safety Office personnel must notify the receiving institution of the impending shipment and verify that personnel there have authorization from their regulatory agency to receive/possess the sealed source.

² You will only be able to request approval to purchase the radioisotopes for which you are already approved. If you do not have current authorization to possess and use the radioisotope you wish to purchase, you will not be able to enter a request. Authorization must be in place before you can obtain approval to purchase.

- Radiation Safety Office personnel must determine proper shipping labeling and proper container, as appropriate, in conjunction with University Mailing Services personnel.
- o All transportation arrangements must be made through the Radiation Safety Office.

When a PI is disposing of a sealed source

- If the sealed source is part of an instrument, arrangements must be made with the manufacturer to remove and transport the sealed source for final disposal. In rare cases, Radiation Safety Office personnel may be able to remove a sealed source from a device, but this is determined on an individual basis.
- If a sealed source is to be disposed of through the University as hazardous waste,
 Radiation Safety Office personnel will need to make arrangements for Environmental
 Health and Safety (EHS) personnel to pick up the source and transport it to the OSU Stillwater waste storage facility.

RAM sealed sources may not be sold under any circumstances.

Section 4: Leak Tests

Leak tests will be performed on all non-exempt¹ sealed sources by Radiation Safety Office personnel at either quarterly or semi-annual intervals, per regulation and/or license condition. Radiation Safety Office personnel will call to make an appointment with a PI in order to perform leak tests. In the event that the sealed source is being used and cannot be leak tested during the appointment time, Radiation Safety Office personnel may leave leak test supplies with the PI and instruct him/her on how to perform the leak test and properly return the swipe to the Radiation Safety Office for processing.

These leak tests fulfill a regulatory and license requirement, and therefore the PI must make accommodations for Radiation Safety Office personnel so that they may have access to the sealed source in order to obtain the swipes.

Section 5: Personnel Safety

A primary concern for any RAM laboratory is the safety of RAM and non-RAM personnel. Students, faculty, and staff who use sealed sources should have a general understanding of RAM safety, but they also need to know the steps to take to avoid the hazards presented by the specific sealed source system/device with which they will work.

¹See the <u>Generally Licensed Materials and Devices</u> webpage for more information.

The most important aspect of personnel safety is proper training. See Section 6 of this handbook, which covers training requirements.

5.a: Mitigation of Exposure to Radiation

All users of radiation sources must work in such a manner as to keep their own exposure and that of others As Low As Reasonably Achievable (ALARA). In order to follow the ALARA principle, users must be aware of the specific radiation hazards associated with the sealed source with which they will be working. Different types of sealed source systems/devices have different safety features, which are dependent upon the type of radiation emitted and the total activity of the sealed source. It is the PI's responsibility to understand the safety features of his/her set up and ensure that all users are well trained on the safety features. It is important that all users understand the safety features that are designed into any sealed source set up they use. Operators should know not only what the safety features are, but also how they work and, most importantly, how to determine if they are not working properly. This information should be incorporated into the Lab Specific Training (LST) specific to the use of the sealed source such that all users sign the document to indicate that they understand how the safety devices work in the system/device they will work with.

Following is a list of common types of sealed source system set ups, common safety features, and the user training requirements that are associated with each.

- Castles are systems designed to completely enclose the sealed source with appropriate shielding material, most often lead (gamma emitters). These castles are designed in a way that the sealed source is not removed from the enclosure. Rather, the castle will either have a sample chamber into which the material to be irradiated will be placed, or a beam path where the radiation emitted from the source will exit the enclosure in a controlled manner. The castle composition provides protection to the users from the emitted radiation, but users should be aware that the exposure rates in the immediate vicinity of the castle may be above background levels. Users should be trained on maintaining safe distances from the castle, and what the exposure rates are in the use vs. storage configurations so they can verify that the sealed source is properly shielded at the end of each experiment.
- <u>Sealed source instruments</u> are manufactured with the sealed source contained inside the instrument. Shielding is built into the unit. Estimated exposure rates in working vs. storage configurations should be noted in the user's manual, as well as any other safety features the user should be aware of. Users should be trained on these safety features and on how to determine if the shielding is in the storage configuration before transporting or storing the instrument. These devices can be stationary (e.g. electron capture devices) or they can be portable (e.g. moisture density gauges, hand-held lead detection instruments). Some of these instruments will be listed on a general license, but will still require Radiation Safety Office

authorization for use of the instrument for research purposes. As for portable instruments, these require ODOT/USDOT training for anyone involved in transporting the instrument.

Depending on the type of sealed source, additional safety precautions may need to be incorporated into a PI's procedure in order to ensure that the operator receives minimal exposure. In general, any shielding configuration that allows a beam of radiation to escape from containment will have additional requirements. Radiation Safety Office personnel can assist with determining what, if any, additional precautions need to be taken.

5.b: Monitoring Operator Radiation Exposure

Some sealed source working areas will be assigned area dosimeters, as determined by the RSO.

Whole body dosimeters, and in some cases extremity dosimeters, will be issued by the Radiation Safety Office to personnel who use sealed sources, in accordance with Radiation Safety Committee decisions. The type of dosimeter(s) that is issued will depend on the emitted radiation of your sealed source.

PIs are responsible for funding appropriate dosimetry for sealed source users working within facilities they manage or are responsible for. See RSO Dosimeter Billing Policy for billing information.

Section 6: Training for Users

If the use of a RAM sealed source requires that a SOP be on file with the Radiation Safety Office (see Section 2), then all users of the source must be adequately trained prior to working with the source.

6.a: Online Training

Each individual who plans to use RAM sealed sources is required to complete the online training provided by the Radiation Safety Office. Radiation Safety Training Request Forms are available on the Radiation Safety website and should be submitted to the Radiation Safety Office *via* campus mail or email.

There are several online training courses provided by the Radiation Safety Office, but only two are required of sealed source users and PIs.

The <u>RAM – Sealed Sources</u> training course is required of all sealed source PIs and users. This
training consists of a series of slides and a subsequent test, which must be completed every two
years.

• The <u>PI Responsibilities</u> training is required of all RAM PIs. This training consists of a series of slides followed by an acknowledgement that the trainee has read and understood his/her responsibilities as a PI. This is a one-time training that is required of all RAM PIs.

6.b: Lab Specific Training

RAM PIs are responsible for training their users on the specific hazards of their sealed source systems/devices and how to operate them safely. This is completed *via* lab specific training, or LST. Users should be made aware of how to ascertain when the system or device is functioning properly and when it is not working properly. They should be able to use a survey meter, if applicable, to verify that the sealed source is properly shielded after use. Safety features of the sealed source system/device should be covered in the LST, as well.

LST is a required portion of the RAM use application and is ultimately approved by the RSC. If LST is updated between application approvals, it must be approved by the RSO.

LST must be completed by all users on an annual basis. PIs must have documentation of LST for all users readily available for review upon request. Since PIs create their own LST and are expected to know the safety features and proper procedures for their sealed source system/device, PIs do not need to complete the LST.

Because the Radiation Safety Office tracks LST (see Section 9.a), copies of all completed LST must be sent to the Radiation Safety Office. All LST documents must be properly signed and dated in order to be valid.

LST will not be required of any PI who indicates in his/her application that he/she will be the sole user of the sealed source. However, LST must be submitted to and approved by Radiation Safety Office personnel if additional users are added to the PI's permit.

6.c: Other Training Requirements

Other training requirements may be in place for certain types of sealed sources. Portable nuclear gauge use requires specific training, and anyone who will transport a portable sealed source device in a vehicle is required to complete appropriate transportation training. Contact Radiation Safety Office personnel for help in determining what types of training may be required and how to satisfy and maintain these requirements.

Section 7: Transportation

The USDOT considers most¹ RAM to be hazardous materials, and therefore all aspects of vehicular transportation of RAM¹ on public-access roadways is regulated by USDOT and ODOT. Contact Radiation Safety Office personnel for information on how to ship/transport sealed sources.

<u>Under no circumstances should vehicular transportation of any RAM be attempted by persons who are not certified to participate in hazardous materials transportation.</u>

¹ There are very small quantities of RAM that may be transported without shipping papers, but other factors must be considered in order for this DOT exemption to apply. To avoid potential personal and/or institutional fines, you should never attempt to transport RAM without consulting the Radiation Safety Office.

Section 8: Inspections

Radiation Safety Office personnel will inspect and survey all approved sealed source laboratories on the OSU-Stillwater and OSU-Tulsa campuses.

8.a: Initial Inspections

Any new regulated sealed source must be approved by the RSC (or RSO if applicable) before it can be used. Part of the approval process is the inspection of the system/device, the set up, and the proposed location by Radiation Safety Office personnel.

Initial inspections will be performed for any new regulated sealed source on the OSU campus. A RAM notebook may be provided to the PI for record keeping purposes by Radiation Safety Office personnel. The sealed source notebook will have the following sections:

- RSO Training Certificates: Current training certificates should be maintained in the notebook and readily available for review upon request.
- Lab Specific Training Documentation: Current LST documentation for all users should be retained in the notebook and readily available for review upon request.
- Survey Equipment Calibration Records: All survey meters used to measure exposure rates of sealed source systems/devices must be calibrated at least once per year. Calibration records must be maintained and be readily available for review upon request.
- **RSO Inspections and Quarterly Reports:** These should be maintained in the PI's records and referenced as needed.
- Current RAM Applications and Approvals: These should be maintained in the PI's records and referenced as needed.

The initial inspection may require multiple visits by Radiation Safety Office personnel. Specific signage and notices must be posted by Radiation Safety Office personnel. In addition, information about the sealed source will need to be recorded so that it can be properly registered with the Radiation Safety Office and the ODEQ. An initial survey of the sealed source system/device will be performed after installation and before regular use. For this reason, it is strongly recommended that you notify the RSO of your intent to purchase a sealed source prior to the acquisition.

8.b: Annual Inspections

All approved sealed sources and RAM laboratories on the two referenced campuses must be inspected once per year at a minimum. Radiation Safety Office inspectors will verify that regulatory requirements are being met. These regulatory requirements include, but are not limited to:

- sealed sources are properly registered;
- use of sealed sources is consistent with that described in current approved applications;
- before/after surveys are being logged as described in current approved applications (if applicable);
- uses are being logged as described in approved applications (if applicable);
- records described in RAM Notebook (see Section 6.a) are being maintained and are up-to-date;
- dosimeters, both area and personal if applicable, are being used properly;
- sealed source system/device is secured from unauthorized access as described in the approved application;
- RAM facility has the required postings in clear view;
- a survey of sealed source in storage configuration may be performed;
- interlocks, if applicable, may be tested on sealed source instruments in order to verify that they
 are working properly. Please note that the failure of any interlock device will result in
 immediate closure of the instrument and cessation of sealed source instrument use until such
 time as the interlock is functioning properly. Only RSO personnel can make this
 determination.

Upon the scheduling of annual inspections, Radiation Safety Office personnel will send the PI a copy of his/her current inventory and a list of users and each users' training due date(s). If updates are required, it is best if the PI can address these prior to an inspection in order to expedite the inspection process.

If Radiation Safety Office personnel identify items during an inspection that need to be addressed, the PI will receive an e-mail message listing the concerns and the corrective actions that must be taken. Upon completion of addressing all listed corrective actions, the PI will receive a signed inspection report from the RSO for his/her records.

If a RAM PI does not schedule his/her annual inspection, or does not comply with corrective actions in a timely manner, the RSO will place restrictions on his/her RAM permit that may include inactivation of the

<u>PI's RAM permit and administratively lock out the RAM inventory until the inspection is completed and</u> all corrective actions have been adequately addressed.

Section 9: Radiation Safety Office and Radiation Safety Committee Responsibilities

The Radiation Safety Office is managed by the RSO, who is charged with providing guidance and support to OSU faculty, staff, and students who use RAM in their research and instructional activities. With the help and support of the RSC, the RSO works to ensure that applicable policies, safety standards, and regulations are being met. The RSO, with the assistance of his/her staff, will inspect RAM laboratories no less than once per year. Other inspections may be scheduled as new RAM sealed sources are placed in service.

The RSO will report overall inspection findings and trends to the RSC, which is composed of OSU faculty, a physician from University Health Services, a representative from OSU executive management, and the RSO. This committee works with executive management and the RSO to implement the Radiation Safety program and establish policies and procedures for managing the Radiation Safety program.

The RSO is ultimately charged with ensuring that activities involving RAM are performed safely utilizing best practices on the OSU-Stillwater and OSU-Tulsa campuses. The RSO ensures that each RAM PI is operating in compliance with regulations so that OSU's RAM permits, which are issued by ODEQ, are not adversely affected.

9.a: Quarterly reports

Radiation Safety Office personnel will distribute reports to RAM PIs every three months (i.e. quarterly). These reports will list the current RAM inventory, approved lab locations, and the training status of all authorized RAM users listed on the PI's permit. The PI should note any changes in authorized users on the report and provide updated LST for users, if required. The PI should also make note of impending training due dates for all personnel, including him/herself. The PI will then need to sign the report and return it to the Radiation Safety Office. These reports will allow the PI to verify that the information on file with the Radiation Safety Office is accurate and up-to-date.

9.b: Radiation Safety Office as a Resource for Principal Investigators

Radiation Safety Office personnel strive to guide and assist faculty, staff and students in conducting activities involving RAM sealed sources in such a way that the safety risks to RAM users and non-users alike are minimized. It is the goal of Radiation Safety Office personnel and the RSC to work <u>with</u> RAM PIs

to ensure that activities involving the use of RAM sealed sources continues while promoting safety and compliance with pertinent regulations, policies, and best practices.

Questions about RAM regulations and procedures can be e-mailed to <a href="mailed-emai