**Section 370.110 Equipment Quality Assurance Tests**

a) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density and density difference, using the mammography film used clinically at the facility.

1) The base plus fog density shall be within plus 0.03 of the established operating level.

2) The mid-density shall be within plus or minus 0.15 of the established operating level.

3) The density difference shall be within plus or minus 0.15 of the established operating level.

b) Weekly quality control tests. Facilities with screen-film systems shall perform a phantom image quality evaluation test at least weekly, using the Mammography Image Evaluation Protocol found in Appendix B of this Part.

1) The optical density of the film at the center of an image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.

2) The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.

3) The mammography system shall be capable of producing images of the mammography phantom in which the following objects are visualized:

A) The three largest masses with thicknesses of 2.0, 1.0 and 0.75 millimeter.

B) The three largest speck groups with diameters of 0.54, 0.40 and 0.32 millimeter.

C) The four largest fibers with thicknesses of 1.56, 1.12, 0.89 and 0.75 millimeter.

4) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

c) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

1) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

2) Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reasons for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

d) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.20, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

2) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

3) Compression device performance. The compression device performance shall:

A) Be capable of maintaining a compression force of at least 111 newtons (25 pounds) for at least 15 seconds;

B) Not be capable of exceeding a compression force of more than 209 newtons (47 pounds) when used in an automatic or power drive mode.

e) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

1) Automatic exposure control performance.

A) The AEC shall be capable of maintaining film optical density within plus or minus 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that shall be used so that optical densities within plus or minus 0.30 of the average under phototimed conditions can be produced.

B) The AEC shall be capable of maintaining film optical density within plus or minus 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

C) The optical density of the film in the center of the phantom image shall not be less than 1.20.

2) Kilovoltage peak accuracy and reproducibility. The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at:

A) The lowest clinical kVp that can be measured by a kVp test device;

B) The most commonly used clinical kVp;

C) The highest available clinical kVp; and

D) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

3) Focal spot dimensions. Facilities shall evaluate focal spot condition by determining the system resolution. For focal spot dimensions, the measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode-cathode axis) shall be within the tolerance limits specified in this subsection (e)(3).

|  |
| --- |
| Focal Spot Tolerance Limit |
|  |
| Nominal Focal | Maximum Measured Dimensions |
| Spot Size (mm) | Width (mm) | Length (mm) |
|  |  |  |
| 0.10 | 0.15 | 0.15 |
| 0.15 | 0.23 | 0.23 |
| 0.20 | 0.30 | 0.30 |
| 0.30 | 0.45 | 0.65 |
| 0.40 | 0.60 | 0.85 |
| 0.60 | 0.90 | 1.30 |

4) System resolution. Facilities shall evaluate focal spot condition by determining the system resolution as follows:

A) Each x-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeter (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

B) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

C) When more than one target material is provided, the measurement shall be made using the appropriate focal spot for each target material.

D) When more than one source-image receptor distance is provided, the test shall be performed at SID most commonly used clinically.

E) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

5) Beam quality and half-value layer (HVL). For mammography systems operating at x-ray tube potentials of less than 50 kVp, the HVL in millimeters of aluminum of the useful beam shall be equal to or greater than the product of the measured tube potential in kilivolts multiplied by 0.01. The half-value layer shall be measured with the compression device in the beam and shall be measured at the same tube potential used in Appendix A of this Part, Mammography Dose Measurement Protocol, and Appendix B of this Part, Mammography Phantom Image Evaluation.

 AGENCY NOTE: If the measured half-value layer is significantly greater than the specified minimum, image contrast will be reduced and overall image quality will be degraded. For screen-film mammography systems, it is recommended that the HVL not exceed the minimum acceptable HVL by more than 0.1 millimeter of aluminum, as specified in the Mammography Quality Control Manual: Medical Physicist's Section, Revised Edition, 1999.

6) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

7) Dosimetry. The average glandular dose delivered during a single craniocaudal view of a phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast (see Appendix A of this Part).

8) X-ray field/light field/image receptor/compression paddle alignment.

A) All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

B) If a light field that passes through the x-ray beam limitation device is provided, it shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.

C) The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

9) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

10) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

11) Radiation output.

A) The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 mR per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. The system, under the same measuring conditions, shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.

B) The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

12) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

A) An override capability to allow maintenance of compression;

B) A continuous display of the override status; and

C) A manual emergency compression release that can be activated in the event of power or automatic release failure.

f) Quality control tests-other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in subsection (e)(7) of this Section.

g) Mobile units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in subsections (a) through (f) of this Section. In addition, at each examination location, before any examinations are conducted, mobile mammography systems shall be tested using the mammography phantom image evaluation, or shall meet the following requirements:

1) A medical physicist shall establish a protocol for measurement of the radiation output of the mammography system, including the radiation measuring device to be used, procedures for performing the measurement and the anticipated result of the measurement.

2) Measurements shall be performed using the technique factors that were used for the most recent phantom image evaluation. If a change is made in the technique factors used for the measurements required in this subsection (g)(2), the image quality shall be tested using the mammography phantom image evaluation protocol found in Appendix B of this Part.

AGENCY NOTE: If the phantom image evaluation is performed using a phototimer, the medical physicist may specify appropriate technique factors that approximate those used by the phototimer for the measurements required in this Section.

3) After each relocation of a mobile mammography system, measurements of the radiation output of the machine shall be performed according to the protocol established in this Section.

4) If the radiation output measurement exceeds plus or minus 15 percent of the value established by the medical physicist, the system shall not be used to image human patients until the cause for the variation has been investigated and corrected.

5) Records of radiation output measurements for mobile mammography systems shall be maintained at the location of the mammography system for a period of not less than one inspection cycle.

AGENCY NOTE: The Agency recommends that mobile mammography systems be tested for image quality after each relocation and prior to use on patients, with mammography phantom image evaluation protocol in Appendix B of this Part.

h) Use of test results.

1) After completion of the tests specified in subsections (a) through (g) of this Section, the facility shall compare the test results to the corresponding specified action limits, or for nonscreen-film modalities, to the manufacturer's recommended action limits, or for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

2) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in subsection (a), (b), (d)(1), (d)(2), (d)(3), (e)(7), (f) or (g) of this Section;

B) Within 30 days after the test date for all other tests described in this Section.

i) Surveys.

1) At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in subsections (e) and (f) of this Section and the weekly phantom image quality test described in subsection (b) of this Section.

2) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every 2 years and each time the instrument is repaired. The instrument calibration shall be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

3) The results of all tests conducted by the facility in accordance with subsections (a) through (g) of this Section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

4) The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

5) The survey report shall be sent to the facility within 30 days after the date of the survey.

6) The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

j) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in this Section and Section 370.80 of this Part. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

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