



**Carnegie Mellon University**

Environmental Health and Safety (EHS)

Radiation Safety Committee

Procurement, Control and Safe Operation of

Radiation-Producing Devices

1.0	Registration and Procurement.....	3
2.0	Radiation Surveys.....	3
7.0	Operation.....	8
8.0	Safety Devices and Bypass Procedures for Analytical X-Ray Machines.....	9
9.0	Records .....	10
10.0	Transfer and Disposal .....	10
11.0	Revisions .....	10
	Appendix.....	11

## **1.0 Registration and Procurement**

- 1.1 Registration - In Accordance With (IAW) Title 25 § 216.2 of Pennsylvania Code, all Radiation Producing Devices (RPDs) must be registered with the Pennsylvania Department of Environmental Protection (PADEP). The Radiation Safety (RS) Office will register all RPDs annually. It is the responsibility of the primary researcher to notify the RS Office upon acquisition of any such machine.
- 1.2 Procurement - Radiation producing devices must be purchased via purchase order using the appropriate object code as specified in the Hazardous Materials Purchasing Guideline.

## **2.0 Radiation Surveys**

- 2.1 Analytical X-Ray machines:
  - 2.1.1 IAW Title 25 of the Pennsylvania Code, §227.12a(a-c), the RS Office shall ensure that radiation surveys are performed:
    - 2.1.1.1 Upon installation of the machine and at every 12 months thereafter.
    - 2.1.1.2 Whenever safety and warning devices have been disassembled
    - 2.1.1.3 Following maintenance requiring the disassembly or removal of a local component.
    - 2.1.1.4 During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when a local component in the system is disassembled or removed
    - 2.1.1.5 When a visual inspection of the local component in the system reveals an abnormal condition.
    - 2.1.1.6 When the machine is operated in a manner other than the routine procedure specified in the written operating manual.
    - 2.1.1.7 Following a change in the initial arrangement, number or type of local components in the radiation producing machine system
  - 2.1.2 Delegation of Responsibility
    - 2.1.2.1 Radiation Safety staff will perform the radiation surveys required under §2.1.1.1 and 2.1.1.2
    - 2.1.2.2 The Principle Investigator (PI) responsible for the specific machine, or an individual designated by the PI and deemed qualified by the RSO, shall perform the radiation surveys required under §2.1.1.3 through 2.1.1.7. The following conditions must also be met:
      - 2.1.2.2.1 All surveys shall be documented in the machine's usage log,

and

- 2.1.2.2.2 The RSO shall be notified whenever such a survey reveals radiation levels exceeding the limits defined in §2.1.3
- 2.1.2.3 A Radiation Safety staff member will inspect each machine's logbook at least once per calendar quarter.
- 2.1.3 IAW Title 25 of the Pennsylvania Code §227.12a (a-c):
  - 2.1.3.1 The source housing construction shall be of a type that when all shutters are closed and the source is in any possible operating mode, the leakage radiation will not be in excess of 2.5 mR/hr at a distance of 5 cm from the housing surface.
  - 2.1.3.2 The X-ray generator shall have a protective cabinet constructed so that the leakage radiation will not be in excess of 0.5 mR/hr at a distance of 5 cm from the housing surface.
  - 2.1.3.3 The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control so that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the limits given in 10 CFR §20.1301 (relating to dose limits for individual members of the general public). For systems utilizing X-ray tubes, these requirements shall be met at any specified tube rating.
- 2.2 Shielded Room Radiography
  - 2.2.1 IAW Title 25 of the Pennsylvania Code, §225.84(1), the RS Office shall ensure that no individual is likely to be exposed to radiation in excess of the limits established in Chapter 219 by requiring that radiation surveys are performed:
    - 2.2.1.1 Upon installation of the machine and at least every 12 months thereafter.
    - 2.2.1.2 Whenever safety and warning devices have been disassembled
    - 2.2.1.3 Following maintenance requiring the disassembly or removal of a local component.
    - 2.2.1.4 During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when a local component in the system is disassembled or removed
    - 2.2.1.5 When a visual inspection of the local component in the system reveals an abnormal condition.
    - 2.2.1.6 When the machine is operated in a manner other than the routine procedure specified in the written operating manual.

- 2.2.1.7 Following a change in the initial arrangement, number or type of local components in the radiation producing machine system
- 2.2.2 Delegation of Responsibility
  - 2.2.2.1 Radiation Safety staff will perform the radiation surveys required under §2.1.1.1 and 2.1.1.2
  - 2.2.2.2 The Principle Investigator (PI) responsible for the specific machine, or an individual designated by the PI and deemed qualified by the RSO, shall perform the radiation surveys required under §2.1.1.3 through 2.1.1.7. The following conditions must also be met:
    - 2.2.2.2.1 All surveys shall be documented in the machine's usage log, and
    - 2.2.2.2.2 The RSO shall be notified whenever such a survey reveals radiation levels exceeding the limits defined in §2.1.3
  - 2.2.2.3 A Radiation Safety staff member will inspect each machine's logbook at least once per calendar quarter.
- 2.3 Vacuum Spectroscopy
  - 2.3.1 IAW §227.11(h)(1)-(6) the RS Office shall ensure that surveys on Vacuum Spectrometers are performed:
    - 2.3.1.1 After setup, relocation, and
    - 2.3.1.2 After maintenance or repair requiring the disassembly of a local component or radiation shielding,
    - 2.3.1.3 And that units are designed so that when operating at the maximum kilovoltage and current ratings, the leakage radiation will not be in excess of 0.5 milliroentgens per hour at a distance of 4 centimeters from any external surface.
  - 2.3.2 Delegation of Responsibility
    - 2.3.2.1 Radiation Safety staff will perform the radiation surveys required under §2.3.1.1
    - 2.3.2.2 The Principle Investigator (PI) responsible for the specific machine, or an individual designated by the PI and deemed qualified by the RSO, shall perform the radiation surveys required under §2.3.1.2. The following conditions must also be met:
      - 2.3.2.2.1 All surveys shall be documented in the machine's usage log, and
      - 2.3.2.2.2 The RSO shall be notified whenever such a survey reveals radiation levels exceeding the limits defined in §2.1.3
    - 2.3.2.3 A Radiation Safety staff member will inspect each machine's logbook at

least annually.

#### 2.4 Electron Microscopes (EMs)

- 2.4.1 The RS Office shall survey EMs after setup, relocation, and annually thereafter, to ensure that radiation levels at 5 centimeters from any accessible surface may not exceed 0.5 mR/hr.

### **3.0 Warnings and Safety Devices**

#### 3.1 Analytical X-Ray Machines

- 3.1.1 Open-beam configurations shall have a device that either prevents the entry of any portion of the body into the primary beam path, or causes the beam to be terminated or interrupted upon entry into the beam path.
- 3.1.2 Open-beam configurations shall have easily identified devices located near one of the following:
- 3.1.2.1 The radiation source housing that gives a clear, visible indication of the X-ray tube status (on or off) if the primary beam is controlled in this manner.
- 3.1.2.2 Each port on the radiation source housing that gives a clear indication of the shutter status (open or closed) if the primary beam is controlled in this manner.
- 3.1.3 A warning label shall be posted on the X-ray source housing which states, "Caution - High intensity X-ray Beam," and another label which states, "Caution Radiation -This Equipment Produces Radiation When Energized", near any switch that energizes the X-ray tube.
- 3.1.2 A readily visible warning light illuminated when the X-ray tube is energized and labeled with the words "X-ray ON".
- 3.1.3 Unused ports on radiation housings shall be secured in the closed position in a manner, which will prevent casual opening.
- 3.1.5 Warning lights and devices on equipment manufactured and installed after December 19, 1987 shall have fail-safe characteristics.
- 3.1.6 On equipment with an open beam configuration manufactured and installed after December 19, 1987, each port on the radiant source housing shall be equipped with a shutter that cannot be opened unless a collimator or coupling has been connected to the port.

#### 3.2 Electron Microscopes

- 3.2.1 A warning label shall be posted on the electron microscope that states, "Caution Radiation -This Equipment Produces Radiation When Energized."

### **4.0 Personnel Monitoring**

#### 4.1 Analytical X-Ray Machines

- 4.1.1 Finger or wrist personnel monitoring devices shall be provided to and shall be used by all users working with open-beam configuration X-ray machines or performing maintenance on analytical X-Ray machines.
- 4.1.2 If an operator is exposed or suspects that he/she is exposed to the primary beam then he/she shall immediately notify the RS Office. The RSO will inform the operator of the required steps to follow.
- 4.2 Shielded Room Radiography
  - 4.2.1 Personnel monitoring devices shall be provided to and used by all users working with or performing maintenance on shielded room radiograph machines.
- 4.3 Exposure reports from the dosimetry vendor shall be kept, at a minimum until termination of all pertinent licenses by the PADEP.
- 4.4 Personal Monitoring Processing Service - a personal monitoring processing service with NVLAP accreditation will be used and the badge processing frequency is once every three months.

## **5.0 Radiation Safety Training**

- 5.1 Analytical X-ray Machines
  - 5.1.1 All personnel using analytical X-Ray machines shall complete radiation safety training for analytical X-ray machines. This training shall be conducted in two parts.
    - 5.1.1.1 Part 1 will be a didactic training provided by the Radiation Safety Office staff, IAW 10 CFR §19.12 (a) and 25 PA Code §227.14.
    - 5.1.1.2 Part 2 will be a practical training, designed to orient new users to a specific machine. The instruction will cover those requirements in §19.12 (a) and 25 PA Code §227.14 that are performed by the operator, such as the written operating and emergency instructions, the use of survey and personnel monitoring, and the significance of the various safety and warning devices incorporated into the equipment. This training will be provided by the pertinent department's designated technical supervisor.
- 5.2 Shielded Room Radiography
  - 5.3.1 All personnel using shielded room radiography shall complete radiation safety training for shielded room radiographers. This training shall be conducted in two parts.
    - 5.3.1.1 Part 1 will be a didactic training provided by the Radiation Safety Office staff, IAW 10 CFR §19.12 (a) and 25 PA Code §225.4(a).
    - 5.3.1.2 Part 2 will be a practical training, designed to orient new users to a specific machine. The instruction will cover those requirements in §19.12 (a) and 25 PA Code §225.4(a) that are performed by the operator, such as the written operating and emergency instructions, the use of survey and

personnel monitoring, and the significance of the various safety and warning devices incorporated into the equipment. This training will be provided by the pertinent department's designated technical supervisor.

### 5.3 Vacuum Spectroscopy

5.4.1 All personnel using vacuum spectrometers shall complete radiation safety training for those systems. This training shall be conducted in two parts.

5.4.1.1 Part 1 will be a didactic training provided by the Radiation Safety Office staff, IAW 10 CFR §19.12 (a) and 25 PA Code §227.14.

5.4.1.2 All personnel using vacuum spectrometers shall receive direction and instruction on the proper operation of vacuum spectrometers by the Department's designated technical supervisor. A copy of the operating procedure shall be readily available to the operator.

### 5.4 Electron Microscopes

5.5.1 All personnel using electron microscopes shall complete radiation safety training for EMs. This training shall be conducted in two parts.

5.5.1.1 Part 1 will be a didactic training provided by the Radiation Safety Office staff, IAW 10 CFR §19.12 (a) and 25 PA Code §227.33.

5.5.2.2 All personnel using electron microscopes shall receive direction and instruction on the proper operation of electron microscopes by the Department's designated technical supervisor. A copy of the operating procedure shall be readily available to the operator.

## **6.0 Over-exposures from the primary beam of any radiation producing device**

6.1 Reporting - Personnel using any radiation producing device shall report to the RSO any suspected or actual over-exposures caused by the primary beam.

6.1.1 The RSO shall direct that individual to seek medical attention.

6.1.2 The RSO shall investigate the circumstances surrounding the actual or suspected overexposure.

6.1.3 The RSO shall inform the PADEP within 5 days of a suspected overexposure regardless if subsequent investigation reveals no actual over-exposure actually occurred.

## **7.0 Operation**

7.1 Radiation Producing Devices

7.1.1 Operating procedures shall be written and made available to the radiation producing device operators. These procedures shall include:

7.1.1.1 Sample insertion and manipulation

7.1.1.2 Data recording procedures



- 7.1.1.3 Alignment Procedures
- 7.1.1.4 Emergency Procedures
- 7.1.2 An individual may not operate a radiation producing device in a manner other than that specified in the operating procedures unless the individual has obtained written approval from the RSO.
- 7.1.3 All personnel operating a radiation producing device shall receive instruction from the primary researcher and must demonstrate competence in the following topics prior to operating the machine(s):
  - 7.1.3.1 Identification of radiation hazards for that particular radiation producing device
  - 7.1.3.2 Significance of warning and safety devices associated with that particular radiation producing device
  - 7.1.3.3 Written operating procedures for that particular radiation producing device

7.2 (Reserved)

## **8.0 Safety Devices and Bypass Procedures for Analytical X-Ray Machines**

- 8.1 No person may bypass or otherwise circumvent a safety device (interlock) unless the individual has obtained the written approval of the RSO. The RSO shall grant the permission only if the following exist:
  - 8.1.1 The RSO establishes administrative controls and procedures to assure the radiation safety of individuals working around the system.
  - 8.1.2 The period for the bypass of the safety device is no longer than 30 days unless permission is obtained from PADEP for a longer period.
  - 8.1.3 A readily discernible sign bearing the words "Safety Device Not Working" is placed on the radiation source housing.
- 8.2 The purpose of 8.1 is to prevent the inadvertent exposure of an individual to the primary beam while the X-ray device is bypassed for other than routine sample or sample jig alignment procedures.
- 8.3 **UNDER NO CIRCUMSTANCE SHALL THE X-RAY UNIT BE LEFT UNATTENDED AND OPERATING WHILE ANY OF ITS SAFETY DEVICES ARE BYPASSED.**
- 8.4 Except as specified in 8.1, an operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops may not be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.
- 8.5 No person may bypass or otherwise circumvent a safety device (interlock) on a shielded room radiography machine.

## 9.0 Records

- 9.1 The following items will be maintained with each RPD and available for inspection:
  - 9.1.1 All users of RPDs shall make a record of their use of the device in a log book to include:
    - 9.1.1.1 Make and model of machine
    - 9.1.1.2 Identity of operator
    - 9.1.1.3 Date and time of use
  - 9.1.2 Training records for each person using a specific RPD
  - 9.1.3 Records of maintenance performed on each RPD
- 9.2 The Radiation Safety Office will maintain records of training and inspections in the Radiation Safety Office

## 10.0 Transfer and Disposal

- 10.1 Transfer - IAW 25 PA Code §216.6, whenever the University sells, leases, lends, gifts or transfers possession of an RPD, the Radiation Safety Office will notify the PA DEP, if not already notified by a registered radiation producing machine service provider, of the following information within 30 days:
  - 10.1.1 The name and address of persons that have received the machines or components
  - 10.1.2 The manufacturer, model, and serial number of a transferred machine.
  - 10.1.3 The date of RPD transfer
- 10.2 Disposal - The primary researcher shall notify the RS Office prior to disposal or transfer of any radiation producing-machines. The RS Office has 15 days to notify PADEP of the method of disposal used.

## 11.0 Revisions

Date	Documented Changes	Initials
7/18/2019		
4/27/2021	Updated Format and Accessibility Update	MAS
5/4/2023	Reviewed, but no updates needed	AJL
5/1/2024	Reviewed, but no updates needed	AJL

## **Appendix A - DEFINITIONS**

**Analytical X-ray machine** -An assembly of components utilizing X-rays to determine the elemental or chemical composition or to examine the microstructure of materials usually by X-ray diffraction or fluorescence.

**Cabinet X-ray system** -An X-ray system with the X-ray tube installed in an enclosed, interlocked cabinet.

**Certified cabinet X-ray system** -An X-ray system which has been certified under 21 CFR 1010.2 (relating to certification) as being manufactured and assembled under 21 CFR 1020.40 (relating to cabinet X-ray systems)

**Fail-safe characteristics** -A design feature which causes X-ray production to cease, beam port shutters to close or otherwise prevents emergence of the primary beam, upon failure of a safety or warning device.

**Local components** -Parts of an analytical X-ray system, such as radiation source housings, port and shutter assemblies collimators, sample holders, cameras, goniometers, detectors and shielding, that contain or are in the path of the X-ray beam. The term does not include power supplies, transformers, amplifiers, readout devices, and control panels.

**Non-Medical Fluoroscopic Facility** -Facility that uses Non-Medical Fluoroscopic machines for analytical research.

**Open-beam configuration** -An analytical X-ray system in which the beam is not enclosed or shielded so any portion of an individual's body could accidentally be placed in the beam path during normal operation

**Operating procedures** -Step-by-step instructions necessary to accomplish the analysis

**Permanent radiographic installation** -A shielded installation or structure designed or intended for radiography in which radiography is regularly performed.

**Primary beam** -Radiation that passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

**Shielded room radiography** - Industrial radiography that is conducted in an enclosed room, the

interior of which is not occupied during radiographic operations.

***Vacuum Spectroscopy*** – a vacuum technique that uses low energy X-rays to excite orbital electrons for chemical analysis. These instruments are typically exempt from many of the requirements of analytical X-ray machines under 227.11a (h).