

# RADIATION PRODUCING DEVICE POLICY MANUAL

## INTRODUCTION/PURPOSE/SCOPE

The purpose of this manual is to provide clinicians and technologists who use radiation-producing devices in the healing arts and for research purposes with policies and procedures regarding the safe use of these devices as approved by the WVU Radiological Safety Committee (RSC).

The privilege to use ionizing radiation at West Virginia University and WVU Hospitals requires individuals to follow all federal, state, and local policies and procedures.

The policies in this manual, when followed will ensure that appropriate protective and regulatory actions required of WVU are satisfied.

In order to help facilitate the need for use of radiation producing devices, one should contact the Radiation Safety Department (RSD) in order to determine the next RSC meeting.

The policies and procedures in this manual are based on and meant to meet and adhere to the rules and regulations set forth from the following agencies:

- The Nuclear Regulatory Commission (NRC) codified in 10 CFR 20 (the Standards for Protection against Radiation).
- The State of West Virginia Radiological Health Rule 64-23.
- The U.S. Food and Drug Administration's (FDA) (performance standards for ionizing radiation (FDA 2014g).
- The Environmental Protection Agency (EPA) standards when applicable.

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# EQUIPMENT REGISTRATION POLICY

## Registration

- a. The WVU Radiation Safety Department requires registration of all diagnostic, therapeutic and analytical radiation producing devices (x-ray) currently being used at WVU or WVUH. Prior to purchasing a radiation-producing device, the purchasing department must complete a Radiation Safety Radiation Producing Device Registration application form and submit to Radiation Safety Department. Information requested with the application form includes:
  - i. Primary user contact information Device description: including manufacturer, model, make, console serial number and x-ray tube serial number
  - ii. Location of x-ray device use
  - iii. Description of how the x-ray device will be utilized
  - iv. Shielding design information
  - v. This equipment is required to be registered through not only Radiation Safety, but also through the West Virginia State Radiological Health Program (WV RHP). Registration of this equipment is required and is in accordance with the WV State Radiological Health Rules 64-CSR-23. The following rules also apply to applicant:
    1. An applicant must read, be aware, and provide the information contained in state code 64-23-5.5
    2. State Rule 64-23-5.6 states that once it has been determined that the applicant meets the requirements of the applicable state rules, they will be issued a notice of registration.
    3. State Rule 64-23-5.11a states that when any radiation-producing device is temporarily brought into the state, written notice must be provided two business days before such device is to be used.
    4. Information of notice shall include:
      - i. The type of Radiation Device
      - ii. The nature, duration, and scope of use.
      - iii. The exact location or locations where the radiation-producing device is to be used.
      - iv. Temporary operation of said radiation producing devices shall not exceed 180 days per calendar year (5.11.c.3.)
- b. RHP Registration is facilitated through the Radiation Safety Department. Application for registration of radiation facilities must be submitted to the State within 30 days prior to the operation of a radiation facility.

## Shielding Designs

- a. Prior to construction and purchase, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation machines must be submitted to the RSO for approval by the appropriate Radiation Safety Committee. Subsequently, the

RSO will submit the shielding design to the WV RHP for review and approval.  
(64.23-7.4.1)

- b. The following must be considered:
  - i. Does the machine require shielding housing?
  - ii. Who will create the shielding design and are they an outside consultant/vendor?
  - iii. Is the consultant/vendor registered on the WV State Radiological list?
  - iv. Shielding Plan drawings shall include a scale drawing of all rooms containing a stationary radiation machine indicating the radiation machines location and maximum rated technique factors; the use of areas adjacent to the x-ray room with an estimation of the extent of occupancy by individuals in such areas; and the type and thickness of materials, or lead equivalency of each wall or protective barrier. It should also include an estimated workload of areas identified in this shielding/construction plans.
- c. The structural shielding requirements of any new installation, or an existing one in which changes are contemplated, shall be discussed in writing with the RSD. If there is any change within existing shielding design, inform the RSD immediately.
- d. Shielding Design and Requirements may be found in WV CSR 64-23-Q through S.
- e. The State Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval (64-23-7.4.b)
- f. Prior to construction of any X-ray system, the floor plans and the shielding specification must be reviewed. The information required in these plans is found in WV State Code 64-23 Q, and 64-23 R.

### Installation/Setup

- a. The Radiation Safety Department must be notified when an x-ray machine arrives and of installation schedule. Installation must be performed and documented by a State authorized service provider (64-CSR-23.5.3.a.4, 64-CSR-23.5.4.b)
- b. Following installation of a radiation producing device, the Radiation Safety Department will perform initial environmental surveys for radiation present at the operator's position and at pertinent points outside the room at specified test conditions.

### Registration Renewal

- a. WV State RHP Registration must be renewed every three years following the initial registration (64-CSR-23.5.8). Registration renewal will be facilitated by Radiation Safety Department. At the time of registration renewal, Radiation Safety will ensure the accuracy of information contained on the registration renewal application. The State will send the new Notice of Registration, which must be promptly posted.

## Report of Changes

- a. Departments shall notify the Radiation Safety Department, in writing, within five days after any change, which renders the information on the registration no longer accurate. Such changes may include any device installation, modification or relocation, maintenance, disposition or transfer. In case of disposition or transfer of a radiation device, such notification must specify the recipient of these sources. This is to provide ample time to properly notify the state in writing (see below).
- b. State Rule 64-23-5.9 states that ***licensees shall report in writing within 10 days any change in status when these changes render the information provided during the application process no longer accurate.***

## Warnings/Signage/Postings

- a. All radiation machines shall be labeled at the control panel near the energizing switch with "Caution-Radiation: This Equipment Produces Radiation When Energized" CSR 64.23-6.29c
- b. "Caution Radiation Area" signage and any other required signage will be posted on all entrance doors of each radiographic room as appropriate by Radiation Safety Department during the initial room setup/installation. 64.23-6.27a
- c. A current registration certificate must be posted at each facility, which possesses a radiation-producing device prior to using their x-ray equipment.
- d. The Agency Form X "Notice to Employees" must be posted by each registrant in a sufficient number of places so it may be easily viewed by employees.

## Inspections

- a. The Radiation Safety Department will perform, at least annually, an inspection of each radiation producing machine and areas in which these machines are located. This is in addition to inspections conducted by the WVRHP. Diagnostic X-Ray and therapeutic machines will be inspected periodically by a representative of the West Virginia Department of Health and Human Resources (WVDHHR).
- b. Each registrant shall afford the agency, at all reasonable times, opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used and or stored. (64.23.4.3)
- c. Records pursuant to this rule shall be made maintained and made available upon reasonable notice. (64.23.4.3)
- d. Each Registrant shall perform, or allow the state agency to perform such reasonable tests as the agency deems appropriate or necessary including, but not limited to tests of (64.23.4.4):
  - i. Sources of ionizing radiation
  - ii. Facilities where sources of radiation are used and/or stored
  - iii. Radiation detection and monitoring instruments
  - iv. Other equipment and devices used in conjunction with utilization or storage of registered sources of radiation.

- e. The agency may impose upon the registrant any additional requirements deemed necessary or appropriate to minimize danger to public health, safety, or property. (64.23.4.5)
- f. After installations, RSD will inspect all radiation safety aspects of the operational procedures. All radiation producing machines must be surveyed prior to routine use and at one year intervals. A dosimetry badge should be worn by those in the vicinity when the machine is in use unless it is totally contained within adequate shielding.
- g. RSD will conduct environmental surveys and inspections according to RSD policies and procedures.
- h. Periodically, the RSD will request an inventory of all x-ray generating equipment be taken. These records will be kept on file and will aide in ensuring that information is current and accurate.
- i. Specific areas of inspection include:
  - i. Management/administrative items such as proper postings and notices
  - ii. Radiation Protection Program requirements including ALARA policy, training, operator protection, human holder policy, and safety procedures
  - iii. Individual radiation monitoring requirements including declared pregnant worker policy
  - iv. General safety requirements for all x-ray systems
  - v. Shielding plan adequacy
- j. There are specific requirements related to each type of radiation producing device contained on the registration including dental, mammography, C.T, therapeutic radiation machines, fluoroscopic machines, or veterinary systems.
  - i. The registrant shall maintain the following information for each X-ray system for inspection by the agency:
  - ii. Model and Serial Number of all major components and the associated user's manuals for said components. (WV 64-23-7.3.a.12.A).
  - iii. Tube Rating Charts and Cooling curves (WV 64-23-7.3.a.12.B).
  - iv. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system or systems (WV 64-23-7.3.a.12.C).
  - v. A copy of all correspondence with this agency regarding this system (WV 64-23-7.3.a.12.D).
  - vi. An X-ray utilization log (except for veterinary facilities and analytical systems that do not produce images) containing the patient's name, type of examination, date of examination, and the name of any human holder's utilized in the examination (WV 64-23-7.3.a.13).

## VIOLATIONS

- a. If the representative of the State were to find any violations, the following may apply:
  - i. The director shall, depending upon the severity of the violations and upon the degree of health hazard created, reprimand, suspend, or revoke the registration of any registered facility for the conditions listed in State Rule (64.23.4.6)

# ALARA POLICY AND RADIATION PROTECTION PROGRAM

## ALARA Policy

- a. To minimize the biological effects of radiation, special rules and regulations are set forth for individuals occupationally exposed to radiation. There is, in general, minimal external radiation hazard to personnel from procedures involving radiation. Adherence to guidelines contained in this manual will help employees and students keep their exposures as low as reasonable achievable (ALARA) (64-23-6.4.b), and should reduce radiation exposures to levels allowable for individuals or in some cases, to levels indistinguishable from natural background.
- b. The radiation protection program is guided by the concept of keeping radiation exposure ALARA. The ALARA concept is based on the assumption that any radiation dose, no matter how small, can have some adverse effect. Under the ALARA program, every reasonable means of lowering exposure is used.
- c. Radiation exposure can be minimized by utilizing three basic principles:
- d. Time: Shorter exposure time means a lower dose.
- e. Distance: Doubling the distance from a radiation source means one-fourth the dose rate.
- f. Shielding: The use of appropriate shielding greatly reduces the dose rate. Standing in a protected area during x-ray exposures is one example.

## Radiation Dose Limits

- a. West Virginia University Hospitals, Inc. must comply with the radiation protection limits specified by the WV RHP in 64 CSR 23.6.5. These dose limits apply to radiation exposures above those received from background radiation and medical exposure.
- b. Limits are issued for occupationally exposed individuals: adults, minors, and an embryo/fetus. Dose limits for individual members of the public are also included.
  - i. For adults, an annual limit shall not exceed:
    1. 5 rems (0.05 Sv) for the total effective dose equivalent (TEDE), which is the sum of the deep dose equivalent (DDE) from external exposure to the whole body and the committed effective dose equivalent (CEDE) from intakes of radioactive material.
    2. 50 rems (0.5 Sv) for the total organ dose equivalent (TODE), which is the sum of the DDE from external exposure to the whole body and the committed dose equivalent (CDE) from intakes of radioactive material to any individual organ or tissue, other than the lens of the eye.
    3. 15 rems (0.15 Sv) for the lens dose equivalent (LDE), which is the external dose to the lens of the eye.
    4. 50 rems (0.5 Sv) for the shallow dose equivalent (SDE), which is the external dose to the skin or to any extremity.



5. For minor workers, the annual occupational dose limits are ten percent (10) of the dose limits for adult workers.
  6. For protection of the embryo/fetus of a declared pregnant woman, the dose limit is 0.5 rem (5 mSv) during the entire pregnancy. Efforts must be made to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the aforementioned limit. Thus, the monthly exposure during pregnancy should be less than 50 mrems (0.5 mSv).
- c. For individual members of the public, the total effective dose equivalent to individual members of the public from licensed operations at the University or Hospital shall not exceed 100 mrems (1 mSv) in a year, exclusive of any dose contribution from the Authorized User's disposal of radioactive material into sanitary sewage, and the dose in any unrestricted area from external sources shall not exceed 2 mrems (0.02 mSv) in any one hour (64-23-6.13).

### Radiation Protection Program

- a. A radiation protection program has been developed and implemented sufficient to ensure compliance with the provisions of WV State Radiological Health Rules 64-CSR-23.
- b. The Radiation Protection Program uses, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that area as low as is reasonably achievable (ALARA).
- c. The radiation protection program is reviewed by the Radiation Safety Department annually as part of its inspection program.

### RADIATION MONITORING POLICY

- a. The Radiological Safety Committee has adopted the policy that all radiation exposures are kept as low as reasonably achievable (ALARA). West Virginia University Hospitals is committed to comply with the radiation protection limits specified by United States Nuclear Regulatory Commission (NRC) in 10 CFR 20.1201 and by WVRHP in 64 CSR 23.6.5. These dose limits apply to radiation exposures above those received from background radiation and medical exposure. The regulations require that doses from external and internal sources must be monitored if an individual is likely to receive a dose in excess of 10% of the applicable dose limits. If both external and internal doses must be monitored, the dose resulting from each must be added together and the sum compared to the appropriate annual limit.
- b. Radiation Monitors-Individuals working directly with or in the same vicinity as radiation producing machines are required to wear personal radiation dosimeters to monitor their radiation dose. Radiation Safety distributes radiation monitors to employees on a quarterly and/or monthly basis. Employees will wear their radiation

dosimeters for the 1 or 3-month wear period, and at the end of the wear period, a new dosimeter will be provided to them to wear for the next 1 or 3 months.

- c. At the conclusion of the wear period, employees must turn in their monitors to their departmental badge Coordinator who will return them to Radiation Safety to send out for processing. It is important that you return all dosimeters whether used or non-used at the end of each wear period. The radiation dosimeters must be received by Radiation Safety Department no later than the 15th of the month following the wear period end date to ensure it is returned to Mirion for processing. Late badges and non-returned badges are considered a regulatory non-compliance violation and may result in unfavorable disciplinary action. You must return all the radiation dosimeters (Whole Body Badges or TLD Rings), not only to comply with regulatory guidelines and commitments but in order to receive credit for the chips and filter components that are removed for recycling. The shipping containers that the Department Coordinators received containing the monthly or quarterly radiation dosimeters are designed to be reused for returning the dosimeters to Radiation Safety Department.
- d. To obtain a radiation monitor for an employee, complete the online Badge Application form so a monitor can be promptly issued to the employee.
- e. Wearing the Dosimeter-The dosimeter shall be worn at all times when working around sources of radiation. The dosimeter should be worn at the waist, chest or collar with the front of the dosimeter forward.
  - i. When protective lead is worn, the wear location is typically at the neck outside of the lead. Care must be taken to store dosimeters in a safe place where it is not exposed to radiation. Dosimeters are designed to track the dose of the person for which it was issued, therefore, employees should never wear another individual's dosimeter.
  - ii. Dosimeters must not be stored on any lead apparel while not in use. Dosimeters should be stored at a central location in the department sufficiently away from any sources of radiation.
- f. Declared Pregnancy Policy-If a pregnant employee chooses, she may declare her pregnancy to the Radiation Safety Officer (RSO) to take advantage of lower dose limits during the pregnancy. If the employee intends to declare her pregnancy, she must inform her supervisor and the RSO in writing. If she chooses not to declare her pregnancy, only the individual monitoring limits for an adult radiation worker will be in effect. It is recommended that an employee who utilizes radioactive materials and/or radiation producing devices in their job assignment should declare their pregnancy.
  - i. The employee will receive pregnancy counseling with the RSO during which the employees will receive information on risk associated with radiation exposure during pregnancy and recommendations for keeping doses low. A monthly fetal radiation dosimeter will be issued to the employee to track doses per month and is to be worn in conjunction to any other monitoring devices. The fetal dosimeter must be worn at the waist and underneath any lead apron worn. The monthly fetal dosimeters will be exchanged each month and a monthly report of dose reviewed by the RSO.

- ii. The change in monitoring, and associated dose restrictions will be in effect until the employee withdraws the declaration. The declaration may be withdrawn at any time with no explanation necessary.
- g. **Radiation Monitoring for Fluoroscopy**-For all personnel performing fluoroscopically guided interventional procedures, two radiation monitors must be worn, one at the waist under the lead apron, and one at the collar outside of the lead (based on the recommendation of the NCRP Report No. 168). Special care must be taken to avoid accidental exchange of the two locations as consistency of wear location allows for the best estimate of radiation dose.
  - i. Personal monitoring dosimeters shall be worn at their respective positions at all times during the fluoroscopy procedure.

### **SENTINEL EVENT POLICY**

- a. The Joint Commission considers the following a Sentinel Event:
  - i. Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field.
    - 1. Cumulative dose should be monitored over a period of six months to a year.
  - ii. Any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose.
- b. The Radiation Safety Department must be notified immediately if a Sentinel Event involving radiation occurs.
- c. Notification to the WV Radiological Health Program may be necessary.
- d. Refer to the Sentinel Event Policy III.041 in the West Virginia University Hospitals and Ambulatory Services Policy and Procedure Manual for additional requirements.

### **MISADMINISTRATION**

- a. A misadministration is an administration of an external beam therapy dose:
  - i. Involving the wrong patient, wrong treatment modality or wrong treatment site; or
  - ii. When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 % of the total prescribed dose; or
  - iii. When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30%; or
  - iv. When the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.
- b. The Radiation Safety Department must be notified immediately of a misadministration.
- c. The Radiation Safety Department will make the necessary notification to the WV Radiological Health Program:

- i. Notify the WV RHP no later than the next calendar day after discovery of the misadministration;
  - ii. Submit a written report no later than 15 days after discovery of the misadministration.
- d. The referring physician and the patient must be notified of the misadministration no longer than 24 hours after its discovery.

## LEAD APRON POLICY

WVUH provides lead equivalent shielding that meet/exceed WVDHHR requirements (aprons and thyroid shields) for protection of employees from direct scatter radiation created during procedures involving radiation producing devices. Lead protection will be checked for its shielding integrity on at least an annual basis to ensure an optimal level of protection is provided. Lead shielding that has been purchased by an employee and used as their personal lead must be incorporated into the annual integrity testing. Proper care and storage practices must be followed to prevent wear and degradation of the lead shielding. Each facility shall have lead aprons and gloves available in sufficient **numbers and size** to provide protection to **all** personnel who are involved with x-ray operations and who are otherwise not shielded.

### **Procedure:**

#### **Thickness Requirements:**

- a. All newly purchased lead aprons must provide at least 0.5 mm lead equivalent protection in the front and at least 0.25 mm lead equivalent protection in the back.
- b. All newly purchased thyroid shields must provide at least 0.5 mm lead equivalent protection.

#### **Lead Shielding Integrity Check:**

- a. Departments that require lead shields as part of their operations, order those shields as needed.
- b. Upon receipt of newly purchased lead, the lead integrity shall be checked with fluoroscopy.
- c. Each piece of lead shield should be marked with a unique identifier to accurately track that shield.
- d. Each lead shield shall be checked annually for integrity by one of the following options:

#### **Option 1 Check via Fluoroscopy**

- i. Lay out the item on the fluoroscopy table.
- ii. Examine all areas of the item using a setting which minimizes the amount of scatter radiation produced.
- iii. Shielded areas will appear dark and defects, seams, stitching will appear light.
- iv. Document the results.

#### **Option 2 Fluoroscopy Unit is Not Available**

- v. Closely visually inspect each item for irregularities (tears, holes, cracks, bumps).
  - vi. Take a radiograph of any suspect areas.
  - vii. Inspect the image for breaks in the lead.
  - viii. Document the results.
- 
- a. Consideration should be given to minimizing the exposure of inspectors by minimizing unnecessary fluoroscopy.
  - b. Annual surveillance of OR lead aprons will be conducted by Radiology and coordinated by designees of Director, Perioperative Services.
  - c. Any defect or tear in the lead shielding may render the apron useless in protecting the wearer from direct scatter radiation. If any detectable flaws, such as holes or cracks are found, then the lead apron or thyroid shield in question shall be removed from service and disposed of by Safe Harbors.
  - d. Departments will report to Radiation Safety Department any lead protection that has failed the annual integrity testing.

#### **Care and Storage of Lead Shielding**

- a. Lead shields are stored on apron trees or hooks when not in use. Lead shields are never folded or otherwise bent for storage.
- b. Prior to each use, individuals should visually inspect their lead aprons and thyroid shields for obvious signs of damage, such as cracks or holes.
- c. Personal dosimeters should not be stored on lead aprons or thyroid shields.
- d. The manufacturer's recommendation regarding the care and storage of protective lead must be strictly observed.

#### **Disposal of Lead Aprons**

- a. When a number of aprons begin to get more and larger defects, then they should be collected and either repaired or disposed of. When they are considered not fit for repair, the lead within the aprons presents a disposal problem. A group of lead aprons can be boxed up and easily manifested for disposal according to Hospital Environmental and Health rules and regulations.

## **DIAGNOSTIC X-RAY EQUIPMENT SAFETY REQUIREMENTS**

#### **General Administrative Requirements:**

- a. Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. (64-23.7.3.a.2)
- b. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 mm lead equivalent material. (64-23.7.3.a.5.A)

- c. Only the staff, ancillary personnel or other persons required for the medical procedure shall be in the room during the radiographic exposure. (64-23.7.3.a.5)
- d. The x-ray exposure should be controlled from a location within the shielded control booth.
- e. All operators and other staff shall be instructed to remain in a specified protected area during exposures.
- f. The x-ray operator, other staff, ancillary personnel, or other persons required for the medical procedure must be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent material. (64-23.7.3.a.5.B)
- g. Gonad shielding of not less than five-tenths (0.5) millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure. **(See Policy recommendations by the AAPM Policy PP 32-A and the supporting agencies on shielding use and possible interference.)** (64-23.7.3.a.6)
- h. Personnel must, at all times, keep as far away from the x-ray beam as practicable. Radiation exposure of personnel by the x-ray beam must never be allowed unless the beam is adequately attenuated by the patient and by protective screens or protective clothing.
- i. Individuals must not be exposed to the useful beam except for healing arts purposes. This specifically prohibits deliberate exposure for training, demonstration, or other non-healing arts purposes. (64-23.7.3.a.7 (A,B))
- j. X-ray Utilization Log: X-ray procedures shall be documented maintaining a record of the patient's name, the type of examination and the dates the examination was performed. (64-23.7.3.a.13)

**Human Holder Policy (64-23.7.3.a.4):**

- a. The registrant shall create and make available to X-ray operators written safety policies which includes selection of a holder. (64-23.7.3.a.4)
- b. If a patient must be provided with auxiliary support during a radiation exposure, mechanical holding devices shall be used when the technique permits. (64-23.7.3.a.8)
- c. No single person should be identified to regularly hold a patient during an x-ray examination. (64-23.7.3.a.8.D)
- d. The human holder shall be instructed in personal radiation safety. (64-23.7.3.a.8.C)
- e. If someone must hold a patient they should be provided with protective aprons, gloves. Never should a holder place any part of his or her body in the useful beam even if it is covered by protective lead. (64-23.7.3.a.8.F)
- f. Persons who periodically hold a patient (i.e, a family member or personal care giver) will not need to be supplied with a radiation monitoring device.
- g. Human Holder Log: When the patient or film must be provided with human auxiliary support, the name of the human holder shall be documented. (64-23.7.3.a.13)

### X-ray Safety Requirements

- a. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.
- b. The operator must be able to observe 1) the visible indication of radiation initiation, 2) the audible indication of radiation termination, and 3) the patient from the operators protected area.

### Fluoroscopy Safety Requirements

- a. Radiation exposure during fluoroscopy is directly proportional to the length of time the unit is activated by the foot switch. Unlike regular x-ray units, fluoroscopic units do not have an automatic timer to terminate the exposure after it is activated. Instead, depression of the foot switch determines the length of the exposure, which ceases only after the foot switch is released. Fluoroscopy machines are equipped with a timer and an alarm which sounds at the end of five (5) minutes. The alarm serves as a reminder of the lapsed time and can then be reset for another five (5) minutes.
- b. Entrance exposure rate measurements shall be performed by a qualified expert and be made annually or after any maintenance of the system which might affect the exposure rate.
- c. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope. Results must include the name of the individual performing the measurements and the date the measurements were performed.
- d. Protective aprons of at least 0.5mm lead equivalent and thyroid shield shall be worn during fluoroscopy procedure at all times.
- e. Leaded-glass eye shields and radiation-attenuating surgical gloves should be utilized by the surgeon to reduce radiation exposures.
- f. The beam ON-time shall be kept at a minimum.
- g. The useful beam shall be limited to the smallest area practicable and consistent with objectives of the fluoroscopy examination or treatment.

### Mobile X-ray Unit General Safety

- a. Mobile units must be used only for examinations where it is impractical to transfer patients to a stationary x-ray installation.
- b. During operation, the x-ray beam should be directed away from occupied areas if at all possible, and every effort must be made to ensure that the useful beam does not irradiate any other persons in the vicinity of the patient.
- c. A protective apron must be assigned to each mobile x-ray unit.
- d. The operator must be provided either with a protective barrier at least 6.5 feet high or means must be provided to allow the operator to be at least 9 feet from the tube housing assembly during the exposure.



### C-arm Unit Safety Requirements

- a. Only individuals required for the radiographic procedure shall be in the radiographic room during exposures.
- b. Operators should use the smallest collimation and shortest beam on time to reduce patient and staff dose.
- c. Except for the patient, no unprotected body part shall be in the useful beam.
- d. Exposure to the operator's hands, even with mini c-arm can be high. Keep hands out of the primary beam.
- e. C-arm units are mobile devices and can be moved from room to room for use.
- f. All individuals in the room must wear protective apparel of at least 0.5mm lead equivalent or otherwise be protected by whole body protective barriers.

### Mini C-arm Unit Safety Requirements

- a. Mini c-arm generate much less scatter radiation than do regular c-arm units, however, good radiation safety practices must still be followed to keep radiation doses to patients and staff ALARA.
- b. Only individuals required for the radiographic procedure shall be in the room during exposures.
- c. The operator of the mini c-arm unit must wear protective lead apparel.
- d. All other individuals required to be in the room during a procedure must be able to move at least 6 feet from the mini c-arm during exposures. If that is not possible, then those individuals must also wear protective lead apparel.
- e. Mini c-arm use should be limited to extremity use only. They are not designed to be used on thick structures.

### Computed Tomography X ray System Safety Requirements

- a. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. (7.10.c.1)
- b. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel (7.10.c.2.A)
- c. The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation (7.10.d.4.A)
- d. Means shall be provided to terminate the X-ray exposure automatically by de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure during data collection. The exam duration shall not be permitted to exceed 110% of the exams preset value (7.10.b.1.A)
- e. The operator shall be able to terminate the scan at any time during a scan or series of scans on CT X-ray system control of greater than 0.5 second duration (7.10.b.1.C).
- f. A visible signal shall indicate when the x-ray exposure has been terminated (7.10.b.1.B).

- g. CT spot check procedures shall be in writing and developed by a qualified expert (7.10.d.3.A). A qualified expert should be at a minimum a lead CT technologist or senior under American College of Radiology guidelines. These spot checks shall be performed at intervals determined by the qualified expert. (ACR-requires daily spot checks)
- h. Spot Check images shall be acquired using a dosimetry phantom and the images shall be retained either on the display device, digital form, or in photographic form until new spot check images are acquired (7.10.d.3.D) (7.10.d.3.D.1)(7.10.d.3.D.2)
- i. Written records of the spot checks shall be maintained for the state agency review (7.10.d.3.E). The WVU Radiation Safety Department requires these records to be maintained at a minimum of 3 years to coincide with ACR accreditation renewal standards.

### Mobile Computed Tomography (CT) X ray System Safety Requirements

- a. Mobile Computed Tomography X-ray systems are subject to the applicable requirements listed above and must adhere to the additional guidance below:
  - i. Mobile CT units must be used only for examinations where it is impractical to transfer the patient to CT department or specific exams which require the use of a mobile CT unit.
  - ii. No unnecessary personnel shall be permitted to remain in the room while the patient is being imaged.
  - iii. All remaining personnel must have a protective lead apron meeting the requirements detailed in this manual.
  - iv. The operator must be provided either with a protective barrier at least 6.5 feet high or means must be provided to allow the operator to be at least 9 feet from the tube housing assembly during the exposure.
  - v. CT Spot check images shall follow the rules for CT X-Ray systems listed above but at a frequency determined by a qualified expert, and follows Federal and State Regulations, and is in compliance with manufacture recommendations.

### Mammography Safety Requirements

- a. Quality Assurance Program Required (7.11.b.1). The registrant shall have a written, on-going equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic x-ray imaging system, to ensure consistently high-quality images with minimum patient exposure. Responsibilities under this requirement include providing qualified individuals who are to:
  - b. Conduct equipment performance monitoring functions (7.11.b.1.A-D)
  - c. Analyze the monitoring results to determine if there are problems requiring correction;
  - d. Carry out or arrange for the necessary corrective actions when results of quality control tests including those indicate the need; and

- e. Maintain records for a minimum of two years documenting that actions have been completed.
- f. Quality Assurance Program Review (7.11.b.2) At intervals not to exceed twelve months, the registrant shall (7.11.b.2.A,B):
  - i. Have the annual quality control tests specified in 7.11.b.3. performed by a qualified individual (table 64-23 P) and obtain the results of those tests, incorporating them into the records specified in Subparagraph 7.11.b.1.D.; and
  - ii. Conduct a review of the effectiveness of the quality assurance program and maintain a written report of such review. Records of annual reviews shall be maintained for a minimum of two (2) years and shall be available for agency review.
  - iii. The operator of the x-ray machine shall be certified by the american registry of radiologic technologists or an equivalent state licensing body and shall have had specialized training in mammography.
- g. Image Quality testing using a test phantom shall be performed monthly for stationary systems, and on each day of use for mobile systems (7.11.b.3.L)

#### Operator Protection for Veterinary Systems

- a. All stationary, mobile or portable X-ray system used for veterinary work shall be provided with either two (2) meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least two and seven tenths meters (9 feet) from the tube housing assembly during exposures (7.8.b.7 ).

#### Therapeutic Radiation Machines:

- a. The registrant shall be registered as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy and be certified by one of the agencies list under state rule 64-23.7.a.5.12.
- b. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program (7.12.c.7)( 7.12.c.7.A-D)
- c. The registrant shall maintain a record of acceptance testing, records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine, and after any repairs. These records must include the names of the personnel performing the maintenance (7.12.c.6.B)( ( 7.12.c.7.A-D)
- d. These records shall be maintained until disposal is authorized by the state agency (7.12.c.8)
- e. Radiation protection surveys shall be performed on any new and existing facilities in the "BEAM-ON" condition utilizing a scatter phantom with the largest clinically available treatment field (7.12.d.1-7.12.d.1.A, A1-2)(7.12.d.1.B, B1-B4)
- f. The facility shall implement a Quality Management Program (7.12.e)

- g. Quality Assurance and Calibration testing shall be performed under the direct supervision of a radiation therapy physicist.
  - i. Checks shall be performed before the first medical use following installation, reinstallation, annually, after repair, or when quality assurance checks indicate that the radiation output differs by more than five (5) percent from the value obtained at the last full calibration and the difference cannot be reconciled. (7.12.f.16.A, A1-3,3.a,3.b)
- h. Periodic Quality Assurance checks shall be performed on therapeutic radiation machines in accordance with QA procedures established by the radiation therapy physicist. The QA procedures shall dictate the type of testing, the frequency and acceptance criteria of each test (7.12.f.17.B.1-2)
  - i. The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient irradiation (7.12.f.17.C)
  - ii. Any other discrepancies in the quality assurance process shall be investigated and evaluated. State Rule 64-23.7.12 should be referenced for further instruction.
- i. The registrant shall maintain a record of each quality assurance check for three (3) years. The record shall include: the date, the manufacturer's name, model number, and the serial number of the radiation therapy machine (7.12.f.17.J)
- j. Each facility location authorized to possess a therapeutic radiation machine shall possess appropriately calibrated portable monitoring equipment with at a minimum range of 1 mrem per hour to 1000 mrem per hour (7.12.f.19)

## ANALYTICAL X-RAY EQUIPMENT

**DISCLAIMER:** Analytical X-ray equipment is classified by the state of WV as "Industrial: Other" and may be subject to the Requirements of 64-23.9.1 in addition to the requirements of sections 23.8.1 if used in an industrial setting. For example: Some Analytical X-ray equipment may only be used in a laboratory or field setting to determine elemental composition of a substance and it does not produce a visible image, therefore the requirements of sections 23.8 would not apply. Care should be taken when identifying the type of analytical machine possessed. The Radiation Safety Department Staff will assist in helping to make this determination when registering the device with the State of WV.

- a. Each X-ray tube housing (containing a radiation source) shall be constructed that with all shutters closed, the leakage radiation measured at five (5) cm from its surface shall not exceed 2.5 mrem per hour (9.3.g)

- b. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured five (5) cm from its surface to less than 0.25 mrem (9.3.h)
- c. A radiation survey is required upon installation and at least once every twelve months to assure that there is no scattered radiation (WV 64-23-9.4.b.1.A)
- d. A safety device must be present on all open-beam configurations which prohibits the entry of any portion of the human body into the primary X-ray beam path; or triggers the beam to automatically shut off upon entry into the beams path (WV 64-23-9.3.b)
- e. Open-beam configurations must be provided with a readily discernible indication of: X-ray tube status (ON-OFF) located near the radiation source housing, if 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 (WV 64-23-9.3.b.1)
- f. All analytical X-ray equipment 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 intent, on the X-ray source housing; and, "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube (WV 64-23-9.3.d.1)
- g. An easily visible warning light labeled with the words "X- RAY ON," must be located: Near any switch that energizes an X-ray tube and must be illuminated only when the tube is energized (WV 64-23-9.3.f).
- h. Each area or room containing analytical X-ray equipment must be noticeably posted with one or more signs bearing the radiation symbol and the words "CAUTION X-RAY EQUIPMENT." (WV 64-23-9.4.c).
- i. Analytical X-ray equipment must be operated as specified in the instruction manual unless written permission is obtained from the Radiation Safety Officer (WV 64-23-9.5.a).
- j. A safety device must not be bypassed unless written approval is obtained from the Radiation Safety Officer that will include a specified length of time. When a safety device has been bypassed, a noticeable sign must be placed on the X-ray housing bearing the words "SAFETY DEVICE NOT WORKING." (WV 64-23-9.5.b).
- k. No individual will be permitted to operate and/or maintain any analytical X-ray equipment unless the individual has received proper instruction from the registered Primary Authorized User and demonstrate competence to operate the device. User/Operator must be trained by the PAU and meet all training or skill requirements. Training shall include (WV 64-23-9.6):
  - i. The radiation hazards associated with the equipment in use;
  - ii. The significance of the various radiation warning devices, safety devices, and interlocks;
  - iii. Equipment operations manual; Protocol for reporting accidental exposure;
  - iv. Modifications to X-ray apparatus that affects radiation protection such as shielding; X-ray tube housing, cameras, and safety interlocks;
  - v. The importance of wearing personal radiation monitoring devices and the use of area radiation monitors;
  - vi. And, investigating unusual radiation exposure to occupational workers and, if necessary, taking remedial action.

- l. Notify Radiation Safety: When known or suspected occurrence of radiation exposure to an occupational worker or member of the public; A registered X-ray unit is to be relocated and/or the data on file requires updating or modification; Proposed changes are to occur with the approved shielding design; or Major maintenance or repairs are required on the X-ray unit.
- m. Each research laboratory must assure security of x-ray machines. This may require locking of laboratory doors and/or locking the device. All laboratory areas in which x-ray machines are used should have a sign displayed on all entrances. And transfers between buildings should be arranged (or get RSO's approval) through RSD to ensure safe handling and transport.

## INDUSTRIAL X-RAY EQUIPMENT

**DISCLAIMER:** *Industrial X-ray equipment may include Analytical X-ray equipment that has been classified by the state of WV as "Industrial: Other" Care should be taken when identifying the type of Industrial machine possessed. The Radiation Safety Department Staff will assist in helping to make this determination when registering the device with the State of WV.*

- a. The requirements in section 64-23.8 regarding the use of industrial Radiation Producing devices are in addition to the other applicable requirements of this rule.
- b. Radiation Producing Devices classified as an Industrial device can include those devices that utilize machines and or sealed sources to produce radiation. (8.2)
- c. Locked radiographic exposure devices, source changers, storage containers, and radiation machines shall be physically secured to prevent tampering or removal by unauthorized personnel.
- d. Utilization Logs- Each registrant shall maintain current logs, which shall be kept available for inspection by the RSD and the State Agency for two (2) years from the date of the recorded event showing for each source of radiation the following information (8.11):
  - i. A unique identification, such as a serial number, of each radiation machine, each radiographic exposure device in which a sealed source is located, and each sealed source (if applicable).
  - ii. The identity of the radiographer to whom assigned.
  - iii. Locations and dates of use, and when each source was removed and returned to storage.
  - iv. The voltage, current, and exposure time for each radiographic exposure employing a radiation machine.
- e. Each registrant shall conduct a program of at least quarterly inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers to assure proper functioning of components important to safety. Records of inspection shall be maintained for two (2) years from the date of the recorded event (8.12.b)

- f. If any inspection conducted pursuant to subdivisions 8.12.a or b reveals damage to components critical to radiation safety, the device shall be removed from service and labeled defective until repairs have been made (8.12.c)

### Cabinet X-Ray Systems (WV 64-23-8.3.2)

- a. A machine that has been certified in accordance with 21CFR 1010.2 and manufactured and assembled pursuant to the provisions of 21CFR1020.40 is a certified Cabinet X-ray system. (8.3.3)
- b. Less than 0.5 mrem/hr at 5 cm from the external surface per FDA 21 CFR 1020.40.(c)
- c. A cabinet X-Ray system is a device with an X-Ray tube installed in an enclosure (cabinet) which, independently of existing architectural structures except the floor on which the device may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation. Examples of a cabinet X-ray system would be an X-ray system designed primarily for the inspection of carry-on baggage. An X-ray tube used within a shielded part of a building, or X-ray equipment which may temporarily or occasionally incorporate portable shielding would not be considered a cabinet x-ray system 21 CFR 1020.(b)(3).
- d. A cabinet x-ray system must have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system 21 CFR 1020.40. (c). (2).
- e. The cabinet x-ray system must have safety features, which prevents the insertion of any part of the human body into aperture 21 CFR 1020.40. (c). (3). (ii).
- f. The system must also have at a minimum two (2) safety interlocks. One shall be an interlock that de-energizes the system if the door is opened. Each access panel shall have at least one safety interlock 21 CFR 1020.40. (c).(4).(i)
- g. The x-ray system shall have control or controls to initiate and terminate the generation of x-rays 21 CFR 1020.40. (c). (6). (ii).
- h. One control must be a key actuated control to insure that x-ray generation is not possible when the key is removed 21 CFR 1020.40.(c).(6).(i)
- i. The x-ray system must have 2 independent means to indicate when and only when x-rays are being generated 21 CFR 1020.40.(c).(6).(iii)
- j. Additional controls and indicators for cabinet x-ray systems designed to admit humans include:
  - i. A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from outside the cabinet 21 CFR 1020.40.(c).(7).(i).
  - ii. No means by which x-ray generation may be initiated from within the cabinet 21 CFR 1020.40. (c). (7). (ii).
  - iii. Audible and visual warning signals within the cabinet which remains actuated when and only when x-rays are being generated, unless the generation period is less than ½ second in which case the indicators shall be active for ½ a second.

- k. 21 CFR 1020.40.(c).(8).(i) states there shall be permanently and clearly affixed or inscribed on the cabinet at the location of the controls used to initiate x-ray generation a warning label that states : **CAUTION: X-RAYS PRODUCED WHEN ENERGIZED**
- l. There shall also be a clear, legible, and visible warning label adjacent to each port which states: **CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED. X-RAY HAZARD.** 21 CFR 1020.40. (c). (8). (ii).

### X-RAY FILM PROCESSING (7.3.b.1.A)

- a. All radiographs are processed with the film and chemistry manufacturer recommendations. (7.3.b.1.A.2)
- b. Darkrooms should have a method to prevent accidental entrance such as a lock or a “Darkroom: Do Not Enter” sign. (7.3.b.2.C)
- c. A darkroom or daylight processing system should be light tight. All types of x-ray film used should be stored in light tight containers; and must not be expired. (7.3.b.2.)
- d. Darkrooms shall have proper safe lights (GBX-2) placed at least 3ft above the film handling countertop.
- e. The film processor manufacturer recommended developer temperature and immersion time should be posted in the darkroom. (7.3.b.1.B.2)
- f. Ensure that you have documented cassette and intensifying screen cleaning and inspection as the screen manufacturer recommends.
- g. Ensure that you have documented processor maintenance and chemistry changes according to manufacturer recommendations.
- h. The registrant shall also maintain the X-ray film processing facilities in accordance with those listed under WV 64-23.7.3.b. As access to digital technology has increased such that these systems are infrequently used.
- i. If a film processing facility is to be utilized contact the **Radiation Safety Department** to ensure that all State and Federal requirements are met. The chemicals and materials utilized in the film processing method (developer, fixer, and exposed film) may be subject to hazardous material regulations. Please contact [EHS\\_chemicals@wvu.edu](mailto:EHS_chemicals@wvu.edu) for guidance on storage and disposal of these materials.

## DENTISTRY

### Cone Beam Computed Tomography (CBCT)

- a. Cone Beam Computed Tomography (CBCT) - The information presented is in the context of use of CBCT in a Dentistry setting, however the information is applicable to use of CBCT for other clinical settings. Although a CBCT scan radiation dose is usually less than that from a traditional CT scan, it is higher than that of conventional dental radiographic modalities, such as a panoramic image. According to NCRP report 177, the scatter radiation from a CBCT scan may be 10 times greater than a panoramic image. Therefore, the following should be observed to keep



radiation dose to occupational workers and member of the public ALARA (adapted from NCRP report no. 177).

- i. CBCT should be performed only when necessary to provide clinical information that cannot be provided using other imaging modalities.
- ii. In the dental clinic, CBCT should not replace conventional bitewing, panoramic, or cephalometric imaging. CBCT should only be used when the question cannot be answered by conventional dental radiology.
- iii. Installation of a CBCT unit will require a shielding design completed by a qualified person and reviewed by the WV RHP office.
- iv. In the dental clinic, replacement of conventional imaging modalities such as panoramic or cephalometric with a CBCT without consideration of the shielding characteristics of the room may result in potential for substantial radiation dose to individuals in the vicinity of the CBCT system. Therefore, a shielding design must be completed before replacing (or upgrading) conventional imaging equipment with CBCT.
- v. CBCT scanners must be used according to the manufacturer's recommendations.
- vi. CBCT examinations shall use the smallest field of view (FOV) and technique factors that provide the lowest dose appropriate with the clinical purpose.

### Handheld X-Ray Systems

- a. Handheld X-ray Systems - Safe use of handheld x-ray systems within the Dentistry clinic requires adherence to additional equipment design and use considerations beyond those of permanently mounted systems. Due to the proximity of the operator to the x-ray tube there is potential for significant radiation dose to the operator if used improperly. However, handheld units provide radiation doses to the operator that are comparable to those of permanently mounted systems when manufactured and used appropriately. Dental facilities who have purchased or plan to purchase handheld x-ray systems should adhere to the following requirements (adapted from NCRP report no. 177):
  - i. Ensure the unit has been cleared by the US Food and Drug Administration (FDA) before purchase.
  - ii. All units must include a clear, external, non-removable, radiation protection shield containing a minimum of 0.25 mm lead equivalence between the operator and the patient.
  - iii. Additional training is necessary for all operators to introduce them to the proper operation.
  - iv. Operators of the equipment must have the physical ability to hold the system in place for multiple exposures. Operator fatigue could lead to poor positioning of the unit resulting in poor quality exposures and higher radiation dose to the operator. Operator fatigue should be considered when evaluating operator workloads.

- v. Operators shall store handheld x-ray equipment such that it is not accessible to members of the public when not in use.
- vi. Exposures should not be taken with other individuals in the room.
- vii. Use of protective lead apparel when operating a handheld x-ray unit is not required.
- viii. Operate the unit according to the manufacturer's instructions to ensure safety of the patient and operator.