

Guidance in Bold Text

Rule 3701:1-66-08 Effective Date: 02/01/14

Mammography

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:

These regulations apply to radiation-generating equipment used for the following:

- **Screening mammography;**
- **Diagnostic mammography;**
- **Mammography equipment used for invasive localization; and**
- **Mammography equipment used for stereotactically-guided breast biopsy.**

Radiation-generating equipment used exclusively for radiography of tissue from a biopsy must meet the requirements of paragraphs (E) or (F) of this rule.

- (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.

Any facility performing screening or diagnostic mammography must have a valid MQSA certificate.

Inspectors will review the MQSA certificate to verify compliance.

- (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.

Shielding and protective barriers must be used such that no person other than the patient being examined receives a total effective dose equivalent in excess of the limits prescribed in rules 3701:1-38-12 and 3701:1-38-13 of the Ohio Administrative Code.

In addition, the operator station shall be either in a separate room or behind a protective barrier that intercepts the useful beam and any direct scatter radiation.

Finally, the operator must be able to see the patient without having to leave the protected area during exposure.

Inspectors will review the area to verify compliance.

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(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:

Clinical images shall be processed within 24 hours. Mammography films processed more than 24 hours from the time the image was taken may not be used for either primary or comparison interpretation purposes.

The certainty that film processing can occur within 24 hours should be considered prior to imaging patients. For example, the processor will be fixed within 24 hours or the use of a backup processor will be available within 24 hours.

'Batch processing' is any processing where the films from more than one patient are processed together.

Compliance determined by interview with facility staff and/or review of batch processing records.

Inspectors will interview facility staff and/or review batch processing records to verify compliance.

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

Although the type of container is not specified in the rule, the handler should consider the environment to which the container will be exposed (i.e. transporting films in the possession of the mammography technologist versus shipping by common carrier would call for different container designs).

If the integrity of the container is suspect, fog testing should be performed using the same method as used for testing dark room fog (i.e. the lights in the area surrounding the container must be ON during testing).

Inspectors will interview facility staff and review batch processing records to verify compliance.

(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.

Where batch processing occurs, a log to include date, identification of each patient, time of first exposure of each batch,

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and the date and time that each batch is processed must be maintained.

Inspectors will interview facility staff and/or review batch processing records to verify compliance.

- (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:

An individual must hold a radiographer's license in accordance with Chapter 3701-72 and meet the requirements of either subparagraph (a) or (b) of this rule prior to operating mammography radiation-generating equipment to irradiate human beings.

Inspectors will review the Ohio license document to verify compliance.

- (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

A licensed radiographer who does not hold advance certification in mammography [R.T.(M)] by the American Registry of Radiologic Technologists (ARRT) must complete sixteen hours of structured education in mammography which is university-awarded or approved by a Recognized Continuing Education Evaluation Mechanism (RCEEM) accepted by the ARRT to meet the initial education requirements. Acceptance documents to show compliance with this paragraph include:

- **University-awarded: Transcript(s) or certificate(s) from the university; or**
- **RCEEM/ARRT: Category A or A+ CEU certificates**

Inspectors will review education transcripts and/or certificates to verify compliance.

- (b) Proof of advanced certification in mammography issued to the operator by the "American Registry of Radiologic Technology."

A licensed radiographer who holds advanced certification in mammography [R.T.(M)] by the American Registry of Radiologic Technologists meets the initial education requirements to operate mammography equipment on human beings.

Inspectors will review the ARRT certificate to verify compliance.

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- (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.

All quality control images (including those generated during the annual QC testing performed by the physicist) must be kept in either hard-copy or soft-copy format for at least three months.

Inspectors will review the documents of the quality assurance program for appropriateness.

- (E) Radiation-generating equipment designed for mammography but used exclusively for radiography of tissue from a biopsy, shall be exempt from paragraphs (A) through (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 Ohio Administrative Code.

This rule applies ONLY to equipment that is used for radiography of excised tissue (not in a living human). Typically, these units are de-certified mammography units that are no longer used for screening or diagnostic purposes. This rule does NOT apply to equipment used for invasive procedures such as invasive localization or stereotactically-guided breast biopsy.

Reference the indicate paragraphs of rule 3701:1-66-02 of the OAC. These paragraphs address warning label, structural shielding, protective barriers, user manuals, record keeping etc...

Inspectors will observe the area and review the documents for compliance.

- (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.

This rule applies ONLY to equipment that is used for radiography of excised tissue (not in a living human) using a totally enclosed cabinet system. The paragraph from rule 3701:1-68-03 is associated with the regulation of non-medical cabinet x-ray systems and addresses safe operating procedures, operator competency, radiation area control devices, warning lights etc...

Reference the indicated paragraph of rule 3701:1-68-03.

Inspectors will review the documents for compliance.

- (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

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biopsy equipment shall follow the “American College of Radiology (ACR) Practice Guidelines 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.”

The following tests must be conducted annually by the medical physicist:

- **Collimation assessment: *X-ray beam aligned to image receptor and biopsy window aligned with the image field of view;***
- **Focal spot performance and system limiting resolution;**
- **KVp accuracy and reproducibility;**
- **Beam quality assessment (half-value layer or HVL measurement);**
- **Automatic exposure control (AEC) system or manual exposure performance assessment;**
- **Screen speed uniformity (screen-film) or digital receptor uniformity**
- **Breast entrance exposure;**
- **Average glandular dose and exposure reproducibility;**
- **Image quality evaluation;**
- **Artifact evaluation; and**
- **Localization accuracy: *This test is performed annually by the technologist under the supervision / direct observation of the medical physicist and must be performed as described in the physicist’s portion of the ACR manual. This testing utilizes a biopsy needle and involves the retrieval of an object from the ‘gel’ phantom.***

Inspectors will review the documents for compliance.

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

According to the ACR guideline, the medical physicist must meet the requirements of the Mammography Quality Standards Act (MQSA) final rule published by the Federal Drug Administration (FDA). Please reference FDA guidelines for further information.

Inspectors will review the documents to verify compliance.

- (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.

If annual quality control test results exceed the tolerance limits specified in the ACR guideline, the facility must have the medical physicist review any corrective actions taken. The medical physicist must provide the facility with documentation that verifies the corrective actions were adequate.

Inspectors will review the documents to verify compliance.