Ohio Administrative Code

Rule 3701:1-66-08 Mammography radiation-generating equipment.

Effective: December 20, 2019

This rule provides standards forradiation-generating equipment used for screening and diagnostic mammography,and mammography equipment used for invasive localization andstereotactically-guided breast biopsy purposes, except as provided byparagraphs (E) and (F) of this rule. In addition, a handler of mammographyradiation-generating equipment that uses either stationary or mobileinstallations, shall comply with all applicable standards in 21 C.F.R. part1020 (as effective on the effective date of this rule).

(A) In addition to meeting the applicable equipment standards in rule 3701:1-66-02 of the Administrative Code, a handler performing screening or diagnostic mammography shall have a valid certificate issued by the U.S. department of health and human services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900 (as effective on the effective date of this rule).

(B) A handler of all types of mammography radiation-generating equipment shall comply with the shielding requirements in paragraphs (H)(2) to (H)(4) of rule 3701:1-66-02 of the Administrative Code.

(C) In addition to applicable radiation safety requirements in rules adopted pursuant to Chapter 3748. of the Revised Code and rule 3701:1-66-02 of the Administrative Code, a handler of all types of screening and diagnostic mammography radiation-generating equipment shall comply with the following:

(1) When a film/screen mammography system is used, clinical films shall be processed as soon as possible, but not to exceed twenty-four hours from the time the first clinical image is taken. Facilities utilizing batch processing shall:

(a) Use a container to transport clinical films that will protect the film from exposure to light, excessive heat and radiation; and

(b) Maintain a log to include date and identification of each patient, time of first exposure of each batch, and date and time of each batch processing;

(2) Individuals who perform mammography procedures on human beings shall hold an Ohio radiographer license in accordance with Chapter 3701-72 of the Administrative Code and shall meet at least one of the following qualifications:

(a) Documented evidence of having completed the forty contact hours of training required by 21 C.F.R. 900.12(a)(2)(ii); or

(b) Hold advanced certification in mammography issued by the "American Registry of Radiologic Technologists."

(D) In addition to all applicable quality assurance requirements in rules 3701:1-66-02 and 3701:1-66-04 of the Administrative Code, the facility shall maintain phantom and quality control images for three months.

(E) Radiation-generating equipment designed for mammography, but used exclusively for radiography of tissue from a biopsy, shall be exempt from paragraphs (A) to (D) of this rule, and shall comply with paragraphs (E), (H)(2), (H)(3) and (J) of rule 3701:1-66-02 of the Administrative Code.

(F) Radiation-generating equipment used for radiography of tissue from a biopsy and equipped with an x-ray tube enclosure designed to exclude personnel from its interior during x-ray generation shall be exempt from paragraphs (A) to (E) of this rule, and shall comply with the requirements set forth in rule 3701:1-68-06 of the Administrative Code.

(G) Quality control testing by a medical physicist shall be conducted on mammography radiation-generating equipment used for invasive localization or having stereotactically-guided breast biopsy capability. Quality control testing for stereotactically-guided breast biopsy equipment shall follow the "American College of Radiology (ACR) Practice Parameter for the Performance of Stereotactic-Guided Breast Interventional Procedures" (as revised in 2016). This document is available from the

"American College of Radiology, 1891 Preston White Drive, Reston, Virginia 20191, telephone (703) 648-8900."

(1) The medical physicist shall meet the requirements of the aforementioned ACR guideline; and

(2) The medical physicist shall document and verify that the facility is taking proper corrective actions when results of the quality control tests indicate the need.