

PART VII

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

64E-5.701 Equipment Requirements.

- (1) 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 may apply to the department for an exemption from the requirement of a safety device. Such application shall include:
 - (a) A description of the various safety devices that have been evaluated;
 - (b) The reason each of these devices cannot be used; and
 - (c) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that the operator and others in the area will be informed of the absence of safety devices.
- (2) Warning Devices.
 - (a) Open-beam configurations shall be provided with a readily discernible indication of:
 1. X-ray tube on-off status located near the radiation source housing, if the primary beam is controlled in this manner; or
 2. Shutter open-closed status located near each port on the radiation source housing, if the primary beam is controlled in this manner.
 - (b) Warning devices shall be labeled so that their purpose is easily identified.
 - (c) Warning devices shall have fail-safe characteristics.
- (3) Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent inadvertent opening.
- (4) Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:
 - (a) "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the x-ray source housing; and
 - (b) "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.

- (5) Shutters. On open-beam configurations, 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.
- (6) Warning Lights. An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, having fail-safe characteristics, shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized.
- (7) Radiation Source Housing. Each x-ray tube housing installed after the effective date of these regulations shall be so constructed that, with all shutters closed, the leakage radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 mrem (0.025 mSv) in any given hour at any specified tube rating.
- (8) 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 0.25 mrem (2.5 uSv) in any given hour.

Specific Authority: 404.051, 404.141, 404.22, F.S.
Law Implemented: 404.051(1)(4)(6), 404.141, 404.22, F.S.
History: New July 17, 1985, Formerly 10D-91.803.

64E-5.702 Area Requirements.

- (1) Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or have 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 64E-5.312. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.
- (2) Surveys.
 - (a) Radiation surveys, as required by 64E-5.314, of all analytical x-ray systems sufficient to show compliance with (1), above, shall be performed:
 1. Upon installation of the equipment and at least once every 12 months thereafter;
 2. Following any change in the initial arrangement, number or type of local components in the system;
 3. Following any maintenance requiring the disassembly or removal of a local component of the system;

4. 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;
 5. Any time a visual inspection of the local components of the system reveals an abnormal condition; and
 6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 64E-5.312.
- (b) Radiation survey measurements shall not be required if a registrant can demonstrate compliance with (1), above, to the satisfaction of the department.
- (3) 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.

Specific Authority: 404.051, 404.141, 404.22, F.S.

Law Implemented: 404.051(1)(4)(6), 404.141, 404.22, F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.804.

64E-5.703 Operating Requirements.

- (1) Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No individual shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such individual has obtained the written approval of the radiation safety officer.
- (2) Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the written approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock 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.
- (3) Repair or Modification of X-ray Tube Systems. Except as specified in (2), above, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops shall be performed without first 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.

Specific Authority: 404.051, 404.081, 404.22, F.S.

Law Implemented: 404.051(1)(4)(6), 404.081(1), 404.22, F.S.

History: New July 17, 1985, Formerly 10D-91.805.

64E-5.704 Personnel Requirements.

- (1) Instruction. No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instruction in and demonstrated competence as to:
 - (a) Identification of radiation hazards associated with the use of the equipment;
 - (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) Proper operating procedures for the equipment;
 - (d) Symptoms of an acute localized overexposure; and
 - (e) Proper procedures for reporting an actual or suspected overexposure.
- (2) Personnel Monitoring.
 - (a) Finger or wrist dosimetric devices shall be provided to and shall be used by:
 1. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
 2. Personnel maintaining analytical x-ray equipment, if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.
 - (b) Reported dose values shall not be used for the purpose of determining compliance with 64E-5.304 unless evaluated by a qualified person, as defined in 64E-5.501(61).

Specific Authority: 04.051, 404.22, F.S.

Law Implemented: 404.051(1)(4), 404.22, F.S.

History: New July 17, 1985, Amended January 1, 1994, Formerly 10D-91.806.