

## PART H

### RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL AND OTHER INDUSTRIAL RADIATION MACHINES.

1. **Purpose and Scope.** This part provides special requirements for the use of analytical and other industrial radiation machines not otherwise covered by the regulations. The requirements of this part are in addition to, and not in substitution for, applicable requirements in other parts of these regulations. This includes, but is not limited to, the following sections of Part F: F.1, F.2, F.3.M, F.4, and F.7.

2. **Definitions.** As used in this part, the following definitions apply:

**Analytical radiation machine** includes, but is not limited to, x-ray diffraction, fluorescence analysis, spectroscopy, or particle size analysis.

**Cabinet x-ray system** is an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system. The cabinet x-ray system is intended to:

- (a) Contain at least that portion of a material being irradiated;
- (b) Provide radiation attenuation; and
- (c) Exclude personnel from its interior during generation of radiation.

**Certifiable cabinet x-ray system** is an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR Parts 1010 through 1020.

**Certified cabinet x-ray system** is an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled on or after April 10, 1975, according to the provisions of 21 CFR 1020.40.

**Fail-safe characteristics** mean 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.

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

**Local components** mean part of an x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

**Normal operating procedures** mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include, sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures, which are related to radiation safety.

**Open-beam configuration** means a radiation machine in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

**Other Industrial Radiation Machines** includes, but is not limited to, x-ray equipment (including cabinet x-ray equipment) used for cathodoluminescence, ion implantation, gauging, or electron beam welding.

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

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**Safety Device** means a device that prevents the entry of any portion of an individual's body into the primary x-ray beam path or that causes the beam to be shut off upon entry into its path.

**X-Ray system** means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

### 3. Equipment Requirements.

A. 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 shall be provided on all open-beam configurations. A registrant or licensee may apply to the Agency for an exemption from the requirement of a safety device. Such application shall include:

- (1) a description of the various safety devices that have been evaluated;
- (2) the reason each of these devices cannot be used; and
- (3) a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

B. Warning Devices.

- (1) Open-beam configurations shall be provided with a visible indication of:
  - (a) x-ray tube "ON-OFF" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or
  - (b) shutter "OPEN-CLOSED" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.
- (2) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after effective date of these regulations, warning devices shall have fail-safe characteristics.
- (3) The x-ray control shall provide visual indication whenever x-rays are produced.

C. Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner, which will prevent casual opening.

D. Labeling. All radiation machines shall be labeled in a conspicuous manner to caution individuals that radiation is produced when it is energized with a sign or signs bearing the radiation symbol and the words:

- (1) "**CAUTION - HIGH INTENSITY X-RAY BEAM,**" or words having a similar intent, on the x-ray source housing; and
- (2) "**CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED,**" or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or
- (3) "**CAUTION - RADIOACTIVE MATERIAL,**" or words having similar intent, on the source housing in accordance with Part D.1901 of these regulations if the radiation source is a radionuclide.

E. Shutters. On open-beam configurations installed each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

F. Warning Lights.

- (1) An easily visible warning light labeled with the words "**X-RAY ON,**" or words having a similar intent, shall be located:
  - (a) near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or

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- (b) in the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.
- (2) On equipment installed after effective date of these regulations, warning lights shall have fail-safe characteristics.
- G. Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:
  - (1) Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.
  - (2) Each radioactive source housing or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 centimeters from its surface is not capable of producing a dose in excess of 25  $\mu$ Sv (2.5 mrem) in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.
- H. Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet, which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 2.5  $\mu$ Sv (0.25 mrem) in one hour.
- 4. Hand Held XRF Analyzers (Non Medical).** All persons/companies purchasing hand held analyzers that emit electronically produced x-rays (XRF) shall be held to the following requirements.
  - A. Safety Plan, analytical procedures, training manual and registration paperwork shall be submitted and approved by the X-Ray Section of the State of Maine's Department of Health and Human Services Radiation Control Program prior to use of the analyzer.
  - B. When not in use, the unit shall be stored in a secured area, so that it is not accessible to anyone without authorization to use it.
  - C. Personnel using the analyzer shall wear appropriate radiation dosimetry to assess exposure to both "whole body" and "extremities". Personnel exposure will be reported to the X-Ray Section of the State of Maine's Department of Health and Human Services Radiation Control Program on a quarterly basis for a minimum of 1 year. (Dosimetry requirement may be relaxed after this initial monitoring period, depending upon exposure values).
  - D. Analyzer shall not be used with "Dead Man Trigger" deactivated prior to specific approval (for this mode of operation) by the X-Ray Section of the State of Maine's Department of Health and Human Services Radiation Control Program. Any procedure that uses this mode of operation shall include proper radiological postings and / or securing of the area (per guidance from the state RCP personnel).
  - E. All manufacturer recommendations for periodic maintenance and calibration frequency shall be followed.
  - F. A Radiological Safety Officer shall be designated to be responsible for proper storage, usage, training of authorized employees, distribution of dosimetry, maintenance of exposure records (including reporting of quarterly exposure records to the X-Ray Section of the State of Maine's Department of Health and Human Services Radiation Control Program), procedural compliance, and all other safety requirements regarding the unit.
  - G. Only personnel who have been trained and certified by the RSO or the manufacturer's training program shall be permitted to operate the unit.
  - H. A trained and certified user shall be present at all times while the unit is being operated.
  - I. The unit and radiation safety program of the registrant shall be inspected by a "Qualified Expert" or RCP Inspector within 30 days of registration. (A list of Maine Certified Qualified Experts can be obtained from the X-Ray Section of the State of Maine's Department of Health and Human Services Radiation Control Program).

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- J. Requests for exemptions from any of these regulations shall be submitted, along with detailed justification, to the X-Ray Section of the State of Maine's Department of Health and Human Services Radiation Control Program in writing. Exemptions shall not be implemented prior to receiving written approval by the Maine RCP.
- K. All companies selling or distributing hand-held XRF analyzers (non-medical) for use in the State of Maine shall notify the state of Maine's Department of Health and Human Services Radiation Control Program of all sales and include Part H.4 in their sales agreement.

The following Information shall be provided to the State of Maine's Department of Health and Human Services Radiation Control Program.

- (1) Model name and number of unit
- (2) Number of units
- (3) Name of company / person purchasing unit(s)
- (4) Address company / person purchasing unit(s)
- (5) Phone number of company / person purchasing unit(s)
- (6) Email address of company / person purchasing unit(s)

#### 5. Area Requirements.

- A. Radiation Levels. The local components of an x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in Part D.1301 of these regulations. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.
- B. Surveys.
  - (1) Radiation surveys, as required by Part D.1501 of these regulations, of all radiation machines and x-ray systems sufficient to show compliance with H.5.A shall be performed:
    - (a) upon installation of the equipment, and as specified in Part F.3.C.3(f);
    - (b) following any change in the initial arrangement, number, or type of local components in the system;
    - (c) following any maintenance requiring the disassembly or removal of a local component in the system;
    - (d) during the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;
    - (e) any time a visual inspection of the local components in the system reveals an abnormal condition; and
    - (f) whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in D.1201 of these regulations.
  - (2) Radiation survey measurements shall not be required if a registrant or licensee can demonstrate compliance with H.5.A to the satisfaction of the Agency.
- C. Posting. Each area or room containing analytical x-ray equipment; shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "**CAUTION - X-RAY EQUIPMENT**" or words having a similar intent.

## 6. Operating Requirements.

- A. Procedures. Normal operating procedures shall be written and available to all radiation machine operators. No person shall be permitted to operate radiation machines in any manner other than that specified in the procedures unless such person has obtained written approval of the radiation safety officer.
- B. Bypassing. No person shall bypass a safety device unless such person has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device has been bypassed, a readily discernible sign bearing the words "**SAFETY DEVICE NOT WORKING**," or words having a similar intent, shall be placed on the radiation source housing.
- C. Repair or Modification of radiation machines. Except as specified in H.6.B, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.
- D. Radioactive Source Replacement, Testing, or Repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, or an Agreement State.
- E. Whenever x-ray work is performed at a location other than a permanent installation, the radiographer must notify the requesting site's radiation safety officer or the person responsible for safety matters for those site's that do not have a radiation safety officer, before taking or utilizing radiation machines on the jobsite.

## 7. Personnel Requirements.

- A. Instruction. No person shall be permitted to operate or maintain radiation machines unless such person has received instruction in and demonstrated competence as to:
  - (1) identification of radiation hazards associated with the use of the equipment;
  - (2) significance of the various radiation warning, safety devices and interlocks 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;
  - (3) proper operating and safety procedures for the radiation machine;
  - (4) recognition of symptoms of an acute localized exposure; and
  - (5) proper procedures for reporting an actual or suspected exposure in excess of limits specified in Part D.
- B. Personnel Monitoring.
  - (1) Finger or wrist dosimetric devices shall be provided to and shall be used by:
    - (a) radiation machine workers using systems having an open-beam configuration and not equipped with a safety device; and
    - (b) personnel maintaining radiation machines if the maintenance procedures require the presence of a primary x-ray beam when any local component in the x-ray system is disassembled or removed.
  - (2) Reported dose values shall not be used for the purpose of determining compliance with D.1201 of these regulations unless evaluated by a qualified individual per H.8.B.

## 8. Periodic Inspection

- A. Pursuant to 22 MRSA section 682 duly authorized employees of the Department of Health and Human Services may enter into establishments during working hours to determine whether there is compliance with provisions of the Radiation Protection Act.

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- B. Only those individuals, who meet the qualifications below and authorized by the Agency, shall be utilized to perform inspection and calibration services, and to certify x-ray units and radiation machines pursuant to this Part. To be eligible for qualification, an individual must:
- (1) Apply for and be listed as a Qualified Expert per F.5 of these regulation; or
  - (2) Apply for and be listed as a Qualified Individual as outlined below:
    - (a) Possess a High School diploma; and
      - (i) a BS or BA degree in Health Physics or Radiological Health degree and have one year of experience in the field of analytical or industrial x-ray machines;
      - (ii) Have educational training equivalent to the above criteria; as determined by the Agency; and have five years experience in the field of analytical or industrial x-ray machines.
- C. Except as stated in Part F.3.C.4, the licensee of all x-ray facilities shall have radiation machines and tubes inspected once every two years.
- D. Upon notification or discovery of a violation to the rules stated in this section, the Department may, in its notice of violation to the licensee, require a re-inspection, by a Qualified Individual per H.8.B. This increase in frequency of inspection will depend upon the severity of the violation.

**9. Annual Registration Fees.** All annual fees are to be paid to the Agency as outlined in Part F Appendix F, by January 1 of each year.