

**641—41.6(136C) X-ray machines used for screening and diagnostic mammography.**

**41.6(1) Definitions.** In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

“*Accreditation body*” means an entity that has been approved by FDA to accredit mammography facilities.

“*Acquisition workstation*” or “*AWS*” means the soft copy display workstation used in conjunction with the mammography unit.

“*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 must 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. Adverse events include but are not limited to:

1. Poor image quality;
2. Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and
3. Use of personnel who do not meet the applicable requirements of this chapter.

“*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 Gray of absorbed dose is delivered by 114 roentgens (R) of exposure.

“*Annually*” means within 10 to 14 months of previous occurrence.

“*Artifact*” means a substance or structure not naturally present in living tissue but of which an authentic image appears in a radiograph.

“*Automatic exposure control systems*” means automatic exposure control systems, often referred to as phototimers, which are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the X-ray intensity after passage through the patient and image receptor.

“*Average glandular dose*” means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness. For a 50 percent-50 percent adipose and glandular 4.2 centimeter breast, the average glandular dose shall not exceed 300 millirad (3 mGy). See also: “Dose.”

“*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 1*” means medical education activities that have been designated as Category 1 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 41.6(2)“a”(2).

“*Certification*” means the process of approval of a facility by the FDA or this agency to provide mammography services.

“*Clinical image*” means a mammogram.

“*Compression device*” means a firm plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

“*Computed radiography mammography*” means a type of digital mammography in which the digital image receptor must be removed from the X-ray unit for the image to be read and processed by a separate image receptor reader.

“*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).

“*Contact hour*” means an hour of training received through direct instruction.

“*Continuing education unit*” or “*continuing education credit*” means one contact hour of training.

“*Craniocaudal view*” means one of two routine views for mammography. The detector system is placed caudad to (below) the breast and the vertical X-ray beam is directed from cranial to caudad (downward) through the breast.

“*Dedicated mammography equipment*” means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

“*Digital breast tomosynthesis*” or “*DBT*” means mammography that uses reconstructions to create three-dimensional images of the breasts.

“*Direct detector technology*” means a digital mammogram captured using a material which converts the X-ray energies directly to an electric signal.

“*Direct instruction*” means:

1. Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or
2. The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

“*Direct supervision*” means that:

1. 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
2. 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.

“*Dose*” means the amount of energy deposited per unit mass of tissue due to X-radiation. The newer unit of absorbed dose is the Gray: 1 Gray=1 Joule of energy deposited per kilogram of tissue. The older unit of absorbed dose is the rad: 1 rad=0.01 Gray, 1 centiGray, or 10 milliGray.

“*EQUIP*” means Enhancing Quality Using the Inspection Program and uses inspection questions related to the image quality regulations of MQSA to emphasize the significance of continuous clinical image quality.

“*Exposure*” means the amount of X-radiation, quantitated by measuring the amount of ionization in air caused by the radiation. The units of exposure are Coulombs of charge ionized per kilogram of air. The older unit of exposure is the Roentgen: 1 Roentgen= $2.58 \times 10^{-4}$  Coulombs of charge per kilogram of air.

“*Facility*” means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

“*FDA*” means the Food and Drug Administration.

“*First allowable time*” means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The “first allowable time” may vary with the certifying body.

“*Full field digital mammography*” or “*FFDM*” means radiographic imaging of the breast using a digital image receptor with minimum dimensions of 18×23 cm to allow imaging the average size breast in a single exposure.

“*Grids*” means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

“*Image noise.*” See “Radiographic noise.”

“*Image receptor support device*” means, for mammography X-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

“*Inspection*” means to assess and determine compliance with regulations.

“*Interpreting physician*” means a licensed radiologist who interprets mammograms and who meets the requirements set forth in 41.6(3)“a.”

“*Kerma*” means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

“*Laterality*” means the designation of either the right or left breast.

“*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 this chapter. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

“*Mammogram*” means a radiographic image produced through mammography.

“*Mammographic modality*” means a technology for radiography of the breast. Examples are screen-film mammography, full field digital mammography and digital breast tomosynthesis.

“*Mammography*” means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or
2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or
3. Radiography of the breast performed as part of either a breast localization procedure or a post-stereotactic clip placement localization procedure.

“*Mammography equipment evaluation*” means an on-site assessment of the mammography unit or review workstation by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards.

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

“*Mammography unit(s)*” 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 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 for a medical physicist set forth in 41.6(3)“c.”

“*Mediolateral view*” means one of the routine views for mammography in addition to the craniocaudal view. The detector system is placed lateral to the breast and the horizontal X-ray beam is directed from medial to lateral aspect through the breast.

“*MQSA*” means the Mammography Quality Standards Act of 1992.

“*Multi-reading*” means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram. A radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

“*Oblique mediolateral view*” means one of the standard two views of the breast. The detector system is angled 30-60 degrees from horizontal so that the detector system is parallel to the pectoral muscle and

the corner of the detector system fits comfortably into the axilla. The X-ray beam is directed from the supero-medial to the infero-lateral aspect of the breast.

*“Patient”* means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

*“Phantom”* means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

*“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 certification”* means the six-month certification time period in which a facility has to complete the accreditation/certification process.

*“Qualified instructor”* means individuals whose training and experience adequately prepare them to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 41.6(3) would be considered qualified instructors in their respective areas of mammography. Radiological technologists who meet the requirements of 41.6(3) and have passed a state-approved mammography examination such as the examination given by the American Registry of Radiography Technologists would be considered qualified instructors in their respective areas of mammography. The examination would include, but not necessarily be limited to: breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this chapter include, but are not limited to, instructors in a post-high school training institution and manufacturers’ representatives.

*“Quality control technologist”* means an individual meeting the requirements of 41.6(5) “a”(4) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

*“Radiographic equipment”* means X-ray equipment used for the production of static X-ray images.

*“Radiologic technologist”* means an individual specifically trained in the use of radiographic equipment and in the positioning of patients for radiographic examinations and who meets the requirements set forth in 41.6(3) “b.”

*“Radiologist continuing experience”* means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

*“Reinstatement”* means the process of recertification of a facility that has lost or voluntarily given up previous accreditation/certification.

*“Review workstation”* or “RWS” means soft copy display device intended for use in mammography interpretations.

*“Screen-film mammography”* means mammography performed with high-detailed intensifying screen(s) in close contact with the film.

*“Screening mammography”* means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

*“Serious adverse event”* means an adverse event 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 on-site 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 two years and the results of the proficiency test conducted within 24 months of calibration show agreement within  $\pm 3$  percent of the national standard in the mammography energy range.

“*Written report*” means interpreting physician’s technical narrative of a mammography evaluation.

“*Written statement*” means interpreting physician’s description of a mammography examination written in lay terms.

**41.6(2) *Registration and application standards and requirements.***

*a. Registration and certificates.*

(1) Each radiation machine used to perform mammography shall be registered according to 641—subrule 39.3(2).

(2) A certificate issued by the FDA or this agency is required for lawful operation of all mammography facilities subject to the provisions of this subrule. To obtain a certificate from the FDA or this agency, facilities are required to meet the quality standards in 641—41.6(136C) and to be accredited and approved by an approved accreditation body.

*b. Each facility wishing to perform mammography shall apply for authorization by providing or verifying the following information for each mammography machine:*

(1) The mammography unit meets the criteria for agency-approved mammography accreditation bodies.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

(4) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated at least annually by a medical physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

(8) Provisional or reinstatement certification. A new facility beginning operation after September 30, 1994, is eligible to apply for provisional or reinstatement certification. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive provisional or reinstatement certification, a facility must meet the requirements of 641—41.6(136C). Provisional or reinstatement certification shall be effective for up to six months from the date of issuance and cannot be renewed. The facility may apply for one 90-day extension.

*c. Suspension, revocation, or denial of mammography certification.*

(1) Mammography certification may be suspended or revoked with cause if any facility or machine does not meet one or more of the standards of these rules, will not permit inspections or provide access to records or information in a timely fashion, or has been guilty of misrepresentation in obtaining the certification.

(2) The facility shall have opportunity for a hearing in connection with a denial, suspension or revocation of mammography certification in accordance with 641—Chapter 173.

(3) An emergency order suspending or revoking certification may be issued in accordance with 641—173.31(17A) if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If certification is revoked, the radiation machine shall not be used for mammography until reinstated.

(5) If a facility's certification is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility in Iowa within two years of the date of revocation.

*d.* Reinstatement of mammography certification after revocation.

(1) An application for reinstatement shall be submitted and processed as an initial application. Appropriate corrective actions must be submitted with the application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A full certificate shall be issued only after the agency has inspected the radiation machine and determined that it meets the requirements of these rules.

*e.* Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial mammography certification and at least annually thereafter.

*f.* An application for authorization shall be submitted to the department and processed for agency approval. A mammography authorization is effective for three years.

*g.* A phantom image taken with the authorized unit(s) shall be reviewed at the time of annual inspection by the agency.

*h.* Federal mammography regulations. All Iowa facilities performing mammography shall comply with the applicable regulations found in 21 CFR Part 900 which has an effective date of April 28, 1999. Persons certified to perform mammography in Iowa shall be responsible for ensuring compliance with the appropriate CFR regulations or Iowa administrative rules, whichever are more stringent.

*i.* Review workstation (RWS) requirements.

(1) RWS used for final interpretation of mammogram images must meet the following criteria:

1. Have 5 megapixel resolution; or

2. Be approved by the United States Food and Drug Administration 510K process and be intended for digital mammography use.

(2) The workstation must have a quality control program substantially the same as that outlined by the mammography unit manufacturer's quality control manual, that outlined by the RWS monitor manufacturer's quality control manual or the quality control program outlined by an FDA-approved accrediting body.

**41.6(3) Mammography 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 radiologists interpreting mammograms shall meet the following qualifications:

(1) Initial qualifications. Unless the exemption in 41.6(3) "a"(3)"1" applies, before beginning to interpret mammograms independently, the interpreting radiologist shall:

1. Be licensed to practice medicine in Iowa;

2. Either:

- Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or

- Have had at least three 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 radiologist who meets the requirements of 41.6(3) "a"; and

3. 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, and physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be Category 1 and at least 15 of the Category 1 hours shall have been acquired within the 36 months immediately prior to the date that the radiologist qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography

will be considered as equivalent to Category 1 continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution;

4. Unless the exemption in 41.6(3)“a”(3)“2” applies, have interpreted or multi-read at least 240 mammographic examinations within the six-month period immediately prior to the date that the radiologist qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician; and

5. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality other than the modality in which the initial training was received, the interpreting physician shall have at least eight hours of training in the new mammographic modality.

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

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“a”(1) were completed, the interpreting physician shall have read or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility’s annual MQSA inspection, during the 24-month period ending on the last day of the calendar quarter preceding the inspection, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“a”(1) were completed, the interpreting physician shall have taught or completed at least 15 Category 1 continuing education units in mammography during the 36 months immediately preceding the date of the facility’s annual MQSA inspection, during the 36-month period ending on the last day of the calendar quarter preceding the inspection, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

3. Units earned through teaching a specific course can be counted only once towards the 15 required by 41.6(3)“a”(2)“2” even if the course is taught multiple times during the previous 36 months.

4. A current state of Iowa medical license must be in effect whenever mammography interpretations are performed by the physician.

(3) Exemptions.

1. Those physicians who qualified as interpreting physicians under 41.6(3)“a” or FDA interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 41.6(3)“a.” They may continue to interpret mammograms provided they continue to meet the licensure requirements of 41.6(3)“a”(1)“1” and the continuing experience and education requirements of this subrule.

2. Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six-month period during the last two 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 41.6(3)“a”(1)“4.”

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

1. Interpreting physicians who fail to meet the continuing experience requirements of 41.6(3)“a”(2)“1” shall:

- 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 to at least 960 examinations for the prior 24 months, whichever is less. The interpretations required under 41.6(3)“a”(4)“1” shall be done within the six months immediately prior to resuming independent interpretation. Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

2. Interpreting physicians who fail to meet the continuing education requirements of 41.6(3)“a”(2)“2” shall obtain a sufficient number of additional Category 1 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.

*b. Radiologic technologists.* All mammographic examinations shall be performed by general radiographers who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(1) General requirements. Be permitted to operate as a general radiographer in Iowa; and

(2) Mammography requirements. Have qualified as a radiologic technologist under 41.6(3)“b” before April 28, 1999, or have completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor after successful completion of a formal radiography training program. The hours of documented training shall include, but not necessarily be limited to:

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

2. The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under 41.6(3)“b”; and

3. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3)“b”(2)“3,” the technologist shall have at least eight hours of continuing education units in the new modality. The eight hours may not be derived from the supervised examination of patients; and

(3) Continuing education requirements.

1. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“b”(1) and (2) were completed, the radiologic technologist 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, during the 36-month period ending on the last day of the calendar quarter preceding the inspection, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

2. Units earned through teaching a specific course can be counted only once towards the 15 required in 41.6(3)“b”(3)“1” even if the course is taught multiple times during the previous 36 months.

3. Requalification. A radiologic technologist who fails to meet the continuing education requirements of 41.6(3)“b”(3)“1” shall obtain a sufficient number of continuing education units in mammography to bring the total up to at least 15 in the previous 36 months. The continuing education for requalification cannot be obtained by performing supervised mammography examinations. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

4. An Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

5. Only 50 percent of the total required mammography continuing education hours may be obtained through presenting, or acting as a trainer for, a continuing education or training program.

(4) Continuing experience requirements.

1. Following the second anniversary date on which the requirements of 41.6(3)“b”(1) and (2) were completed, 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 inspection, during the 24-month period ending on the last day of the calendar quarter preceding the inspection, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Requalification. Radiologic technologists who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

(5) Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

*c. Medical physicists.* All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under 41.6(3)“c”(2) shall meet the following:

(1) Initial qualifications.

1. Be Iowa approved; and
2. Have a master’s degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics; and
3. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

4. Have at least eight hours of training in surveying units of a new modality other than the one for which the physicist received training to qualify under 41.6(3)“c”(1)“3” before independently performing the new mammographic modality; and

5. Have experience conducting surveys in at least one mammography facility and have 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 must be acquired under the direct supervision of a medical physicist who meets all the requirements of this subrule; or

(2) Alternative initial qualifications.

1. Have qualified as a medical physicist under FDA interim regulations and have retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

2. Prior to April 28, 1999, have:
  - 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.

- Forty contact hours of documented specialized training in conducting surveys of mammography facilities.

- Experience conducting surveys in at least one mammography facility and have 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 must be met after fulfilling the degree requirement.

- At least eight hours of training in surveying units of a new modality other than the one for which the physicist received training to qualify under 41.6(3)“c”(1)“3” before independently performing the new mammographic modality.

(3) Continuing qualifications.

1. Continuing education. Following the third anniversary date on which the requirements of 41.6(3)“c”(1) or (2) were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility shall choose one of these dates to determine the 36-month period. Units earned through teaching a specific course shall be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

2. Continuing experience. Following the second anniversary date on which the requirements of this subrule were completed, the medical physicist shall have surveyed at least two mammography facilities and a total of at least 6 mammography units during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period 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 shall be counted towards this requirement.

3. Continuing qualifications must be met whenever medical physics services are provided by the medical physicist.

(4) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of this subrule may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows:

1. Medical physicists who fail to meet the continuing education requirements of this subrule shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.

2. Medical physicists who fail to meet the continuing experience requirements of this subrule shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of this subrule to bring their total surveys up to the required two 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, general radiographers, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the agency has determined that the facility is in compliance with the MQSA personnel requirements.

**41.6(4) Obtaining and preserving records.**

*a.* The facility performing the current mammography examination must make all reasonable efforts to obtain the patient's recent mammography records, including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from other facilities, for comparison with the current mammography records.

*b.* The facility must make, for each patient, a written report of each mammography examination performed. This report shall include:

- (1) The date the mammography procedure was performed.
- (2) The date of the interpretation.
- (3) The name of the interpreting physician.
- (4) The name of the patient and an additional patient identifier.
- (5) A description of the procedures performed.
- (6) The name of the referring physician (if any) or other physician (if any) identified by the patient to receive the interpreting physician's written report.
- (7) The date the interpreting physician's written report was sent to the appropriate physician or patient.

(8) A separate and distinct section entitled, "Assessment" with the appropriate assessment term. One of the following terms in quotations or an approved equivalent must be included in the assessment:

1. "Negative": Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).
2. "Benign": Also a negative assessment.
3. "Probably benign": Finding(s) has a high probability of being benign.
4. "Suspicious": Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.
5. "Highly suggestive of malignancy": Finding(s) has a high probability of being malignant.
6. "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment in cases where no final assessment category can be assigned due to incomplete workup, and reasons why no assessment can be made shall be stated by the interpreting physician.

(9) 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.

(10) Information on a patient's breast density, as categorized by an interpreting physician at the facility based on standards as defined in nationally recognized guidelines or systems for breast imaging reporting of mammography screening, including the breast imaging reporting and data system of the American College of Radiology.

*c.* Preservation of records.

(1) The facility must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent mammography procedures and the related written reports of the interpreting physician for each patient are either placed in the patient's medical record kept by the facility or sent for placement in the patient's medical record as directed by the patient's physician or the patient.

(2) Records retained by the facility must be retained for at least 60 calendar months following the date of service, as long as the patient continues consecutive mammograms. If no additional mammograms of the patient are performed, the records must be retained for at least ten years.

(3) If the facility should cease to exist before the end of the retention period, the records must be transferred to the patient or patient's physician or other mammographic facility.

(4) The facility 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.

(5) Any fee charged to the patient for providing the services in subparagraph (4) above shall not exceed the documented costs associated with this service.

*d.* Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated in lay terms to each patient in a time period not to exceed 30 days from the date of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4) "e"(1) in addition to a written notification of results in lay terms.

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

(3) The breast density information as designated in the report pursuant to 41.6(4) "b"(10) shall be included in the patient lay letter with a reference to a department-accepted site or document where the patient can obtain more information about breast density. For patients categorized as having heterogeneously dense breasts or extremely dense breasts, or an equivalent determination by another nationally recognized density gradient system, the notification to the patient shall include evidence-based information on dense breast tissue, the increased risk associated with dense breast tissue, and the effects of dense breast tissue on screening mammography and shall be stated in language appropriate for the facility's patient population.

*e.* Communication of 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 all of the items listed in 41.6(4) "b," to the health care provider as soon as possible, but no later than 30 days from the date of the 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.

*f.* 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 and approved by the FDA 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) Mammography unit identification, if there is more than one unit in the facility.

**41.6(5) *Quality assurance program.***

*a.* The facility shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system to ensure consistently high-quality images with minimum patient exposure. 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, EQUIP included, meets all requirements of these rules. 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:

1. Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

2. 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(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the applicable reports.

(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(s). 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 41.6(5) "e" through "j."

*b.* The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

*c.* Under the direction of the lead interpreting physician, the medical physicist shall have responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

- (1) Conducting or training others to conduct equipment performance monitoring functions.
- (2) Analyzing the monitoring results to determine if there are any problems requiring correction.
- (3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

*d.* Calibration of equipment. All variable parameters of the equipment shall be calibrated:

- (1) When the equipment is first installed.
- (2) After any major changes or replacement of parts.

(3) At least annually during use based on recommendations of the mammography imaging medical physicist.

(4) When quality assurance tests indicate that calibration is needed.

*e.* Performance monitoring. The facility shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored shall include all testing as outlined in the manufacturer's mammography unit's quality control manual and the RWS quality control requirements of 41.6(2) "i"(2).

*f.* Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.

*g.* Evaluation of monitoring results. FFDM and DBT mammography units must comply with the quality control test requirements outlined by the performance criteria in the appropriate manufacturer's quality control manual.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a 4.2 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed 300 millirad for full field digital units.

(2) The monitoring results shall be compared routinely by the facility staff to the standards of image quality in 41.6(5) "j." If any test results fall outside the performance criteria range listed for the unit, specific actions as directed in the appropriate quality control manual shall be followed.

*h.* Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) 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 women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and pathology results, or both, and review of the mammograms taken prior to the diagnosis of a malignancy. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the facility's records.

(2) 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, or 12 months after April 28, 1999, whichever date is the latest. 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.

(3) Reviewing 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 period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and notifying other interpreting physicians of the results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up. The reviewing physician shall sign the medical audit as proof of the evaluation of the data.

*i.* 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 these rules until the next annual inspection has been completed and 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.

*j.* Quality assurance—equipment.

(1) Daily, weekly, biweekly, monthly, quarterly, semiannual and annual quality control tests. Facilities shall perform quality control tests as required by the manufacturer's mammography unit's quality control manual, the RWS quality control requirements of 41.6(2) "i"(2) or the quality control program outlined by an FDA-approved accrediting body.

(2) Surveys.

1. At least annually, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. The survey shall include testing as required by the manufacturer's mammography unit's quality control manual, the RWS quality control manual or the quality control program outlined by the accrediting body.

2. The results of the tests, any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

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

4. The survey report shall be sent to the facility within 30 days of the date of the survey.

5. 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.

(3) Mammography equipment evaluations. Additional evaluations of mammography units or image processors or any other applicable mammography system ancillary parts shall be conducted at new installations, at disassembly, at reassembly, at the same or a new location, or when major components are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5) and 41.6(6). All problems shall be corrected before the new or changed equipment is put into service for examinations. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

(4) 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 two years and each time the instrument is repaired. The instrument calibration must 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.

(5) 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 all applicable federal, state, and local regulations pertaining to infection control; and

2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or

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

k. Mammography procedures 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 examination.

(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.

l. 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 three years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body and any other appropriate regulatory entity 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 time frame specified by the accreditation body.

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

*n.* Additional mammography review and patient notification.

(1) 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 or other entity designated by the agency. This additional mammography review will help the agency to determine whether the facility is in compliance with rule 641—41.6(136C) 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.

(2) If the agency determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and a manner specified by the agency.

**41.6(6) Equipment standards.** The equipment used to perform mammography shall meet the following standards:

*a.* Design: Be specifically designed for mammography. This prohibits systems that have been modified or equipped with special attachments for mammography.

*b.* Performance standards: Meet the Food and Drug Administration (FDA) performance standards for diagnostic X-ray systems and their major components found in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31.

*c.* Image receptor systems:

(1) Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

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

*d.* Light fields: For any 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 centimeters or the maximum source-image receptor distance (SID), whichever is less.

*e.* 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.

*f.* 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 this subrule shall not fail in the event of power interruption.

*g.* Focal spot: The focal spot size, magnification factor and source to image receptor distance (SID) shall be appropriate for mammography.

(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 or focal spot, or both, 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 or focal spot, or both, actually used during the exposure.

*h.* Compression devices: Shall have compression devices able to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds. Each system shall provide:

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

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

(3) 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. Such compression paddles for special purposes are not subject to 41.6(6) "h"(6) and (7).

(4) Except as provided in 41.6(6) "h," 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.

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

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor. Equipment intended by the manufacturer's design not to be straight and parallel to the edge of the image receptor shall meet the manufacturer's design specifications and maintenance requirements.

(7) The chest wall edge of the compression paddle may allow for patient comfort but shall not appear on the image.

*i.* Grids: Shall have the capability for using antiscatter grids.

*j.* AEC: Shall have automatic exposure control such that:

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

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

- The selected position of the detector shall be clearly indicated.

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

*k.* Control panel: Shall have a control panel that:

(1) Gives a positive indication when X-rays are being produced.

(2) Gives an audible signal indicating termination of exposure.

(3) Has manual selection of milliamperere seconds (mAs) or at least one of its component parts (milliamperere (mA) or time, or both).

(4) Has the technique factors (peak tube potential in kilovolts (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 indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.

(5) Has a system that, following AEC mode use, shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure.

*l.* mAs: Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.

*m.* Mobile units and vans. Appropriate manufacturer's quality control manual procedures and criteria shall be met.

**41.6(7)** *Safety standards for mammography equipment.*

- a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel, and facilities. The equipment shall be operated only from a shielded position.
- b. Equipment operators shall be monitored in accordance with 641—40.37(136C).
- c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.
- d. Equipment shall be shockproof and grounded to protect against electrical hazards.
- e. Records of all inspection reports and medical physicist surveys shall be maintained for at least seven years.

RULE 641—41.6(136C)—APPENDIX I  
Rescinded IAB 4/5/00, effective 5/10/00

RULE 641—41.6(136C)—APPENDIX II  
Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure

4.2 cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue\*

[ARC 1401C, IAB 4/2/14, effective 5/7/14; ARC 3393C, IAB 10/11/17, effective 11/15/17; ARC 6164C, IAB 2/9/22, effective 3/16/22]