

RADIATION PRODUCING MACHINE SAFETY MANUAL

Environmental Health, Safety & Risk Management

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X-RAY MACHINES AND OTHER IONIZING RADIATION PRODUCING DEVICES

The guidelines in this manual, when followed will ensure that appropriate protective and regulatory actions required of the university in the x-ray certificate of registration and applicable regulations are satisfied. To that extent, all intended users of x-ray machines and other ionizing radiation producing devices must receive prior authorization from the Radiation Safety Officer before procurement, installation, testing, use and disposal of x-ray machines and other ionizing radiation producing devices. Please contact the Radiation Safety Officer at 956- 665-2903 for assistance on guidelines. The designated Radiation Safety Officer for The University of Texas Rio Grande Valley X-Ray Registration is

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PROCUREMENT PROCEDURES

X-ray machines and other ionizing radiation producing devices must be ordered via the Purchasing Department using a purchase order/requisition, regardless of dollar amount. Requisitions, along with the Preapproval Form (Addendum B for Requisitions) must be submitted to the department of Environmental Health, Safety and Risk Management (EHSRM) via email at ehsrp@utrgv.edu for approval. Transferred equipment and donations must also receive prior approval to ensure it can be installed and operated safely at The University of Texas Rio Grande Valley (UTRGV) in compliance with applicable regulations.

The Radiation Safety Office (RSO) will verify that Principal Investigators (PIs) are authorized for x-ray machine use prior to receipt of donation, installation, testing, operation and subsequent disposal.

X-ray safety devices, such as shielding and interlocks (if applicable), should be purchased and installed along with the x-ray machine (for non-certified units). Failure to plan for and install required safety devices will delay the final approval to operate the x-ray machine.

Purchase order information must include:

- X-ray machine information as such as type, model number, serial number (if known) and other pertinent information.
- Brief machine description or copy of technical specification sheet / manual.
- Name of the PI who will be overseeing x-ray machine operation.
- Directions for shipment delivery (x-ray machine should be delivered to proposed installation location, not EHSRM).

Any renovations to the facility must be approved prior to submitting the purchase requisition for the purchase of the x-ray machine.

X-RAY APPLICATION

All x-ray machines and other ionizing radiation producing devices must be registered with the Texas Department of State Health Services (DSHS) under UTRGV's Certificate of X-Ray Registration (R32915) via the Radiation Safety Office within 30 days of initial installation. Proposed operating procedures for all x-ray machines and other ionizing radiation producing devices must receive authorization from the Radiation Safety Office post-installation, prior to normal operations. For registration purposes, covered equipment categories, include:

- Minimal threat machines (radiation not emitted in an open beam configuration)
- Other industrial machines (research x-ray for non-human / not-live animal use)
- Medical radiographic (x-ray for human use)
- Veterinary x-ray machine (research not-live animal use)
- Dental x-ray machine
- Any other equipment that may produce ionizing radiation

To initiate registration, Principal Investigators (PIs) must complete an application for x-ray sub-registration and submit to RSO for review and subsequent approval by the RSO. Application forms are available at www.utrgv.edu/ehsrm. To guarantee timely approval from the RSO, completed application forms must be submitted to the RSO following procurement approval to allow sufficient time for RSO review.

The use of x-ray machines often requires specialized safeguards, procedures and associated controls. Investigative procedures also vary widely as do applicable safety techniques. The information provided on the use application will enable the RSO to review the adequacy of safety measures and assist the PI with implementation to ensure operational compliance and public safety. Information requested with the application form includes:

1. Contact information, location, purpose of use, and portable monitoring instruments that are available.
2. Description of the device. Specify the type(s), manufacturer, model number, serial number, and beam currents and tube voltage.
3. X-ray control measures. Access control/hazard warning signs and device labels, engineering controls, administrative controls, and safety controls.
4. Operating and safety procedures for the device. Include documentation procedures for training new staff or students.
5. A brief summary of the pertinent training and experience of the PI.
6. A sketch of the laboratory facility.
7. The PI (purchaser) must consult with RSO concerning the adequacy of the facility shielding where the equipment will be used (if the unit is not self-shielded). Facilities with shielding requirements are required to have a shielding design plan review from a qualified expert or manufacturer-approved installer, prior to installation. A copy of such plan must be submitted along with the application to the RSO. Device alignment and maintenance information per manufacturer recommendation.

Apart from testing as approved by the RSO, the x-ray machine must not be operated until final approval is granted by the RSO as communicated in writing by the RSO. Anyone not listed on the sub-registration permit must not be allowed to operate the x-ray machine for any reason.

RECEIPT, SETUP, DOCUMENTS, AND USE

The RSO must be notified when an x-ray machine arrives with installation schedule. Installation must be performed and documented by manufacturer representative or a state agency registered service provider. Out of state vendors will be required to present reciprocity agreement before performing installation (contact RSO for clarification). Following installation, a certificate of installation is required of certified units. For non-certified units, equivalent report from the manufacturer representative or agency registered service provider must be provided to the RSO in lieu of installation reports. Specific documentation below must be maintained by the PI and provided to the RSO during registration application:

- Equipment manuals
- Purchase records
- Receipt/installation records (includes transfers or donations).
- Written, stand-alone operational procedures for each x-ray machine including start-up, shut-down, safety device by-pass, alignment, and emergency
- Calibration, maintenance, and modification plans/records
- Safety devices (interlocks, activation warning lights, etc.)
- Other requested information

Copies of these documents must be submitted to the RSO and will be maintained in PI files.

Post Installation Survey

Radiation safety personnel will inspect the x-ray machine setup before operation begins (post installation survey) to assure radiation safety prior to x-ray machine use. Post installation survey shall also be conducted following relocation, alteration or modification to the machine. The PI may only turn on the x-ray machine for testing during the initial setup, with the consent of the RSO and/or presence of radiation safety staff. All necessary signage and regulatory postings will be supplied and posted by radiation safety personnel during post installation reviews.

All safety devices must be installed and verified operational. The x-ray machine must not be operated without the final approval of the RSO. It is the responsibility of the PI to promptly notify the RSO if anything changes that warrant an inspection such as repairs or modification to a machine. Please contact Environmental Health, Safety and Risk Management (EHSRM) at 956-665-3690, if an x-ray signage/posting is missing or defaced.

X-RAY SUB-REGISTRATION AMENDMENT GUIDELINES

Proposed changes to the X-Ray Machine Use Authorization require a registration amendment request, review and approval prior to the change. These include any additions or deletions to the registration, such as personnel change (addition or deletion), machine relocation (within or out of current location), alteration or modification to the machine which could affect shielding or beam quality, machine transfer to another user or subsequent disposal, etc. X-ray Registration Amendment form is available at www.utrgv.edu/ehsrm. Amendments to x-ray sub-registration require Radiation Safety Committee (RSC) review and approval before implementation. To accommodate research objectives, the RSO may grant interim approval to PIs until the next RSC meeting. When the RSO finds reason to grant an interim approval prior to RSC's approval, the authorization will be limited to 90 days to allow sufficient time for the next RSC meeting. Such interim approvals will be presented for review at the next RSC meeting. The RSC will ratify RSO's approval, disapprove, or stipulate additional conditions to be fulfilled by the PI. Approved PIs will receive an Authorization Permit to work with x-ray machines, which is proof of radiation authorization at UTRGV. Once authorized, PIs will remain authorized until either voluntary termination by the PI or revoked by the RSC for noncompliance.

BASIC X-RAY SAFETY GUIDELINES

Good Safety Practices

Designated responsible operator: Each laboratory should designate a primary responsible operator for the x-ray machine. This person will be responsible for the interlock bypass keys, perform the alignments, and manufacturer required changes/maintenance on the x-ray machines. This person will also coordinate calibrations, repairs, and modifications of the equipment with the company or manufacturer representative. This individual will also be responsible for ensuring that all persons operating the machine are properly trained.

Radiation Protection Practices

Time: The shorter the time spent around an x-ray machine, the less the radiation dose. Authorized Users should minimize their exposures to keep their occupational doses As Low As Reasonably Achievable (ALARA).

Distance: Radiation levels decrease significantly with increase in distance. The use of distance is one of the easiest and most effective methods for radiation protection.

Shielding: Lead shielding should be used to reduce radiation levels below 2 mR/hr.

Authorized User Training

All users are required to complete (attend and pass) the initial UTRGV x-ray safety training course. Users will learn about basic x-ray safety practices and the standard protective devices incorporated into each unit to minimize or prevent unnecessary radiation exposure. In addition, authorized users must receive training from the PI to be able to recognize machine specific protection system failures or other unusual conditions that could lead to radiation exposures as well as UTRGV radiation safety program administrative policies in the safety manual.

Operational Procedures

Start up, shut down, alignment, and emergency procedures for all x-ray machines must be written and readily available to, and acknowledged by all users. The safety and basic operations sections in the manufacturer's manual should include much of the necessary information for the standalone document. X-ray machines classified as minimal threat devices only require the availability of the manual for compliance.

Personnel Monitoring and Equipment Survey Program

Radiation badges (dosimeter) are provided to primary users of x-ray diffraction machines and other such potentially high exposure units. Survey meters are required for potential high exposure units. Radiation safety personnel conduct inspections and exposure surveys of all x-ray machines at the initial setup, after modifications, calibrations, and moving and on an annual basis.

Signage and Postings

Regulatory required x-ray use location door signage and postings will be provided by Radiation Safety personnel to assure standardization and compliance. A "Caution Safety Device Not Working" sign must be used whenever the interlocks are bypassed for alignments and equipment changes, as pre-approved by the RSO.

Records

Certain records are required to be maintained by all x-ray PIs and readily available for internal and/or external inspections. All records should be maintained in one central location in the lab. Applicable records are outlined in the "Receipt, Document and Set up" section of this manual.

Engineering Protection Systems

All interlocks, fail safe lighting and shielding must be maintained and inspected at each operation of the x-ray machines with conditions documented.

REQUIREMENTS FOR ANALYTICAL X-RAY MACHINES AND OTHER INDUSTRIAL RADIATION MACHINES

The University of Texas Rio Grande Valley's X-ray Safety Program sets forth controls and safety guidance for research and educational activities involving x-ray machines. The procedures herein are consistent with the regulations in Title 25 of the Texas Administration Code (TAC), Chapter 289, Section 228. This program establishes prudent safety practices to meet the regulatory requirements. If any conflict exists between this program and the state regulations, the latter shall prevail.

Equipment Safety Practices (Analytical Units)

- **Ports:** All unused ports must be securely closed to prevent accidental opening.
- **Interlocks:** All interlocks on the x-ray machine must be functional and in operation for x-ray production. Bypassing should only be performed by the designated responsible operator and only during alignments and equipment changes as required.
- **Alignments:** Alignments should be performed at minimal power settings and only by the designated responsible operator specially trained and designated by the PI to perform alignments.
- **Maintenance:** Maintenance should only be performed by trained qualified individuals and at the manufacturer's recommended time intervals.
- **Warning Lights:** Analytical x-ray machine warning lights must have fail-safe characteristics.
- **Beam Stops:** The x-ray beam must be terminated within the enclosure at all times and must be pointed away from the door.

Equipment Requirements

- **Safety Devices:** A safety device shall be provided on all open-beam configurations. Exemptions, where necessary, must meet regulatory guidelines in 25 TAC §289.231.
- **Warning Devices:** Open-beam configurations shall be provided with a visible indication of:
 - x-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or
 - shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

The x-ray control shall provide visual indication whenever x-rays are produced. Warning devices shall be labeled so that their purpose is easily identified and shall have fail-safe characteristics.

- **Ports:** Unused ports on radiation machine source housings shall be secured in the closed position in a manner which will prevent inadvertent opening.
- **Labeling:** Registrant shall ensure that each radiation machine is labeled in a conspicuous manner to caution individuals that radiation is produced when unit is energized. The label shall be affixed in a clearly visible location on the face of the control unit.
- **Shutters:** On open-beam configurations, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.
- **Radiation source housing:** Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.
- **Generator cabinet:** Each x-ray generator shall be supplied with a protective cabinet that limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.5 millirem (5 microsieverts) in any one hour.

Area Requirements

- The local components of an x-ray system shall be located and arranged, and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present in the area in excess of the dose limits.
- Radiation surveys of all radiation machines and x-ray systems sufficient to show compliance with area requirements above shall be performed upon installation of the equipment; following any change in the initial arrangement, number, or type of local components in the system; following any maintenance requiring the disassembly or removal of a local component in the system; during the performance of maintenance and alignment procedures, if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed; any time a visual inspection of the local components in the system reveals an abnormal condition; or whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits.
- Each area or room containing radiation machines shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words “**CAUTION - X-RAY EQUIPMENT**,” or words having a similar intent.

Personnel Requirements

- No one shall be permitted to operate the radiation machine unless such person has received instruction in, and demonstrated competence with the operating and safety procedures for the radiation machine; radiation warning and safety devices incorporated into the equipment and the room; identification of radiation hazards associated with the use of the equipment; and, procedures for reporting an actual or suspected exposure in excess of the dose/exposure limits.
- All Authorized Users including the Principal Investigator must successfully complete the UTRGV X-ray Safety Training Course.
- The Principal Investigator must provide and document specific training on the use of the x-ray machine and associated radiation hazards to all Authorized Users prior to being authorized through an amendment to operate the specific device.
- Authorized Users must know how to use a survey meter (if needed in the laboratory). A copy of the current operating and the safety procedures shall be maintained near the x-ray machine and also acknowledged by all operators.
- In addition to any assigned radiation dosimeters, finger badges shall be provided to and shall be used by personnel maintaining analytical radiation machines if the maintenance procedures require the presence of a primary x-ray beam when any local component in the x-ray system is disassembled or removed.

Operating Requirements

- Operating and safety procedures shall be written and made available to, and acknowledged by all radiation machine operators
- No person shall be permitted to operate radiation machines in any manner other than that specified in the procedures, unless that person has obtained written approval of the RSO.
- No person shall bypass a safety device unless such person has obtained the written approval of the RSO. When a safety device has been bypassed, a readily discernible sign bearing the words “**SAFETY DEVICE NOT WORKING**,” or words having a similar intent shall be placed on the radiation source housing.

Machine Security

Radiation machines shall be secured from unauthorized removal or use. Security devices and/or administrative procedures shall be used to prevent unauthorized use of radiation machines.

CERTIFIED X-RAY SYSTEMS

Certified x-ray systems, including those designed to allow admittance of individuals shall

- Not be modified without prior approval of the RSO.
- They shall not be operated by any individual without receiving training and instructions in the operating procedures for the unit.
- The unit is to be tested for proper operation of the interlocks at intervals not to exceed 12 months and the documentation maintained for inspection.
- Also, the registrant is required to perform an evaluation to ensure radiation emitted at 5 cm from the external surface of the unit does not exceed 0.5 millirem (5.0 microsieverts) in any one hour.
- The registrant is required to maintain associated documentation from above for inspection by the agency.

Package x-ray systems require annual evaluations to ensure radiation levels emitted at 5 cm from the external surface do not exceed 0.5 millirem per hour. Also, tests for proper operation of interlocks shall be conducted and recorded at least annually and the documentation and records maintained for state inspections.

RADIATION SAFETY REQUIREMENTS FOR X-RAY MACHINES IN THE HEALING ARTS

The University of Texas Rio Grande Valley's X-ray Safety Program sets forth controls and safety guidance for research, educational and healing arts activities involving x-ray machines. The procedures herein are adapted from the regulations in Title 25 of the Texas Administration Code (TAC), Chapter 289, Section 228 and Section 231. This program establishes prudent safety practices and to meet the regulatory requirements. If any conflict exists between this program and the state regulations, the latter shall prevail.

- Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. The university currently maintains a bone densitometer for research with humans and will comply with applicable requirements in 25 TAC 289.227(g). Among others, PIs must apply for and obtain authorization for healing arts screening from the institutional RSC and IRB before initiating a screening program per 25 TAC 289.226(h). Operating and safety procedures must be established in accordance with 25 TAC 289.227(i)(2)
- Operator credentialing shall be maintained in accordance with 25 TAC 289.227(i)(5) as further described in Training and Certification section below.
- Recordkeeping requirements per 25 TAC 289.227(g)(10) also apply

Other human use applications at UTRGV must receive prior approval by RSC. This manual will be revised to accommodate other applications consistent with regulations and certificate of registration as need arises.

Training and Certifications

Individuals who operate radiation machines for human use shall meet the appropriate requirements of rules in accordance with the Medical Radiologic Technologist Certification Act, Texas Occupations Code. A copy of the document shall be provided to RSC and maintained at the location where the individual is working. Required surveys, tests, or evaluations that constitute the practice of medical physics or as determined by the RSO/RSC will require the use of an outside consultant with a license from the Texas Board of Licensure for Medical Physicists in accordance with the Medical Physics Practice Act, Texas Occupations Code.

Access Restriction

No individual other than the patient, operator, and ancillary personnel shall be in the x-ray room or area while exposures are being made unless such individual's assistance is required.

Gonadal shielding shall be used on patients in accordance with 25 TAC 289.227(i)(13) when the gonads are in or within 5 cm of the useful beam. This requirement does not apply if the shielding will interfere with the diagnostic procedure. Gonadal shielding shall be of at least 0.5 mm lead equivalent material.

A radiographic x-ray equipment performance evaluation shall be performed by a state licensed Medical Physicist annually. Such document must be submitted to the RSO. Mechanical maintenance will be performed by a vendor as required to maintain compliance. Quality assurance tests will be performed by authorized personnel and vendors as required to maintain compliance. In addition, Radiation safety personnel will periodically perform reviews to assure compliance.

REQUIREMENTS FOR X-RAY MACHINES IN VETERINARY MEDICINE

The University of Texas Rio Grande Valley's X-ray Safety Program sets forth controls and safety guidance for research, educational, and veterinary medicine activities involving x-ray machines. The procedures herein are adapted from the regulations in Title 25 of the Texas Administration Code (TAC), Chapter 289, Section 233. This program is established to institute prudent safety practices and to meet the regulatory requirements. If any conflict exists between this document and the state regulations, the latter shall prevail.

Operating and Safety Procedures

- No radiation may be deliberately applied to animals except by, or under the supervision of a veterinarian authorized by the Texas Board of Veterinary Medical Examiners to engage in veterinary medicine.
- A technique chart relevant to the particular radiation machine shall be provided in the vicinity of the control panel and used by all operators.
- Each registrant shall have and implement written operating and safety procedures. These procedures shall be acknowledged and made available to each individual operating a radiation machine including any restrictions of the operating technique required for the safe operation of the particular machine or x-ray system. Written operating and safety procedures for the Veterinary Facility are based on the Texas Department of State Health Services' Regulatory Guide 4.5.
- Except as otherwise exempted, all individuals who are associated with the operation of a radiation machine are subject to the occupational dose limits of this title regarding dose limits to individuals, and the personnel monitoring requirements of this title.
- Protective devices shall be utilized when required. Protective devices shall be made of no less than 0.25 mm lead equivalent material. Protective devices including aprons, gloves, and shields shall be inspected annually for defects, such as holes, cracks, and tears. If a defect is found, protective devices shall be replaced or removed from service until repaired. A record of this test shall be made and maintained by the registrant for inspection by the agency.
- No individual other than the animal, operator, and ancillary personnel shall be in the x-ray room or area while exposures are being made unless such individual's assistance is required. When an animal or image receptor must be held in position during radiography, mechanical supporting or restraining devices shall be used when the exam permits. If an animal or image receptor must be held by an individual during an exposure, that individual shall be protected with appropriate shielding devices. The registrant's written operating and safety procedures shall include a list of circumstances in which mechanical holding devices cannot be routinely utilized; and a procedure for selecting an individual to hold or support the animal or image receptor.
- The operator's position during the exposure shall be such that the operator's exposure is as low as reasonably achievable (ALARA) and the operator is a minimum of six feet from the source of radiation or protected by an apron, gloves, or other shielding having a minimum of 0.25 mm lead

equivalent material. In no case shall an individual hold the tube or tube housing assembly supports during any radiographic exposure.

- The technique factors to be used during an exposure shall be indicated before the exposure begins except when automatic exposure controls are used, in which case the technique factors that are set prior to the exposure shall be indicated. On equipment having fixed technique factors, there must be permanent markings.
- The x-ray control shall provide visual indication of the production of x-rays. The indicated technique factors shall be accurate to meet manufacturer's specifications. If these specifications are not available from the manufacturer, the factors shall be accurate within plus or minus 10% of the indicated setting.

Performance Maintenance & Evaluation

A radiographic x-ray equipment performance evaluation shall be performed by a Board Licensed Physicist at intervals specified by regulations or as required by RSO and or Radiation Safety Committee. Mechanical maintenance will be performed only by qualified vendors as required to maintain compliance. Quality assurance tests will be performed by authorized personnel and vendors as required to maintain compliance. In addition, Radiation Safety personnel will periodically perform reviews to assure compliance.

RADIATION SAFETY REQUIREMENTS FOR CABINET X-RAY MACHINES

The University of Texas Rio Grande Valley X-ray Safety Program sets forth controls and safety guidance for research and educational activities involving X-ray machines. The procedures herein are adapted from the regulations in Title 25 of the Texas Administration Code (TAC), Chapter 289, Section 228. This program is established to institute prudent safety practices and to meet the regulatory requirements. If any conflict exists between this program and the state regulations, the latter shall prevail.

Equipment Requirements

The additional rules in this chapter apply to certified cabinet x-ray system only:

1. Key-activated control must be provided to ensure that x-rays will not be generated when the key is removed.
2. Each door of a cabinet x-ray system must have a safety interlocks. Each access panel also must have at least one safety interlock.
3. A control, other than the safety interlock, must be provided to resume x-ray generation following x-ray interruption by a safety interlock.
4. Two independent indicators must be provided to indicate when x-rays are being generated. One may be an x-ray tube current indicator; the other indicator must consist of an easily seen warning light labeled "**X-RAY ON**".
5. A clearly legible and visible label bearing the statement: "**CAUTION: X-RAYS PRODUCED WHEN ENERGIZED**" must be posted near the controls that energize the x-ray tube.

Radiation limits

Radiation emitted from a cabinet x-ray system must not exceed exposure rate of 0.5 mrem/hr at any point 5 cm from the external surface, and at maximum power. A cabinet x-ray system must contain sufficient shielding and be located so that exposure rates in unrestricted areas do not exceed 2 mrem in any one-hour and 100 mrem/yr.