TITLE 32: ENERGY
CHAPTER II: ILLINOIS EMERGENCY MANAGEMENT AGENCY
SUBCHAPTER b: RADIATION PROTECTION

PART 370
QUALITY STANDARDS AND CERTIFICATION REQUIREMENTS FOR FACILITIES PERFORMING MAMMOGRAPHY

Section

AUTHORITY: Implementing and authorized by the Radiation Protection Act of 1990 [420 ILCS 40].

SOURCE: Old Part repealed at 15 Ill. Reg. 10846, effective July 15, 1991; new Part adopted by emergency rule at 22 Ill. Reg. 14972, effective August 3, 1998, for a maximum of 150 days; adopted at 22 Ill. Reg. 21915, effective December 3, 1998; amended at 24 Ill. Reg. 18258, effective December 1, 2000; recodified from the Department of Nuclear Safety to the Illinois Emergency Management Agency at 27 Ill. Reg. 13641; amended at 29 Ill. Reg. 20963, effective

December 16, 2005; amended at 33 Ill. Reg. 2224, effective January 23, 2009; amended at 36 Ill. Reg. 17392, effective November 30, 2012.

Section 370.10 Scope

This Part establishes quality standards and certification requirements for facilities performing mammography to ensure that all mammography facilities are adequately and consistently evaluated for compliance with the standards provided in this Part. The provisions of this Part are in addition to and not in substitution for other applicable provisions of 32 Ill. Adm. Code 310, 320, 340, 400, 401 and 410.

(Source: Amended at 24 Ill. Reg. 18258, effective December 1, 2000)

Section 370.20 Definitions

As used in this Part, the following definitions apply:

"Accreditation body" or "body" means an entity that has been approved by FDA to accredit mammography facilities.

"Action limits" or "action levels" means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action shall be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

"Adverse event" means an undesirable experience associated with mammography activities that include but are not limited to:

Poor image quality;

Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

Use of personnel that do not meet the requirements of Section 370.70 of this Part.

"Agency" means the Illinois Emergency Management Agency.

"Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad.

"Breast implant" means a prosthetic device implanted in the breast.

"Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30 or October 1 through December 31.

"Category I" means medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society or an equivalent organization.

"Certificate" means the certificate described in Section 370.50 of this Part.

"Certification" means the process of approval of a facility by the Agency to provide mammography services.

"Clinical image" means a mammogram.

"Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

"Continuing education unit" or "continuing education credit" means one contact hour of training.

"Contact hour" means an hour of training received through direct instruction.

"Diagnostic mammography" means mammography performed on a patient with:

clinical signs, symptoms or physical findings suggestive of breast cancer;

an abnormal or questionable screening mammogram;

a history of breast cancer with breast conservation surgery regardless of absence of clinical breast signs, symptoms or physical findings; or

augmented breasts regardless of absence of clinical breast signs, symptoms or physical findings.

AGENCY NOTE: Diagnostic mammography is also called problem-solving mammography or consultative mammography. This definition excludes mammography performed during invasive interventions for localization or biopsy

procedures.

"Direct instruction" means:

Face-to-face interaction between instructor and students, as when the instructor provides a lecture, conducts demonstrations or reviews student performance; or

The administration and correction of student examinations by an instructor with subsequent feedback to the students.

"Direct supervision" means that:

During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or

During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

"Director" means the Director of the Illinois Emergency Management Agency.

"Established operating level" means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

"Facility" or "mammography installation" means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician or other facility that conducts mammography activities, including operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram and maintaining viewing conditions for that interpretation.

"First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body.

"FDA" means the U.S. Food and Drug Administration.

"Interim regulations" means the regulations entitled "Requirements for Accrediting Bodies of Mammography Facilities" (58 FR 67558-67565) and

"Quality Standards and Certification Requirements for Mammography Facilities" (58 FR 67565-67572), published by FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808-49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994 and April 28, 1999.

"Interpreting physician" means a licensed physician who interprets mammograms and who meets the requirements of Section 370.70(a) of this Part.

"Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of Sections 370.100, 370.110, 370.120(b) and (c) and 370.130 of this Part. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

"Mammogram" means radiographic image produced through mammography.

"Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography and digital mammography.

"Mammography" means radiography of the breast.

"Mammography equipment evaluation" means an onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in this Part.

"Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

"Mammography unit" or "units" means an assemblage of components for the production of x-rays for use during mammography, including, at a minimum, an x-ray generator, an x-ray control, a tube housing assembly, a beam limiting device and the supporting structures for these components.

"Mean optical density" means the average of the optical densities (OD) measured using phantom thicknesses of 2, 4 and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

"Medical physicist" means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications set forth in Section 370.70(c) of this Part.

"MQSA" means the federal Mammography Quality Standards Act of 1992, as amended by the Mammography Quality Standards Reauthorization Act of 1998.

"Multi-reading" means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.

"Patient" means any individual who undergoes a mammography evaluation in a facility.

"Phantom" means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. It is equivalent to a nominal 4.2 centimeter compressed breast of average density (i.e., 50 percent adipose and 50 percent glandular tissue) and shall contain the following objects:

Spherical masses, composed of phenolic plastic, with thicknesses of: 2.00, 1.00, 0.75, 0.50 and 0.25 millimeter;

Specks, composed of aluminum oxide, with diameters of: 0.54, 0.40, 0.32, 0.24 and 0.16 millimeter;

Fibers, composed of nylon, with thicknesses of: 1.56, 1.12, 0.89, 0.75, 0.54 and 0.40 millimeter.

AGENCY NOTE: The Mammographic Accreditation Phantom Model 156, manufactured by Radiation Measurements, Inc., meets the above criteria and was chosen for use by the American College of Radiology's Mammography Accreditation Program.

"Phantom image" means a radiographic image of a phantom.

"Physical science" means physics, chemistry, radiation science (including medical physics and health physics) and engineering.

"Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

"Provisional certificate" means the provisional certificate described in Section 370.50(b) of this Part.

"Qualified instructor" means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists or medical physicists who meet

the requirements of Section 370.70 of this Part would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the requirements of this Part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

"Quality control technologist" means an individual meeting the requirements of Section 370.100(a)(4) of this Part who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

"Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and when performing mammography without direct supervision, also meets the requirements set forth in Section 370.70(b) of this Part.

"Screening mammography" means mammography performed on an asymptomatic patient to detect the presence of breast cancer at an early stage.

"Serious adverse event" means an adverse advent that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

"Serious complaint" means a report of a serious adverse event.

"Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

"Survey" means an onsite physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

"Time cycle" means the film development time.

"Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within plus or minus 3 percent of the national standard in the mammography energy range.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

Section 370.30 Incorporations by Reference

All rules, standards and guidelines of agencies of the United States or nationally recognized organizations or associations that are incorporated by reference in this Part are incorporated as of the date specified in the reference and do not include any later amendments or editions. Copies of rules, standards and guidelines that have been incorporated by reference are available for public inspection and copying at the Illinois Emergency Management Agency, 1035 Outer Park Drive, Springfield, Illinois.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

Section 370.40 Exemptions

a) Mammography units used only during invasive interventions for localization or biopsy procedures are exempt from the requirements of this Part, except that such systems shall satisfy the criteria specified in Section 370.170 of this Part.

b) Each mobile mammography facility based outside of Illinois that operates in Illinois and that has not been certified by the Agency is exempt from the requirements of Sections 370.50 and 370.60 of this Part, provided that:

1) The mobile mammography facility is certified to perform mammography by FDA or other FDA-approved certifying agency at all times while conducting operations in Illinois; and

2) The mobile mammography facility meets the requirements of Section 370.145 of this Part.

AGENCY NOTE: Mobile mammography facilities exempt under this subsection (b) shall meet the standards of this Part except those Sections specifically exempted.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

Section 370.50 Requirements for Certification

a) Except as otherwise provided in subsection (b)(1)(C) and Section 370.40, a certificate issued by the Agency is required for lawful operation of all mammography facilities subject to the provisions of this Part. Facilities performing mammography shall meet the requirements of Sections 370.70, 370.80, 370.90, 370.100, 370.110, 370.120 and 370.130 and be accredited by an FDA-approved accreditation body. Each mammography unit shall be accredited by or have an application pending for accreditation with an FDA-approved accrediting body.

AGENCY NOTE: Currently, the only FDA-approved accrediting body in Illinois is the American College of Radiology.

AGENCY NOTE: Except for provisional certificates and interim notices, the term of certificates issued under this Section shall be for 3 years.

b) Application.

1) Certificates.

A) In order to qualify for a certificate, a facility shall apply to an accreditation body.

B) Following the Agency's receipt of the accreditation body's decision to accredit a facility, the Agency may issue a certificate to the facility, or renew an existing certificate, if the Agency determines that the facility has satisfied the requirements for certification or recertification.

C) An interim notice authorizes the facility to perform mammography until the facility receives its certificate but in no case for more than 45 days. No more than one interim notice may be issued to a facility per application for certification. The Agency may issue an interim notice of mammography certification by facsimile to a facility if a delay is anticipated in providing a certificate to the facility under one or more of the following circumstances:

i) The Agency has been notified by an accreditation body that the facility meets the requirements for a provisional or provisional reinstatement certificate and delivery of the certificate may take more than 24 hours;

ii) The Agency has been notified by an accreditation body that the facility has completed accreditation or reaccreditation and delivery of the certificate to the facility may take more than 24 hours; or

iii) The Agency has been notified by an accreditation body that the facility has timely submitted an application for accreditation or reaccreditation but the completion of the accreditation process may extend beyond the expiration date of a facility's existing certificate through no fault of

the facility.

2) Provisional certificates. A new facility is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process.

A) To receive a provisional certificate, a facility shall apply and submit the required information to an FDA-approved accreditation body.

B) Following the Agency's receipt of the accreditation body's decision that a facility has submitted the required information, the Agency may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements for provisional certification. A provisional certificate shall be effective for up to 6 months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90 day extension of the provisional certificate.

C) In the event the facility is denied accreditation by the accrediting body with time remaining on the provisional certificate, the provisional certificate expires immediately with the denial and the facility must stop performing mammography.

3) Extension of provisional certificate.

A) To apply for a 90 day extension to a provisional certificate, a facility shall submit to its accreditation body a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

B) Following the Agency's receipt of the accreditation body's decision that a facility has submitted the required information, the Agency may issue a 90 day extension of the provisional certificate to the facility upon determination that the facility has satisfied the requirements for the 90 day extension.

C) There can be no renewal of a provisional certificate beyond the 90-day extension.

c) Reinstatement policy. A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA or the Agency, or that has had its certificate suspended or revoked by FDA or the Agency, may apply for reinstatement. If reinstated, the facility will be eligible for a provisional certificate.

1) Unless prohibited from reinstatement under subsection (c)(4), a facility applying for reinstatement shall:

A) Contact an FDA-approved accreditation body to determine the requirements for reapplication for accreditation;

B) Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

i) Name and address of the facility under which it was previously provisionally certified or certified;

ii) Name of previous owner/lessor;

iii) Facility identification number assigned to the facility under its previous certification; and

iv) Expiration date of the most recent provisional certificate or certificate; and

C) Justify application for reinstatement of accreditation by submitting to the accreditation body a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse, denial of renewal or revocation of its certificate.

2) The Agency may issue a provisional certificate to a previously certified facility:

A) Following the Agency's receipt of the accreditation body's decision that a facility has adequately corrected, or is in the process of correcting, pertinent deficiencies at the facility; and

B) The Agency determines that the facility has taken sufficient corrective action since the lapse, denial of renewal or revocation of its previous certificate.

3) After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for certification.

4) If a facility's certificate was revoked on the basis of an act described in Section 370.160, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years after the date of revocation.

d) Appeals of adverse accreditation or reaccreditation decisions. The appeals procedures described in this subsection (d) are available only for adverse accreditation or reaccreditation decisions that preclude certification or recertification by the Agency.

1) Upon learning that a facility has failed to become accredited or reaccredited, the Agency will notify the facility that the Agency is unable to certify that facility without proof of accreditation.

2) A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the accreditation body. A facility shall avail itself of the accreditation body's appeal process before appealing that decision to the FDA.

3) In the event that a facility, after availing itself of the accreditation body's appeal process, receives an adverse accreditation or reaccreditation decision, the facility may appeal that decision to the FDA. In order to appeal, the facility shall send a request for reconsideration to the FDA

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

Section 370.60 Fees

a) Except as provided in subsection (b), the Agency shall assess each certified mammography installation an annual certification fee of $1,300 in each State fiscal year (July 1-June 30). The Agency shall bill the mammography installation for the annual fee after July 1. The annual fee shall be due and payable within 60 days after the date of billing. Failure to pay the required fee may result in revocation of the certificate.

AGENCY NOTE: The annual fee described in subsection (a) applies to both fully and provisionally certified mammography installations.

b) A new mammography installation issued an initial provisional certificate after December 31 of any State fiscal year shall not be required to pay a certification fee for that State fiscal year.

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

Section 370.70 Personnel Requirements

Personnel. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

a) Interpreting physicians. All physicians interpreting mammograms shall meet the following qualifications:

1) Initial qualifications. Unless the exemption in subsection (a)(3) of this Section applies, before beginning to interpret mammograms independently, the interpreting physician shall:

A) Be a physician licensed under the Medical Practice Act of 1987 to practice medicine in all its branches [225 ILCS 60];

B) Be certified in diagnostic radiology by either the American Board of Radiology, the American Osteopathic Board of Radiology, or Royal College of Physicians and Surgeons of Canada or have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of subsection (a) of this Section;

C) Have a minimum of 60 hours of documented medical education in mammography, which shall include instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography and quality assurance and quality control in mammography. All 60 of these hours shall be Category I and at least 15 of the Category I hours shall have been acquired within the 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to

mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; and

D) Unless the exemption in subsection (a)(3) of this Section applies, have interpreted or multi-read at least 240 mammographic examinations within the 6 month period immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

2) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

A) Following the second anniversary date of the end of the calendar quarter in which the requirements of subsection (a)(1) of this Section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24 month period.

B) Following the third anniversary date of the end of the calendar quarter in which the requirements of subsection (a)(1) of this Section were completed, the interpreting physician shall have taught or completed at least 15 Category I continuing medical education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36 month period. This training shall include at least 6 Category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.

C) Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new

mammographic modality.

D) Units earned through teaching a specific course can be counted only once towards the 15 units required by subsection (a)(2) of this Section, even if the course is taught multiple times during the previous 36 months.

3) Exemptions.

A) Those physicians who qualified as interpreting physicians under FDA's interim regulations prior to April 28, 1999, are considered to have met the initial requirements of subsection (a)(1) of this Section. These physicians may continue to interpret mammograms provided they continue to meet the requirements of subsection (a)(1) of this Section and the continuing experience and education requirements of subsection (a)(2) of this Section.

B) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6 month period during the last 2 years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from subsection (a)(1)(D) of this Section.

4) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements of subsection (a)(2) of this Section, shall reestablish their qualifications before resuming the independent interpretation of mammograms as follows:

A) Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.

B) Interpreting physicians who fail to meet the continuing education requirements of subsection (a)(2)(B) of this Section shall obtain a sufficient number of additional Category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming

independent interpretation.

C) The interpretations required under this Section shall be done within the 6 months immediately prior to resuming independent interpretation.

b) Radiologic technologists who perform mammographic examinations shall be accredited by the Agency and shall meet the following:

1) Training requirements.

A) Have, prior to April 28, 1999, qualified as a radiologic technologist under FDA's interim regulations; or

B) Complete at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

i) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques and imaging of patients with breast implants;

ii) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under subsection (b) of this Section; and

iii) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams.

2) Continuing education requirements.

A) Following the third anniversary date of the end of the calendar quarter in which the requirements of subsection (b)(1) of this Section were completed, the radiologic technologist who performs mammography shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36 month period.

B) Units earned through teaching a specific course can be counted only once towards the 15 hours of continuing education requirements required in subsection (b)(2) of this Section, even if the course is taught multiple times during the previous 36 months.

C) At least 6 of the continuing education units required in subsection (b)(2) of this Section shall be related to each mammographic modality used by the technologist.

D) Requalification. Radiologic technologists who fail to meet the continuing education requirements of subsection (b)(2)(A) of this Section shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist shall not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

E) Before a radiologic technologist may begin independently performing mammography examinations using a mammographic modality other than one of those for which the technologist received training under subsection (b)(1)(B)(iii) of this Section, the technologist shall have at least 8 hours of continuing education units in the new modality.

3) Continuing experience requirements.

A) Following the second anniversary date of the end of the calendar quarter in which the requirements of subsection (b)(1) of this Section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24 month period.

B) Requalification. Radiologic technologists who fail to meet the continuing experience requirements of subsection (b)(3)(A) of this Section shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised

mammography.

C) Programs, courses or other activities intended to meet the requirement for initial, or requalification, mammography training or continuing education in mammography shall be approved by the Agency.

D) Completion of initial, or requalification, mammography training and continuing education in mammography shall be verified to the Agency.

c) Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program shall be approved by the Agency as diagnostic imaging specialists pursuant to 32 Ill. Adm. Code 410, and meet the following:

1) Initial qualifications.

A) Be certified in diagnostic radiological physics or radiological physics by either the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP);

B) Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics;

C) Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

D) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys shall be acquired under the direct supervision of a medical physicist who meets all the requirements of subsections (c)(1), (c)(2) and (c)(3) of this Section.

2) Alternative initial qualifications.

A) Have qualified as a medical physicist under FDA's interim regulations and retained that qualification by maintenance of the

active status of any licensure, approval or certification required;

B) Have, prior to April 28, 1999, obtained a bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics;

C) Have 40 contact hours of documented specialized training in conducting surveys of mammography facilities; and

D) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements shall be met after fulfilling the degree requirement.

3) Continuing education and experience. All medical physicists shall maintain their qualifications by meeting the following requirements:

A) Continuing education. Beginning 3 years after the end of the calendar quarter in which the requirements of subsection (c)(1) or (c)(2) of this Section were completed, the medical physicist shall have taught, or completed, at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36 month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 continuing education units in a 36 month period, even if the course is taught multiple times during the 36 months.

B) Continuing experience. Beginning 2 years after the end of the calendar quarter in which the requirements of subsection (c)(1) or (c)(2) of this Section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least 2 mammography facilities and a total of at least 6 mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of

the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24 month period. No more than one survey of a specific facility within a 10 month period or a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

C) Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under subsection (c)(1) or (c)(2) of this Section, the physicist shall receive at least 8 hours of training in surveying units of the new mammographic modality.

4) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing education and experience qualifications of subsection (c)(3) of this Section may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists shall reestablish their qualifications, as follows:

A) Medical physicists who fail to meet the continuing educational requirements of subsection (c)(3)(A) of this Section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 units in the previous 3 years.

B) Medical physicists who fail to meet the continuing experience requirement of subsection (c)(3)(B) of this Section shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of subsection (c)(1) or (c)(2) of this Section, to bring their total surveys up to the required 2 facilities and 6 units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

d) Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists or medical physicists. These records shall be available for review by the Agency. Records of personnel no longer employed by the facility shall not be discarded until the next annual inspection has been completed and the Agency has determined that the facility is in compliance with the personnel requirements of this Section.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

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)

Section 370.90 Medical Records and Mammography Reports

a) Contents and terminology. Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

1) The name of the patient and an additional patient identifier;

2) Date of examination;

3) The name of the interpreting physician who interpreted the mammogram;

4) Overall final assessment of findings, classified in one of the following categories:

A) "Negative." Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);

B) "Benign." Also a negative assessment;

C) "Probably Benign." Finding(s) has a high probability of being benign;

D) "Suspicious." Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

E) "Highly suggestive of malignancy." Finding(s) has a high probability of being malignant;

5) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

6) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

b) Communication of mammography results to the patient. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days after the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy", the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

1) Patients who do not name a health care provider to receive the

mammography report shall be sent the report described in subsection (a) of this Section within 30 days, in addition to the written notification of results in lay terms.

2) Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

c) Communication of mammography results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

1) Provide a written report of the mammography examination, including the items listed in subsection (a) of this Section, to that health care provider as soon as possible, but no later than 30 days after the date of the mammography examination; and

2) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

d) Recordkeeping. Each facility that performs mammograms:

1) Shall (except as provided in subsection (c)(2) of this Section) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility;

2) Shall upon request by, or on behalf of, the patient permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly. Any fee charged to the patient for providing the services in this subsection (d) shall not exceed the documented costs associated with this service.

e) Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

1) Name of patient and an additional patient identifier.

2) Date of examination.

3) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body shall be used to identify view and laterality.

4) Facility name and location. At a minimum, the location shall include the city, state and zip code of the facility.

5) Technologist identification.

6) Cassette/screen identification.

7) Mammography unit identification, if there is more than one unit in the facility.

(Source: Amended at 24 Ill. Reg. 18258, effective December 1, 2000)

Section 370.100 Quality Assurance Requirements

Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity and accuracy of mammography services performed at the facility.

a) Responsible individuals. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of this Section and Sections 370.110, 370.120(b) and (c) and 370.130 of this Part. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

2) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

A) Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality; and

B) Participate in the facility's medical outcomes audit program.

3) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the reports described in Section 370.110(i) of this Part.

4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist. The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of Section 370.110 of this Part.

b) Personnel quality assurance records. The lead interpreting physician, quality control technologist and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in Section 370.110 of this Part until the next annual inspection has been completed and the Agency has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

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 Spot Size (mm)	Maximum Measured Dimensions	
	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.

(Source: Amended at 33 Ill. Reg. 2224, effective January 23, 2009)

Section 370.120 Additional Administrative Requirements

a) *Every operator of a radiation installation at which mammography services are provided shall ensure and have confirmed by each mammography patient that the patient is provided with a pamphlet that is orally reviewed with the patient and that contains the following:*

1) How to perform breast self-examination;

2) That early detection of breast cancer is maximized through a combined approach, using monthly breast self-examination, a thorough physical examination performed by a physician, and mammography performed at recommended intervals;

3) That mammography is the most accurate method for making an early detection of breast cancer, however, no diagnostic tool is 100% effective;

4) If the patient is self-referred and does not have a primary care physician, or if the patient is unfamiliar with the breast examination procedures, that the patient has received information regarding public health services where she can obtain a breast examination and instructions. [420 ILCS 40/5(c)]

b) Facility cleanliness.

1) The facility shall establish and implement adequate protocols for maintaining darkroom, screen and view box cleanliness.

2) The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

c) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

2) If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

d) Mammographic procedure and techniques for mammography of patients with breast implants.

1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.

2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

e) Consumer complaint mechanism. Each facility shall:

1) Establish a written and documented system for collecting and resolving consumer complaints;

2) Maintain a record of each serious complaint received by the facility for at least 3 years after the date the complaint was received;

3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;

4) Report unresolved serious complaints to the accreditation body in a manner and timeframe specified by the accreditation body.

f) Clinical image quality. Clinical images produced by any certified facility shall continue to comply with the standards for clinical image quality established by that facility's accreditation body.

Section 370.130 Mammography Medical Outcomes Audit

Each facility shall establish and maintain a mammography medical outcomes audit program to follow up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity and accuracy of the interpretation of mammograms.

a) General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among patients imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

b) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

c) Audit interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit periods and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the audit interpreting physician shall also be responsible for documenting the nature of the followup.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

Section 370.140 Additional Mammography Review and Patient Notification

a) If the Agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the Agency, for review by the accreditation body. This additional mammography review will help the Agency to determine whether the facility is in compliance with this Part and, if not, whether there is a need to notify affected patients, their physicians or the public that the reliability, clarity and accuracy of interpretation of mammograms has been compromised.

b) If the Agency determines that the quality of mammography performed by a facility, whether or not certified under Section 370.50 of this Part, was so inconsistent with the quality standards established in this Part as to present a significant risk to individual or public health, the Agency may require the facility to notify patients who received mammograms at the facility, and their referring physicians, of the deficiencies presenting the risk, the potential harm resulting, appropriate remedial measures and other relevant information as the Agency may require.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

Section 370.145 Notification Requirements for Mobile Mammography Facilities Certified by Another Certifying Entity

Mobile mammography facilities that operate in Illinois and are certified under MQSA by the FDA, or another state authorized by FDA to certify mammography facilities under MQSA, shall:

a) Notify the Agency by telephone, facsimile or letter of each date and location of operation of the mobile mammography facility in Illinois prior to conducting such operation.

AGENCY NOTE: Notifications submitted by the mobile mammography facility to the Agency may contain notice of multiple dates and locations of operation by the mobile mammography facility.

b) At all times while operating in Illinois, have the following documentation available for review and inspection by the Agency:

1) A copy of the mammography facility certificate issued by the FDA or another state, showing that the facility is currently certified.

2) A summary of the most recent physics survey of the mammography machine and documentation of any corrective actions recommended by the medical physicist who performed the physics survey.

3) Documentation that personnel meet the qualifications of Section 370.70 of this Part.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

Section 370.150 Revocation of Accreditation and Revocation of Accreditation Body Approval

If a facility's accreditation is revoked by an accreditation body, the Agency may conduct an investigation into the reasons for the revocation. Following the investigation, the Agency may act to suspend or revoke the facility's certificate and may take whatever other action or combination of actions will best protect the public health, including requiring the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is suspended or revoked because it has lost its accreditation may not practice mammography.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

Section 370.160 Suspension, Revocation or Denial of Certificates

a) The Agency may suspend, revoke or deny a certificate if the Agency finds that the owner, operator or any employee of the facility:

1) Has been guilty of misrepresentation in obtaining the certificate;

2) Has failed to comply with the standards of Sections 370.70, 370.80, 370.90, 370.100, 370.110, 370.120 and 370.130 of this Part;

3) Has failed to comply with reasonable requests of the Agency or the accreditation body for records, information, reports, or materials that the Agency believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of Sections 370.70, 370.80, 370.90, 370.100, 370.110, 370.120, 370.130 and 370.140 of this Part;

4) Has refused a reasonable request of a duly designated FDA inspector, Agency inspector, or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

5) Has violated or aided and abetted in the violation of any provision of this Part;

6) Has failed to comply with prior sanctions imposed by the Agency; and

7) Has failed to pay any required fees.

b) If, based upon any of the grounds in subsection (a) of this Section, the Agency determines that action to suspend, revoke or deny certification is warranted, the Agency shall notify the owner or operator of a facility and shall provide an opportunity for hearing in accordance with 32 Ill. Adm. Code 200.

c) The Agency may suspend the certificate of a facility before holding a hearing if the Agency determines that:

1) The failure to comply with required standards presents a serious risk to human health;

2) The refusal to permit inspection makes immediate suspension necessary; or

3) There is reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.

d) If the Agency suspends a certificate in accordance with subsection (c) of this Section:

1) The Agency shall provide the facility with an opportunity for a hearing under 32 Ill. Adm. Code 200 not later than 30 days after the effective date of the suspension;

2) The suspension shall remain in effect until the Agency determines that:

A) Allegations of violations or misconduct were not substantiated;

B) Violations of required standards have been corrected to the Agency's satisfaction; or

C) The facility's certificate is revoked in accordance with subsection (e) of this Section.

e) After providing a hearing in accordance with subsection (d)(1) of this Section, the Agency may revoke the facility's certificate if the Agency determines that the facility:

1) Is unwilling or unable to correct violations that were the basis for

suspension; or

2) Has engaged in fraudulent activity to obtain or continue certification.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

Section 370.165 Failure of Mobile Mammography Facilities Certified by Another Certifying Entity to Meet Requirements

If the Agency has reason to believe that the owner, operator or any employee of a mobile mammography facility certified by another certifying entity:

a) has been guilty of misrepresentation in obtaining the certificate;

b) has failed to comply with the standards of Sections 370.70, 370.80, 370.90, 370.100, 370.110, 370.120 or 370.130 of this Part;

c) has failed to comply with reasonable requests of the Agency for records, information, reports, or materials that the Agency believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of Sections 370.70, 370.80, 370.90, 370.100, 370.110, 370.120, 370.130 or 370.140 of this Part; or

d) has refused a reasonable request of a Agency representative for permission to inspect the facility or the operations and pertinent records of the facility;

the Agency shall notify the certifying entity of the facts and circumstances and may take other actions as may be appropriate under Sections 36, 38 or 40 of the Radiation Protection Act of 1990 [420 ILCS 40/36, 38, and 40].

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

Section 370.170 Mammography Units Used for Localization or Biopsy Procedures

a) Personnel. The following requirements apply to all personnel involved in localization or biopsy procedures performed with mammography units:

1) The mammography unit shall be operated by or under the direction of a physician licensed under the Medical Practice Act of 1987 [225 ILCS 60].

2) Radiologic technologists operating mammography units for localization or biopsy procedures shall meet the general requirements, mammography requirements and continuing education and experience requirements as

specified in Section 370.70(b) of this Part.

3) Medical physicists who perform and provide oversight of quality assurance programs for mammography units used for biopsy procedures shall meet the requirements of Section 370.70(c) of this Part.

b) Equipment. Mammography units used for localization or biopsy procedures shall meet the requirements of Section 370.80 of this Part, except that digital output mammography systems that do not use screen-film image receptors are exempt from the requirements of Section 370.80 of this Part as they relate to screen-film image receptors.

c) Quality assurance. Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity and accuracy of mammography localization or biopsy procedures performed at the facility.

1) Each facility shall have the services of a medical physicist available to survey mammography equipment and to oversee the equipment-related quality assurance practices of the facility.

2) The quality assurance program shall be in writing and shall have been developed by a medical physicist. The program shall include, but need not be limited to, the following:

A) Specifications of the tests that are to be performed, including instructions to be employed in the performance of those tests; and

B) Specifications of the frequency at which tests are to be performed, the acceptable tolerance for each parameter measured and actions to be taken if tolerances are exceeded.

3) The medical physicist shall conduct a review of the quality assurance program each year. Such review shall include evaluation of the results of quality assurance testing.

d) Each facility shall maintain written records of the radiation dose measurements and quality assurance testing performed, as required in this Section, for inspection by the Agency for a period of at least one year. Such records shall include, but need not be limited to, the following:

1) The date of the test and identification of the person performing the test;

2) Identification of the type of testing that was performed; and

3) Notation of whether the results of the testing were within the parameters established by the medical physicist.

AGENCY NOTE: The Agency recommends that facilities performing interventional mammography seek accreditation through the Stereotactic Breast Biopsy Program of the American College of Radiology.

(Source: Amended at 29 Ill. Reg. 20963, effective December 16, 2005)

Section 370.APPENDIX A Mammography Dose Measurement Protocol

The technique factors used for performing a mammography examination shall not permit the mean glandular absorbed dose to exceed the limits specified in Section 370.110(e)(7) of this Part. Radiation measurements shall be performed with an integrating radiation measuring device that is appropriate to the high beam intensity and mammographic kilovoltage peak (kVp) used, and sufficiently sensitive to determine compliance with the criteria specified in Section 370.110(i)(2) of this Part. The instrument shall have been calibrated as specified in Section 370.110(i)(2) of this Part.

The mammography exam dose limits are based on an average compressed breast value of 4.2 centimeters having an average density (i.e., 50 percent adipose and 50 percent glandular).

Perform the following steps to determine the mean glandular dose to a nominal 4.2 centimeter compressed breast:

a) Measure and record the x-ray system's useful beam half-value layer (HVL). (See Section 370.110(e)(5) of this Part.) Any compression device normally in the useful beam during mammography procedures shall be required to be placed between the x-ray tube target and measuring device when determining the HVL. The useful beam shall be collimated to a size encompassing the detector.

AGENCY NOTE: Filters used for the HVL evaluation should be placed as close to the target as practical. The HVL for screen-film mammography should not exceed the minimum acceptable HVL by more than 0.1 millimeter of aluminum equivalent.

b) Determine the glandular dose to entrance exposure factor from the Mammography Dose Evaluation Table (see Table A of this Part) using the appropriate HVL, kVp and x-ray tube target-filter material.

AGENCY NOTE: The kVp of screen-film mammography systems with molybdenum target-filter combinations should be accurately measured to determine the appropriate glandular dose to entrance exposure factor from Table A of this Part.

c) If the equipment has the capability for variable source-image receptor distance, set the craniocaudal source-image receptor distance (SID) for the image receptor system used.

d) Position in the useful beam any compression apparatus normally used.

AGENCY NOTE: Some mammography systems have the capability of providing

automatic adjustment of technique factors through feedback from the position of the compression device. On such systems, the compression device should be lowered to a position 4.2 centimeters above the breast support assembly (BSA). The device should then be removed, inverted and replaced to allow placement of the phantom and measuring device on the BSA below the compression device. If the compression device cannot be replaced in an inverted position, the device should be placed in the beam using auxiliary support.

e) Placement of the Radiation Measuring Device

1) For systems equipped with automatic exposure control (AEC):

A) Place a properly loaded film cassette in the cassette holder.

AGENCY NOTE: The loaded cassette is placed in the cassette holder to simulate, as much as is possible, the conditions under which actual patient exposures are made. Following radiation measurements, the film should be discarded and the cassette reloaded with unexposed film.

B) Place a mammography phantom (see the definition for "Phantom" in Section 370.20 of this Part) on the breast support assembly (BSA). Align the phantom so that the edge of the phantom is aligned with the chest wall side of the BSA and the phantom is over the automatic exposure control device(s).

C) Place a radiation measuring device in the useful beam so the center axis of the device is parallel to the breast support assembly (BSA). The geometric center of the measuring device shall be positioned 4.5 centimeters above the BSA, 2.5 centimeters from the chest wall edge of the BSA and immediately adjacent to either side of the mammography phantom.

2) For systems not equipped with AEC, place a radiation measuring device in the useful beam so that the center axis of the device is parallel to the breast support assembly (BSA). The geometric center of the measuring device shall be positioned so that it is centered 4.5 centimeters above the BSA, 2.5 centimeters from the chest wall edge of the BSA and at the center line of the BSA. No part of the device's detector area shall be outside of the useful beam.

f) Collimate the x-ray field to the size normally used and assure that the area covered by the useful beam includes the detector area of the radiation measuring

device and the mammography phantom if the equipment is equipped with automatic exposure.

g) Set the appropriate technique factors or automatic exposure controls normally used for a nominal 4.2 centimeter compressed breast.

h) Measure and record the exposure in air with the radiation measuring device.

i) Calculate the mean glandular dose for a 4.2 centimeter compressed breast by multiplying the measured exposure in millicoulombs per kilogram or in roentgens by the glandular dose to entrance exposure factor, which was determined using the procedure described in subsection (b) of this Section.

EXAMPLE: A mammography system is provided with a molybdenum target-filter combination, and the HVL and kVp are determined to be 0.3 and 30, respectively. Therefore, for a 4.2 centimeter compressed breast, the glandular dose to entrance exposure factor from the Mammography Dose Evaluation Table (Table A of this Part) would be 159 mrad. The measured roentgen output determined in subsection (h) of this Appendix is determined to be 1.8 R. Therefore, the mean glandular dose would be 1.8 R multiplied by 159 mrad/R. This results in a mean glandular dose measurement of 286 mrad. As such, the system would be in compliance with Section 370.110(e)(7) of this Part.

Section 370.APPENDIX B Mammography Phantom Image Evaluation

Mammography phantom image evaluation shall be performed using the procedure below. The evaluation shall be performed weekly as a part of the quality assurance program. The evaluation shall be performed with the mammography phantom specified in Section 370.20 of this Part.

a) Equipment necessary for mammography phantom image evaluation includes a densitometer, the mammography phantom and mammographic cassette and film.

b) Load film in the mammographic cassette according to the manufacturer's instructions.

c) Place the properly loaded cassette in the cassette holder.

d) Place the mammography phantom on the breast support assembly (BSA) so that the edge of the phantom is aligned with the chest wall side of the BSA. Align the phantom so that the masses in the phantom are nearest the chest wall edge of the BSA and the fibers in the phantom are away from the chest wall edge of the BSA. If the mammography machine has the capability of automatic exposure control, place the phantom so that the phantom covers the phototimer sensor.

e) Position the compression device so that it is in contact with the phantom.

f) Select the technique factors used most frequently in the clinical setting for a 4.2 centimeter compressed breast and make an exposure of the phantom.

g) Process the film in the processor used for clinical mammography films.

h) Examine the processed image for areas of non-uniformity of optical density and for the presence of artifacts due to dirt, dust, grid lines or processing.

AGENCY NOTE: If any of the problems noted above are evident on the processed image, the mammography machine film processor and film cassette(s) should be evaluated and the problem corrected. The phantom image evaluation should be repeated after the problem is corrected.

i) Measure and record the optical density of the film near the center of the phantom image. The optical density of the film at the center of the image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.

j) Examine the phantom image and count and record the number of masses visualized. Repeat this procedure for the speck groups and the fibrils and record the number of objects visualized. There are a total of 16 imaging objects (5

masses, 5 speck groups and 6 fibrils) in the phantom. Evaluation criteria for objects visualized in the phantom image are in Section 370.110(b)(3) of this Part. As a minimum, the objects that must be visualized in the phantom image are:

1) The masses that are 0.75 millimeter or larger (a total of 3 masses);

2) The speck groups that are 0.32 millimeter or larger (a total of 3 speck groups);

3) The fibrils that are 0.75 millimeter or larger (a total of 4 fibrils).

AGENCY NOTE: The phantom image should be compared with previous films, including the original phantom image, to determine if subtle changes are occurring from week to week.

Section 370.TABLE A Mammography Dose Evaluation Table

This Table is used to determine the mean glandular dose in milligrays delivered by 25.8 mC/kg (or millirad) delivered by 1 R in air incident on a 4.2 centimeter thickness compressed breast of average density (50 percent adipose and 50 percent glandular tissue). Values listed are for the first half-value layer (HVL) in millimeters of aluminum (mm Al), for x-ray tube target-filter combinations of molybdenum/molybdenum (Mo/Mo) and tungsten/ aluminum (W/Al). Linear extrapolation or interpolation shall be made for any HVL not listed.

Mean Glandular Dose in milligrays for 25.8 mC/kg (or millirad for 1 R) Entrance Exposure for a 4.2 Centimeter Compressed Breast of Average Density

HVL (mm AL)	Mo/Mo Target-Filter X-Ray Tube Voltage (kVp)											W-A1 Target-Filter Combination
	23	24	25	26	27	28	29	30	31	32	33	
0.23	116											
0.24	121	124										
0.25	126	129	131									
0.26	130	133	135	138								
0.27	135	138	140	142	143							
0.28	140	142	144	146	147	149						
0.29	144	146	148	150	151	153	154					
0.30	149	151	153	155	156	157	158	159				170
0.31	154	156	157	159	160	161	162	163	164			175
0.32	158	160	162	163	164	166	167	168	168	170	171	180
0.33	163	165	166	168	169	170	171	173	173	174	175	185
0.34	168	170	171	172	173	174	175	176	177	178	179	190
0.35		174	175	176	177	178	179	180	181	182	183	194
0.36			179	181	182	183	184	185	185	186	187	199
0.37				185	186	187	188	189	190	191	191	204

0.38					190	191	192	193	194	195	195	208
0.39						196	197	198	198	199	200	213
0.40							201	202	203	204	204	217
0.41								206	207	208	208	221
0.42									211	212	212	225
0.43										215	216	230
0.44											220	234
0.45												238

AGENCY NOTE: Adapted from: Mammography Quality Control Manual: Medical Physicist's Section, Revised Edition, 1999.

(Source: Amended at 33 Ill. Reg. 2224, effective January 23, 2009)