OKLAHOMA STATE UNIVERSITY
X-RAY MACHINE PROGRAM AND PI HANDBOOK

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Overview

Researchers on the Oklahoma State University (OSU) -Stillwater and OSU-Tulsa campuses who use x-ray producing machines for research must adhere to applicable federal and state regulations and institutional policies. Refer to OSU's Institutional Radiation Safety Policy and the Radiation Safety website for specific regulatory links and additional guidance.

This guide is designed to outline the responsibilities of x-ray Principal Investigators (PIs) and assist in helping them design their projects and research while maintaining compliance with safety regulations and best practices.

This guide is **not** intended for those who use x-ray equipment for diagnostic or therapeutic purposes or those specifically exempted from regulation. See OSU's Institutional Radiation Safety Policy or contact the RSO for more information on these machines.

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

Section 1: X-ray Program Oversight

1.a: Institutional Oversight

All x-ray producing machines used for research or analytical purposes on the OSU-Stillwater and OSU-Tulsa campuses must have approval on file in the Radiation Safety Office. The Radiation Safety Office is located in the Office of University Research Compliance (URC). URC is under the purview of the Vice President for Research (VPR).

The Radiation Safety Office is overseen 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 a variety of research activities involving the use of x-rays 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

The Oklahoma Department of Environmental Quality (ODEQ) issues permits for analytical and industrial x-ray producing machines to entities or individuals who use them within the state. The ODEQ may

incorporate by reference Nuclear Regulatory Commission (NRC) regulations into Oklahoma Radiation Management Rules.

State Regulations: ODEQ-Oklahoma Administrative Code (OAC) 252:410
Federal Regulations: Code of Federal Regulations (CFR); 10 CFR Parts 19, 20, and 30-33

Section 2: Inventory

It is the PI's responsibility to ensure that the Radiation Safety Office has adequate time to register his/her x-ray producing machine(s) with ODEQ. Additionally, the PI must ensure that x-ray equipment is properly removed from his/her inventory prior to transfer or disposal. Inventory verification by Radiation Safety personnel is part of each annual inspection. PIs are required to verify their inventory on a quarterly basis via the quarterly reports provided to them by the Radiation Safety Office.

2.a: Registration

All x-ray producing machines that are subject to ODEQ regulations must be registered with the state in a timely fashion. OSU currently has two x-ray permits issued by ODEQ, one for the Stillwater campus and one for the Tulsa campus. These permits require that OSU, via the Radiation Safety Office, keep a current inventory of all x-ray units in use for each permit and provide a copy to ODEQ whenever that inventory changes. By regulation, the Radiation Safety Office has thirty days from the date of delivery of a new x-ray unit to report the change in inventory to ODEQ.

PIs are strongly encouraged to notify the Radiation Safety Office well in advance of planning to purchase a new x-ray producing machine. There are a number of important items that will need to be addressed before the instrument can be put into use, some of which can be done prior to the instrument arriving. This can reduce, or in some cases eliminate, any delay in the use of the instrument, which may be needed in order to satisfy training (see Section 5), authorization (see Section 3), and facility inspection (see Section 6) requirements.

Some instruments may produce x-rays that are either incidental to their function (e.g. electron microscopes) or are designed in such a way that escape of x-rays from the unit is highly improbable (e.g. x-ray photoelectron spectroscopy systems). These instruments must still be reported to the Radiation Safety Office, and the RSO will determine if they need to be registered with ODEQ.

2.b: Removal from Inventory

PIs must notify the Radiation Safety Office when an x-ray instrument is being removed from their permit. The Radiation Safety Office will need to update the campus x-ray inventory on file with ODEQ if the instrument will no longer be on campus.

2.b.1: Transfer of x-ray to another PI

In most cases, when PIs leave the university their x-ray instruments remain on campus. When this occurs, the Radiation Safety Office must be notified so that another PI can be identified to take responsibility for the x-ray machine. It is always best to notify the Radiation Safety Office of such events as soon as possible to give the Radiation Safety Office enough time to work with the new PI and ensure that all training and regulatory requirements are met. **Any x-ray instrument 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 the Radiation Safety Office until all requirements have been met.**

2.b.2: X-ray instrument is leaving campus

The PI must notify the Radiation Safety Office when his/her instrument will leave the OSU campus for any reason. *Radiation Safety personnel will always need to notify ODEQ when an instrument needs to be removed from the campus' x-ray permit*, but additional action may be required for the following scenarios:

- **PI is leaving OSU and taking x-ray instrument to new location:** The Radiation Safety Office will need to notify the receiving institution that they will need to register the x-ray machine with their regulatory agency.
- **PI is trading in x-ray instrument for a newer model:** Additional requirements will need to be determined on a case-by-case basis.
- **PI is sending the x-ray instrument to surplus:** The Radiation Safety Office will need to disable the x-ray instrument and post notification labels on it to instruct the buyer that he/she may need to register it if it is repaired after purchase.

Section 3: Approval/SOP

Any x-ray instrument that is used on the OSU-Stillwater campus or OSU-Tulsa campus must have current authorization for use on file in the Radiation Safety Office. PIs begin the process of obtaining authorization by submitting an application for x-ray use to the Radiation Safety Office. Authorizations must be renewed every three years.

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

- Model, serial number, and maximum power capabilities of the instrument;
- Type of x-ray instrument (e.g. XRD, XRF, portable, open/closed beam);
- Proposed use;
- Safety features;
- Personnel training (see Section 5) and safety (see Section 4);
- Instrument security and prevention of unauthorized access;
- Step-by-step start-up and shut-down operating procedures;
- A copy of the manufacturer's operating manual must be provided to the RSO at the time of application. This manual can be in the form of a hard copy or an electronic version.

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

Upon RSC approval of your application, you will receive a copy of the application with all required signatures and a signed Letter of Approval via campus mail. This 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 x-ray instrument,
2. Your approval date,
3. Your approval expiration date.

You will need to maintain copies of both the signed application and the Letter of Approval for your records. Copies of the Letter of Approval will also be sent to your Department Head via campus mail.

Section 4: Personnel Safety

The primary concern for any x-ray laboratory should be the safety of x-ray and non-x-ray personnel. Students, faculty, and staff who operate x-ray instruments need to have not only a general understanding of x-ray safety, but they also need to know the steps they should take to avoid potential hazards presented by the specific x-ray instrument(s) with which they will work.

The most important aspect of personnel safety is proper training. See Section 5 for training requirements.

4.a: Mitigation of Exposure to X-rays

All users of x-ray equipment must work in such a manner as to keep their own exposure and that of others **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA). In order to follow the ALARA principle, users must be aware of the specific radiation hazards associated with the x-ray instrument(s) they will use.

4.a.1: Time, Distance, and Shielding

The three major factors in reducing exposure and following the ALARA principle while working with x-ray equipment are **TIME, DISTANCE,** and **SHIELDING**. These factors will have a significant impact, either good or bad, on your overall exposure during x-ray operations. To reduce your exposure, use them as follows:

1. When possible, **reduce time** spent working near the instrument while x-rays are being produced.
2. When you must be present at the instrument during operation, **increase the distance** between yourself and the x-ray instrument as much as practical.
3. **Use shielding.** For enclosed beam systems, the shielding is built in. For open beam systems, this is a significant factor in reducing your exposure.

4.a.2: Machine Specific Safety

Different types of x-ray machines have different safety features. It is the PI's responsibility to understand the safety features of his/her x-ray instrument and ensure that all users are well trained on them. It is important that all operators of your x-ray instrument understand the safety features that are designed into your x-ray device. 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 Machine Specific Training (MST) for the x-ray instrument such that all users sign the document indicating that they understand how the safety devices work on the instrument they will use.

Following is a list of some common types of x-ray units and the common safety features with which they are equipped.

- **Enclosed beam** units are designed to contain the x-rays produced during operation. These instruments will have a shielded housing that completely encloses the x-ray system and prevents leakage of x-rays. The doors or access panels to sample chambers should be interlocked in one of two ways: 1) the opening of the x-ray beam shutter will engage a mechanical interlock that prevents the door/access panel from being opened while the shutter is open, or 2) the opening of the shutter will require an electronic signal that is only engaged when the door/access panel to the sample chamber is closed so that interruption of this signal will close the x-ray beam shutter.

- **Open beam** units do not have housing to contain the x-rays produced. These instruments may come with a variety of safety features designed to reduce the operator's risk of exposure as well as individuals in the area during operation. Some units will have a "fan" beam, which spreads

the x-ray beam as it leaves the instrument, effectively reducing the potential exposure to the direct beam.

- **Hand-held devices** are **open beam** instruments designed to be portable so they can be used outside of controlled laboratory environments. These devices will likely have sensors on the nose of the instrument that must be depressed against the objects they are to analyze before the shutter will open. Other safety features may vary.

- **Custom built** units are those designed and assembled in a laboratory. The safety features of these instruments will vary with the design but will always be required to have standard features such as warnings lights, interlocks and caution signs. *The plans and designs of such instruments should be reviewed by the RSO before and during the building process to ensure that certain features required by regulation are included in the system.*

Depending on the type of x-ray instrument you have, additional safety precautions may need to be incorporated into your procedure to ensure minimal exposure to the operator. In general, any open beam and custom built units will have additional requirements, but Radiation Safety personnel will assist with determining what kind of additional precautions will be necessary.

4.b: Monitoring X-ray Exposures to Operators

Some instruments will be assigned area dosimeters as determined by the RSO.

Body and extremity dosimeters will be issued by the Radiation Safety Office to operators of all open-beam units, regardless of frequency of use. This will satisfy one of the "alternate safety measures" required by ODEQ for open beam devices.

Operators of other x-ray instruments will be assigned personal body dosimeters. See RSO Dosimeter Billing Policy for billing information.

4.c: Non-X-ray Hazards

Some x-ray instruments have other associated hazards that are not radiation related, e.g. coolants, electrical/shock hazards, or use of compressed gases. Operators of such instruments should be informed of these hazards as well.

Section 5: Training for Users

All users of x-ray producing equipment on the OSU-Stillwater and OSU-Tulsa campuses must be adequately trained prior to operating any x-ray equipment.

5.a: Online Training

All x-ray operators are required to take the online training provided by the Radiation Safety Office. Radiation Safety Training Request Forms and Non-User Training Request Forms are available on the Radiation Safety website and should be submitted to the Radiation Safety Officer via campus mail or e-mail.

There are many types of training provided by the Radiation Safety Office, but only two pertain to x-ray users and PIs.

- The X-ray Training Course is required of all x-ray PIs and users. This training consists of a series of slides and a subsequent test, which must be repeated on an annual basis.
- The PI Responsibilities training is required of all x-ray 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 required of all PIs.

5.b: Machine Specific Training

X-ray PIs are responsible for training their users on the specific hazards of their x-ray instruments and how to operate the x-ray instrument(s) safely. This is completed via machine specific training, or MST. Users should be made aware of the warning lights that indicate when x-rays are being produced, when the beam shutter is open, and how the interlocks on their system work. Dosimetry requirements as applicable, and emergency shut down procedures should be covered in the training.

MST is a required portion of the x-ray use application and is approved by the RSC. If MST is updated between application approvals, it must be approved by the RSO.

MST must be repeated by all users on an annual basis. Documentation of MST for all users must be readily available upon request (see Section 6). As PIs create their own MST and are expected to know the safety features and proper procedures for their x-ray instrument(s), PIs do not need to complete the MST.

MST will not be required of any PI who indicates in his/her application that he/she will be the sole operator of the instrument.

5.c: Non-User Training

In some cases, x-ray PIs will have people who work in or have access to their x-ray labs but do not use the x-ray equipment. In these situations it is prudent to identify these workers as "non-users" and document their "training" by having them sign a statement of non-use. This will document that the user has been instructed that there is x-ray equipment in their work area and that they are not authorized to use/operate the x-ray equipment until further notice from the PI.

While an x-ray PI may request a non-user status and training for any of his/her workers as deemed necessary, they are typically given this status when they meet one or more of the following criteria:

- Worker has access to the lab where x-ray equipment is located/used;
- Worker may be present when instrument is in operation;
- X-ray instrument in worker's lab is not password protected and may be left unattended while in operation (enclosed beam systems only – must be approved by RSO).

The training requirements for non-workers are as follows:

1. Signed statement of non-use – one-time only, not required to be repeated but the statement document must be approved by the Radiation Safety Office.
2. Online training – no online training is required by the Radiation Safety Office, but the PI may choose to have the non-user take the online X-ray Training. If such requirements are requested, then the non-user will be required to repeat the training annually.

Section 6: Inspections and X-ray Instrument Surveys

Radiation Safety personnel will inspect and survey all x-ray equipment approved for use in laboratories on the OSU-Stillwater and OSU-Tulsa campuses.

6.a: Initial Inspections

All new x-ray equipment must be approved by the RSC (or RSO if applicable) before it can be used. Part of the approval process is inspection of the instrument and the proposed location by Radiation Safety personnel.

Initial inspections will be performed for any new x-ray instrument on the OSU campus. An x-ray notebook will be provided to the PI for record keeping purposes. X-ray notebooks have sections for the following records:

- **Machine use logs**: A template is provided so that required information can be recorded. Alternatively, PIs may use a notebook, but it must be readily available and kept up-to-date with the following information:
    - Date and time of use (required);
    - Name of user (required);
    - kV and mA settings (required);
    - A place for the name of the user's PI is helpful for common-use instruments (not required);
    - A place for comments, which is helpful, should the user need to note type of sample analyzed or encounter any software issues (not required).
- **List of authorized users/operators**: A template is provided for this, but it is not required. It is helpful to keep this list up-to-date when a PI is responsible for multiple x-ray machines or when multiple PIs are authorized to use a single x-ray instrument.
- **RSO Training Certificates**: Current training certificates should be maintained in the notebook and readily available upon request.
- **Machine Specific Training Documentation**: Current MST documentation for all users should be maintained in the notebook and readily available upon request.
- **Machine Maintenance Records**: Any records of maintenance or repair done on the x-ray instrument should be kept in the notebook. Note that certain types of maintenance/repair will require that Radiation Safety personnel perform a post-maintenance survey of the x-ray machine before the instrument can be used by OSU faculty, staff, or students.
- **Machine Monitoring Dosimetry Records**: If applicable, you should maintain copies of *area* dosimeter reports for your x-ray instrument. DO NOT keep copies of personal dosimeter records in a public place.
- **RSO Instrument Surveys and Inspection Reports:** You should maintain copies of instrument surveys and inspection reports in this section of the notebook.
- **OSU's Written Radiation Protection Plan for X-ray Machine Registrants:** A copy of this written plan is provided to you in the x-ray PI notebook as required by ODEQ 252:410-3-32. This written plan is also available online here.

You should note that the initial inspection may require several visits by Radiation Safety personnel. There are required signs and notices that must be placed by Radiation Safety personnel, information about the x-ray instrument will need to be recorded so that it can be properly registered with the Radiation Safety Office and ODEQ. An initial survey of the x-ray instrument will need to be performed after installation and before regular use. For open beam instruments, additional room requirements may need to be in place. For this reason, **it is strongly recommended that you notify the RSO of your intent to purchase an x-ray instrument prior to the purchase**.

6.b: Annual Inspections

All approved x-ray instruments and x-ray laboratories on campus must be inspected once per year. Inspections will verify that regulatory requirements are being met. These requirements include, but are not limited to, the following:

- X-ray instruments are properly registered;
- Use of x-rays is consistent with that described in current approved applications;
- Records described in X-ray Notebook provided to PI (see Section 6.a) are being maintained and are up-to-date;
- Dosimeters, both area and personal if applicable, are being used properly;
- X-ray instrument is secured from unauthorized access as described in the approved application;
- X-ray facility has the required postings in clear view;
- X-ray instrument has required notifications of the following:
    - X-rays are being produced when energized;
    - X-ray beam shutter is open;
- Survey of x-ray instrument while it is powered on and beam shutter is opened must be performed to either ensure there is no leakage of x-radiation (enclosed beam systems) or to confirm that prescribed exclusion zones or safe distances are adequate. Interlocks will be tested to verify that they are working properly by attempting to open the door to enclosed instruments while the beam shutter is open. **Please note that failure of any interlock device will result in immediate closure of the instrument and cessation of x-ray activities until such time as the interlock is functioning properly. Only RSO personnel can make this determination.**

Upon scheduling of your annual inspection, Radiation Safety personnel will send PIs copies of their current inventory and list of users with and users' training due dates. If updates are required, it is best if PIs can address them prior to an inspection in order to expedite the inspection process.

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

Please note that if an x-ray 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 x-ray permit that may include inactivation of the PI's x-ray permit and administratively locking out the x-ray instrument until the inspection is completed and all corrective actions have been adequately addressed.

Section 7: Radiation Safety Office and Radiation Safety Committee Responsibilities

The Radiation Safety Office is overseen by the RSO, who is charged with providing guidance and support to OSU faculty, staff, and students who use x-ray producing machines in their research to ensure that applicable policies, safety standards, and regulations are being met. The Radiation Safety Officer, with the assistance of his/her staff, will inspect x-ray laboratories no less than once per year. Other inspections may be scheduled as new x-ray instruments 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 in implementing the Radiation Safety program and establishing policies and procedures for managing the Radiation Safety program.

The RSO is ultimately charged with ensuring that research involving x-ray instruments can continue to be performed safely on OSU-Stillwater and OSU-Tulsa campuses. He/she must ensure that individual x-ray PIs are operating in compliance with regulations so that OSU's x-ray permits issued by ODEQ are not adversely affected.

7.a: Quarterly reports

The Radiation Safety Office will distribute reports to x-ray PIs every three months. These reports will have the current x-ray inventory, approved lab locations, and training status of all authorized x-ray users on the PI's permit. The PI should note any changes in authorized users and provide updated MST for users if required. He/she should also make note of impending training due dates for him/herself and his/her users. 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 in the Radiation Safety Office is accurate and up-to-date.

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

The Radiation Safety Office strives to guide faculty, staff and students in performing their research involving x-ray instruments in such a way that the safety risks to x-ray users and non-users alike are minimized. It is the goal of the Radiation Safety Office and the Radiation Safety Committee to work ***with*** x-ray PIs to ensure that research involving the use of x-ray instruments continues while promoting safety and compliance with regulations, policies, accepted standards, and best safety practices.

Questions about x-ray practices and procedures can be e-mailed to radsafe@okstate.edu.

Radiation Safety Committee contact information can be found here.