

641—42.20(136C) Radiation safety requirements for analytical X-ray equipment. This rule provides special requirements for analytical X-ray equipment. The requirements of these rules are in addition to, and not in substitution for, 641—Chapters 37, 38, 39, and 40.

1. No person shall receive, possess, use, transfer, own, or acquire an analytical X-ray device except as authorized by a registration issued in accordance with rule 641—37.8(136C).

2. Each analytical X-ray device shall be registered in accordance with the requirements of 641—subrule 37.8(2).

42.20(1) Equipment requirements.

a. Safety device. 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 are required on all open-beam configurations. A registrant or licensee may apply to the department for an exemption from the requirement of a safety device. Such application shall include all of the following:

(1) A description of the various safety devices that have been evaluated;

(2) The reason each of these devices cannot be used;

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to ensure 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 readily discernible indication of the following:

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.

(2) An easily visible warning light labeled with the words “X-RAY ON” or words having a similar intent shall be located:

1. Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

2. 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.

(3) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after July 1, 2026, warning devices shall have fail-safe characteristics.

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

d. Labeling. All analytical X-ray equipment shall be labeled with a readily discernible sign(s) 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 a similar intent on the source housing if the radiation source is a radionuclide.

e. 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.

f. 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 constructed so that with all shutters closed the radiation measured at a distance of five centimeters from its surface is not

capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing X-ray tubes, this limit shall be met at any specified tube rating.

g. Generator cabinet. Each X-ray generator shall be supplied with a protective cabinet that limits leakage radiation measured at a distance of five centimeters from its surface so that it is not capable of producing a dose in excess of 0.25 millirem (2.5 mSv) in one hour.

42.20(2) Area requirements.

a. Radiation levels. The local components of an analytical X-ray system shall be located and arranged, and shall include sufficient shielding or access control, so that no radiation levels exist in any area surrounding the local component group that could result in a dose to an individual present in excess of acceptable dose limits. For systems utilizing X-ray tubes, these levels shall be met at any specified tube rating.

b. Surveys. Radiation surveys of all analytical X-ray systems shall be performed at all of the following frequencies:

- (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 in 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 in the system reveals an abnormal condition;
- (6) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the allowable limits.

c. Compliance. Radiation survey measurements may not be required if a registrant or licensee can demonstrate compliance to the satisfaction of the department.

d. Posting. Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign(s) bearing the radiation symbol and the words "CAUTION—X-RAY EQUIPMENT" or words having a similar intent.

42.20(3) Operating requirements.

a. 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 that individual has obtained written approval of the radiation safety officer.

b. Bypassing. No individual shall bypass a safety device or interlock unless that individual has obtained the 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 displayed 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 X-ray tube systems. 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, an agreement state, or a licensing state.

42.20(4) Personnel requirements.

a. Instruction. No individual shall be permitted to operate or maintain analytical X-ray equipment unless such individual has received instruction in, and demonstrated competence as to, all of the following:

- (1) Identification of radiation hazards associated with the use of the equipment;

(2) Significance of the various radiation warnings, 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 procedures for the equipment;

(4) Recognition of symptoms of an acute localized exposure;

(5) Proper procedures for reporting an actual or suspected exposure.

b. Personnel monitoring.

(1) Finger or wrist dosimetry devices shall be provided to, and used by, the following:

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.

(2) Reported dose values shall not be used for the purpose of determining compliance with 641—subrule 37.2(1) unless evaluated by a qualified expert.

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