**Section 370.80 Equipment Requirements**

The equipment requirements of this Section are intended to ensure that mammography equipment is capable of producing quality mammograms over the full range of clinical conditions.

a) Prohibited equipment. Radiographic equipment designed for general purpose shall not be used for mammography. Mammography shall only be performed with a special purpose radiation machine specifically designed for and used solely for mammography procedures.

b) General. All radiographic equipment used for mammography shall be certified under the "Performance Standards for Diagnostic X-Ray Systems and their Major Components", published at 21 CFR 1020.30, effective as of April 1, 2012. Each radiographic unit used for mammography shall be accredited by an approved accrediting body or have an application for accreditation pending with an approved accrediting body.

c) Motion of tube-image receptor assembly.

1) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

2) The mechanism ensuring compliance with subsection (c)(1) shall not fail in the event of power interruption.

d) Image receptor sizes.

1) Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

e) Beam limitation and light fields.

1) All systems shall have beam-limiting devices.

2) For any mammography system with a light beam that passes through the x-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

f) Magnification.

1) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

g) Focal spot selection.

1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

3) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

h) Compression. All mammography systems shall incorporate a compression device.

1) Application of compression. Each system shall provide:

A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

B) Fine adjustment compression controls operable from both sides of the patient.

2) Compression paddle.

A) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. The compression paddles for special purposes are not subject to the requirements of subsections (h)(2)(D) and (h)(2)(E).

B) Except as provided in subsection (h)(2)(C), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

C) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

D) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

E) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

i) Technique factor selection and display.

1) Manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere (mA) and/or time) shall be available.

2) The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

3) Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

j) Automatic exposure control.

1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid, magnification, nonmagnification and various target-filter combinations.

2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

A) The size and available positions of the detector shall be clearly indicated at the x-ray input surface of the breast compression paddle.

B) The selected position of the detector shall be clearly indicated.

3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

k) X-ray film. The facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

l) Intensifying screens. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

m) Film processing solutions. For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

n) Lighting. The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

o) Film masking devices. Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

(Source: Amended at 36 Ill. Reg. 17392, effective November 30, 2012)