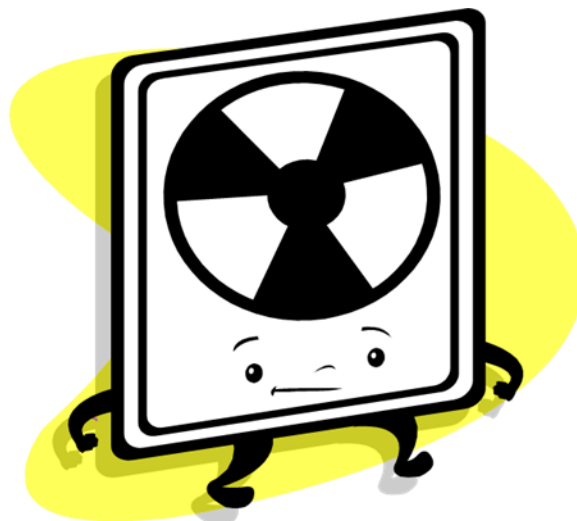


X-ray Safety Manual



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THE
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1. Introduction

Radiation Safety is the responsibility of all individuals at the University of Rhode Island (URI) including faculty, staff, students, researchers, and visitors. Those individuals using X-ray machines or radiation producing devices at URI must strictly comply to federal and state regulations, and university policies which is important for the safety and protection of all individuals at the University.

The Radiation and Laser Safety Committee (RLSC), under the functional authority of the President, is responsible for the Radiation Safety Program outlined in this manual and represents official university policy on radiation and radioactive materials. The purpose of the X-ray Safety Manual (Separate manuals for Radioactive Material Safety and Laser Safety) is to assist all individuals in complying with the Rhode Island Department of Health (RIDOH) radiation regulations and the URI Radiation Safety Program.

The URI's X-ray Safety Program sets forth controls and safety guidance for research and educational activities involving X-ray machines and other radiation producing machines. The procedures herein are consistent with the RIDOH regulations in 216 RICR 40 Subchapter 20. This program establishes prudent safety practices to meet the regulatory requirements. Where existing or future federal, state, local regulations or the University policies are found to be different from the requirements contained in this manual, those legally accepted regulations shall supersede this document.

This manual is not intended to be a fully comprehensive reference. Further advice concerning hazards associated with specific X-ray or radiation producing devices and/or the development of new and unfamiliar procedures should be obtained through consultation with the Radiation Safety Officer (RSO). The X-ray Safety Manual is an enforceable component of the URI's X-ray registration under which URI is authorized, and violations of its policies and procedures are citable as areas of non-compliance by the RIDOH.

This manual has been submitted and approved by the RLSC to support the University's RIDOH X-ray registration and replaces all previous such documents. The format and administrative content of the forms associated with this manual can be revised with pending approval of the RLSC. New forms may also be added as necessary. However, changes which would result in any condition of non-compliance with applicable regulations or license conditions shall not be approved.

The RSO will submit a copy of the revised manual to the RLSC for approval when the revised manual has substantial changes.

2. Telephone Numbers and Information

Environmental Health and Safety	(401) 874-7993
Environmental Health and Safety (Emergency)	(401) 874-2121
Environmental Health and Safety (Fax)	(401) 874-9069
Radiation Safety Office	(401) 874-2600
Radiation Safety Officer	(401) 874-9439
Health Physicist	(401) 874-9451
URI Health Services	(401) 874-2246
URI Public Safety (Emergency)	(401) 874-2121
URI Public Safety (Non-Emergency)	(401) 874-4553
Medical Emergencies	911

Radiation Safety Office hours are Monday through Friday, 8:30 a.m.-4:30 p.m.

For assistance with a radiation incident during normal office hours, call the Radiation Safety Office at (401) 874-2600. In the event of an after-hours radiation incident, contact the URI public Safety emergency line at (401) 874-2121.

3. X-ray Use Application and Application Amendment

X-ray Use Application

All X-ray machines and other ionizing radiation producing devices must be registered with the Rhode Island Department of Health (RIDOH) under URI's certificate of X-ray registration. The Radiation Safety Office handles this process and manages all X-ray machines and radiation producing devices on the campus.

A new Authorized User (AU) must submit an Application for X-ray Use to the Radiation Safety Office, Rhode Island Nuclear Science Center, 16 Reactor Road, Narragansett Bay Campus for the RSO's review. An Application form can be obtained by contacting the Radiation Safety Office. The application must be filled out completely and the standard operating procedures (SOP) must accompany the application when it is submitted to the Radiation Safety Office. Anyone not listed on the application **must not** be allowed to work with X-ray machines for any reason. The RSO will review the application and the SOP and submit to the Radiation and Laser Safety Committee (RLSC) for approval. A post-installation survey will be conducted by the Radiation Safety Office prior to normal operations. AUs must notify the Radiation Safety Office of the X-ray installation date. The radiation safety personnel will visit during the installation and after its completion; the RSO will report to the RIDOH and register the X-ray machine.

Any new AUs planning to use X-ray machines with animals must be approved by the URI Institutional Animal Care and Use Committee (IACUC) or have submitted an application to use animals to IACUC before submitting the Application for X-ray Use, and must attach an IACUC approval or a submitted IACUC application with the application. Details concerning the use of animals must be coordinated with animal care and approved by the IACUC.

X-ray Use Application Amendment Guidelines

AUs planning to make a change to their authorization must complete and submit an X-ray Use Authorization Amendment Form to the Radiation Safety Office. The form can be obtained by contacting the Radiation Safety Office. The form must include any additions or deletions to the authorization such as machine relocation or transfer, machine modification which could affect shielding or beam quality, machine disposal, etc.

The RSO will submit an amendment to the RLSC for approval. The RSO may give temporary approval to AUs until the RLSC's approval if necessary. Approved AUs will receive an Authorization Permit to work with X-ray machines, which is proof of radiation authorization at URI and may be submitted with Grant Proposals. Once authorized, the AUs will remain authorized until either authorization termination is requested by the AU or the authorization is revoked by the RLSC for noncompliance.

4. Receipt, Installation, and Records

X-ray Receipt

The RSO must be notified when an X-ray machine arrives and of the scheduled installation date. Installation must be performed and documented by a manufacturer representative or a state agency registered service provider.

Following installation, a certificate of installation is required of certified units. For non-certified units, an equivalent report from the manufacturer representative or agency registered service provider must be provided to the RSO. At a minimum, the below listed documents must be provided to the RSO after installation within 30 days.

- Purchase records
- Receipt/Installation records (Includes transfers or donations)
- SOP for each X-ray machine including start-up, shut-down, safety device by-pass, alignment, and emergency
- Calibration, maintenance, and modification records

In addition to the documents listed above, AUs must maintain the below documents.

- Equipment manuals
- Safety devices (interlocks, activation warning lights, etc.) information
- Other requested information by the RSO, regulations, or the University policies
- X-ray log book unless the X-ray machine is solely used by the AU or a computerized automatic log is available

Post Installation Survey

Radiation safety personnel will inspect the X-ray machine setup in addition to the manufacturer's installation records before operation begins to assure radiation safety prior to X-ray machine use. A post installation survey must also be conducted following relocation, machine modification, and other changes made to the machine. The AU may only turn on the X-ray machine for testing during the initial setup, and must notify the Radiation Safety Office when it is ready to be operated. The radiation safety personnel will conduct a post installation survey and all necessary signage and regulatory postings will be supplied and posted by the radiation safety personnel during or after the post installation survey.

All safety devices must be installed and verified to be operational. The X-ray machine must not be operated without the final approval of the RLSC. However, The RSO may give temporary approval to AUs until the RLSC's final approval if necessary.

It is the responsibility of the AU to promptly notify the RSO of any changes that warrant an inspection such as repairs or modification to a machine. Please contact the Radiation Safety Office at (401) 874-2600, if any X-ray signage/posting is missing or defaced.

Record of Use

Unless the X-ray machine is solely used by the AU or a computerized automatic log is available, users must record every time the X-ray is used. This record includes at least the date, time, name, and purpose.

5. X-ray Procurement Procedures

X-ray machines and other ionizing radiation producing devices must be ordered through the Purchasing Department and the purchase requisitions must be submitted to the Radiation Safety Office for approval prior to submitting to the Purchasing Department. Transferred and donated machines must also receive prior approval by the RSO in compliance with applicable regulations to ensure they can be installed and operated safely at URI. During this process, the Radiation Safety Office verifies that AUs are authorized for X-ray machine use at URI, the current registration information for the X-ray machine, current user/organization information, etc.

X-ray safety devices, such as shielding and interlocks (if applicable) should be purchased and installed along with the X-ray machine if they do not come with the unit. Without installing required safety devices, X-ray machines will not be approved for use on the campus.

Purchase order information must include:

- X-ray machine information such as Type, Model and Serial number, Power, etc.
- Brief machine description or copy of technical specification sheet/manual
- Name of the AU who will be responsible for the X-ray machine operation
- Address for shipment delivery (X-ray machine must be delivered to proposed installation location directly)

6. Basic X-ray Safety Guidelines

General Safety Guidelines

The X-ray AU should designate a primary responsible operator for the X-ray machine if the AU cannot be in the X-ray use area or on the campus during operation all the time. The primary responsible operator's responsibility will be the same as the AU when the AU is not present on the campus including interlock bypass keys, perform the alignments, and manufacturer required changes/maintenance on the X-ray machines. The primary responsible operator can also coordinate calibrations, repairs, and modifications of the equipment with the company or manufacturer representative. X-rays can only be operated when the AU or the designated primary responsible operator is present in the X-ray lab or on the campus. The AU or the designated primary responsible operator must know who uses the machine when the machine is in use. When neither of them are available to supervise the X-ray operation, the X-ray must be turned off and the key must be removed from the machine to secure it from unauthorized operation.

X-ray User Training

All users are required to complete (attend and pass) the initial URI X-ray safety training and annual refresher trainings thereafter. The initial training will provide basic radiation physics, and information on X-ray types, hazards, regulations and policies. After the initial URI X-ray safety training, all users must receive training from the AU for the specific X-ray machine that includes the SOP for the X-ray machine, system failures or other unusual conditions that may occur. In addition, all users must read and acknowledge the SOP and it is the AUs responsibility to keep the records.

All new X-ray users are recommended to review the X-ray Safety manual. Copies of the X-ray Safety manual can be obtained by direct request to the Radiation Safety Office or at the website <https://web.uri.edu/radiation/x-ray-resources/>.

Operational Procedures

An SOP including 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 can be used but a standalone specific X-ray manual is strongly recommended. The X-ray operation must follow basic radiation safety practices. All users should minimize their exposures to keep their occupational doses As Low As Reasonably Achievable (ALARA). Certified and closed unit X-ray machines should have enough shielding to reduce radiation level below 2 millirem (mrem) per hour or 2 milliRoentgen (mR) per hour during operation. If the shielding is not sufficient to maintain the

radiation level below the 2 mR per hour from the surface where any person can have access, the AU must contact the Radiation Safety Office to consult to have additional access controls added for using the X-ray machine, such as a key card access, or an X-ray in use indicator at the entrance.

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. In addition, the AU can request dosimeters for his/her users if necessary even if they are not primary users and there is no potential exposure above 10 percent of the regulatory limits. Dosimeters are exchanged every quarter unless an AU or the RSO suggests that more frequent exchange is needed. The badge request form can be obtained by contacting the Radiation Safety Office. Survey meters are required for potentially high exposure units. Radiation safety personnel conduct required inspections of all X-ray machines at the initial setup, after modifications, calibrations, and moving. Radiation safety personnel also perform annual routine inspections and exposure surveys of the X-ray machines.

More details of the personnel monitoring program can be found in section 7 in the Radioactive Material Safety Manual located via the Internet at <http://web.uri.edu/radiation/radioactive-materials-resources/>

Signage & Postings

The regulatory required X-ray use location door signage and postings will be provided by the Radiation Safety Office to assure standardization and compliance. A “Caution Safety Device Not Working” sign must be used whenever the interlocks are bypassed such as during or after alignments, maintenance, and equipment changes, and all users of the X-ray must be notified. When the X-ray is back to its normal operating condition, an AU or a designated primary responsible operator must verify all safety devices are operational including interlock and warning lights. If it is discovered that the safety devices are not working, users must notify the AU or designated primary responsible operator and the RSO immediately.

Records

Certain records are required to be maintained by all X-ray AUs and readily available for the radiation safety annual audit and the RIDOH inspections. All records should be maintained in one central location in the lab. Minimum required records are:

- Equipment manuals
- Purchasing/Receipt/Installation records (Includes transfers or donations) – AU can keep these records in his/her office
- SOP for each X-ray machine
- Calibration, maintenance, and modification records

- Use log book

Engineering Protection Systems

All interlocks and fail safe lighting must be maintained and inspected at each operation of the X-ray machines and must be documented in the log book.

7. Safe Practice Guidelines for Analytical X-ray Machines and Other Industrial Radiation Machines

Radiation exposures from X-ray diffraction or fluorescence units can be extremely hazardous. Dose rates in the primary beam can exceed 10,000 R/min. Any part of the body momentarily placed in the beam would receive enough radiation to cause serious radiation burns. X-ray diffraction machines must be operated in accordance with the basic X-ray safety guidelines in this manual as well as the following additional requirements.

Equipment Safety Practices and requirements

All unused ports must be securely closed to prevent accidental opening and the X-ray beam must be terminated within the enclosure at all times and must be pointed away from the door. All interlocks on the X-ray machine must be functional and in operation for X-ray production. Bypassing should only be performed by the AU or the designated primary responsible operator and only during alignments and equipment changes as required and a "Caution Safety Device Not Working" sign or other equivalent signage must be posted.

Alignments should be performed at minimal power settings and only by the AU or the designated primary responsible operator. They must be specifically trained and/or well experienced with the machine to perform alignments. Maintenance should only be performed by the AU or the designated primary responsible operator who is trained and at the manufacturer's recommended time intervals.

Safety devices must be provided and must meet RIDOH regulatory guidelines. X-ray units must have a visible indication of X-ray tube and shutter on and off status located near the radiation source housing, near each port on the radiation source housing, and/or outside of a shielding which anyone can easily recognize. The X-ray control must provide visual indication whenever X-rays are produced. Warning devices or lights must be labeled such as "X-ray on" or similar so that their purpose is easily identified and they must have fail-safe characteristics.

Each X-ray tube housing must 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. Each X-ray generator shall be supplied with a protective case 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 2 mrem in any one hour (or 2 mR/hr).

Radiation surveys must be conducted by an AU or designated primary responsible operator periodically and any time a visual inspection of the local components in the system reveals an abnormal condition. The Radiation Safety Office conducts surveys at least once a year to show compliance with regulatory requirements. An additional survey will be conducted by the Radiation Safety Office at least but not limited to when new machines are installed, after

modification, alignments, any maintenance requiring the disassembly or removal of a local component in the units, and whenever personnel dosimeter results show a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits.

Area Requirements

An X-ray system must be located away from heavy traffic areas and must provide sufficient shielding such that no radiation levels exist in any area outside the X-ray use area, restricted area, above 2 mrem in any one hour or 50 mrem in a year above the background. An AU or designated primary responsible operator should monitor routinely for stray or scattered radiation in the immediate vicinity of the X-ray machine with an appropriate survey meter if applicable.

Each area or room containing X-ray machines or ionizing radiation producing devices shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION - X-RAY" or words having a similar intent.

Personnel Requirements

No one is permitted to operate the radiation machine unless they have received X-ray safety training, specific X-ray training, and demonstrated competence with the operating and safety procedures for the X-ray machine. Users must be able to recognize radiation warning signs and safety devices incorporated into the equipment and the room, recognize radiation hazards, and acknowledge the X-ray safety manual and the SOP for the machine.

For any user who previously received an applicable training from another institute within a recent year, the Radiation Safety Office will honor the training and only the annual refresher training will be required. The AU must provide and document specific training on the use of the X-ray machine to all X-ray users prior to being authorized to operate the specific device. A current SOP must be maintained near the X-ray machine and also acknowledged by all users.

All users must wear a dosimeter that is specifically assigned to them including a finger badge if assigned.

Operating Requirements

SOPs must be available in a written format and acknowledged by all radiation producing machine users. No one is permitted to operate X-ray machines or radiation producing machines in any manner other than that specified in the procedures, unless that person has obtained written approval of the RSO. No one is allowed to bypass a safety device except an AU and/or designated primary responsible user for alignment, maintenance, and other permitted activity approved by 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 must be placed on the radiation source housing or radiation producing machines.

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 X-ray machines or radiation producing machines.

High Voltage Hazards

The high voltage power supply of X-ray machines can be particularly hazardous. Personnel must never tamper with high voltage equipment. Only properly trained personnel are permitted to install, repair, or modify high voltage equipment.

8. X-ray Machine Use on Animals in a Research setting and in Veterinary Medicine

Operating and Safety Procedures

No radiation may be deliberately applied to animals in a research setting except when approved by the URI Institutional Animal Care and Use Committee (IACUC). The IACUC must include a veterinarian who is registered with the State to practice veterinary medicine.

When applying radiation to animals unrelated to research (e.g., veterinary medicine), the AU must be under the supervision of a veterinarian registered with the State to practice veterinary medicine.

A technique chart relevant to the particular radiation machine and animal shall be provided to and used by all operators. Each AU shall have and implement written operating and safety procedures. These procedures shall be acknowledged and made available to each user 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 SOP must be in compliance with the RIDOH regulation.

Protective devices shall be used when required. 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 must be replaced or removed from service until repaired. The AU must inspect protective devices periodically for their safety. In addition, the Radiation Safety Office conducts annual inspections which includes a protective device inspection and maintains records of these inspections for the agency.

No individual other than the animal and operator shall be in the X-ray room or area while being X-rayed unless the operator needs assistance. When an animal or image receptor must be held in position during exposure, a mechanical supporting or restraining device must be used. If an animal or image receptor must be held by an individual during an exposure, The RSO must be consulted. If it is approved, the individual's dose will be monitored and a dose record will be maintained.

The operator's position during the exposure must be in an area that exposure rates are below the regulatory limits and as low as reasonably achievable (ALARA). No one is allowed to hold the X-ray tube or tube housing assembly supports during any exposure.

Performance Evaluation and Maintenance

A veterinary X-ray equipment performance evaluation shall be performed by a State registered licensed physicist at intervals specified by the required regulations. The RSO or the RLSC may request more frequent evaluations if necessary. 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, the Radiation Safety Office conducts annual inspections other than performance evaluation and maintenance to assure compliance and requests the evaluation report for records.

9. X-ray Machine Use in the Healing Arts

Operating and Safety Procedures

Individuals shall not be exposed to the useful beam except for healing arts purposes that has been authorized by a licensed practitioner or URI Institutional Review Board (IRB) approved research. The university currently maintains a bone densitometer for research with humans and will comply with applicable requirements in 216 RICR 40-20. Among others, AUs, if not licensed practitioner, must complete a training given by the manufacturer or manufacturer's approved vendor before applying for and obtain authorization for healing arts screening from the institutional RSC and IRB before initiating a screening program. No radiation may be deliberately applied to human in a research setting except when approved by the University's IRB.

Each AU shall have and implement written operating and safety procedures. These procedures shall be acknowledged and made available to each user 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 SOP must be in compliance with the RIDOH regulation. Records especially human subject consent forms must be maintained until duration required.

Protective devices shall be used when required. 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 must be replaced or removed from service until repaired. The AU must inspect protective devices periodically for their safety. In addition, the Radiation Safety Office conducts annual inspections which includes a protective device inspection and maintains records of these inspections for the agency.

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 if necessary. This requirement does not apply if the shielding will interfere with the procedure.

The operator's position during the exposure must be in an area that exposure rates are below the regulatory limits and as low as reasonably achievable (ALARA). No one is allowed to hold the X-ray tube or tube housing assembly supports during any exposure.

Training and Certifications

Individuals who operate radiation machines for human use shall meet the appropriate requirements of rules in accordance with the Rhode Island Code of Regulation, 216 RICR 40-20.

A copy of the document shall be provided to the Radiation Safety Office and should be maintained at the location where the individual is working.

Performance Evaluation and Maintenance

A radiographic x-ray equipment performance evaluation shall be performed by a state licensed Medical Physicist annually or intervals specified by the required regulations. A copy of such documents must be submitted to the Radiation Safety Office. 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, the Radiation Safety Office conducts annual inspections other than performance evaluation and maintenance to assure compliance and requests the evaluation report for records. The RSO or the RLSC may request more frequent evaluations if necessary.

10. Minimal Threat Devices Including Electron Microscopes

X-rays can be produced in electron microscopes and other devices by primary electron beam or back-scattered electrons striking metal parts of the microscopes or devices. X-ray is typically generated with over 15 kV of energy. X-rays are also produced during X-ray fluorescence measurements. The shielding provided for these devices are usually adequate to ensure that radiation exposure to personnel is kept to a minimum. These devices are typically categorized as minimal threat devices and exempt from registration requirement. They must have an exposure rate below the 0.5 mrem per hour or 0.5 mR/hr from 5 centimeters on surfaces.

Users must notify the radiation safety office of each newly acquired device that can generate X-rays. If a user has or receives an older device, they must contact the Radiation Safety Office to conduct a survey. Some older units have been reported to leak above the limit of 0.5 mR/hr at the surface. The Radiation Safety Office will conduct a survey and maintain the records if necessary. These device users are exempt from X-ray safety training requirements.

11. X-ray Machine Out-of-State-Use, Transfer, Donation, and Disposal

Out-of-State-Use

Any user planning to use an X-ray unit out of state (for ex. Portable) must contact the Radiation Safety Office at least two weeks prior to use for purpose of notifying appropriate state agencies, or other counties if applicable.

Transfer or Donation

An X-ray unit can be transferred or donated to another organization as long as the organization has appropriate registration. AUs must contact the URI Property Office and the Radiation Safety Office before processing the transfer or donation.

Disposal

Most of newer X-ray units do not contain hazardous materials except beryllium and lead. Generally beryllium is contained within the X-ray tube and must be removed from the system and disposed of as chemical waste. You must verify the manufacture's information about the X-ray tube. Most of the time, it is indicated on the tube. Before the disposal process, the AU must remove the head, being careful not to break the X-ray tube. The tube is under a vacuum seal and, if broken, could splinter and cause injuries and exposure to beryllium. Some X-ray systems have beryllium windows and a "poison" sign on the window unit that warns users that the window unit contains a very toxic chemical and must be disposed of properly. If you need assistance, please contact the Radiation Safety Office.

For disposal of X-ray units, contact the URI Property Office. Contact the Radiation Safety Office to assist in disposing of the unit.

Hazardous Materials - Older X-ray machines may contain hazardous materials including hazardous metals and toxic chemical called polychlorinated biphenyls or PCBs in the transformer oil if the X-ray machines were manufactured before July 1979. Before taking a machine out of service you need to be aware of what's in the machine and what needs to be done to dispose of it properly. Contact the Radiation Safety Office and the EH&S for assistance. The Radiation Safety Office and the EH&S can help you to determine if your old machine contains a hazardous waste regulated by the U.S. Environmental Protection Agency and assist you to properly dispose of it.

12. Emergency Response

Radiation exposure by X-ray incidents may require medical attention and reporting to the State Agency. All events may raise exposure with potentially increased dose to the X-ray users and members of the public. Each incident must be carefully evaluated before proceeding and approached properly to prevent additional exposure. Contact numbers are listed below for assistance.

Radiation Incident & Emergency Phone Numbers

Working Hours:

Radiation Safety Office	(401) 874-2600
Radiation Safety Officer	(401) 874-9439
Health Physicist	(401) 874-9451

After Hours:

Environmental Health and Safety (Emergency)	(401) 874-2121
URI Public Safety (Emergency)	(401) 874-2121
URI Public Safety (Non-Emergency)	(401) 874-4553
Medical Emergencies	911

General procedures

- Immediately shut off the machine.
- Notify all personnel in the room.
- Notify the AU and/or designated primary responsible operator and the RSO.
- If suspected exposure is high, seek medical attention immediately.