Radiation Safety Procedures Manual

Non-Medical Radiation-Generating Equipment

THE OHIO STATE UNIVERSITY

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Executive Summary

X-ray generating machines and other ionizing radiation-generating equipment (RGE) present a potential safety hazard to students, staff and faculty if the equipment is not used and/or stored properly. Safety requirements for radiographic, analytical, particle accelerators and cabinet irradiation devices are described in this manual and the Ohio Department of Health regulations.

The Ohio Department of Health (ODH) regulates the registration, use, transfer, and disposal of radiation-generating devices in the State of Ohio.

This document outlines The Ohio State University (University) rules and regulations for the safe operation of radiation-generating devices (non-human use) and specifies practices to aid radiation-generating equipment users in minimizing their exposure to radiation. These measures will help ensure compliance with ODH regulations but will succeed only when each user follows the guidelines contained in this document.

Ohio Administrative Code, Chapter 3701:1-68, "Non-Medical Radiation-Generating Equipment" includes regulations specific for non-medical radiographic, analytical, accelerator and cabinet irradiation systems including the following:

- X-ray Diffraction Devices
- X-ray Fluorescence Devices
- Security Screening Systems
- Industrial Radiography Systems
- Gauging Units
- X-Ray Irradiation Devices
- Portable Non-Medical X-ray Radiography
- Industrial/Research Computed Tomography
- Particle Accelerator

This equipment may be intended for laboratory or field use as well as academic settings. Much of this equipment is manufactured commercially, however, custom-built x-ray generating equipment is found at the University.

This manual was developed to assist University personnel in meeting safety and regulatory requirements and provide integration of ODH occupational radiation protection standards. Reviewed in this manual are types of equipment, occupational radiation exposure limits, and radiation protection regulations and recommendations. Additionally, safety program issues pertaining to equipment, facilities and personnel are discussed.

Surveys of various instruments and equipment have shown that changes in operating conditions or components have the potential for increasing ambient radiation fields. The implementation of sound radiation safety principles when operating x-ray generating equipment will provide personnel protection from acute radiation hazards and limit chronic radiation exposure to levels **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA).

Introduction

X-ray generating machines and other ionizing RGDs present a potential safety hazard to students, staff, and faculty if the device is not used and/or stored properly. The Radiation Safety Section of Environmental Health and Safety is required to register, maintain a current inventory / registration and, through inspection, ensure the compliance of all x-ray devices located within the University to applicable regulatory standards / guidance. The ODH will inspect the University's x-ray devices and operations on a periodic basis. For research and analytical devices this period is every three (3) years. The ODH has the authority to issue violations for any regulation that an x-ray user, researcher, or Principal Investigator (PI) is not following.

This manual is intended to inform non-human/non-medical use x-ray device users of the regulations with which they are required to comply. If there are any questions concerning the applicability of any regulation, please contact the Radiation Safety Section of Environmental Health and Safety at:

1) (614) 292-1284 (Main Office)
2) radiation.safety@osu.edu

Radiation Emergency Cell Phone – (614) 561-7969 (24-Hour)

Additional information, registration forms and standard operating procedure templates for radiation-generating equipment can be found at ehs.osu.edu.

Potential Hazards of Radiation-Generating Equipment

Non-Medical Analytical Systems

The most common non-medical x-ray device found throughout the University is referred to as an analytical x-ray or analytical radiation-generating equipment. This includes x-ray diffractometers, x-ray fluorescence spectrometers, and gauging units. These types of devices are used to evaluate the elemental or chemical composition or microscopic structure of a material. These devices feature a primary x-ray beam consisting of low energy x-rays at a very high intensity and are strictly collimated to examine the properties of a material. For that reason, the exposure to the primary x-ray beam can result in a high amount radiation absorbed (dose) to the user. Despite the low energy of the x-rays, primary beam intensities up to 40,000 roentgens per minute (R/min) may be possible. Exposure of extremities to the primary x-ray beam can result in severe radiation burns in a matter of seconds. Radiation burns are the principle hazard associated with the use of analytical x-ray devices.

The primary x-ray beam is not the only hazard associated with these devices. Leakage or scatter of the primary x-ray beam through apertures in ill-fitting or defective devices can produce very high intensity beams of possibly small and irregular cross section. Dose rates near the device from scattered radiation can be also be very high. Although not likely to cause burns, exposure to and subsequent absorbed doses from the scattered radiation can exceed regulatory limits if the beam is not properly enclosed or contained. In fluorescence, the primary beam strikes the sample inside a shielded enclosure and only scattered radiation and secondary beam radiation excited in the sample, as a result, irradiation emerges from the machine for analysis. Consequently, external levels are much lower in the fluorescence mode than in the x-ray diffraction mode.

Modern x-ray diffraction machines incorporate shielding and safety design features to prevent both acute local accidental exposure and chronic exposure to radiation. Operators should be especially cognizant of protective devices incorporated into their machines and the possibility for failure or malfunction. In addition, decreasing time, increasing distance and shielding represent the most practical methods a radiation worker can use to minimize radiation exposure.

Non-Medical Radiographic Systems

X-ray radiography systems use non-destructive methods to examine the macroscopic structure of materials. Radiography systems can be categorized as open beam systems which are generally contained within a permanent radiographic installation or an enclosed system where the primary beam is contained within an enclosure and excludes all personnel and extremities from admittance.

Non-Medical Accelerator Systems

Accelerator laboratories and technologies continue to make significant contributions to the diverse needs of radioisotope supply, research, security and defense. These applications range from providing fundamental data-bases for radiation interactions with materials, nuclear forensics, radioisotope production and high energy density physics to system-level technology developments of directed energy system concepts, cargo inspection and interrogation, industrial and medical radiological source replacement and stockpile stewardship.

Radiation-generating equipment used for particle acceleration can create x-rays in addition to radioisotopes in the target material placed in the beam of accelerated particles.

Non-Medical Cabinet Systems

Cabinet irradiation systems are used to alter the chemical, biological, or physical properties of materials or to sterilize materials. Cabinet irradiation systems generate irradiations that occur within an enclosed x-ray system. The shielded enclosure limits the dose rates at all exterior surfaces while excluding all personnel and extremities from admittance.

For these reasons, an even greater potential hazard exists with these devices as higher applied voltages and the longer exposure times are used as compared to analytical x-ray devices. Typical applied voltages of 200 kiloelectron volts (keV) or greater are common. Additional regulations apply to these devices.

Definitions

- “Analytical system" means non-medical radiation-generating equipment used to determine properties of materials being measured or analyzed. Analytical systems include, but is not limited to, gauging units, x-ray diffraction and x-ray fluorescence equipment.
- "Annual" means at least once a year, not to exceed thirteen months.
- "Cabinet irradiation" means irradiation conducted using a cabinet x-ray system.
- "Cabinet radiography" means radiography conducted using a cabinet x-ray system.
- "Cabinet system" means non-medical radiation-generating equipment which is installed in a shielded enclosure that excludes all personnel, including extremities, from the primary beam during the generation of radiation.
- "Calibration" means the determination of the response or reading of an instrument relative to a series of known radiation values over the range of the instrument.
- "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.
- "Enclosed system" means radiation-generating equipment operated in an enclosure or cabinet and may include, but is not limited to, cabinet radiography, irradiation devices and other equipment.
- "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon failure of a safety or warning device.
- "Hand-held system" means non-medical radiation-generating equipment that is specifically designed to be held in the hand during operation. Hand-held systems include analytical and radiographic systems.
- “Individual user” is a trained and qualified operator using RGE under the supervision of a PI.
- “Individual responsible for radiation protection (IRRP)” means an individual designated by the registrant who has the knowledge and responsibility for the overall quality assurance and radiation safety program at the facility, to include the implementation of the daily radiation safety operations and compliance with the rules.
- "Industrial radiation-generating equipment" means any x-ray device other than those used on patients for medical diagnosis or therapy purposes, including, but not limited to, industrial radiography equipment, irradiators, analytical devices, and particle accelerators.
- "Irradiation system" means non-medical radiation-generating equipment used to alter the chemical, biological, or physical properties of materials or to sterilize materials.
- "Leakage radiation" means all radiation coming from within the x-ray tube housing except the useful beam.
- “Locked out and tagged” means a process for equipment security and safety in which non-medical radiation-generating equipment is locked to prevent operation and tagged with specific information as to why it is not to be used.
- "Nondestructive testing (NDT)" means the development and application of technical methods to examine materials or components in ways that do not impair future usefulness and serviceability in order to detect, locate, measure and evaluate flaws; to assess integrity, properties and composition; and to measure geometrical characteristics.
- “Non-medical radiation-generating equipment” means any x-ray equipment other than a security screening system designed to scan individuals, or those used on patients or human research subjects for medical or therapy purposes.
- "Open-beam analytical system" means an analytical radiation-generating equipment system in which an individual could place any part of his or her body in the primary beam during normal operation.
- “Particle accelerator system” means non-medical radiation-generating equipment designed for, or capable of, accelerating electrically charged particles.
- "Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which industrial radiography is performed. Permanent radiographic installation includes a cabinet x-ray system used for industrial radiography that is large enough to walk into.
- “Principle Investigator (PI)” is the individual responsible for the operation and handling of the device.
- “Radiographer” means an individual who operates or personally supervises the operation of radiographic systems, related equipment, or radiation survey instruments for radiographic operations.
- “Radiographic system” means non-medical radiation-generating equipment used to examine the macroscopic structures of material.
- "Shutter" means a device, fixed to any radiation source housing to intercept the primary beam.

Responsibilities

University Radiation Safety Officer and the Radiation Safety Section (RSS)

1) Maintain an accurate inventory and registration of all devices with ODH.
2) Perform audits / inspections, surveys and inventory checks of all registered radiation-generating equipment at intervals required.
3) Actively advise PIs and individual users on the safe use of radiation-generating equipment.

Principle Investigator (PI)

1) Primary authority, responsibility, and accountability for ensuring regulatory compliance and radiological safety within their work group as set forth in this manual and with the ODH regulations.
2) Notify RSS of the acquisition, relocation, transfer, or disposal of any x-ray or radiation-generating equipment.

   Notification should be submitted in a timely fashion via form RGD-1 "Registration for the Use/Storage of Radiation-Generating Devices," located at:

   Registration for the Use/Storage of Radiation-Generating Devices

   Please email the completed form to radiation.safety@osu.edu.

3) Actively train and advise individual users on the safe use of radiation-generating equipment.
4) Development of a safe operating procedure (SOP) for radiation-generating equipment system.
5) Reporting any unsafe working conditions and/or defective devices to Radiation Safety Section.

Individual Users

1) Compliance with this manual, laboratory/facility SOPs and ODH regulations.
2) Reporting any unsafe working conditions and/or defective devices to their associated PI and/or Radiation Safety Section.

Planning

The importance of planning the installation and use of machines cannot be overemphasized. Adequate lead times must be allowed for review of facilities that require new construction or remodeling and registration with ODH. Pre-operational evaluation of shielding and operating procedures is required before routine use of such machines can be authorized.

Inspections, Surveys, and Inventory

The ODH will inspect all x-ray and radiation-generating devices on a periodic basis. The current ODH inspection schedule is every three (3) years. ODH has the authority to issue violations of the regulations. If the device PI does not correct these violations within 30 days, the ODH has the authority to issue a "Cease Operations Order". Financial penalties may also be assessed the PI.

The Radiation Safety Section shall perform audits / inspections, surveys, and inventory checks with the appropriate frequencies as indicated in the appropriate section of the ODH regulations. RSS will also perform an annual inventory of all inoperable units.

Violations

It is the responsibility of the PI to provide written corrective actions to inspections performed by the ODH to the Radiation Safety Section of Environmental Health and Safety. RSS is responsible for providing a collective response to the ODH. Failure of a PI to provide the written corrective action within the 30-day period may result in civil penalties by the ODH and a "Cease Operations Order" from the ODH.

Violations posing an imminent health hazard shall result in immediate cessation of the specific activity in that facility.

Administrative violations not corrected promptly will be referred to the University Radiation Safety Officer for resolution and may result in temporary suspension of the use of the equipment.

Availability of Applicable Documents

Copies of the University's registrations, inspection findings, and a current copy of the Ohio Administrative Code are available for review in the Radiation Safety Section of Environmental Health and Safety located in Room 106, Research Center Building, 1314 Kinnear Road, Columbus, Ohio 43212.

A copy of the Ohio Administrative Code (OAC) regulations is available at:

1) ODH Radiation Protection Rules and Regulations
2) Non-Medical Radiation-Generating Equipment
    a. 3701:1-68-03 ~ Non-medical radiographic systems
    b. 3701:1-68-04 ~ Non-medical analytical systems
    c. 3701:1-68-05 ~ Non-medical accelerator systems
    d. 3701:1-68-06 ~ Non-medical cabinet systems

Radiation Safety Procedures

Non-Medical Radiographic Systems

- Principle investigators and individual users of non-medical radiographic radiation-generating equipment must maintain compliance with OAC http://codes.ohio.gov/oac/3701:1-68-03v1

- **Note handlers of hand-held radiographic systems are exempt from paragraphs (B)(1-3,6-11) and (C)(1-4) of OAC 3701:1-68-03.**

  Requirements include (but are not limited to) the following items:

  - Submission of a completed RGE-1 Form, "Registration for the Use/Storage of Radiation Generating Equipment" to Radiation Safety Section as described in the Responsibilities section (Page 7).
  - Laboratory/equipment location should be labeled as follows (or similar). Contact Radiation Safety Section or your Laboratory Compliance Officer for room signage.

  - All irradiation radiation-generating equipment shall conspicuously display a clearly legible label or labels bearing the radiation symbol and the words "CAUTION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or appropriate words having a similar intent, near any switch or control that directly energizes the unit. Contact Radiation Safety Section or your Laboratory Compliance Officer for labels. Example:

  - No PI shall permit any individual to operate the device until such individual has received a copy of, and instruction in, the operating procedures for the equipment and has demonstrated competence in its use. Maintain documentation that individual users have received appropriate training.
  - Maintain written standard operating procedures. This may include the manufacturer's manual, but may not rely exclusively upon it.
  - Tests for proper operation of high radiation area control devices, interlocks, warning lights and labels shall be conducted, recorded and maintained on three (3) month intervals, not to exceed fourteen (14) weeks.

- Non-medical radiographers and assistants must be certified through an independent approved program.
  - No individual other than a radiographer or a radiographer's assistant who is under the personal supervision of a radiographer shall manipulate controls or operate equipment used in radiographic operations.
- Laboratory/device location should be labeled as follows (or similar) as applicable. Contact Radiation Safety Section or your Laboratory Compliance Officer for room signage.

- A lock designed to prevent unauthorized or accidental production of ionizing radiation shall be provided.
  - Non-medical radiographic systems shall be kept locked at all times, to prevent tampering or removal by unauthorized personnel, except when under the direct surveillance of an authorized radiographer.
- Non-medical permanent radiographic installations enclosed in a shielded room, cell or vault involves a high radiation area in which radiation levels could result in an individual exposure of 0.1 rem in one hour at 30cm from the x-ray source shall be equipped with the following:
  - Failsafe interlock at each entrance used for personnel access to the high radiation area.
  - A visible signal that is activated when radiation is produced.
  - An audible signal that is activated when an attempt is made to enter the high radiation area while radiation is being produced.
- A readily visible warning light, labeled with the words "X-RAY ON" or words or symbols having a similar intent, shall be located on or near the source of radiation and its controls and shall be illuminated when the radiation source is energized.
- The exposure switch of hand-held radiographic systems shall be of the "dead-man" type resulting in the exposure stopping upon release of the exposure control switch.
- Non-medical radiographic systems shall be checked prior to each day or shift of use to identify any obvious defects.
- Entrance control devices and alarm systems shall be tested at the beginning of each day of equipment use for proper operation.
- A physical inventory and tests for proper operation of high radiation area control devices, interlocks, warning lights, and labels shall be conducted, recorded, and maintained on three (3) month intervals, not to exceed fourteen (14) weeks of all industrial radiography devices to assure proper functioning of components important to safety.

- Non-medical radiographic systems must be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:
    - "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar meaning on or near the x-ray source housing.

    - "CAUTION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar meaning near any switch or control that energizes the unit.

- Sufficient calibrated and operable radiation survey instruments shall be maintained to make physical radiation surveys as required by this rule and rule OAC 3701:1-38-14. Instrumentation shall have a range such that two (2) millirem per hour through one (1) rem per hour can be measured and be calibrated at intervals not to exceed one year and after each instrument servicing other than battery replacement.
    - No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation is available and used at each site where radiographic exposures are made.
    - Radiation survey instrumentation shall be checked at the beginning of each day of use and at the beginning of each work shift using check sources or other appropriate means to ensure it is operating accurately.
    - A physical radiation survey shall be made after each radiographic exposure to verify that the radiation-generating equipment is not still producing radiation unless personnel devices providing an audible signal when activated by radiation and proper operation of the audible detection device is checked and recorded daily or stationary area monitors providing an audible signal when activated by radiation with daily checks/recordings of proper operation.
- Radiographer and radiographer assistant must wear a direct reading and personnel dosimeter during radiographic operations. Direct reading dosimeters are read and exposures recorded at the beginning and end of each shift. Personnel dosimeters must be exchanged monthly unless the IRRP has completed an evaluation that indicates the exchange frequency can be extended to three months.

- A utilization log shall be maintained between inspections showing the following information for each radiographic system used:
  - Manufacturer, model number and serial number.
  - Locations and dates of the radiographic system's use.
  - Results of radiation surveys.
  - Operating kilovoltage, tube current and exposure time for each radiographic exposure.
  - Name and signature of the radiographer/operator.
- Maintain operating and emergency procedures. A template standard operating procedure (SOP) including a training log for RGE is available at: (http://ehs.osu.edu/RadSafety/Xray.aspx).
- Non-medical radiographic equipment shall not be used to intentionally irradiate human beings for any purpose.
- ODH "Notice to Employees" is conspicuously posted. Contact Radiation Safety Section or your Laboratory Compliance Officer for a copy of this posting.

- Radiation Safety Section Responsibilities

  - Perform radiation surveys:
    - Upon installation of the non-medical radiographic system.
    - Following any change in the initial arrangement, number or type of components
    - Following any maintenance requiring the disassembly or removal of components
    - During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any component in the system is disassembled or removed.
    - Any time a visual inspection of the components in the system reveals an abnormal condition.
    - Whenever personnel monitoring reports show an unexplained increase over the previous monitoring period or the readings are approaching the limits specified in rules adopted pursuant to Chapter 3701:1-38 of the Administrative Code.
  - Perform quarterly inspections of all radiation safety devices, such as interlocks, lights and labels. Additionally, an audit of the device documentation will be performed on a semi-annual basis.
  - Perform an annual inventory of all inoperable units.
  - Maintain the ODH registration of non-medical radiographic equipment.

Non-Medical Analytical Radiation-Generating Systems

- Principle investigators and individual users of non-medical analytical radiation-generating equipment must maintain compliance with OAC http://codes.ohio.gov/oac/3701:1-68-04v1

  Note that handlers of gauging units shall be exempt from the requirements of paragraphs (C)(2)(c) to (C)(2)(e) of OAC 3701:1-68-04.

  Note that handlers of hand-held open beam analytical systems shall be exempt from the requirements of paragraphs (A)(1) and (A)(3) but maintain compliance with paragraph (E)(2) of OAC 3701:1-68-04.

- Requirements include (but are not limited to) the following items:

  - Submission of a completed RGE-1 Form, "Registration for the Use/Storage of Radiation Generating Equipment" to Radiation Safety Section as described in the Responsibilities section (Page 7).

- Laboratory/equipment location should be labeled as follows (or similar). Contact Radiation Safety Section or your Laboratory Compliance Officer for room signage.

- Analytical systems must have an appropriate warning label located near the exposure switch or control. The label must display the radiation symbol and the words "CAUTION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or wording having similar intent.

  Open beam analytical systems must have an additional warning label located on or near the x-ray housing with the radiation symbol with the words "CAUTION - HIGH INTENSITY X-RAY BEAM" or wording having similar intent. Contact Radiation Safety Section or your Laboratory Compliance Officer for labels. Examples:

- Analytical systems installed after February 10, 2006, must have functioning warning lights located both near the x-ray source and near the x-ray control panel. The warning lights must read "X-RAY ON" or have a similar intent and must illuminate during x-ray exposure. In addition, open beam configurations shall be provided with a readily discernible indication of:
  - X-ray source power "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; or
  - Shutter "open-closed" status located near each radiation port on the source housing if the primary beam is controlled in this manner.
- Except for gauging units, open-beam analytical systems installed after February 10, 2006 must have warning devices or a system of warning devices such as redundant lights with fail-safe characteristics.
- X-ray source housings of analytical systems installed on or after August 1, 2011 must have an interlock that shuts the radiation off before a door or port is opened and before the housing is disassembled. X-ray source housings of analytical systems installed prior to August 1, 2011 and not equipped with an interlock shall have administrative procedures requiring the power be disconnected prior to any disassembly.
- Except for hand-held analytical units, open-beam analytical systems must have an automatic shut-off feature that prevents any part of the body from being exposed to the primary x-ray beam path. If an open-beam system does not have an automatic shut-off feature to comply with this rule, the handler can request a variance to the rule from the Director of Health.
- Unused radiation ports (collimators) on x-ray source housings shall be secured in the closed position or mechanically blocked.

- Leakage radiation measured at five (5) centimeters from the surface shall not exceed 0.25 millirem in one hour. Radiation Safety Section will perform a radiation survey of the analytical system after installation and maintenance thereafter. Additional radiation surveys may be necessary as described below.
- No PI shall permit any individual to operate the device until such individual has received a copy of, and instruction in, the operating procedures for the equipment and has demonstrated competence in its use. Maintain documentation of training of individual users.
- Maintain written standard operating procedures. This may include the manufacturer's manual, but may not rely exclusively upon it. A template standard operating procedure (SOP) including a training log for analytical RGE is available at: (http://ehs.osu.edu/RadSafety/Xray.aspx).
- Inform Radiation Safety Section of the repair, acquisition, relocation, transfer or disposal of any unit. Radiation Safety Section must also be notified if an operable unit becomes inoperable or an inoperable unit is returned to service.
- ODH "Notice to Employees" is conspicuously posted. Contact Radiation Safety Section or your Laboratory Compliance Officer for a copy of this posting.

- Radiation Safety Section Responsibilities:

  - Perform radiation surveys:
    - Upon installation of the analytical radiation-generating equipment.
    - Following any change in the initial arrangement, number or type of components.
    - Following any maintenance requiring the disassembly or removal of a component.
    - During the performance of maintenance and alignment procedures if the procedures require energizing primary x-ray beam when any component in the system is disassembled or removed.
    - Any time a visual inspection of the components reveals an abnormal condition.
    - Whenever personnel monitoring reports show an unexplained increase over the previous monitoring period or the readings are approaching the limits specified in rules adopted pursuant to Chapter 3701:1-38 of the Administrative Code.
  - Perform semi-annual inspections of radiation safety properties such as interlocks, lights and labels. Additionally, a semi-annual audit of the radiation generating equipment documentation will be performed.
  - Perform an annual inventory of all inoperable units.
  - Maintain the ODH registration of all non-medical analytical radiation-generating equipment.

Non-Medical Particle Accelerator Systems

- In addition to the applicable rules in this chapter and OAC Chapter 3701:1-38, principle investigators and individual users of non-medical particle accelerator systems must maintain compliance with OAC Chapter 3701:1-68-05 available at: http://codes.ohio.gov/oac/3701:1-68-05v1

- Requirements include (but are not limited to) the following items:

  - Submission of a completed RGE-1 Form, "Registration for the Use/Storage of Radiation Generating Equipment" to Radiation Safety Section as described in the Responsibilities section (Page 7).

- Laboratory/equipment location should be labeled as follows (or similar). Contact Radiation Safety Section or your Laboratory Compliance Officer for room signage.

- Radiation-generating equipment used for particle acceleration shall meet the following standards:
  - Safety instrumentation, readouts and controls shall be clearly identified
  - Safety interlocks must operate independently
  - Safety systems shall be designed so that a defect or component failure prevents operation
  - Safety interlocks must be manually reset after tripping to resume operation of accelerator
  - A warning label indicating radiation is produced when the accelerator is energized shall be located on the control console
- Handlers of particle accelerator systems shall comply with the following radiation safety requirements:
  - Particle accelerator installation shall be provided with such shielding to assure compliance with applicable rules of OAC Chapter 3701:1-38.
  - Each entrance into a target room must have a safety interlock that shuts down the equipment in the event of any barrier penetration.
  - Each high radiation area shall have an audible and visual signal which shall be activated prior to the possible creation of such a high radiation area.
  - Each location designated as a high radiation area, and each entrance to such location, shall be equipped with visible signals that illuminate when the high voltage portion of the equipment is energized.
  - An emergency power cutoff switch shall be located in all high radiation areas and shall include a manual reset so that the accelerator cannot be restarted from the control panel without resetting the cutoff switch.
  - Appropriate portable monitoring equipment, calibrated at intervals not to exceed one year and after each servicing/repair, shall be available at each particle accelerator facility.
- Particle accelerator operator must wear a direct reading and personnel dosimeter during operations. Direct reading dosimeters are read and exposures recorded at the beginning and end of each shift. Personnel dosimeters must be exchanged monthly unless the IRRP has completed an evaluation that indicates the exchange frequency can be extended to three months.
- Safety interlock system shall not be used to turn off the particle accelerator beam except in an emergency or when testing the safety interlock system.
- If it is necessary to intentionally bypass a safety interlock system, such action must be authorized by the University Radiation Safety Officer/IRRP, recorded in a permanent log, posted as a written notice at the control panel and terminated as soon as possible.
- No PI shall permit any individual to operate the device until such individual has received a copy of, and instruction in, the operating procedures for the equipment and has demonstrated competence in its use. Maintain documentation that individual users have received appropriate training.

- In addition to the requirements of OAC 3701:1-68-02, handlers of particle accelerator systems shall comply with the following quality assurance requirements:
  - A health physicist or radiation expert, with education and experience acceptable to the Director of Health, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is capable of producing radiation.
  - A radiation shielding survey shall be completed when changes have been made in shielding, operation, equipment or occupancy of adjacent areas.
  - All surveys shall be made in accordance with the written procedures established by a health physicist or radiation expert with education and experience acceptable to the Director of Health.
  - Portable monitoring equipment shall be tested for proper operation and results recorded daily.
  - Particle accelerator systems shall be evaluated for proper functioning of interlocks and appropriate signage/labels and the results recorded at least every three months not to exceed fourteen weeks unless the system has been locked out and tagged "DO NOT USE" and is under administrative control of the University Radiation Safety Officer/IRRP.
  - Radiation levels in all high radiation areas shall be continuously monitored
- Maintain written standard operating and emergency procedures. This may include the manufacturer's manual but may not rely exclusively upon it.
  A template standard operating procedure (SOP) including a training log for particle accelerator equipment is available from Radiation Safety Section (http://ehs.osu.edu/RadSafety/Xray.aspx).
- Inform Radiation Safety Section of the repair, acquisition, relocation, transfer or disposal of any unit. Radiation Safety Section must also be notified if an operable unit becomes inoperable or an inoperable unit is returned to service.
- ODH "Notice to Employees" is conspicuously posted. Contact Radiation Safety Section or your Laboratory Compliance Officer for a copy of this posting.

- Radiation Safety Section Responsibilities:

  - Perform an initial radiation survey of all newly installed particle accelerator systems.
  - Perform an annual inspection / audit of all operable particle accelerator systems including device documentation.
  - Perform an annual inventory of all inoperable devices.
  - Maintain the ODH registration of all particle accelerators.
  - Confirm the University Radiation Safety Officer/IRRP is qualified in accordance with paragraph (B)(14) of OAC 3701:1-68-01 and paragraph (I) of OAC 3701:1-68-02

Non-Medical Cabinet Radiation-Generating Systems

- Principle investigators and individual users of non-medical cabinet radiation-generating equipment must maintain compliance with OAC http://codes.ohio.gov/oac/3701:1-68-06v1

- Requirements include (but are not limited to) the following items:

  - Submission of a completed RGE-1 Form, "Registration for the Use/Storage of Radiation Generating Equipment" to Radiation Safety Section as described in the Responsibilities section (Page 7).

- Laboratory/equipment location should be labeled as follows (or similar). Contact Radiation Safety Section or your Laboratory Compliance Officer for room signage.

- Cabinet systems shall be designed to limit leakage radiation at 5cm from the surface to no more than 0.5mR/hr. Area surveys must be completed initially on cabinet systems.
- Cabinet systems shall be designed to prevent insertion of the human body through any port or aperture into the primary beam.
- Cabinet system doors shall be designed with two safety interlocks.
    - One safety interlock must be designed to disconnect the energy supply circuit from the high-voltage generator to stop radiation production when the door is opened.
    - Cabinet systems shall be designed with at least one safety interlock on the access panel.
    - If radiation generation is disrupted by a safety interlock, a control must be used to restart the production of radiation from the cabinet system.
- Cabinet systems shall have a key-actuated control to generate radiation.
    - The cabinet system shall not be able to generate radiation without the key.
    - Cabinet systems shall be designed with specific controls to initiate and terminate radiation. Turning the main power switch must not initiate radiation generation and tripping the safety interlocks must not be the only way to terminate radiation generation.
- Cabinet systems shall be designed with at least two independent means to indicate when radiation is being generated. The two means that indicate radiation generation must be visible from the control area that initiates radiation generation. Failure of a single part of the cabinet system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled “X-RAY ON”.
- Cabinet systems shall be designed with clearly visible indicators of x-ray generation at each door, access panel and port.
- Cabinet systems must have an appropriate warning label located near the exposure switch or control. The label must display the radiation symbol and the words "CAUTION – X-RAYS PRODUCED WHEN ENERGIZED" or wording having similar intent.

- Cabinet systems with ports must have an additional warning label located on or near each port. The label must display the words "CAUTION – DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED" or wording having similar intent. Contact Radiation Safety Section or your Laboratory Compliance Officer for labels. Examples include:

- Cabinet systems designed to admit humans must have additional controls to assure safety of users.
  - Cabinet systems designed to admit humans must include a control within the enclosure that can prevent or stop the radiation from generating. This control must be electrically and/or mechanically separated from the interlock system and cannot be reset, overridden or bypassed from outside the enclosure.
  - Cabinet systems designed to admit humans shall not have a way to initiate radiation from within the enclosure.
  - Cabinet systems designed to admit humans must have audible and visual signals within the enclosure that are activated ten seconds prior to the first initiation of radiation production after closing any admittance door. Failure of any single part of the cabinet system shall not cause failure of both the audible and visual warning signals.
  - Cabinet systems designed to admit humans must have a functioning visible signal inside the enclosure that illuminates when and only when radiation is being produced.
  - Cabinet systems designed to admit humans must have a functioning visible signal at the entrance that illuminates when and only when radiation is being produced.
  - Cabinet systems designed to admit humans must have signs explaining that if you see and/or hear the warning signals while in the enclosure, press the stop control and immediately evacuate the enclosure.
  - Cabinet systems designed to admit humans must always have a way for a person to leave the enclosure at any time, usually through the admittance door, which also trips the safety interlocks to terminate radiation.
- Cabinet systems with assessable openings must have the means for operators to be at the controls and observe the openings and doors.
  - The operator at the controls must have a means to terminate the exposure or preset succession of exposures at any time.
  - A means to allow completion of the exposure in progress is permissible but the operator shall be allowed to prevent additional exposures from the controls.

- Cabinet systems must be evaluated and the results recorded at least every three months. The individual performing the evaluation must be qualified to operate cabinet systems. This evaluation does not need to be completed if the cabinet system is locked out and tagged "DO NOT USE". Evaluation shall include:
    - Check for proper functioning of the interlocks and warning lights.
    - Check to make certain warning tags and labels are readable and affixed in the proper locations.
    - If an interlock, control or warning signal is not functioning properly, it must be immediately labeled as defective and repaired or replaced within seven calendar days. Otherwise, the cabinet system must be locked out and tagged "DO NO USE" and placed under administrative control of the IRRP.
- Radiation area surveys shall be performed and the results recorded to confirm compliance with this rule and OAC 3701:1-38-14 paragraph (A).
    - Radiation area survey must be performed upon installation
    - Radiation area survey must assure the occupational dose limits of OAC 3701:1-38-12(A) are observed.
    - Radiation area survey must assure the TEDE to an individual member of the general public and the dose in any unrestricted area from external radiation sources not exceed the limits specified in OAC 3701:1-38-13 paragraph (A)(1 and 2).
    - Radiation area survey must be performed during maintenance, calibration or other testing of the cabinet system requiring the presence of the primary x-ray beam to confirm compliance with OAC 3701:1-38-14(A).
    - Radiation a survey must be performed any time a visual inspection reveals abnormal conditions or damage to confirm compliance with OAC 3701:1-38-14(A).
- A physical radiation survey using a radiation survey instrument must be made after each exposure and before entry into a cabinet system designed to admit humans to verify the radiation-generating equipment is not still producing radiation unless appropriate personnel monitoring devices are being used.
    - Personnel devices providing an audible signal can be used for physical radiation entry surveys with proper operation of the device checked and recorded daily.
    - Personnel devices providing an audible signal used for physical radiation entry surveys must be designed to detect entry into a 2mrem/hr or greater radiation field.
    - If personnel devices providing an audible signal are used for physical radiation entry surveys, all personnel working with the walk-in cabinet system are required to have and use the personnel device providing audible signal.
    - Stationary area monitors providing an audible signal when activated by radiation can be used for physical radiation entry surveys with proper operation of the device checked and recorded daily.
    - Stationary area monitors providing an audible signal used for physical radiation entry surveys must be designed to detect entry into a 2mrem/hr or greater radiation field.
    - If stationary area monitors providing an audible signal are used for physical radiation entry surveys, the monitors must be evaluated annually to determine that the audible signal operates in a 2mrem/hr or greater radiation field.

- The IRRP shall be qualified in accordance of OAC 3701:1-68-01(B)(14) and OAC 3701:1-68-02(H) requiring the following training;
  - Safe operating procedures for the equipment
  - Precautions and measures to take to minimize radiation exposure
  - Significance of various warning, safety devices and interlocks incorporated into the system or reasons they have not been installed
  - Recognition of the potential hazards of use, biological effects of radiation, radiation risks and recognition of signs and symptoms of an acute localized exposure
  - Procedures for reporting an actual or suspected accidental exposure or other radiation safety concerns
  - Performing radiation surveys where applicable.
- Maintain written standard operating procedures. This may include the manufacturer's manual but may not rely exclusively upon it. A template standard operating procedure (SOP) including a training log for analytical RGE is available at: (http://ehs.osu.edu/RadSafety/Xray.aspx).
- Inform Radiation Safety Section of the repair, acquisition, relocation, transfer or disposal of any unit. Radiation Safety Section must also be notified if an operable unit becomes inoperable or an inoperable unit is returned to service.
- ODH "Notice to Employees" is conspicuously posted. Contact Radiation Safety Section or your Laboratory Compliance Officer for a copy of this posting.

- Radiation Safety Section Responsibilities:

  - Perform radiation surveys:
    - Upon installation of the cabinet system radiation-generating equipment.
    - Following any change in the initial arrangement, number or type of components.
    - Following any maintenance requiring the disassembly or removal of a component.
    - During the performance of maintenance and alignment procedures if the procedures require energizing primary x-ray beam when any component in the system is disassembled or removed.
    - Any time a visual inspection of the components reveals an abnormal condition.
  - Perform quarterly inspections of radiation safety properties such as interlocks, lights and labels. Additionally, a quarterly audit of the radiation generating equipment documentation will be performed.
  - Perform an annual inventory of all inoperable units.
  - Maintain the ODH registration of all non-medical cabinet systems radiation-generating equipment.

Radiation Dose Limits and Notification to the Ohio Department of Health of Overexposures

Occupational Dose Limits

In order to detect and evaluate exposure to external radiation, individual monitoring devices will be issued to individuals who are likely to receive, in one year from sources external to the body, a dose in excess of ten (10) percent of the applicable annual limits.

Annual Limits

Category	ODH Dose Limit (rem per year)
Adult Worker	
Total Effective Dose Equivalent	5
Total Organ Dose Equivalent	50
Lens of Eye	15
Extremities / Skin	50
Declared Pregnant Worker (Embryo / Fetus)	
Total Effective Dose Equivalent	0.5 rem per 9 months
Minor (Less than 18 Years of Age)	
All	10% of Adult Limits

Most radiation injuries are "local" injuries, frequently involving the hands. These local injuries seldom cause the classical signs and symptoms of the acute radiation syndrome. Symptoms may include a skin lesion, erythema, blistering, dry or wet desquamation, epilation and ulceration. Local injuries to the skin evolve very slowly over time and symptoms may not manifest for days to weeks after exposure.

Instructions for Principal Investigators and Individual Users

All suspected occupational radiation overexposures shall be immediately reported to the Radiation Safety Section (RSS) of the Office of Environmental Health and Safety by contacting the RSS 24-hour emergency response cell phone, (614) 561-7969. If any redness or unusual discoloring of the skin occurs (erythema), mention this to RSS and seek attention from a medical doctor for possible radiation overexposure.

Instructions for Radiation Safety Section

All occupational radiation exposures measured by whole-body dosimeters and finger rings are reviewed every quarter by the Health Physicist with responsibility for dosimetry operations. Any results above action levels I or II will require documented review and action as per the dosimetry procedures of the *Radiation Safety Standards for The Ohio State University.*

Any radiation overexposures, pursuant to Chapter 3701:1-38 of the Ohio Administrative Code, will be reported to the Director of the Ohio Department of Health in accordance with the *Radiation Safety Standards for The Ohio State University.* Radiation overexposures will be reported in the same manner regardless of the occupational source. Any verbal notifications will be followed up with written notification.