

PART VIII
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL USES OF RADIOGRAPHIC
SOURCES

RHB 8.1 Scope. The regulations in this part establish radiation safety requirements for industrial uses of X-ray machines. The requirements of this part are in addition to and not in substitution for the other requirements of these regulations.

RHB 8.2 Locking of X-ray Machines. Each x-ray machine shall be provided with a locking device designed to prevent unauthorized or accidental production of radiation, and shall be kept locked at all times except when under the direct surveillance of a radiographer, radiographer's assistant, a radiation safety officer, or an operator, as applicable.

RHB 8.3 Permanent Storage Precautions. Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

RHB 8.4 Radiation Survey Instruments. All provisions of RHB 1.4.4 apply.

RHB 8.5 Labeling. There shall be a durable permanent label indicating the maximum operating current, kVp, the standard radiation symbol, and a caution notice which shall read as follows or similarly: "CAUTION-RADIATION; THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED." In addition, a label which reads, "CAUTION-RADIATION; THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" shall be located near or adjacent to each switch that controls the production of x-rays.

RHB 8.6 Registration and Posting Requirements.

8.6.1 Registration. Each facility shall meet the requirements of RHB 2.3 and 2.4 of these regulations.

8.6.2 Posting. Areas in which radiography is being performed shall be conspicuously posted as required by RHB 3.15 and 3.16.

RHB 8.7 Minimum Personnel Radiation Safety Requirements For Radiation Safety Officers and Operators.

8.7.1 No registrant shall permit any individual to act as a radiation safety officer until such person:

8.7.1.1 Has been instructed in the subjects outlined in RHB 8.11 of this Part;

8.7.1.2 Has received copies of and instruction in: the regulations contained in this Part, Part IX, the applicable sections of Part III, and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

8.7.1.3 Has demonstrated competence to use the X-ray machine, related handling tools, and survey instruments which will be employed in the assignment.

8.7.2 No registrant shall permit any individual to act as an operator or radiographer until such person:

8.7.2.1 Has been instructed in the subjects outlined in RHB 8.11 of this Part;

8.7.2.2 Has received copies of and instruction in: Part IX, of these regulations, and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

8.7.2.3 Has demonstrated competence to use, under the personal supervision of the Radiation Safety Officer, the X-ray machine, related handling tools, and survey instruments which will be employed in his assignment.

8.7.2.4 The registrant shall have all training procedures and testing documented in writing, and available for the Department's review.

RHB 8.8 Operating and Emergency Procedures. The registrant shall have written operating and emergency procedures. These procedures shall include instruction in:

8.8.1 The handling and use of X-ray machines to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in Part III of these regulations;

8.8.2 Methods and occasions for conducting radiation surveys;

8.8.3 Methods for controlling access to radiographic areas;

8.8.4 Methods for locking and securing X-ray machines, when not in use or in storage;

8.8.5 Personnel monitoring and the use of personnel monitoring equipment; including steps that must be taken by radiography personnel in the event a pocket dosimeter is found to be off-scale;

8.8.6 The proper handling of exposed personnel;

8.8.7 Minimizing exposure of individuals in the event of an accident;

8.8.8 The procedure for notifying proper persons in the event of an accident. This shall include the listing of names, addresses, and telephone numbers; and

8.8.9 Maintenance of records.

RHB 8.9 Inspection and Maintenance. Each registrant shall ensure that checks for obvious defects in radiation machines are made at the beginning of each day of equipment use.

8.9.1 At least annually, each registrant shall inspect and repair components associated with radiation safety of the machines. Records of inspection and maintenance shall be maintained for the Department's inspection.

8.9.2 If any inspection conducted by the registrant reveals damage to the components affecting radiation safety, the radiation machine shall not be used and shall be labeled as defective until repaired.

RHB 8.10 Personnel Monitoring. No registrant shall permit any individual to act as a Radiation Safety Officer or as an operator unless, at all times during radiographic operations, each such person wears a film badge, thermoluminescent dosimeter (TLD), or other dosimeters approved by the Department. All provisions of Part III of these Regulations apply.

RHB 8.11 Minimum Subjects To Be Covered In Training Radiation Safety Officers and Radiographers.

8.11.1 Fundamentals of Radiation Safety:

- 8.11.1.1 Characteristics of ionizing radiation;
- 8.11.1.2 Units of radiation dose (rem or Sievert);
- 8.11.1.3 Hazards of exposure to radiation;
- 8.11.1.4 Levels of radiation from sources of radiation;
- 8.11.1.5 Methods of controlling radiation dose;
 - 8.11.1.5.1 Working time;
 - 8.11.1.5.2 Working distances; and
 - 8.11.1.5.3 Shielding.

8.11.2 Radiation Detection Instrumentation to be Used:

- 8.11.2.1 Use of radiation survey instruments;
 - 8.11.2.1.1 Operation;
 - 8.11.2.1.2 Calibration; and
 - 8.11.2.1.3 Limitations.
- 8.11.2.2 Survey techniques; and
- 8.11.2.3 Use of personnel monitoring equipment:
 - 8.11.2.3.1 Film badges or other approved dosimeters; and
 - 8.11.2.3.2 Pocket dosimeters or pocket chambers, if applicable.

8.11.3 Operation and control of X-ray machines.

8.11.4 The requirements of pertinent state regulations.

8.11.5 The registrant's written operating and emergency procedures.

RHB 8.12 Special Requirements for Certain Industrial Radiographic Techniques.

8.12.1 Cabinet Radiography.

8.12.1.1 Upon installation, a cabinet radiography unit shall not be operated until a physical radiation survey of the unit and areas adjacent to the unit has been performed. A radiation survey of the unit and area adjacent to the unit shall also be performed at least annually, and after any repair modification, or maintenance on the system.

8.12.1.2 Tests for proper operation of high radiation area control devices, alarm systems or interlocks must be conducted, at least annually, recorded, and maintained in accordance with RHB 8.9.

8.12.1.3 Radiation emitted from the cabinet x-ray unit shall not exceed 0.5 milliRoentgen per hour at any point five centimeters from the external surface.

8.12.1.4 A cabinet x-ray system shall 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.

8.12.1.5 The insertion of any part of the human body through any port into the primary beam or through any aperture shall not be possible.

8.12.1.6 Interlocks.

8.12.1.6.1 Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

8.12.1.6.2 Each access panel shall have at least one safety interlock.

8.12.1.6.3 Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with RHB 8.12.1.8.2 shall be necessary for resumption of x-ray generation.

8.12.1.6.4 Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

8.12.1.7 A ground fault, or an accidental electrical grounding of an electrical conductor, shall not result in the generation of x-rays.

8.12.1.8 Controls and indicators for all cabinet x-ray systems. For all systems to which this section is applicable, there shall be provided:

8.12.1.8.1 A key actuated control to insure that x-ray generation is not possible with the key removed.

8.12.1.8.2 A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.

8.12.1.8.3 Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this regulation may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled "X-RAY ON."

8.12.1.8.4 Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled "X-RAY ON."

8.12.1.9 Additional controls and indicators for cabinet x-ray systems designed to admit humans. For cabinet x-ray systems designed to admit humans, there shall also be provided:

8.12.1.9.1 A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

8.12.1.9.2 No means by which x-ray generation can be initiated from within the cabinet.

8.12.1.9.3 Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause the failure of both the audible and visible warning signals.

8.12.1.9.4 A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicator shall be activated for one-half second.

8.12.1.9.5 Signs indicating the meaning of the warning signals required by RHB 8.12.1.9.3 and 8.12.1.9.4 and containing instructions for the use of the control required by RHB 8.12.1.9.1. These signs shall be legible, accessible to view, and illuminated when the main power control is in the "on" position.

8.12.1.10 Warning labels. There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED." There shall also be a permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement: "CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED--X-RAY HAZARD."

8.12.1.11 Additional requirements for x-ray baggage inspection systems. X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means to ensure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-rays.

8.12.1.11.1 During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

8.12.1.11.2 During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

8.12.1.12 Exemptions. To qualify for this exemption, registrant must provide documentation regarding the certified and/or certifiable status of each device.

8.12.1.12.1 Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this Part except for the following:

8.12.1.12.1.1 For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

8.12.1.12.1.1.1 No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with this requirement shall be maintained for Departmental review.

8.12.1.12.1.1.2 Tests for proper operation of interlocks must be conducted and documented at intervals not to exceed six months. Records of these tests shall be maintained in accordance with RHB 1.10.2.4.

8.12.1.12.1.1.3 The registrant shall perform an evaluation of the radiation dose limits to determine compliance with Part III of this Regulation and 21 CFR 1020.40, Cabinet X-ray Systems, at intervals not exceed one year. Records of these evaluations shall be maintained in accordance with RHB 1.10.2.4.

8.12.1.12.1.2 Cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40, Cabinet X-ray Systems, and no modification shall be made to the system unless prior Departmental approval has been granted.

8.12.2 Shielded Room Radiography.

8.12.2.1 Each registrant shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by, every individual who operates, makes "set-ups," or performs maintenance on a radiation machine for shielded room radiography.

8.12.2.2 A physical radiation survey shall be conducted to determine that the X-ray machine is "off" prior to each entry into the shielded room. Such surveys shall be made with a radiation measuring instrument capable of measuring radiation of the energies and at the dose rates to be encountered, which is in good working order, and which has been properly calibrated within the preceding twelve months or following the last instrument servicing, whichever is later.

8.12.2.3 Each installation shall be provided with such primary barriers and secondary barriers as are necessary to assure compliance with RHB 3.4, and RHB 3.9.

8.12.2.4 Shielding. All provisions of RHB 4.4 apply.

8.12.3 Field Radiography.

8.12.3.1 Utilization Logs. Each registrant shall maintain current logs, which shall be kept available for inspection by the Department, showing for each X-ray machine the following information:

8.12.3.2 A description (or make and model number) of each X-ray machine;

8.12.3.3 The identity of the radiographer to whom assigned;

8.12.3.4 The plant or site where used and dates used; and

8.12.3.5 The dates each radiation machine is energized or used and number of exposures made.

8.12.3.6 Security. During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, except a) where the high radiation area is equipped with a control device which turns the X-ray machine off upon unauthorized entry into the high radiation area or an alarm system which visibly or

audibly signals the presence of a high radiation area, or b) where the high radiation area is locked to protect against unauthorized or accidental entry.

8.12.3.7 Radiation Surveys and Survey Records. No radiographic operation shall be conducted unless calibrated, operable radiation survey instrumentation is available and used at each site where radiographic exposures are made, as described in RHB 8.4.

8.12.3.7.1 A physical radiation survey shall be conducted to determine that the radiation machine is "off" prior to each entry into the radiographic exposure area.

8.12.3.7.2 Survey results and records of boundary locations shall be maintained and kept available for inspection by the Department.

8.12.3.8 Personnel Monitoring. In addition to the requirements of 8.10, each radiographer or radiographer's assistant shall wear a pocket dosimeter or pocket chamber along with a film badge during all radiographic operations. Pocket chambers or dosimeters shall be:

8.12.3.8.1 Capable of measuring doses from zero to at least 200 milliRoentgen;

8.12.3.8.2 Read and doses recorded daily; and

8.12.3.8.3 Recharged daily or at the start of each shift;

8.12.3.8.4 Reports received from the dosimeter processor and records of the pocket dosimeter and pocket chamber readings shall be maintained for inspection by the Department;

8.12.3.8.5 Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year. Acceptable dosimeters shall read within plus or minus 30% of the true exposure calibration shall be maintained by the registrant for the Department's inspection.

8.12.4 Gauging Devices Radiography and Other Industrial Applications. The source shall be such that no radiation is emitted except by application of an electric current through an x-ray tube. Provisions shall be made to limit both the current through the tube and the voltage across the tube, so that radiation levels do not exceed the device classification under use conditions or through circuit component failures. In the event of fire or abnormal elevated temperatures, provisions shall be made to insure the high voltage is automatically disabled before loss of any integral shielding. This provision exempts x-ray tube sources from accident classification conditions.

8.12.4.1 A useful beam control system shall be provided in gauges whenever the useful beam is accessible and the radiation levels exceed 100 mrem/h (1 mSv/h) at 5 cm from any accessible surface or 5 mrem/h (.05 mSv/h) at 30 cm. The useful beam controls may include (but not be limited to) a moving shutter, a moving source, or a high voltage power supply.

8.12.4.2 A yellow or amber warning light with the radiation "High Voltage On" shall be located on the control panel and on or adjacent to the source housing and shall light only when power is applied to the x-ray tube high voltage circuit.

8.12.4.3 Radiation levels. The local components of an industrial x-ray system shall be located and arranged and shall include sufficient shielding or have access control such that no radiation in any area surrounding the local component group could result in a dose to an individual present therein in excess of the dose limits given in RHB 3.3.2. These levels shall be met at any specified tube rating.