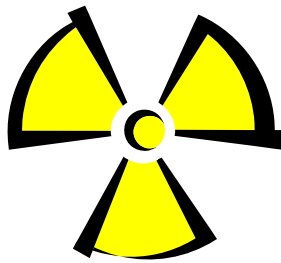


RGE MANUAL

(RADIATION GENERATING EQUIPMENT)



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RADIATION GENERATING EQUIPMENT (RGE) MANUAL

Introduction

The Ohio Department of Health (ODH) regulates the use and possession of equipment capable of generating X-rays.

Equipment is classified according to the categories defined by the ODH. The ODH has two major categories: Medical and Industrial. All dental RGE fall under Medical. The remaining RGE is classified as Industrial. Industrial RGE is further divided into three categories: Industrial Analytical (luminoscopes, fluorescence/spectrometers, electron microscopes, X-ray diffraction units, and Auger guns), Industrial Radiographic units (X-ray cabinets and industrial fluoroscopic units for non-human use), and Particle Accelerators.

Each category is governed by a specific set of ODH regulations. The first portion of this manual will cover general procedures for all users of RGE, and the second portion will cover specific procedures for each category of RGE.

Authorized Possessor

Definition

An Authorized Possessor (AP) is an individual authorized by the Radiation Safety Office (RSOF) to possess and use radiation generating equipment. There is no requirement that the AP be a faculty member. The AP is responsible for the daily usage and maintenance of equipment, production of machine-specific operating procedures, and ensuring that their staff is properly trained for the types of equipment used.

Procedure on how to become an Authorized Possessor

Any individual wishing to become an AP must contact the RSOF at 368-2906. They must also complete general X-ray training.

GENERAL PROCEDURES FOR ALL USERS OF RGE

Training Requirements

Regulatory References:

General Radiation Protection Standards for Sources of Radiation; OAC 3701:1-38-22 (A)
Radiation Generating Equipment; OAC 3701:1-66-07

General X-ray Training

All users of RGE including the AP must attend a general X-ray training session that is given by the RSOF. Please call the RSOF at 368-2906 to register or sign up online at case.edu/ehs/training/x-ray-safety. There is no annual retraining requirement.

Additional training for users of fluoroscopic units must be completed prior to completing site-specific training. This training can be completed by viewing a training presentation provided to the RSOF by University Hospitals Cleveland Medical Center. Please contact the RSOF at 368-2906 to complete this portion of the training.

Exemptions from General X-ray Training

Only state certified dental technicians and Doctors of Dental Surgery are exempt from taking the general X-ray training.

Site-Specific Training

In addition to the general training, each user must undergo site-specific training, which is equipment-specific. This training is given by the AP for each piece of equipment. This training should include a demonstration of the proper use of the equipment (operation of all controls, safety interlocks, and the proper start-up and shut-down procedures). The individual should also be instructed on what to do in the event of an equipment malfunction. Site-specific training must be documented and available for review by the RSOF.

Although there is no annual retraining requirement, site-specific training should be done if a new unit is purchased, or an existing unit is modified (i.e., primary beam direction change, or shielding modification). Documentation of site-specific training is required and must be maintained by the AP. This documentation should include the following information: Worker's name, employee/student ID number, date of training, topics discussed, and worker's signature.

GENERAL PROCEDURES FOR ALL USERS OF RGE (cont'd)

Purchase/Transfer/Disposal of RGE

Regulatory Reference:

General Radiation Protection Standards for Sources of Radiation; OAC 3701: 1-38-03

Purchase of RGE

The appropriate information must be faxed to the RSOF at 368-2236 as soon as the equipment is purchased, and no later than 60 working days before the equipment arrives. Information should include the manufacturer of the equipment, the model number, the serial number, and the date of purchase. CWRU is required to notify the ODH of any equipment added to our registration.

Equipment that is valued at \$5,000 or more should be tagged with a CWRU RFID Tag. The Department Administrator can schedule with CWRU Equipment Accounting to tag the equipment. Non-tagged equipment will receive a tag using a unique identifier that is used for each asset record.

External Transfer of RGE

Transfer Form (Form 1) should be filled out and faxed to the RSOF at 368-2236 approximately 30 days prior to the equipment being transferred. CWRU is required to notify the ODH of any transfer of RGE that is under our registration.

Transfer of equipment requires that the Department Administrator contact CWRU Equipment Accounting to provide the machine details to confirm it is in the asset management system.

Internal Transfer of RGE

The individual must be or become an AP for the RGE before the RGE can be transferred. If the individual is an Authorized Possessor, RGE, the RGE Transfer Form (Form 1) should be filled out and faxed to the RSOF at 368-2236 prior to the transfer. If the individual is not an authorized possessor (AP), please contact the Radiation Safety Office at 368-2906. The individual must complete the General X-Ray Safety Training prior to being approved as an AP.

The Department Administrator should contact CWRU Equipment Accounting about the change in ownership.

GENERAL PROCEDURES FOR ALL USERS OF RGE (cont'd)

Departing CWRU

Notify the RSOF ten (10) working days prior to leaving the University. It is the responsibility of the AP to ensure that all RGE is either disposed of or transferred to another AP prior to leaving CWRU.

Disposal of X-ray Generating Equipment/X-ray Tubes

Disposal of equipment requires that the Department Administrator contact CWRU Equipment Accounting to provide the machine details to confirm it is in the asset management system.

It is the responsibility of the AP to remove the X-ray tube contained in a machine prior to a machine being cleared by Radiation Safety for disposal. Once the X-ray tube is removed, notify Radiation Safety at 368-2906 to arrange tube pickup.

Please note: Radiation Safety will not clear the equipment unless there is paperwork stating that the tube has been removed. CWRU is required to notify the ODH of any disposal of RGE or individual X-ray tubes that are under our registration.

GENERAL PROCEDURES FOR ALL USERS OF RGE (cont'd)

Dosimetry

Regulatory Reference:

General Radiation Protection Standards for Sources of Radiation; OAC 3701:1-38-11

ODH Annual Dose Limits

Whole body	5,000 mrem
Shallow (skin, hands, feet)	50,000 mrem
Lens of eye	15,000 mrem
Fetus during gestation	500 mrem

Dosimetry Requirements for Different Types of RGE

SEM, TEM and Electron Gun users are not required to wear a badge.

Body Badge: All Industrial Analytical Equipment, Industrial Radiographic/Fluoroscopic, Dental, and Veterinary units

Ring Badge: X-ray Diffraction, Particle Accelerators, Industrial Radiographic/Fluoroscopic, Dental Handheld, and Veterinary units

Obtaining a Badge

Badges are obtained through the RSOF by completing the Radiation Worker Dose History Sheet during the general X-ray training class. Badges are issued at the end of the class.

Badge Exchange Frequency

All badges (with the exception of fetal badges) are exchanged quarterly (January, April, July, and October) at the RSOF. Fetal badges are exchanged monthly. Each lab is notified via E-mail of the badge exchange date. Badges are to be returned promptly at the end of each cycle to assure the RSOF can take timely action, consistent with implementation of ALARA (As Low As Reasonably Achievable), in the event any significant dose is measured.

GENERAL PROCEDURES FOR ALL USERS OF RGE (cont'd)

Lost or Damaged Badges

Report lost or damaged badges (crushed, broken, melted, washed, accidentally exposed, contaminated, heated in any way, etc.) to the RSOF as soon as you are aware of the situation so that a new badge can be issued. If the badge has been lost, the individual should come to the RSOF and fill out a Lost Badge Form prior to a new badge being issued.

Pregnant Workers

Any radiation worker who is pregnant, or thinks she may be pregnant, may declare herself a Pregnant Worker by calling the RSOF and completing a Declaration of Pregnancy Form. Declaration of pregnancy is voluntary. Counseling will be provided and an additional dosimeter will be issued which is exchanged every month. This additional fetal badge is worn such that any dose to the developing baby is conservatively measured.

Proper Use and Care of Dosimeters

- The whole body badge shall be worn between the neck and waist. If, however, one area of the body is more likely to be exposed than the rest, the badge should be worn in that area.
- The front of the badge must be exposed toward the source of radiation with no obstruction, such that it correctly samples the actual exposure of the radiation worker.
- The badge shall be worn outside of any personal protective equipment (e.g. apron or laboratory coat).
- Extremity badges (ring badges) should be worn under any protective gloves on the hand most likely to receive the greatest exposure. The front of the ring badge should face toward the radiation source.
- Badges are issued to a single user and shall not be shared.
- Store the badge in a radiation-free area, such as a desk drawer, when not in use. Do not take the dosimeters home.

GENERAL PROCEDURES FOR ALL USERS OF RGE (cont'd)

RGE Records and Record Keeping

Regulatory Reference:

Radiation Generating Equipment; OAC 3701: 1-66-01, 12, 13

Changes in RGE and/or Personnel

All RGE, as well as any personnel changes, must be reported on a quarterly inventory form which is sent to each AP by the RSOF. This also includes any changes in the status of the RGE, since a survey may have to be performed by the RSOF.

RGE Status Classes at CWRU

An RGE can exist in one of three status classes:

Working: The equipment is assembled and functional. The RGE may be in use or in storage.

Storage: The equipment is not assembled but may be assembled and made functional without the use of tools. This RGE is assumed to be in storage.

Disabled: The equipment requires the use of tools and/or parts to assemble the pieces into a functional RGE. This RGE is assumed to be in storage.

The RSOF must be notified immediately of any RGE status change.

RGE Audits

Audits of all RGE are performed by the RSOF on an annual basis. RGE inventory is performed every six months.

GENERAL PROCEDURES FOR ALL USERS OF RGE (cont'd)

General Posting Requirements for all RGE

Regulatory Reference:

General Radiation Protection Standards for Sources of Radiation; OAC 3701:1-38-22(C)

A posted copy of the "Ohio Department of Health Notice to Employees" must be placed in the room containing the RGE. This posting can be obtained by contacting the RSOF at 368-2906.

A copy of specific operating procedures posted at or near each unit.

Any machine that is disabled or in storage must be labeled. In addition to being locked out (either at the main switch or at the plug), these machines must now be tagged with a notice posted indicating that the machine cannot be moved or used without clearance from the RSOF. The notice posting can be obtained from the RSOF or can be made yourself. There is no specific wording requirement.

INDUSTRIAL RADIATION GENERATING EQUIPMENT

Surveys

Regulatory References:

General Radiation Protection Standards for Sources of Radiation; OAC 3701:1-38-18
Radiation Generating Equipment; OAC 3701:1-66-02, 05, 12, 13, 17

Surveys are performed by the RSOF:

- Upon installation of a new piece of 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.
- If any changes in shielding, operation, or equipment could produce a greater radiation hazard than before.
- Any time a visual inspection of the local components in the system reveals any abnormal conditions.
- Whenever personnel monitoring reports show an unexplained increase over the previous monitoring period, or the readings are approaching the dose limits specified in the ODH regulations.
- Once per year during the routine audit. This includes a meter survey using a Geiger-Mueller detector and a dose rate measurement using an ion chamber, if needed.
- No surveys by the laboratory are required.

INDUSTRIAL RADIATION GENERATING EQUIPMENT (cont'd)

Safety Requirements

Any equipment with an all open beam configuration must have a device or feature which prevents the entry of any portion of an individual's body into the primary X-ray beam path, or which causes the beam to be shut off upon entry into its path.

Any alteration to the safety devices must be approved in advance, in writing, by the RSOF. A copy of this memo must be posted near the source housing. A record should include the date the alteration was made, the type of alteration, the length of the alteration, the signature of the individual making the alteration, and the individual who restored the safety device to the original condition.

Analytical X-ray equipment must not be left unattended when the tube is energized unless an interlock is present to prevent accidental entry into the primary beam.

Visual Indicators

A visible warning light labeled with the words "X-ray On," or words or symbols having a similar intent, must be located near the X-ray source and its controls, and shall be illuminated when the X-ray source is energized. **Visual indicators on all XRD units must be inspected every 6 months and every 3 months on cabinet units.**

Interlocks and labels

Each radiation source housing shall be equipped with an interlock that shuts off the radiation beam before the source is removed from the radiation source housing, or before the housing is disassembled. All units must have the Radiation label visibly displayed. **Safety interlocks and labels on all XRD units must be inspected every 6 months by RSOF staff and every 3 months by AP or designated lab member on cabinet units.**

Shielding

The components of the system shall have sufficient shielding such that no radiation levels exist in any area which could result in a dose in excess of the dose limits set by the ODH. Shielding evaluations on new equipment are usually performed by the manufacturer, and by the RSOF during the annual survey of the unit.

Additional shielding requirements for Industrial RGE:

- Operators of industrial radiographic/fluoroscopic units should be protected with at least 0.5 mm lead-equivalent if they are not behind a protective barrier.
- The operator should be at least six feet (6 ft.) from the tube housing the assembly during exposures, or the equipment must have a six and one-half foot (6.5 ft.) barrier for operator protection during exposures.

INDUSTRIAL RADIATION GENERATING EQUIPMENT (cont'd)

Labeling

All regulated equipment shall be labeled with a sign that bears the radiation trefoil symbol and the words: "CAUTION—High intensity X-ray beam" near the X-ray housing **AND** "CAUTION—This equipment produces radiation when energized" near any switch or control that directly energizes the unit. These labels can be obtained from the RSOF if none are posted on the equipment.

Emergency Procedures

In case of an accident, or a suspected accident involving radiation exposure, call:

Monday – Friday (8:30 a.m. – 5:00 p.m.)
RSOF
368-2906

Evenings, Weekends, Holidays
Security
368-3333

Record Keeping

The following records should be made available for inspection:

- A copy of the RGE Manual
- A list of all RGE authorized operators
- Notices of any transfers, installations, and disposals
- Documentation of RGE site-specific training
- Quarterly Safety Check Log for cabinet units only

DENTAL RADIATION GENERATING EQUIPMENT

Operating Requirements

Regulatory References:

Radiation Generating Equipment; OAC 3701:1-66-02, 04, 05, 06, 07, 10
Ohio Dental Practice Act; ORC 4773
Ohio Radiologic Professionals Licensing; ORC 4715
U.S. FDA performance standards for diagnostic X-ray equipment; 21CFR 1020:30-32

Only state certified dental technicians and Doctors of Dental Surgery are permitted to operate dental RGE.

Certification Surveys

- Upon installation of a new piece of equipment by the installer.
- Following any change in the initial arrangement, number, or type of local components in the system by the installer.
- Following any maintenance requiring the disassembly or removal of a local component in the system by the installer.
- 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 by the installer.
- Any time a visual inspection of the local components in the system reveals any abnormal conditions by the installer.
- Whenever personnel monitoring reports show an unexplained increase over the previous monitoring period, or the readings are approaching the dose limits specified in the ODH regulations by the installer.
- Surveys of all dental units (including handhelds) must be performed by a Certified Radiation Expert every 12-14 months.

DENTAL RADIATION GENERATING EQUIPMENT (cont'd)

Safety Requirements

No individual shall be permitted to hold any part of the X-ray tube housing, cone, or mechanical support of the X-ray tube during exposure.

Each installation shall be provided with a protective barrier for the operator, or shall be so arranged that the operator stand at a minimum distance of six feet (6 ft.) from the patient and out of the useful beam.

Except for the patient being examined, all persons required for the dental procedure shall be protected from the direct scatter radiation by protective aprons of not less than 0.5 mm lead-equivalent material, or whole body protective barriers. If the operator is behind a protective barrier, a viewing system shall be provided so that the operator can see the patient without having to leave the protected area during the exposure.

Dental X-ray machines cannot be used by an individual for training, demonstration, or other non-dental or non-medical purpose.

Fluoroscopy shall not be used for dental exams.

Dental equipment for intraoral use shall meet the following standards: The source-to-skin distance (SSD) should be less than – 18 centimeters if operable above 50KVP; or 10 centimeters if operable at 50KVP or below.

Shielding

Dental rooms containing intraoral and panoramic units shall be provided with primary barriers at all areas struck by the useful beam.

When intraoral or panoramic units are in adjacent patient occupied rooms, protective barriers shall be provided between the rooms or areas.

Shielding evaluations on new equipment is usually performed by the manufacturer upon installation, and by the RSOF during the annual survey of the unit.

DENTAL RADIATION GENERATING EQUIPMENT (cont'd)

Labeling

The X-ray control panel shall provide visual indication to the operator whenever X-rays are produced. Certified equipment shall have an audible indication to the operator while X-rays are produced, or on termination of the exposure.

Assure that each X-ray unit bears a warning label, which cautions individuals that radiation is produced when it is energized.

DENTAL RADIATION GENERATING EQUIPMENT (cont'd)

Record Keeping

Regulatory references:

Radiation Generating Equipment; OAC 3701:1-66-02, 04, 06
Ohio Dental Practice Act; ORC 4773
Ohio Radiologic Professionals Licensing; ORC 4715
U.S. FDA performance standards for diagnostic X-ray equipment; 21CFR 1020:30-32

X-ray systems and associated components used on humans, and certified pursuant to 21CFR Part 1020, shall be maintained. A copy of FDA Form 2579 should be on file.

The following information should be maintained for each dental unit:

- Model and serial numbers of all major components
- Records of surveys, calibrations, maintenance, and modifications performed on the equipment
- Copy of all correspondence regarding each RGE

The following information should be posted at or near the control panel:

- Body part and anatomical size or part thickness, pediatric age, and suggested technique factors for each (technique chart)
- Unit's Safe Operating Procedure

Other records that should be available for inspection:

- Operating procedures identifying operating technique restrictions (dental only)
- The Ohio Radiologic License (or copy) for each individual operating the X-ray equipment
- A copy of the RGE Manual
- A list of all RGE authorized operators
- Notices of any RGE transfers, installations, and disposals

VETERINARY RADIATION GENERATING EQUIPMENT

Certification Surveys

Regulatory Reference:

Radiation Generating Equipment; OAC 3701:1-66-05, 07

- Upon installation of a new piece of equipment by the installer
- Following any change in the initial arrangement, number, or type of local components in the system by the installer.
- Following any maintenance requiring the disassembly or removal of a local component in the system by the installer.
- 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 by the installer.
- Any time a visual inspection of the local components in the system reveals any abnormal conditions by the installer.

Surveys of fluoroscopy units must be performed by a Certified Radiation Expert every 12-14 months. Contact the RSOF if you have a unit that requires a survey.

VETERINARY RADIATION GENERATING EQUIPMENT (cont'd)

Safety Requirements

Stationary, mobile, or portable veterinary radiographic equipment shall be provided either with a six and one-half feet (6.5 ft.) high protective barrier for the operator during exposure, or shall provide the means for the operator to be at least six feet (6 ft.) from the tube housing assembly during exposures.

If mobile or portable veterinary radiographic equipment is used in one location for greater than one week, it shall be considered a fixed installation.

For stationary veterinary equipment, all wall, floor, and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of eighty-four inches (84 in.) above the floor. The secondary barrier shall be provided in all wall, floor, and ceiling areas not having primary barriers, or where the primary barrier requirements are lower than the secondary barrier requirements.

If the operator is not behind a protective barrier, a lead apron of not less than 0.5 mm lead-equivalent shall be worn when making exposures.

Labeling

The X-ray control panel shall provide visual indication to the operator whenever X-rays are produced. Certified equipment shall have an audible indication to the operator while X-rays are produced, or on termination of the exposure.

Assure that each X-ray unit bears a warning label, which cautions individuals that radiation is produced when it is energized.

VETERINARY RADIATION GENERATING EQUIPMENT (cont'd)

Record Keeping

Regulatory references:

Radiation Generating Equipment; OAC 3701:1-66-02, 04, 06
Ohio Dental Practice Act; ORC 4773
Ohio Radiologic Professionals Licensing; ORC 4715
U.S. FDA performance standards for diagnostic X-ray equipment; 21CFR 1020:30-32

The following information should be maintained for each unit:

- Model and serial numbers of all major components
- Records of surveys, calibrations, maintenance, and modifications performed on the equipment

Other records that should be available for inspection:

- A copy of the RGE Manual
- A list of all RGE authorized operators
- Notices of any RGE transfers, installations, and disposals

APPENDIX

TRANSFER OR DISPOSAL OF RGE

Please check one of the following:

☐ Internal Transfer (within CWRU)

☐ External Transfer

☐ Disposal

If the equipment is being transferred within CWRU, is the receiving individual authorized to use Radiation Generating Equipment?

☐ Yes

☐ No – Please contact Case Radiation Safety Office at 368-2906

Equipment Identification

Manufacturer	
Model Number	
Serial Number	
Date of Transfer	

Recipient of Equipment

Name
Address (City, State, Zip)
Telephone

RGE Form 1