

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

This rule provides standards for radiation-generating equipment used for screening and diagnostic mammography, and mammography equipment used for invasive localization and stereotactically-guided breast biopsy purposes, except as provided by paragraphs (E) and (F) of this rule. In addition to Chapters 3701:1-38 and 3701:1-66 of the Administrative Code, a handler of mammography radiation-generating equipment that uses either stationary or mobile installations, shall comply with all applicable standards in 21 C.F.R. 1020 (as published in the April 1, 2012, Code of Federal Regulations) and the following:

- (A) In addition to meeting the applicable equipment standards in rule 3701:1-66-02 of the Administrative Code, a facility 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.
- (B) A handler of all types of mammography radiation-generating equipment shall comply with the shielding requirements in paragraphs (I)(2) to (I)(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) An individual, other than a licensed practitioner, operating any type of mammography equipment on human beings shall possess an Ohio radiographer license in accordance with rules in Chapter 3701-72 of the Administrative Code and meet at least one of the following initial qualifications:
    - (a) Documented evidence of having completed sixteen hours of structured education in mammography which was university-awarded or approved by a recognized continuing education evaluation mechanism as accepted by the "American Registry of Radiologic Technologists"; or
    - (b) Proof of advanced certification in mammography issued to the operator by the "American Registry of Radiologic Technology."
- (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 the requirements set forth in paragraphs (A), (F), (H)(1), (I)(2), (I)(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 paragraph (H)(2) of rule 3701:1-68-03 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 Guideline for the Performance of Stereotactically Guided Breast Interventional Procedures" (as revised in 2009). 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.

Effective: 02/01/2014

R.C. 119.032 review dates: 10/09/2013 and 02/01/2019

CERTIFIED ELECTRONICALLY

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Certification

12/16/2013

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Date

Promulgated Under: 119.03  
 Statutory Authority: 3748.04  
 Rule Amplifies: 3748.01, 3748.02, 3748.04, 3748.05, 3748.06  
 3748.07, 3748.12, 3748.14, 3748.15, 3748.17,  
 3748.18, 3748.19, 3748.20, 3748.22, 3748.99  
 Prior Effective Dates 2/15/2001, 2/1/05, 4/15/09