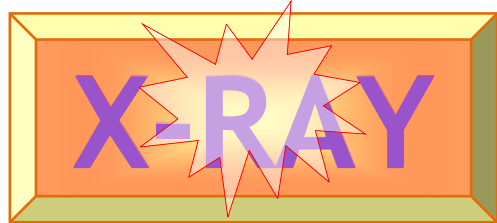


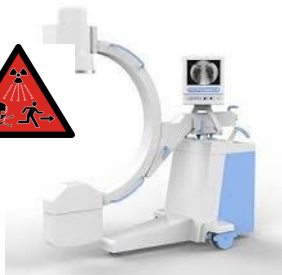
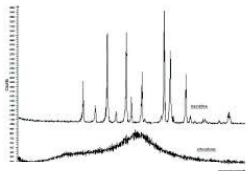
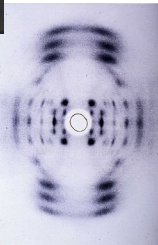
CLEMSON[®]

UNIVERSITY



SAFETY

MANUAL



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I. INTRODUCTION

The possession and use of radiation producing equipment at the Clemson University is authorized by the South Carolina Department of Health and Environmental Control (S.C. DHEC) under the provisions of the Regulation Title-B R61-64, herein after referred to as Title B. This Safety Manual outlines rules and regulations for the safe operation of diagnostic, veterinary, analytical, and industrial X-Ray systems and specifies practices to aid radiation equipment users in minimizing their exposure to radiation.

The Radiation Safety Officer (RSO), in the Office of Research Safety is responsible for development and implementation of the University's Radiation Safety Program. Radiation safety staff will perform periodic inspections of campus radiation facilities to assure compliance with provisions of this manual, Title-B regulations, and special practices or limitations recommended by the Radiation Safety Committee (RSC). Safety violations or operational conditions posing an imminent health hazard will result in immediate cessation of the use of x-ray producing equipment at that facility. Administrative violations not corrected promptly may result in temporary suspension of the use of equipment and will be referred to the RSC for resolution.

Provisions of this manual may prove impractical in certain instances and mechanisms of modifying these procedures are available. Such variances must be requested in writing with sufficient documentation for evaluation by the Radiation Safety Committee and the Radiation Safety Officer. After appropriate review, an exception may be issued which details such modifications.

Copies of State audits, any fines levied against the University, a current copy of Title-B, and various reference materials are available through the Office of Research Safety.

II. RADIATION SAFETY - ORGANIZATION

The President of the University holds the responsibility for all matters pertaining to radiation, laboratory, and general workplace safety and the assurance that the University moves toward compliance with all State and Federal regulations related to safety.

All radiation safety matters are reported to the Director of Research Safety. The Radiation Safety Committee and the Radiation Safety Officer constitute the final authority in all radiation safety matters at University facilities.

The Office of Research Safety administers the University radiation safety policies on a daily basis, through the University's Radiation Safety Officer.

A. Establishment of the Radiation Safety Committee

The Radiation Safety Committee (RSC) has been established as an operational committee with the authority to regulate the safe use of ionizing radiation by the University personnel. It shall develop rules and regulations for this purpose and oversee their implementation in accordance with the RSC bylaws.

1. Radiation Safety Committee Responsibilities

The RSC reviews and grants permission for, or disapproves, the use of all sources of ionizing radiation, including x-ray producing devices, for the institution from the standpoint of radiation safety. It shall monitor the operations of the users of these materials and equipment. Any modifications or improvements it considers necessary in the interest of radiation safety or compliance with federal, state, or internal regulations shall be implemented in the shortest possible interval.

2. Disciplinary Actions

The Committee has the authority to take disciplinary actions up to and including suspension of authority to use radiation producing equipment. The Committee may take disciplinary action in cases of serious noncompliance with established University safety guidelines, variance from approved procedures, or for failure to meet the requirements of Title-B regulations.

B. Office of Research Safety

The Office of Research Safety is charged with the responsibility for the coordination of all safety and health programs at the University not specifically assigned elsewhere, such as police or student health services.

The **Director of Research Safety** supervises the work of the University's Radiation Safety Officer to assure that the all safety guidelines, policies, applicable federal/state, regulations and the decisions of the Radiation Safety Committee are carried out.

C. Radiation Safety Officer (RSO)

The Radiation Safety Officer is a staff member of Research Safety, who by virtue of education, training and experience is qualified to advise others in the safe use of ionizing radiation and to supervise the radiation protection program of the University. The Radiation Safety Officer, with the assistance of his/her staff, shall discharge the duties that are summarized below:

1. The RSO develops and administers the University's radiation safety program providing general surveillance over all activities involving exposure to ionizing radiation including radiation producing equipment to ensure compliance with applicable requirements of Title B regulations.
2. The RSO's written approval is necessary for all activities and procedures that involve actual or potential exposure of personnel to radiation. Where such activities are not covered by previously established procedures, these persons shall bring the activities before the Committee.
3. The RSO shall be available to consult with all users and potential users of radiation producing equipment and give instruction concerning hazards and safety practices to individuals who may be exposed to radiation from x-ray equipment.
4. The RSO shall suspend any operation capable of causing an excessive radiation hazard as rapidly as possible.
5. The RSO shall ensure that surveys are made, procedures are carried out, and radiation safety instructions are given as required by Title B.

III. **X-RAY EQUIPMENT**

The following precautions and limitations apply to all X-ray systems used at Clemson University. These rules are intended to conform to radiation safety standards put forth by the S.C. BRH, Division of Electronic Products Regulation 61-64 Title-B (X-rays). Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the regulatory controls per RHB 2.2.1, providing equivalent dose rate averaged over 10 sq.cm does not exceed 0.5 mrem/h at 5 cm from any accessible surface of such equipment, but it may be included in the radiation safety program at the discretion of the RSO.

A. Classification of Users

Responsible Investigator (RI)- An Responsible Investigator is permitted or authorized by the RSC to purchase, possess, and use X-ray producing equipment; he/she is directly responsible for the proper operation of the equipment and the users on the authorization.

Authorized User (AU) - An authorized user is an individual, who by virtue of training and experience, is authorized to work under the *indirect* supervision of the RI and may supervise others in the use of equipment.

User- A user utilizes X-ray equipment under the *direct* supervision of an Authorized User or Responsible Investigator. A user cannot request amendments to an authorization and has no supervisory authority.

Holder- A holder is authorized only to hold patients, cassettes, or animals during an X-ray exposure.

Student- A student uses equipment only as part of a classroom requirement approved by the Radiation Safety Committee. All students must be under the direct supervision (in the room) of an Authorized Investigator or Authorized User.

B. Responsibilities of X-ray Equipment Users

1. Responsible Investigator

The RI is directly responsible for the safe operation of the X-ray equipment under his/her control to include provision of administrative and/or engineering controls sufficient to prevent unauthorized access to the equipment. RI must ensure that:

- a. Users working under the supervision of the RI are adequately trained and instructed in the safe operating and emergency procedures and are otherwise skilled in the safe use of the equipment. This will be demonstrated by a signature on an "Add Personnel" form or "Approved User List" after instruction.
- b. Users have received training in the radiation safety precautions and limitations considered necessary by the Radiation Safety Committee and required under Title-B.
- c. All X-ray equipment under his/her control is approved for use by the RSC and registered within thirty days of acquisition with the SCDHEC Bureau of Radiological Health, Division of Electronic Products.
- d. DHEC is notified within thirty days of any changes of status affecting the x-ray machine or facility.

- e. Any person furnishing x-ray machine servicing or services as described in Title B must provide evidence that they are registered with DHEC as a vendor.
- f. Users wear the appropriate personnel protective and monitoring devices.
- g. The Radiation Safety Officer is notified of any changes that affect the status of the facility, such as:
 - 1. Changes in personnel using the equipment
 - 2. The addition or deletion of x-ray equipment from an approved place of use.
- h. Security

The RI shall ensure security is sufficient to prevent unauthorized access to x-ray equipment under their supervision by means of:

 - 1. Key control to the x-ray equipment proper, and/or
 - 2. Key control to the areas of approved use.
 - 3. Access control during use is maintained by the approved users.

2. Responsibilities of Other Users

All personnel who work with X-ray producing equipment, faculty, staff, and students, have the following responsibilities:

- a. Follow safe operating procedures to include proper locking of x-ray machines and/or areas when not in use and/or when x-ray use areas are unattended.
- b. Observe the rules presented in this manual for the safe use of ionizing radiation.
- c. Refer to the X-ray Project documentation for additional requirements associated with operation of the equipment.
- d. Immediately notify the RI or the Radiation Safety Officer of any defects or deficiencies in radiation protection devices and procedures.
- e. Maintain radiation doses at a level that is as low as reasonably achievable (ALARA).

C. Obtaining an Authorization

An individual wishing to become an RI, authorized to possess and use X-ray equipment, shall submit an application to the RSC through the Radiation Safety Officer.

The application will be reviewed by the Radiation Safety Committee. The applicant will be notified within 2 weeks or 10 working days of its approval or disapproval. He/she will receive a copy of the application signed by the Chairman of the RSC and the Radiation Safety Officer.

D. Radiation Safety Training Plan

1. All individuals who wish to independently operate, modify, or maintain diagnostic, veterinary, analytical, industrial, or analytical cabinet X-ray systems, or who will be used as patient or film holders, shall receive instruction in and demonstrate ability in:
 - a. Identification of radiation hazards associated with the use of the equipment and levels of radiation expected;
 - b. Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
 - c. Facilities proper operating procedures and control (i.e. locking and securing of x-ray machines) requirements for the equipment;
 - d. Characteristics of x-radiation;
 - e. General information on use of radiation survey instruments: operation, calibration, limitations, and survey techniques if required for use on the x-ray equipment (e.g. specifically required for Industrial Radiographic x-ray use per RHB 8.12.2);
 - f. Units of radiation dose and methods for controlling radiation dose (i.e. time, distance, shielding);
 - g. Personnel monitoring and the use of personnel monitoring equipment (e.g. pocket dosimeters when applicable, use with lead aprons, etc.);
 - h. Symptoms of an acute localized exposure;
 - i. Proper notification procedures for reporting an actual emergency or suspected overexposure

- j. Procedures to minimize exposure in the event of an accident;
- k. Emergency procedures;
- l. Requirements of pertinent state regulations;
- m. Procedures of record control and documentation; and
- n. Ability shall be demonstrated by:
 - 1. Analytical and industrial X-ray users: completing the online “Research X-ray Safety Training” and having the RI/AU verifying a user’s competence with machine operations and emergency procedures by signing approval of the user for the specific x-ray project;
 - 2. Veterinary X-ray users: completing the online “Veterinary X-ray Safety Training” and having the RI/AU verifying a user’s competence with machine operations and emergency procedures by signing approval of the user for the specific x-ray project;
 - 3. Human diagnostic: possession of current, valid certificate from the SC Radiation Quality Standards Association (SCRQSA) and the record of the specific human diagnostic equipment training.
- 2. Users of miscellaneous X-ray equipment shall receive instruction, as necessary:
 - a. General properties of ionizing radiation,
 - b. Biological effects of ionizing radiation,
 - c. Procedures to minimize exposure, and
 - d. Clemson University radiation safety requirements

3. Student use

Students enrolled in a class where diagnostic, analytical or cabinet X-ray equipment is used and who are under the direct supervision of an RI or AU shall receive a short lecture/briefing in basic radiation safety principles given by the RI/AU. This briefing shall be documented as part of the student lesson plan and associated attendance sheet.

E. Training Procedure

- 1. Contact the Radiation Safety Officer or the Research Safety Website at www.clemson.edu/research/safety/manuals to obtain a copy of the X-ray Safety Manual.

2. Contact the RSO to schedule a classroom training lecture and test or complete the online presentation and quiz.
3. On passing the test, contact the RI to complete the machine specific training required.
4. Fill and sign "Add Personnel to an X-Ray Project" form. This form, signed by the RI, serves as a record of the project-specific training on equipment operation and emergency procedures. Alternatively, signed "Authorized User List" may be maintained for the x-ray project with the high user turn-around.
5. If personnel monitoring devices are necessary, the RI or designee will contact Radiation Safety to procure them. The x-ray equipment may not be used until the monitoring device has been issued.

F. X-ray Use in Classroom Instruction

At least 2 weeks before the start of the class, a basic protocol listing the equipment and the intended use should be submitted to the Radiation Safety Officer.

1. The teaching protocol must provide a brief introduction to basic radiation safety training. Training can be performed by the RI or AU and shall include the hazards associated with the equipment, methods to reduce radiation exposure and the biological effects of radiation. At the RI discretion students may be referred to the online "Research X-ray Safety" course. In this case, completion of the online x-ray safety course must be confirmed by the RI.
2. Depending on use and exposure parameters, personnel dosimetry may be issued to students before using the equipment. At no time are students allowed to use the x-ray equipment unsupervised.

G. Obtaining X-ray Equipment

X-ray equipment may only be purchased by an RI.

1. The purchaser should consult with the Radiation Safety Officer concerning the adequacy of the proposed facility where the equipment will be used prior to initiating procurement.
2. Certain type of equipment (eg., human and veterinary diagnostic, industrial shielded room) may require approval of the shielding plan of the proposed location (room) by the SC DHEC before equipment is installed (RHB 4.4 and RHB 8.12.2.4).
3. The purchaser is to notify the Radiation Safety Officer as soon as practical on receipt of the equipment and provide the information necessary to register the unit with the Bureau of Radiological Health, Division of Electronic

Products.

4. Radiation safety personnel will conduct a leakage and area radiation survey during the initial setup and operation of the analytical x-ray equipment. Initial setup surveys for human and veterinary diagnostic and industrial shielded room x-ray equipment must be performed by the vendor accredited by the SC DHEC to perform such surveys.

H. Requests for Inspections

Any worker who believes there is a violation of the rules and regulations presented in this manual may request an inspection of that facility by notifying the Radiation Safety Officer. The worker at their request shall remain anonymous. During inspections the safety officer may confer privately with other workers. Workers may bring to the attention of the safety officer any past or present condition they believe may have contributed to or caused a violation. No Responsible Investigator shall dismiss or in any manner discriminate against a worker because a complaint was filed with the Radiation Safety Officer.

I. Disciplinary Procedures

The Radiation Safety Program stresses compliance. Any program that requires compliance with regulations must have a means for disciplinary actions. The following section describes the disciplinary actions applicable to the use of radiation producing equipment.

1. Classification of Violations

Violations of the rules and regulations in this manual are classified as:

- a. Class I- Administrative or procedural deficiency of a relatively minor nature, e.g., failure to maintain survey records properly, failure to wear a required personnel monitoring device.
- b. Class II - Major violations, e.g. negligence or misuse of ionizing radiation that could reasonably be expected to result in excessive radiation exposures to personnel, or unauthorized use of a x-ray machine.

2. Disciplinary Actions

The RSC will determine the appropriate action to be taken in the case of violations. The RSC is empowered to impose the disciplinary actions it deems necessary up to and including suspension of authorization to possess and use x-ray equipment.

The RSC is the final authority on radiation safety matters at the University.

J. Variances

An Responsible Investigator may apply to the Radiation Safety Committee for an exemption from the requirements of this safety manual.

1. The request must include the reason the variance is being sought, and alternative methods that will be used to ensure that the health and safety of personnel and the environment will not be compromised.
2. The application for a variance should be sent to the Radiation Safety Officer. The request will normally be acted upon at the next scheduled meeting of the RSC.
3. A special meeting may be called by the Chairman if it is believed necessary. The RI must be present at the meeting to discuss his/her request for the variance.
4. Variations from DHEC regulations specified in Title B require prior approval from the SC Department before implementation.

IV. RADIATION EXPOSURE PROTECTION

Although occupational radiation doses at University facilities are very low and current occupational limits provide a very low risk of injury, we recognize that it is sensible to avoid unnecessary exposure. It is therefore the policy of Clemson University to reduce occupational exposures to a level that is as low as reasonably achievable (ALARA). This will be accomplished through sound radiation protection planning and practices, and a commitment to policies that promote vigilance against unsafe practices.

A. Radiation Exposure Limits

State of South Carolina Occupational Dose Limits (RHB 3.4)

Applicable area of the body	Max dose per year
Total effective dose equivalent	5.0 rem (0.05 Sv)
Shallow dose to the extremities (i.e. hands and forearms, feet and ankles up to the elbow/knee)	50 rem (0.5 Sv)
Shallow dose equivalent (averaged over at least 10 cm ² of skin area)	50 rem (0.5 Sv)
Eye dose Equivalent	15 rem (0.15 Sv)

1. Minors

Occupational exposure to any individual under the age of 18 is limited to less than 10% of the limits specified above. For this reason, minors will not be employed as full-time radiation workers.

2. Pregnant women

- a. The U.S. Nuclear Regulatory Commission (NRC) and S.C. BRH require instruction of female radiation workers in the hazards associated with radiation exposure to the embryo/fetus, and in the precautions and safety measures to be followed to minimize radiation exposure.
- b. The limit for prenatal radiation exposure to fetus: 500 millirem (5 mSv) for the entire gestation period. The AU should avoid substantial variation above a uniform monthly exposure rate.
- c. The dose to the embryo/fetus is taken as the sum of the deep dose equivalent to the declared pregnant woman, and any internal dose from radionuclides in the embryo/fetus and the declared pregnant woman.

NOTE:

Prenatal radiation dose limits may not be applied unless pregnant worker submits in writing "Voluntary Declaration of Pregnancy". Each female who works with radiation producing equipment has the right and is encouraged to declare in writing to her employer (e.g. her immediate supervisor and the Radiation Safety Officer) her pregnancy as soon as she is aware of it, and the estimated date of conception per RHB 3.8.

3. Individual members of the public (i.e. non-radiation workers) are limited to 0.1 rem (1 mSv) in a year.

B. Personnel Monitoring

The Radiation Safety Officer will supervise the ordering, distribution, and collection of personnel monitoring devices. All personnel: likely to receive radiation exposure above 10% of the maximum occupational dose limit; entering high or very high radiation area; working with open beam x-ray sources; working with portable human or veterinary diagnostic equipment; or with industrial x-ray sources shall wear a NVLAP approved personnel monitoring device. Area monitoring is not used at Clemson in lieu of personnel monitoring for such applications.

1. The following limitations and precautions apply to personnel monitoring devices:
 - a. Whole-body personnel monitoring devices will be worn routinely in the

area of the breast pocket, collar, or waist. The position of the monitoring device should remain constant during a reporting period.

- b. Personnel monitoring devices designed to measure beta or low-energy X- or gamma-radiation shall not be worn inside of the pocket or obstructed in any manner.
- c. When not in use, personnel monitoring devices shall be stored in an area where they will not be exposed to ionizing radiation above background levels.
- d. Personnel monitoring devices shall not be deliberately exposed to radiation.
- e. The assigned personnel dosimetry shall be worn for all occupational exposure to ionizing radiation situations.
- f. If personnel monitor (dosimeter) is lost or damaged, the worker shall cease work immediately until a replacement badge is provided.
- g. Personnel monitoring devices are not to be worn during non-occupational exposures such as medical x-ray procedures.
- h. When a lead apron or a thyroid shield is worn, the monitoring device shall be worn on the outside of the protective device at the collar.
- i. Declared pregnant radiation workers shall wear a whole-body personnel monitoring device during the pregnancy. If the declared pregnant worker requests an additional badge for monitoring the fetal dose underneath lead aprons, then the additional badge must be provided.
- j. Pocket direct reading dosimeters shall be worn along with a personnel monitoring device when above normal levels of radiation are suspected, for the field industrial x-ray applications or as deemed necessary by the Radiation Safety Officer

2. Specific Requirements

a. Human diagnostic

- 1. All personnel exposed to scatter radiation during any fluoroscopic procedure shall wear personnel monitoring devices per RHB 3.12.4.1.3.1.
- 2. Certain fluoroscopy users may also be required to wear a ring badge if the workers extremities are required to be in or near the primary beam.
- 3. A whole-body dosimeter shall be worn when an employee is required

to hold a patient or film more than three times in a quarter.

4. Personnel monitoring is required for all operators of mobile and portable x-ray systems.

b. Analytical

1. Whole body badges are not required for users of enclosed (“cabinet”) analytical systems.
2. A finger or wrist dosimeter in addition to a whole-body badge is required for users of analytical open-beam configuration systems without an approved safety device.
3. In addition, a finger ring or wrist dosimeter is required for maintenance activities of analytical and research x-ray equipment that require presence of the primary beam when any local component in the system is adjusted, disassembled, or removed.

c. Veterinary

1. If patients are required to be held, then whole body badges are required.
2. In addition, if the holder’s hands are in or near the primary beam, then finger or wrist badges are also required.
3. Personnel monitoring is required for all operators of mobile and portable x-ray systems.

d. Industrial Radiography

1. Whole body dosimetry badges are required for all users of industrial x-ray equipment.
2. For shielded room radiography, personnel monitoring devices are also required for workers who make “set-ups’ and maintenance personnel.
3. For Field radiography applications, a pocket ionization chamber or pocket dosimeter must also be worn.

c. Miscellaneous

1. Personnel monitoring is generally not required when working with this equipment, unless requested by the RSO or the RSC.

C. Exposure Records

The Research Safety Office will maintain exposure records and will notify each individual worker concerning exposure at least annually if specifically requested by the worker.

The office will provide a radiation exposure report to the worker, or an employer at the request of the worker. The Radiation Safety Officer will also supply the worker with a written report if a dose over 10% of the occupational limits is received.

Records of exposure to the embryo/fetus shall be maintained with the records of dose to the declared pregnant woman. The declaration documentation shall also be kept on file but may be maintained separately from the dose records.

D. Pregnant Radiation Workers

1. Pregnant radiation workers *should*:
 - a. Notify the Radiation Safety Officer in writing as soon as her pregnancy is known (confidentiality will be maintained).
 - b. Keep her exposure to the very lowest practical level by reducing the amount of time spent in a radiation area, increasing the distance from a source of radiation, and by using shielding.
2. *Declared* pregnant radiation workers *shall*:
 - a. Be referred to the NRC Regulatory Guide 8.13 "Instructions Concerning Prenatal Radiation Exposure" for guidance on pregnant worker practices.
 - b. Wear a whole-body personnel monitoring device if working with penetrating X or gamma radiation sources.
 - c. Wear a second whole-body monitoring device under a lead apron at waist level, when a lead apron is required to be worn, and when requested by the worker.
 - d. Not hold patients, animals, or imaging device during an X-ray exposure, unless other alternatives are unavailable or impractical.
 - e. Be informed of her radiation exposure on a quarterly basis. A monthly badge evaluation period may be necessary if a non-uniform exposure rate is suspected.
 - f. When fetal dosimetry badges are provided, they must be evaluated on a monthly basis.

E. Diagnostic X-ray Examinations of Pregnant or Potentially Pregnant Women

A sign bearing the words or similar words "*Caution: If you are pregnant or think that you may be pregnant, please inform the technologist before X-rays are taken*" shall be conspicuously posted in the X-ray room.

Precautions and limitations concerning exposure of female patients:

1. Before ordering X-rays of the abdominal or pelvic area of a fertile woman (i.e. childbearing ages of 12 to 55 years), the examining physician should determine whether there is a need to order a pregnancy test.
2. When available, the results of the pregnancy test should be placed on the X-ray request form.
3. If the patient is pregnant and there is an urgent need for the X-ray examination, the physician should advise the patient of the benefits derived from the exam verses the risk to her unborn child.
4. The attending physician or radiologist must grant permission on the X-ray request before X-rays of the abdominal or pelvic area of a pregnant woman can be performed.
5. The X-ray technologist will check the requisition for the results of the pregnancy test before taking X-rays of the abdominal or pelvic area of a woman. If a pregnancy test has not been performed, the technologist will refer the patient back to the examining physician.
6. The physician's approval to X-ray pregnant women is not required when X-rays of areas other than the abdominal or pelvic area are ordered, provided the abdomen is shielded on all sides by 0.5 mm lead equivalency.
7. The abdominal and pelvic area of fertile women shall be covered with a lead apron of 0.5 mm lead equivalency when X-rays are ordered for areas other than the abdominal or pelvic region.

F. Posting

1. Each area or room where fixed diagnostic, analytical, or industrial X-ray equipment is located shall be conspicuously posted with:
 - a. A "Notice to Employees" (Form SC-RHA-20), where work associated with X-ray equipment is performed. (Refer to RHB 10.2)
 - b. Procedures to be followed if there is a radiological emergency to include names and phone numbers of persons to be contacted.

2. Each area or room where human or veterinary diagnostic X-ray equipment is used shall be posted with a "CAUTION: RADIATION AREA" sign (per RHB 4.10.4.2).
3. Each area of a shielded room or field industrial radiographic x-ray application shall be posted as a Radiation, High Radiation or Very High Radiation area as required by RHB 3.16, as appropriate.
4. For analytical and cabinet industrial x-ray equipment, a sign or signs bearing the radiation symbol and the words (or similar words)"CAUTION: X-RAY EQUIPMENT" shall be posted.
5. No area posting is typically required for miscellaneous X-ray producing equipment.
6. Any sign, notice, warning or label applied by the RSO to equipment or the facilities of a licensed user shall not be removed, defaced, or concealed.

G. Inspections/Audits

All licensed activities of the RI are subject to inspection by the Radiation Safety Officer. Inspections may be announced or unannounced and will be conducted at least every year.

A written report specifying any deficiencies will be sent to the RI. The RI will correct the deficiencies within the time specified in the report, unless a variance or an extension of time has been granted by the Radiation Safety Committee. An RI who disagrees with the deficiencies specified in the report may appeal in writing to the Chairman of the Radiation Safety Committee and request a hearing before the Committee.

H. New Experiments

New experiments, which significantly differ in size, kind, or scope from previous experiments shall be submitted to the Radiation Safety Committee in writing and approved before the experiment can be performed. The documentation for new experiments shall include the following information and be initially approved by the Radiation Safety Officer:

1. The purpose of the experiment
2. A description of the experiment
3. An analysis of the possible radiation hazards produced by the experiment.
4. Safety devices and procedures that will reduce hazards.

V. DIAGNOSTIC X-RAY EQUIPMENT

The following rules in addition to those specified above are to ensure the safe use of human-use and veterinary-use diagnostic X-ray equipment at Clemson University. These rules are intended to conform to the radiation safety standards of the Bureau of Radiological Health-Division of Electronic Products, Regulation 61-64, Title-B (X-rays).

A. Patient Protection

The following rules are to protect human patients from exposure to ionizing radiation, except that which is intended for diagnostic purposes.

1. The useful beam shall be collimated to cover only the area of clinical interest.
2. All exposures shall be specifically and individually ordered by a licensed medical doctor or a Doctor of Veterinary Medicine.
3. No person other than a licensed practitioner or a radiologic technologist possessing a current valid certificate front the South Carolina Radiation Quality Standards Association (SCRQSA) shall use equipment emitting ionizing radiation on humans for diagnostic purposes per RHB 1.2.1.
 - a. The SCRQSA certificate needs to be displayed or a notice posted indicating the certificates are available for review.
4. Humans shall not be exposed for training, demonstration, or other non-healing art purposes, unless part of a research protocol authorized by an Institutional Review Board conforming to 21 CFR 50 and 21 CFR 56 per RHB 1.2.13.
5. Exposure of individuals for healing arts screening is prohibited unless prior approval is obtained from the RSC and S.C. BRH per RHB 4.2.11.2.
6. Procedures shall be used to keep patient exposure at a minimum, while still obtaining the necessary diagnostic information.
 - a. The film or screen should be the fastest speed that can be used yet be consistent with the diagnostic objective.
 - b. The radiation exposure to the patient must be the minimum required to produce good diagnostic images.
7. For human-use portable units, other than fluoroscopy, the X-ray tube must be at least 30 cm (approximately 1 ft.) from the patient (SSD) per RHB 4.8.12.
8. The source-to-patient distance (SSD) must be at least 38 cm for image intensified stationary fluoroscopic units, and 30 cm on all mobile and portable units per RHB 4.9.1.

9. Gonadal shielding of at least 0.5 mm lead equivalency must be used on patients of reproductive age, if the gonads are in the primary beam and the shielding does not interfere with the diagnostic procedure.
10. Aluminum equivalent filtration shall be placed in the primary beam to reduce the intensity of soft X-rays to the patient.
11. For fluoroscopic imaging, periodic measurements of entrance exposure rates shall be performed for both typical and maximum values (annually) and posted locally for reference by the fluoroscopist per RHB 4.9.4.3.6.

B. Personnel Protection

The following rules are to protect operators, holders, and other people from exposure to ionizing radiation.

1. Stationary Diagnostic Units
 - a. The area or room where the equipment is being used shall be posted with a "Caution - Radiation Area" sign.
 - b. The operators of human-use units must stand behind the protective barrier at the controls during the exposure, or wear lead aprons for protection (e.g. during fluoroscopic exams).
 - c. For animal diagnostic units, if a shielded booth is not available or if the operator is required to assist in holding an animal while the X-ray exposure is made he/she shall meet all of the dress requirements of a holder, i.e., shielded gloves and apron of not less than 0.5 mm lead equivalency.
 - d. Only individuals required for the radiographic procedure are to be in the room during the exposure.
 - e. All individuals present in the X-ray room during an exposure must be protected from the direct scatter radiation by protective aprons or whole-body protective barriers of not less than 0.5 mm lead equivalency.
 - f. Access to the X-ray room must be secured during the exposure.
2. Portable and Mobile Units
 - a. For units used at multiple locations, operators shall be provided with an adequate protective barrier or protective apron, and a method of control that will permit the operator to stand at least 6 feet from the X-ray tube head and the nearest edge of the useful beam during exposures.

- b. The area or room where the equipment is being used shall be temporarily posted with a "Caution- Radiation Area" sign.
 - c. Mobile X-ray units shall not be hand-held; a tube stand, or other mechanical support shall be used.
3. Holders

When a patient, animal, or film cassette must be provided with auxiliary support during an X-ray exposure:

- a. Mechanical holding devices must be used whenever possible.
- b. No individual shall be used routinely as a holder, to the exclusion of others who could be used.
- c. Personnel used as holders must be protected by at least 0.5 mm of lead equivalency.
- d. Every effort should be made to position the holder so that no part of the body will be struck by the primary beam.
- e. Unless other alternatives are unavailable or impractical, pregnant workers should not be used as holders per RHB 4.2.12.6.

C. Radiation Limits

- 1. Leakage radiation from the diagnostic source assembly (tube head) shall not exceed 100 mrem/hr at 1 meter in any direction when the X-ray tube is operated at its maximum technique factors per RHB 4.3.3.
- 2. Radiation from Capacitor Energy Storage Equipment in Standby Status; with the exposure switch or timer not activated, the X-ray tube shall not exceed 2 mrem/hr at 5 cm with the beam limiting device fully open per RHB 4.3.4.
- 3. All walls, ceilings, doors, and floor areas shall be equivalent to or provided with sufficient protective shielding to ensure that radiation levels in unrestricted areas do not exceed 2 mrem (0.02 mSv) in any one hour per RHB 3.9.1.2.

D. Equipment Requirements

- 1. Stationary, Portable, and Mobile Diagnostic X-ray units shall meet the operating criteria described in DHEC Title B and be labeled as follows.

Control panels containing the main power switch shall contain the following

legible and accessible warning statements:

- a. The control panel containing the main power; "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
 - b. In addition, near any switch which energizes an X-ray tube; "CAUTION: This Equipment Produces Radiation When Energized".
2. Equipment performance tests are required to be performed initially and subsequently on an annual basis per RHB 4.2.16.
 - a. Self-calibrating bone densitometer system is exempt from this requirement.
 - b. Veterinary facilities are only required to perform these tests on a five-year cycle.
 - c. Appendix F to Part IV describes the detailed test requirements.
 3. Repeat Analysis is required for diagnostic exams in accordance with RHB 4.2.16.4.

E. Operator's Booth

The detailed design requirements for the operator's booth are delineated in Appendix C Part IV of Title B.

F. Records

The RI shall maintain or cause to be maintained the following records and information:

1. An X-ray log containing the patient's name (for human use), type of examination, exposure duration, the date, and person performing exam.
2. Maximum ratings and technique factors of the equipment.
3. Model and serial number of all components.
4. Tube rating charts and cooling curves.
5. Reports of Assembly for diagnostic units intended for human use for certifiable system or components. (FDA 2579).
6. Performance test records, records of calibrations, maintenance, and modifications.

7. Aluminum equivalent filtration of the useful beam, including any routine variations.
8. Operator Training and/or Certification records.

G. Surveys And Inspections

Radiation safety and equipment performance surveys shall be performed at least annually by a qualified expert; refer to RHB Part IV, Appendix F.

1. A survey for leakage radiation shall be performed following any maintenance, modification or relocation of an x-ray system.
2. Radiation surveys of areas adjacent to the X-ray producing facility and, in the booth, will be performed after installation of new equipment or the relocation of a unit.
3. The survey shall include a drawing of the areas adjacent to the X-ray room and an estimate of their occupancy.
4. The drawing shall include the type and thickness of the walls or their lead equivalency.
5. Reports of all surveys and inspections will be maintained in the Research Safety Office.
6. Lead Aprons will be inspected annually for cracks and holes that could compromise the radiation protection provided.

VI. ANALYTICAL X-RAY EQUIPMENT

The following rules govern the use of analytical X-ray equipment at Clemson University. These rules are intended to comply with the radiation safety standards of the S.C. BRH.

A. Open and Enclosed-Beam Analytical Systems

The following are requirements for open and enclosed-beam analytical X-ray systems

1. Posting
Any area or room containing analytical X-ray equipment shall be labeled with a conspicuous sign or signs bearing the radiation symbol and the words (or similar words): "CAUTION – X-RAY EQUIPMENT".

2. Labeling

All equipment shall be labeled with a sign or signs bearing the radiation symbol and the words:

- a. "CAUTION- HIGH-INTENSITY X-RAY BEAM" on the X-ray source housing.
- b. "CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" near any switch that energizes an X-ray tube.

3. Warning Lights

An easily visible warning light labeled "X-RAY-ON" shall be located near any switch that energizes an X-ray tube. It is to be illuminated when and only when the tube is energized. This light shall be of a fail-safe design.

4. Beam trap

A beam trap or other primary beam shield shall be provided to intercept the primary beam

B. Additional Requirements for Enclosed-Beam Systems

1. Chamber

The X-ray tube housing, sample detector, and analyzing crystal shall be enclosed in a chamber (or coupled chambers) that prevents entry of any part of the body.

2. Ports

Access ports to the sample chamber shall be of a fail-safe design that prevents X-ray generation or entry of the X-ray beam into the chamber when any port is opened.

C. Additional Requirements for Open-Beam Systems

1. Safety device

An interlocked safety device, which prevents entry of any part of the body into the primary beam or causes the beam to shut off, shall be provided on all open-beam systems.

2. Exemptions

Responsible Investigator may seek an exemption from this requirement by applying to the Radiation Safety Committee. The application shall include:

- a. An evaluation of the safety devices and why they cannot be used.
 - b. A description of the alternative method that will be used to minimize the possibility of an accidental overexposure.
 - c. Procedures that will be used to alert personnel to the absence of a safety device.
3. Warning devices

Open-beam systems shall be provided with the following warning devices:

- a. X-ray tube status (ON-OFF) located near the X-ray source housing, if the primary beam is controlled in this manner; and/or,
- b. Shutter status (OPEN-CLOSED) located near each port on the X-ray source housing, if the primary beam is controlled in this manner.
- c. These devices shall be readily visible and properly labeled as to their purpose. Warning devices shall have fail-safe characteristics.

4. Ports

Each port on the X-ray source housing shall be equipped with a shutter that cannot be opened unless a collimator or other device has been connected to the port

5. Shutters

Shutters at unused ports shall be secured in the closed position to prevent accidental opening.

D. Training

See Item III D above for details on the Clemson training plan.

E. Operating Procedures

Personnel operating analytical x-ray equipment shall be trained in operating procedures specific to that equipment, demonstrated by signature on the "Add Personnel to An X-Ray Project" form or "Authorized Users List" for the equipment.

1. Normal machine operating procedures shall be available to all analytical X-ray equipment users. Analytical X-ray equipment shall not be operated differently from that specified in the operating procedure manual unless written permission has been obtained from the Radiation Safety Committee.

2. A safety device shall not be bypassed unless approval has been obtained from the Radiation Safety Officer. This approval shall be for a specified time. When a safety device has been bypassed, a conspicuous sign shall be placed on the X-ray housing bearing the words (or similar words), "SAFETY DEVICE NOT WORKING."

F. Radiation Limits

1. Enclosed-beam systems – Each X-ray tube housing shall be constructed so that with all shutters closed the leakage radiation shall not exceed 2 milliRoentgen per hour at a distance of 5 cm from the protective chamber walls.
2. Open-beam systems - The exposure rate at the maximum rated current and voltage with all shutters closed shall not exceed 2 milliRoentgen per hour at a distance of 5 cm from the X-ray tube housing.
3. Analytical generator Cabinet -The exposure rate at a distance of 5 cm from the surface of the X-ray generator protective cabinet shall not exceed 0.25 milliRoentgen per hour.
4. During normal operations in restricted areas, scattered radiation levels in accessible areas in any one hour shall not exceed 25 mrem to the hands or 2 mrem to the whole body.
5. During alignment procedures, the dose equivalent to the hands in any 1 hour shall not exceed 25 mrem.
5. The local parts of an analytical X-ray system shall include sufficient shielding and be so located and arranged so that exposure rates in unrestricted areas do not exceed 2 mrem/hr, and in no case shall exceed 100 mrem/yr.

G. Surveys

1. Radiation surveys shall be performed and documented by radiation safety personnel:
 - a. On installation of the equipment and at least once every year thereafter to monitor leakage radiation.
 - b. On at least an annual basis to monitor area radiation levels. Area monitoring located on the equipment is not used in lieu of annual surveys.
2. Radiation surveys shall be performed:
 - a. Following any change in the initial arrangement, number or type of local

parts.

- b. Following any maintenance that requires the disassembly or removal of a local part
- c. During the performance of maintenance and alignment procedures that require the presence of a primary beam and the disassembly or removal of a local part.
- d. When a visual inspection of the local parts reveals an abnormality.

Note: Each area or room containing open-beam analytical X-ray equipment shall be equipped with an appropriate radiation survey instrument.

H. Repair and Alignment Procedures

The following safety precautions shall be taken to reduce risks during repair and alignment procedures:

1. The main switch, rather than the safety interlocks, shall be used to shut down the equipment
2. No X-ray tube shall be used without a suitable housing to restrict the radiation to a well-defined beam.
3. A sign stating "Interlocks Not Working" must be posted on the equipment when the interlocks have been defeated for alignment purposes.
4. Alignment procedures, other than those recommended by the manufacturer, must be approved by the Radiation Safety Officer.
5. Alignment procedures must be written and available to *all* users.
6. If the dose rate in an unrestricted area is exceeded during the repair or alignment procedure, temporary barriers must be set up and the area must be properly posted. The area shall be kept under surveillance until normal operations have been restored.
7. After re-assembly, the X-ray equipment shall be checked for leakage radiation.
8. The smallest practical voltage and current should be used during the alignment procedure.
9. Long-handled tools and extension devices should be used to reduce the risk of the hand entering the beam.

10. Protective glasses should be worn during alignment procedures.
11. Temporary shielding should be added to reduce scattered radiation levels to a minimum.
12. Alignment procedures recommended by the manufacturer should be used

VII. INDUSTRIAL RADIOGRAPHIC X-RAY SYSTEMS

A. Equipment and Control Requirements

1. A key-activated control shall be provided to ensure that X-rays will not be generated when the key is removed. (RHB 8.2)
2. Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals (RHB 8.3).
3. At least annually, the safety components associated with the machine shall be inspected and repaired as necessary.
4. A durable permanent label indicating the maximum operating kVp, the standard radiation symbol, and a notice "CAUTION-RADIATION; THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" shall be conspicuously posted.
6. A clearly legible and visible warning label located near or adjacent to each switch that controls the production of X-rays bearing the statement: "CAUTION-RADIATION; THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED.

B. Training

Refer to section III D above for details on the Clemson Training Plan. In addition, specific to industrial machines the RSO and all operators of the X-ray systems shall demonstrate ability and competence to:

1. Use the X-ray machine, safety features and devices, related handling tools if required, applicable emergency procedures, and survey instruments which will be employed in the use of the machine.
2. This demonstration of competence will be documented in writing.

C. Operating Procedures

Normal operating procedures shall available to all industrial X-ray equipment users.

X-ray systems shall not be operated differently from that specified in the procedure manual unless written permission has been obtained from the Radiation Safety Committee.

D. Posting

1. Area of use shall be posted in accordance with RHB 3.16 (e.g. Radiation Area and High Radiation Area postings as necessary).

E. Personnel Monitoring

2. All users of the industrial x-ray system who are required to use, perform set ups, or maintenance on this equipment shall wear a whole-body personnel monitoring device (RHB 8.12.2.1).
3. In addition, all personnel directly involved in field industrial x-ray applications shall wear an instant-read pocket dosimeter or pocket chamber capable of reading from 0 to 0.2 Roentgen. Pocket dosimeter or chamber readings must be recorded daily during the x-ray equipment use.

F. Surveys

Radiation surveys shall be performed:

1. When the equipment is initially installed. To determine effective radiation levels in the work area and in unrestricted areas.
2. For a shielded room application, a physical radiation survey shall be conducted to assure the X-ray machine is "off" prior to each entry into the room.
3. After maintenance or system relocation.

VIII. MISCELLANEOUS X-RAY EQUIPMENT

The rules in this section apply to the following miscellaneous X-ray producing equipment: electron microscopes, ESCA spectrometers, luminoscopes, and cold cathode gas discharge tubes. These provisions do not apply to television receivers or video display terminals. These requirements are intended to conform with title 21 of the Code of federal Regulations, Part 1020, and the Rules and Regulations for the use of Ionizing Radiation and with S C. BRH Title-B.

A. Electron Microscopes

Electron microscopes are exempt from Title B requirements (RHB 72.) except for

registration and that they shall be installed, shielded and operated in such a manner that no one shall be exposed beyond the limits defined in RHB 3.4.1 of these regulations.

B. Handheld Analytical Equipment

Hand-held analytical X-ray equipment are exempt from the requirements of Title B (RHB 7.3) except that the equipment is registered with DHEC; all operators shall have documented training; the equipment is interlocked to prevent operation unless in contact with or in close proximity to an item, and the equipment is operated in accordance with manufactures' instructions.

C. Posting

No area posting is required for miscellaneous X-ray equipment.

D. Warnings and Labels

1. A clearly legible and visible label bearing the statement: "CAUTION: THIS EQUIPMENT PRODUCES X-RAYS INCIDENTAL TO ITS PRIMARY FUNCTION- TO BE OPERATED BY QUALIFIED PERSONNEL ONLY" shall be posted on all miscellaneous X-ray producing equipment.
2. In addition to the above requirement, cold-cathode gas discharge tubes shall bear the following labels:
 - a. A label stating the maximum safe operating voltage.
 - b. A label that identifies the correct polarity of the terminals.

E. Training

Refer to section B above for hand-held equipment. Any additional training requirements are at the discretion of the RSO and the RI.

F. Operating Procedures

Operating procedures shall be available to all users.

G. Radiation Limits

1. Radiation emitted from electron microscopes, electron microprobes, ESCA spectrometer, and luminoscopes shall not exceed an exposure rate of 0.5 mrem/hr at 5 cm from the external surface. Radiation exposure from cold-cathode gas discharge tubes shall not exceed 10 mrem/hr at 30 cm from the

external surface averaged over 100 square centimeters.

2. All miscellaneous X-ray producing equipment shall contain sufficient shielding, and be located and operated so exposure rates in unrestricted areas do not exceed 2 mrem/hr.

H. Personnel Monitoring

Personnel monitoring is not required for users of miscellaneous X-ray producing equipment.

I. Potential X-ray Exposure from Magnetic-Effect Tubes

Magnetic-effect tubes demonstrate that cathode rays carry an electrical charge that can be deflected by a magnetic field. These tubes may produce X-rays incidental to their intended use and should be used with caution. Where there is a source of electrons, a target, sufficiently high voltage, and tube gas pressure within the proper range, X-ray production will occur. X-ray output from magnetic-effect tubes, however, is unpredictable and intermittent. Under identical operating conditions it may vary from one tube to another; one tube may be an X-ray producer while another may not. X-ray production may vary during a given period of operation or from day to day for the same tube. (Refer to RHB 2.2.1)

Since the educational benefits derived from these tubes are gained by visual observation of their operation, unshielded operation of these tubes is required; with the subsequent potential for student and operator exposure. To keep exposures to a minimum, requirements for the safe use of these tubes are as follows:

1. Magnetic-effect tubes must be used only for demonstrations conducted by the instructor.
2. The instructor should stand as far as practical from the tube during the demonstration.
3. Only the instructor shall operate a magnetic-effect tube.
4. Bystanders should stand at least 8 feet from an operating tube.
5. Tubes must always be operated with the correct polarity and the lowest practical current and voltage.
6. Operating time is to be kept to a minimum.

IX. EMERGENCY PROCEDURES

In a case of a natural disaster, fire, flood, or if the x-ray equipment malfunction or personnel overexposure is known or suspected:

1. Shut down the equipment, if doing so does not jeopardize personnel safety and does not increase radiation dose;
2. Notify personnel and evacuate all potentially dangerous areas;
3. If situation permits, lock and/or post the room or otherwise prevent inadvertent use of the malfunctioning x-ray equipment;
4. Notify Radiation Safety Officer:

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and your Responsible Investigator and/or other personnel in charge of the equipment and facility.

Some cases of personnel overexposure may require medical evaluation and treatment.

In order to properly respond to a critical situation, all x-ray operators should familiarize themselves with location and function of emergency shut-down switches, power breakers, emergency exits and other safety-related features in the x-ray equipment use areas. Please contact your Responsible Investigator and/or RSO for instructions.

X. TERMS AND DEFINITIONS

The following terms and definitions apply to this manual:

Absorbed Dose - is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest? The special units of absorbed dose are the rad or the gray.

Accessible Surface- the external surface of the enclosure or housing provided by the manufacturer.

Added filtration - any filtration which is in addition to the inherent filtration.

Adult - an individual 18 or more years of age

ALARA- (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

Aluminum equivalent- the thickness of type II 00 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

Analytical x-ray equipment - any machine utilizing x-rays for examination of the microscopic structure, or elemental or chemical composition of materials. This includes x-ray equipment used for x-ray diffraction, fluorescence analysis, or spectroscopy.

Analytical X-ray System - a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometry, detectors, and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

Annually- one year from the date of the last event, plus or minus 30 days. Synonymous with *every 12 months, once a year or every year.*

Applicator - a structure which determines the extent of the treatment field at a given distance from the virtual source.

Assembler - any person engaged in the business of assembling, reassembling, replacing, installing, or reinstalling one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system, his employee, or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Automatic exposure control- a device which automatically controls one or more technique factors in order to obtain at a preselected location (s) a required quantity of radiation (See also "Photo timer").

Background radiation - radiation from cosmic sources, naturally occurring radioactive materials, includes radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation regulated by the agency.

Beam Axis - a line from the source through the centers of the x-ray fields.

Beam-limiting device - a device which provides a means to restrict the dimensions of the x-ray field.

Beam monitoring system - a system designed to detect and measure the radiation present in the useful beam.

BRH- S.C. Department of Environmental Health and Control, Bureau of Radiological Health

Cabinet x-ray system - an x-ray system with the x-ray tube installed in an enclosure which is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during x-ray production. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

Calibration -

- a) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
- b) the strength of a source of radiation relative to a standard.

Central axis of the Beam - a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

Change of Status - transfer of ownership, change of address, or disposal of any X-ray system.

Collimator - a device or mechanism by which the x-ray beam is restricted in size.

Controlled area - an area outside of a restricted area but inside the site boundary, access to which can be limited by the registrant for any reason.

Coulomb per Kilogram - (C/kg) is the S.I. unit of exposure. One *Roentgen* is equal to 2.58×10^{-4} Coulomb per kilogram. Submultiples of this unit are the millicoulomb per kilogram (mC/kg) and the microcoulomb per kilogram ($\mu\text{C/kg}$).

Control Panel- that part of the x-ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.

Cooling Curve - the graphical relationship between heat units stored and cooling time.

Dead-man Switch - a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Declared pregnant woman - a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

Deep-dose equivalent (H) - which applies to external whole-body exposure, is the equivalent dose at a tissue depth of 1 cm (1000 mg/cm²).

Department- the South Carolina Department of Health and Environmental Control.

Diagnostic source assembly - the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray imaging system - an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

Diffacted beam - A beam composed of mutually reinforcing scattered x-rays.

Direct scattered radiation - that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered Radiation").

Dose - is a generic term which absorbed dose, dose equivalent, effective dose equivalent, or total effective dose equivalent as defined in these regulations.

Dose Equivalent - (HT) the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

Dose monitoring system - a system of devices for the detection, measurement, and display of quantities of radiation.

Dosimetry processor - an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

Effective dose equivalent- (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiate ($H_E = \sum W_T x H_T$)

Embryo/fetus- the developing human organism from conception until the time of birth.

Enclosed beam configuration - An analytical x-ray system in which all possible x-ray paths are fully enclosed

Entrance or access point- any location through which an individual could gain access to radiation areas or to a source of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Entrance exposure rate- the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

Exposure - is the amount of ionization per unit mass of air due to x-rays. It is the quotient of dQ by

dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The special units of exposure are the Roentgen (R), or the coulomb per kilogram.

Exposure rate- the exposure per unit of time, such as R/min and mR/h.

External dose - that portion of the dose equivalent received from radiation sources outside the body.

Extremities - hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

Eye dose equivalent- applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).

Facility - the location at which one or more x-ray machines are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

Fail-safe characteristics - a design feature which causes beam port shutters to close, or otherwise prevent emergence of the primary beam, upon the failure of a safety or warning device.

Field Radiography- the examination of the macroscopic structure of materials by nondestructive methods of utilizing sources of radiation in a non-fixed or non-permanent location.

Field size - the dimensions along the major axes of an area in a plane perpendicular to the central axis of the useful beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent iso dose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

Filter - material placed in the useful beam to preferentially absorb selected radiation.

Fluoroscopic imaging assembly - a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Focal spot (actual) - the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

Gantry - that part of the system supporting and allowing possible movements of the radiation head.

Gauge - a mechanism designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantities chemical composition. It may include components such as radiation shields and useful beam controls incorporated into the gauge in order to meet the requirements or specifications of this regulation.

Gonadal shield - a protective barrier for the testes or ovaries.

Gray - is the unit of absorbed dose. It is equal to 1 joule per kilogram. One *rad* is equal to 1×10^{-2} Gray. Submultiples included in this document are the milligray (mGy) and the microgray (μ Gy).

Half-value layer (HVL) - the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Healing arts - any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

Healing arts screening - the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Health Professions - the professional persons authorized by the laws of the State to use x-rays in the diagnosis or treatment of human or animal disease.

Heat unit- a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

High radiation area - any area, accessible to individuals, in which there exists radiation at such levels that the whole body could receive in any one hour, a dose in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Image intensifier - a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor - any device, such as radiographic film, which transforms incident photons either into a visible image or into another form which can be made into a visible image by further transformations.

Individual - any human being.

Individual monitoring means:

- b) the assessment of dose equivalent by the use of devices designed to be worn by an individual; or
- c) the assessment of dose equivalent by the use of survey data.

Individual Monitoring Devices - or "individual monitoring equipment" devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent, optically-stimulated or direct ion storage dosimeters (TLD, OSL, DIS), pocket ionization chambers, pocket dosimeters or similar.

Industrial x-ray equipment - means any machine utilizing x-rays for examination of the macroscopic structure of materials. This includes x-ray equipment used for cabinet radiography, shielded room radiography, field radiography, and gauges.

Inherent filtration - the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Inoperative - any x-ray machine or device that is temporarily or permanently rendered incapable of producing x-rays.

Inspection - an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Department.

Interlock - a device for precluding access to a high radiation area by automatically reducing the exposure rate upon entry by personnel.

Irradiation - the exposure of matter to ionizing radiation.

Leakage radiation (non-diagnostic) - all radiation from within the tube housing complex except the useful beam (s).

Leakage radiation (diagnostic) - radiation emanating from the diagnostic source assembly except for the useful beam; and radiation produced when the exposure switch or timer is not activated.

Limits - or "Dose Limits" the permissible upper bounds of radiation doses.

mA- milliamperere.

mA-s - milliamperere second.

Member of the public - an individual in a controlled or unrestricted area; however, an individual is not a member of the public during any period in which the individual receives an occupational dose.

Minor- an individual less than 18 years of age.

Miscellaneous x-ray equipment - Equipment that produces X-rays secondary to its primary function.

Mobile x-ray equipment - (See "X-ray equipment").

Monitoring, Radiation Monitoring or Radiation Protection Monitoring - the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

Non-stochastic effect - health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of non-stochastic effect (also called a deterministic effect).

NVLAP – National Voluntary Laboratory Accreditation Program.

Occupational dose - the dose received by an individual in a restricted area or in the course of employment in which the individuals assigned duties involve exposure to radiation, whether in the possession of the registrant or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

Open beam configuration - an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

Operating procedures- detailed written instructions including, but not limited to, use of the x-ray equipment, use of shielding and barriers, quality assurance methods, occasions and methods for conducting area surveys, use of personnel monitoring devices, and alignment, calibration, or preventative maintenance of x-ray equipment. Routine and emergency radiation safety considerations are part of these procedures. Emergency procedures shall include methods of notifying proper persons in the event of an emergency, to include the listing of names, addresses and phone numbers.

Operative - any x-ray machine or device that is capable of producing x-rays.

Patient - an individual or animal subjected to healing arts examination, diagnosis, or treatment.

Peak tube potential- the maximum value of the potential difference across the x-ray tube during an exposure.

Person - any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, other than entities over which a federal government agency has exclusive jurisdiction.

Personnel monitoring equipment- same as *Individual Monitoring Devices* (see)

Planned special exposure - an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

Portable x-ray equipment- (See "X-ray equipment").

Primary beam - ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube located in the radiation source housing.

Primary protective barrier - (See "Protective barrier").

Protective apron - an apron made of radiation absorbing material used to reduce radiation exposure.

Protective barrier - a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

- a) "Primary protective barrier" - the material, excluding filters, placed in the useful beam, to protect anyone other than the patient from radiation exposure.

- b) "Secondary protective barrier" - a barrier sufficient to attenuate the stray radiation to the required degree.

Protective glove - a glove made of radiation absorbing materials used to reduce radiation exposure.

Public dose- the dose received by a member of the public from exposure to radiation by a registrant, or to another source of radiation either within a registrant's-controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

Qualified expert - an individual who has demonstrated to the satisfaction of the Department that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

Quality Assurance - is a program designed to produce high quality radiographs at minimal cost and minimal patient exposure.

Quality Control - is the routine measurement of image quality and the performance of the diagnostic x-ray imaging system, from x-ray beam output to the viewing of radiographs, and the continual adjustment of that performance to an optimal and consistent level.

Quality Factor (Q) – the modifying factor that is used to derive dose equivalent from absorbed dose. Quality factors are provided in the definition of rem.

rad - is a unit of the absorbed dose of any radiation to body tissue in terms of the energy absorbed per unit mass of the tissue. One rad is the absorbed dose corresponding to 100 ergs per 1 gram of the tissue. One millirad (1 mrad) = 0.001 rad.

Radiation – in this document: *ionizing* radiation, including gamma rays, x-rays, alpha particles, beta particles, high speed electrons, neutrons, high speed protons, and other atomic particles, but not sound or radio waves, or visible, infrared, or ultraviolet light.

Radiation area - any area accessible to individuals in which there exists radiation at such levels that the whole body could receive in any one hour, a dose in excess of 5 millirem (.05 mSv) at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Radiation detector - a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation dose – see *Dose*.

Radiation Installation - is any location or facility where radiation machines are used.

Radiation Safety Officer - one who has the knowledge and responsibility to apply appropriate radiation protection regulations and is approved in writing by the registrant.

Radiograph - an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiographer - any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises field radiography operations, and who is responsible to the registrant for assuring compliance with the requirements of these regulations.

Radiographer's Assistant- any individual who, under the personal supervision of a radiographer uses sources of radiation, related handling tools, or survey instruments in field radiography.

Radiographic imaging system - any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

Rating - the operating limits as specified by the component manufacturer.

Recording - producing a permanent form of an image resulting from x-ray photons.

Registrant- any person who is registered with the S.C. Bureau of Radiological Health and/or is legally obligated to register with the Department pursuant to S.C. DHEC Title-B, R61-64.

rem - is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rads multiplied by the radiation weighting factor (see table below). One rem equals 0.01 sievert. The radiation weighting factors for converting absorbed dose to dose equivalent are as follows:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*
X-, gamma-, or beta-radiation	1	1
Alpha particles, multiple charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

**Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.*

Response time- the time required for an instrument system to reach 90 percent of its final reading when the radiation sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady step midscale reading.

Restricted area - (controlled area) any area, access to which is controlled by the registrant for purposes of protection of individuals from exposure to radiation. A "restricted area" shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

Roentgen (R) - is the special unit of exposure. One Roentgen equals 2.58×10^{-4} Coulombs/kilogram

of air. (See exposure.)

Safety device - a device 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.

Scattered radiation - radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

Shallow-dose equivalent (H_s)- applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.07 centimeter (7mg/cm²) averaged over an area of square centimeter.

Shielded room radiography - industrial radiography using radiation machines, which is conducted in an enclosed room, the interior of which is not occupied during radiographic operations, which is so shielded that every location on the exterior meets conditions for an unrestricted area and the only access to which is through openings which are interlocked so that the radiation machine will not operate unless all openings are securely closed.

Shutter- a device attached to the tube housing assembly which can totally intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SID - (see Source to Image Receptor Distance).

Sievert (Sv) - the unit of dose equivalent. The dose equivalent in Sieverts is equal to the absorbed dose in grays multiplied by the quality factor. 1 Sv = 100 rem. Submultiples included in this document are the millisievert (mSv) and the microsievert (μSv).

Site boundary - that line beyond which the land or property is not owned, leased, or otherwise controlled by the registrant.

Source- the focal spot of the x-ray tube.

Source to image receptor distance (SID)- the distance from the source to the center of the input surface of the image receptor.

Source of radiation - any device or equipment emitting or capable of producing x-ray radiation.

Spot check - a procedure which is performed to assure that a previous calibration continues to be valid.

SSD - the distance between the source and the skin entrance plane of the patient.

Stationary x-ray equipment - (See "X-ray equipment").

Stochastic effects - health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects (also called a probabilistic

effect).

Stray radiation - the sum of leakage and scattered radiation.

Supervision - the delegating of the task of applying radiation pursuant to this part by persons, not licensed in the healing arts or veterinary medicine, who provide services under the practitioner's control. The licensed practitioner assumes full responsibility for these tasks and must assure that the tasks will be administered correctly.

Survey - an evaluation of the use, of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to tests, physical examination, and measurements of levels of radiation.

Target - that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

Termination of irradiation - the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Test - a method for determining the characteristics or condition of sources of radiation or components thereof

Total Effective Dose Equivalent (TEDE) - the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Traceable to a national standard - that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

Tube - an x-ray tube, unless otherwise specified.

Tube housing-apparatus complex- those parts of an analytical x-ray device in which x-rays are produced and utilized for a useful purpose. This includes the x-ray tube housing, shutter or port assemblies, collimators, cameras, goniometers, and electronic radiation detectors.

Tube housing assembly - the tube housing with tube installed. It includes high voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Unrestricted area (uncontrolled area)- any area to which access is not controlled by the registrant for purposes of protection of individuals from exposure to radiation, and any area used for residential quarters.

Vendor - a person who is engaged in the business of selling, leasing, installing, or offering to sell, lease, or install x-ray machines or machine components or is engaged in the business of furnishing or offering to furnish x-ray machine services, which includes, but is not limited to, reinstalling, reassembling, leasing, servicing, maintenance, calibration, and repair of x-ray equipment, facility and shielding design, radiation surveys, instrument calibration, personnel dosimetry, processor cleaning

and maintenance, and health physics consultations.

Very high radiation area- an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rem and sieverts).

Virtual source - a point from which radiation appears to originate.

Whole body - for purposes of external exposure, head, trunk (including male gonads) arms above the elbow, or legs above the knee.

Worker - an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant but does not include the licensee or registrant.

X-ray equipment - an x-ray system, subsystem, or component thereof.

- a) **Mobile** - X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
- b) **Portable** X-ray equipment designed to be hand carried.
- c) **Stationary** - X-ray equipment designed which is installed in a fixed location.
- d) **Transportable** - X-ray equipment installed in a vehicle or trailer.

X-ray system - an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high voltage generator, an x-ray control, a tube housing assembly, a beam limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray subsystem- any combination of two or more components of an x-ray system.

X-ray tube - any electron tube which is designed to be used primarily for the production of x-rays.