ARC 6051C

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Proposing rule making related to radiation machines and radioactive materials and providing an opportunity for public comment

The Public Health Department hereby proposes to amend Chapter 38, "General Provisions for Radiation Machines and Radioactive Materials," and Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code chapter 136C.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 136C.

Purpose and Summary

The proposed amendments to Chapter 38 strike the fee related to the State of Iowa as a mammography accrediting body (AB) and providing services for mammography interpretation fees and accreditation fees. The State of Iowa relinquished the role of AB effective January 1, 2021. The fees are being removed to reflect the current fee collections by the Bureau of Radiological Health.

The proposed amendments to Chapter 41 align with the current changes in technology of X-ray machines for mammography and stereotactic breast biopsy and reflect the requirements of the quality control programs outlined by the unit manufacturers. Additional amendments will align the Department's rules with the Food and Drug Administration (FDA) on certain requirements outlined in the Mammography Quality Standards Act (MQSA).

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department's waiver provisions contained in 641—Chapter 178.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on December 7, 2021. Comments should be directed to:

Angela Leek
Bureau of Radiological Health
Department of Public Health
321 East 12th Street
Des Moines, Iowa 50319
Email: angela.leek@idph.iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend paragraph **38.8(1)"b"** as follows:

b. Each registrant shall, where appropriate, pay the following special inspections/interpretation fee at the written request of the department:

(1) Mammography unit inspections fees:

1. $1,575 for the first unit and, if the facility has additional units at the address of the first unit, a fee of $375 for each additional unit; or

2. $1,575 per portable unit for each site ~~where the unit is off-loaded and used and where the processing and patient films are stored~~; or

3. Dollar amount to be determined and justified by the department on a case-by-case basis for facilities which do not meet the above criteria; or

4. $675 for the second facility follow-up visit to review or determine the corrective action taken to address noncompliances; or

5. $1,575 for each stereotactic breast biopsy unit.

~~(2) Mammography interpretation fees of $100 per mammography examination provided to the department for the purpose of determining film diagnostic quality.~~

~~(3)~~ (2) Industrial and oncology accelerator registrants and electronic brachytherapy registrants shall pay for each inspection a fee of $900 for the first unit and $225 for each additional unit.

~~(4)~~ (3) Industrial radiography X-ray units/walk-in cabinet radiography X-ray unit registrants shall pay for each inspection a fee of $450 for the first unit and $130 for each additional unit.

ITEM 2. Rescind paragraph **38.8(1)"f."**

ITEM 3. Amend subrule 41.6(1) as follows:

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 × 10E-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, ~~xeromammography, and~~ 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 ~~image processor performance~~ 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 ~~(cassette holder assembly)~~ is angled 30-60 degrees from horizontal so that the ~~cassette assembly~~ detector system is parallel to the pectoral muscle and the corner of the ~~cassette holder~~ 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.

~~*"Supplier"* means the individual in control of a mammography facility whose basic responsibility is the overall quality of all mammograms conducted in that particular facility.~~

"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 ± 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.

ITEM 4. Amend paragraph **41.6(2)"b,"** introductory paragraph, as follows:

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

ITEM 5. Amend paragraphs **41.6(2)"f"** to **"i"** as follows:

f. ~~The authorization of facilities is included in the accreditation process for facilities accredited by the state of Iowa. Determination of the quality of the mammograms produced by facilities accredited by the state of Iowa will be made. To make the determination, each facility will:~~ An application for authorization shall be submitted to the department and processed for agency approval. A mammography authorization is effective for three years.

~~(1) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria for the clinical image review process by the agency:~~

~~1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly fatty breast tissue,~~

~~2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly glandular breast tissue, and~~

~~3. Each mammography examination must have been interpreted as a "negative" or "benign" examination.~~

~~(2) Provide randomly, at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2)*"f"*(1).~~

~~(3) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, a phantom image taken with the unit being accredited within six months of the submission date for review by the agency.~~

~~(4) Be billed the fee for the quality review process as set forth in 641—subparagraph 38.8(1)*"b"*(2).~~

~~(5) Be provided with a written explanation of the results of the quality review process which will accompany the returned mammograms referred to in 41.6(2)*"f"*(3).~~

g. ~~Facilities accredited by an approved accrediting body other than the state of Iowa must be authorized by the agency. Quality determination for these facilities will be made by the agency through a phantom image provided at the time of initial authorization, new unit authorization, or reauthorization (at least every three years) thereafter, taken with the unit being accredited within six months of the submission date.~~ A phantom image taken with the authorized unit(s) shall be reviewed at the time of annual inspection by the agency.

h. No change.

i. ~~Soft copy review workstation~~ Review workstation (RWS) requirements.

(1) ~~Soft copy review workstations~~ RWS used for final interpretation of mammogram images must ~~be a configuration of two monitors that meet one of~~ 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 ~~image receptor~~ mammography unit manufacturer's quality control manual ~~or that outlined by the image receptor~~, that outlined by the RWS monitor manufacturer's ~~designated soft copy review workstation~~ quality control manual or the quality control program outlined by an FDA-approved accrediting body.

ITEM 6. Amend subrule 41.6(3) as follows:

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. and 2. No change.

- 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. and 4. No change.

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 8 hours of Category 1 continuing medical education credits in the new mammographic modality or~~ at least ~~8~~ eight hours of training in the new mammographic modality ~~provided by a vendor manufacturing the new mammographic modality equipment~~. ~~An interpreting physician previously qualified to interpret a new mammographic modality in another state will have six months to complete this requirement. The six-month time frame begins when the interpreting physician commences Iowa new mammographic modality interpretation.~~

(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 ~~prior~~ 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 ~~previous~~ 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 ~~prior~~ 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 ~~previous~~ 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. ~~Continuing qualifications must be met and a~~ A current state of Iowa medical license must be in effect whenever mammography interpretations are performed by the physician.

(3) and (4) No change.

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 ~~at least a two-year~~ 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 ~~8~~ eight hours of continuing education units in the new modality. The ~~8~~ 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 ~~prior~~ 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 ~~previous~~ 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. ~~Continuing qualifications must be met and an~~ 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 ~~prior~~ 24 months immediately preceding the date of the facility's annual inspection, during the 24-month period ending on the last day of the ~~previous~~ 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.

~~3. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.~~

(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

~~4.~~ 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 the new mammographic modality before independently performing mammographic surveys of a new mammographic modality other than one for which the physicist received training to qualify under this subrule.~~ 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.

(3) and (4) No change.

d. No change.

ITEM 7. Amend paragraph **41.6(4)"f"** as follows:

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) to (5) No change.

~~(6) Cassette/screen identification.~~

~~(7)~~ (6) Mammography unit identification, if there is more than one unit in the facility.

ITEM 8. Amend subrule 41.6(5) as follows:

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) and (3) No change.

(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 ~~*"k."*~~ *"j."*

b. to *d.* No change.

e. Performance monitoring. The ~~supplier~~ facility shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored ~~for film-screen mammography~~ shall include ~~but not be limited to:~~ 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).

~~(1) Processor performance (through daily sensitometric-densitometric means).~~

~~(2) Half-value layer.~~

~~(3) Output reproducibility and linearity.~~

~~(4) Automatic exposure control reproducibility and linearity.~~

~~(5) Adequacy of film storage (both before use and after exposure if processing does not occur immediately).~~

~~(6) Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.~~

~~(7) Darkroom integrity, to be performed at least semiannually or when conditions have changed, shall include an inspection for light leaks, a fog test, and a safe light test.~~

~~(8) Image quality. The minimum image quality achieved at a mammography facility shall be the ability to observe the image of at least four 0.75-mm fibriles, three 0.32-mm speck groups, and three 0.75-mm masses from an FDA-approved phantom (or equivalent) on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.~~

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

~~(1) Processor performance shall be accomplished daily before processing patient films.~~

~~(2) Image quality shall be monitored at least weekly with a phantom and every time the unit is altered including the replacement of parts.~~

~~(3) All other parameters shall be proportional to the expected variability of each parameter, but at least annually.~~

g. Evaluation of monitoring results. ~~Full field digital~~ 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 ~~100 millirad for film-screen units with no grids, 300 millirad for film-screen units with grids, or~~ 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)~~*"k."* If the results fall outside the acceptable range, the test shall be repeated. For film-screen mammography, if the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted. For full field digital mammography, if~~ 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.* Retake analysis program—film-screen and full field digital.~~

~~(1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.~~

~~(2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first. If more than 250 mammograms are performed in one week, weekly analysis is acceptable.~~

~~(3) 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 reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.~~

~~*i.*~~ *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) to (3) No change.

~~*j.*~~ *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.

~~*k.*~~ *j.* Quality assurance—equipment.

(1) Daily, weekly, bi-weekly, monthly, quarterly, semiannual and annual 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 clinical films are processed 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.~~ 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.

~~1. The base plus fog density shall be below 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.~~

~~(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.~~

~~1. The optical density of the film at the center of an image of a standard FDA-accepted 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 phantom image shall achieve at least the minimum score established by the accreditation body and accepted by the FDA.~~

~~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.~~

~~(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:~~

~~● Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeter.~~

~~(4) 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 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the countertop 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 maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 45 pounds (200 newtons).~~

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

1. Automatic exposure control (AEC) performance.

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

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

2. kVp accuracy and reproducibility.

● The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.

● 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 condition. Facilities shall evaluate focal spot condition only by determining the system resolution.

● 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/millimeters (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.

● The bar pattern shall be placed 4.5 centimeters 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 centimeter of the chest wall edge of the image receptor.

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

● When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.

● 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.

● Focal spot dimensions. 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 tolerance limits specified in Table 1.

Table 1

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. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50	
Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
20	0.20
25	0.25
30	0.30

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

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3 rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

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

- 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 ensure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.
- The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1 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 be not be visible on the image.

8. 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.

9. 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.

10. Radiation output.

- The system shall be capable of producing a minimum output of 800 milliRoentgen (mR) per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector.
- The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. 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:

- An override capability to allow maintenance of compression;
- A continuous display of the override status; and
- A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) 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 41.6(5)*"k"*(5)"6."

(7) Use of test results.

~~1. After completion of the tests specified in 41.6(5)*"k,"* the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-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 the action limits, the source of the problem shall be identified, and corrective actions shall be taken 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 41.6(5)*"k."*~~

~~3. Full field digital unit corrective actions shall be made as prescribed in the appropriate manufacturer's quality control manual or in accordance with the appropriate FDA-approved alternative requirements.~~

~~(8)~~ (2) Surveys.

1. At least ~~once a year~~ annually, 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 41.6(5)*"k"*(5) and (6), the weekly phantom image quality test described in 41.6(5)*"k"*(2) and the quarterly retake analysis results described in 41.6(5)*"k."*~~ 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 all tests conducted by the facility in accordance with 41.6(5)*"k"*(1) through (7) for film-screen units, 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. Surveys of full field digital mammography units shall be conducted as described in the appropriate manufacturer's quality control manual. 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.

~~(9)~~ (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 ~~or film processing~~. 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.

~~(10) Facility cleanliness.~~

~~1. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and viewbox cleanliness.~~

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

~~(11)~~ (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.

~~(12)~~ (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.

~~*l.*~~ *k.* Mammography procedures and techniques for mammography of patients with breast implants.

(1) and (2) No change.

~~*m.*~~ *l.* Consumer complaint mechanism. Each facility shall:

(1) to (4) No change.

~~*n.*~~ *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.

~~*o.*~~ *n.* Additional mammography review and patient notification.

(1) and (2) No change.

ITEM 9. Amend subrule 41.6(6) as follows:

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

a. and *b.* No change.

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.

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

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

~~(3)~~ (2) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

d. to *f.* No change.

~~*g.* Film/screen contact: Shall check film/screen contact when cassettes are first placed into use and semiannually thereafter.~~

~~*h.*~~ *g.* Focal spot: The focal spot size, magnification factor and source to image receptor distance (SID) shall be appropriate for mammography. ~~and in the ranges shown below:~~

~~SID~~	~~Nominal Focal Spot Size~~
~~> 65 cm~~	~~< or = to 0.6 mm~~
~~50 to 65 cm~~	~~< or = to 0.5 mm~~
~~< 50 cm~~	~~< or = to 0.4 mm~~

(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.

~~*i.*~~ *h.* Compression devices: Shall have compression devices ~~parallel to the imaging plane and~~ 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. ~~Effective October 28, 2002, each~~ 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)*"i"*(6)~~ 41.6(6)*"h"*(6) and (7).

(4) Except as provided in ~~41.6(6)*"i"*(5),~~ 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 ~~be bent upward to~~ allow for patient comfort but shall not appear on the image.

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

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

~~(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)~~ (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.

~~(3)~~ (2) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

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

(1) to (5) No change.

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

~~*n. Viewboxes: Shall have a viewbox that is checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.*~~

~~*o. X-ray film: Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.*~~

~~*p. Intensifying screens: Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.*~~

~~*q. Chemicals: Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.*~~

~~*r. Hot-lights: Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.*~~

~~*s.* Masking devices: 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.~~

~~*t.* Mobile units and vans—film-screen.~~

~~(1) A phantom image shall be produced, processed, and evaluated after each relocation and prior to examinations being conducted.~~

~~(2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be recalibrated as necessary to maintain quality of phantom image.~~

~~*u.*~~ *m.* Mobile units and vans~~—full field digital~~. Appropriate manufacturer's quality control manual procedures and criteria shall be met.

ITEM 10. Amend paragraph **41.6(7)"e"** as follows:

e. Records of all ~~inspections,~~ inspection reports~~,~~ and ~~consultations~~ medical physicist surveys shall be maintained for at least seven years.

~~Mo/Mo Target Filter X-Ray Voltage (kVp)~~												~~W/Al Target Filter Combination~~
~~HVL~~	~~23~~	~~24~~	~~25~~	~~26~~	~~27~~	~~28~~	~~29~~	~~30~~	~~31~~	~~32~~	~~33~~	
~~0.23~~	~~109~~											
~~0.24~~	~~113~~	~~116~~										
~~0.25~~	~~117~~	~~120~~	~~122~~									
~~0.26~~	~~121~~	~~124~~	~~126~~	~~128~~								
~~0.27~~	~~126~~	~~128~~	~~130~~	~~132~~	~~134~~							
~~0.28~~	~~130~~	~~132~~	~~134~~	~~136~~	~~138~~	~~139~~						
~~0.29~~	~~135~~	~~137~~	~~139~~	~~141~~	~~142~~	~~143~~	~~144~~					
~~0.30~~	~~139~~	~~141~~	~~143~~	~~145~~	~~146~~	~~147~~	~~148~~	~~149~~				~~170~~
~~0.31~~	~~144~~	~~146~~	~~147~~	~~149~~	~~150~~	~~151~~	~~152~~	~~153~~	~~154~~			~~175~~
~~0.32~~	~~148~~	~~150~~	~~151~~	~~153~~	~~154~~	~~155~~	~~156~~	~~158~~	~~159~~	~~160~~	~~160~~	~~180~~
~~0.33~~	~~153~~	~~154~~	~~155~~	~~157~~	~~158~~	~~159~~	~~160~~	~~162~~	~~163~~	~~164~~	~~164~~	~~185~~
~~0.34~~	~~157~~	~~159~~	~~160~~	~~161~~	~~162~~	~~163~~	~~164~~	~~166~~	~~167~~	~~168~~	~~168~~	~~190~~
~~0.35~~		~~163~~	~~164~~	~~166~~	~~167~~	~~168~~	~~169~~	~~170~~	~~171~~	~~172~~	~~172~~	~~194~~
~~0.36~~			~~168~~	~~170~~	~~171~~	~~172~~	~~173~~	~~174~~	~~175~~	~~176~~	~~176~~	~~199~~
~~0.37~~				~~174~~	~~175~~	~~176~~	~~177~~	~~178~~	~~178~~	~~179~~	~~180~~	~~204~~
~~0.38~~					~~179~~	~~180~~	~~181~~	~~182~~	~~182~~	~~183~~	~~184~~	~~208~~
~~0.39~~						~~184~~	~~185~~	~~186~~	~~186~~	~~187~~	~~188~~	~~213~~
~~0.40~~							~~189~~	~~190~~	~~191~~	~~192~~	~~192~~	~~217~~
~~0.41~~								~~194~~	~~195~~	~~196~~	~~196~~	~~221~~
~~0.42~~										~~200~~	~~200~~	~~225~~
~~0.43~~											~~204~~	~~230~~
~~0.44~~												~~234~~
~~0.45~~												~~238~~

~~To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo Target Filter system at 30 kVp with a measured HVL of 0.36-mm aluminum yields an average glandular dose of (0.50 R) × (174 mrad/R) = 87 mrad or 0.87 mGy.~~

~~*Wu X. Breast dosimetry in screen-film mammography. In: Barnes GT, Frey GD (eds), Screen film mammography: Imaging considerations and medical physics responsibilities. Madison, WI: Medical Physics Publishing; 159-175, 1991. W/Al conversion factors are derived from fits to data from Stanton L et al. Dosage evaluation in mammography. Radiology 1984; 150:577-584.~~

ITEM 11. Amend rule 641—41.6(136C), Appendix II, as follows:

Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
~~4.5-cm~~ 4.2 cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue*

ITEM 12. Adopt the following **new** definitions of "Phantom" and "Stereotactic training phantom" in subrule **41.7(1)**:

"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.

"Stereotactic training phantom" means a training or practice tool or medium used for stereotactically guided breast biopsy procedures.

ITEM 13. Amend subrule 41.7(3) as follows:

41.7(3) *Physicians.* Physicians must be qualified according to the setting and their role in performing stereotactically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) No change.

(2) Maintenance of proficiency and CME requirements.

1. ~~Perform at least 12 stereotactically guided breast biopsies per year.~~ Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following, and demonstration of the chosen combination needs to be clearly documented:

- Stereotactic breast biopsy procedures.
- Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
- Stereotactic breast biopsy case review, which must be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.
- Mammographic-guided, stereotactic-guided, or both, wire localization procedures.
- Ultrasound-guided breast biopsy procedures.
- MRI-guided breast biopsy procedures.

If experience is not maintained, the physician must requalify by performing ~~3~~ three procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. ~~Obtain~~ Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME or three hours of training approved by the agency in ~~stereotactically guided~~ stereotactic-guided breast biopsy ~~every~~ during the 36 months immediately preceding the date of the facility's annual stereotactic biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. ~~Continuing qualifications must be met and a~~ A current state of Iowa medical license must be in effect whenever procedures are performed independently by the physician.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) No change.

(2) Maintenance of proficiency and CME requirements.

1. ~~Perform or participate in at least 12 stereotactically guided breast biopsies per year or~~ Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of the chosen combination needs to be clearly documented:

- Stereotactic breast biopsy procedures.
- Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
- Stereotactic breast biopsy case review, which must be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.
- Mammographic-guided, stereotactic-guided, or both, wire localization procedures.
- Ultrasound-guided breast biopsy procedures.
- MRI-guided breast biopsy procedures.

If experience is not maintained, the physician must requalify by performing ~~3~~ three procedures under direct supervision of a qualified training physician or an agency–approved manufacturer applications specialist before resuming unsupervised procedures.

2. ~~Obtain~~ Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME ~~or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months~~ immediately preceding the date of the facility's annual stereotactic biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. ~~Continuing qualifications must be met and a~~ A current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

c. Requirements for a radiologist performing stereotactically guided breast biopsy independently are as follows:

(1) No change.

(2) Maintenance of proficiency and CME requirements.

1. ~~Perform at least 12 stereotactically guided breast biopsies per year or~~ Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of the chosen combination needs to be clearly documented:

- Stereotactic breast biopsy procedures.
- Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
- Stereotactic breast biopsy case review, which must be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.
- Mammographic-guided, stereotactic-guided, or both, wire localization procedures.
- Ultrasound-guided breast biopsy procedures.
- MRI-guided breast biopsy procedures.

If experience is not maintained, the physician must requalify by performing ~~3~~ three procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. ~~Obtain~~ Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME ~~or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months~~ immediately preceding the date of the facility's annual stereotactic biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection which includes post-biopsy management of the patient. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. ~~Continuing qualifications must be met and a~~ A current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3)*"c"*) performing stereotactically guided breast biopsy independently are as follows:

(1) No change.

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least 480 mammograms every 24 months in consultation with a physician who is qualified according to 41.6(3)*"a."*

2. ~~Perform at least 12 stereotactically guided breast biopsies per year or~~ Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of the chosen combination needs to be clearly documented:

- Stereotactic breast biopsy procedures.
- Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
- Stereotactic breast biopsy case review, which must be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic positioning, biopsy needle pre-fire and post-fire positioning and targeting, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.
- Mammographic-guided, stereotactic-guided, or both, wire localization procedures.
- Ultrasound-guided breast biopsy procedures.
- MRI-guided breast biopsy procedures.

If experience is not maintained, the physician must requalify by performing ~~3~~ three procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

3. ~~Obtain~~ Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME ~~or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months~~ immediately preceding the date of the facility's annual stereotactic biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. The CME credits for requalification cannot be obtained by performing procedures.

4. ~~Continuing qualifications must be met and a~~ A current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

ITEM 14. Amend subrule 41.7(5) as follows:

41.7(5) *Radiologic technologist.*

a. Must be qualified according to 41.6(3)*"b."*

b. Must meet the following initial requirements:

(1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a physician or technologist qualified under rule 641—41.7(136C).

(2) Three contact hours ~~of continuing education~~ in stereotactically guided breast biopsy. ~~The required continuing education cannot be obtained through the performance of supervised stereotactically guided breast biopsy procedures.~~

c. Maintenance of proficiency and continuing education and experience requirements.

(1) Following the first anniversary in which the requirements of this subrule were met, ~~have performed at least 12 stereotactically guided breast biopsies per year or~~ completion of a total of 12 breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of the chosen combination needs to be clearly documented:

1. Stereotactic breast biopsy procedures.
2. Stereotactic biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
3. Stereotactic breast biopsy case review, must be documented to include a review of pre-biopsy mammographic examination, scout and stereotactic images, biopsy needle pre-fire and post-fire images, specimen radiograph images, post-biopsy images and review of post-biopsy pathology results.
4. Mammographic-guided, stereotactic-guided, or both, wire localization procedures.
5. Ultrasound-guided breast biopsy procedures.
6. MRI-guided breast biopsy procedures.

If experience is not maintained, the radiologic technologist must requalify by performing ~~3~~ three stereotactically guided breast biopsies under the supervision of a physician or radiologic technologist qualified under 41.7(3) or 41.7(5).

(2) Following the third anniversary in which the requirements of this subrule were met, ~~have~~ obtain at least three hours of continuing education in stereotactically guided breast biopsy ~~system physics~~ during the ~~previous~~ 36 months immediately preceding the date of the facility's annual stereotactic biopsy inspection, or during the 36-month period ending on the last day of the calendar quarter preceding the inspection, or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months. The CMEs cannot be obtained by the performance of supervised procedures.

(3) If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures during the prior 24 months~~.~~ immediately preceding the date of the facility's annual stereotactic biopsy inspection, during the 24-month period ending on the last day of the previous calendar quarter, or any 24-month period between the two. In this case, all requirements for radiologic technologists must be met with the exception of 41.6(3)*"b"*(4)"1."

(4) Only 50 percent of the total required stereotactic continuing education hours may be obtained through presenting or acting as a trainer for a continuing education or training program.

(5) An Iowa permit to practice radiography must be in effect whenever stereotactic procedures are performed by the radiologic technologist.

ITEM 15. Amend subparagraph **41.7(7)"d"(1)** as follows:

(1) Conducting equipment performance monitoring functions, initially and then at least annually, to include:

1. Evaluation of biopsy unit assembly. Any failed items must be corrected within 30 days of the survey unless the medical physicist deems that the failure poses a serious injury risk to the patient, at which time the failure needs to be corrected before further procedures are performed.
2. Collimation.

- ~~Digital —~~X-ray field must not extend beyond the image receptor by more than 5 mm on any side.
- ~~Film-screen – On all sides other than the chest wall side, the X-ray field must be within the image receptor. The chest wall side must not extend beyond the image receptor by more than 2 percent.~~
- Any failures must be corrected within 30 days of the survey.

3. Evaluation of focal spot.

- ~~Digital —~~Focal spot must not degrade from initial measurement. If reduction in lp/mm is found, focal spot must be corrected within 30 days of survey.
- ~~Film-screen—Film-screen must show 13 lp/mm parallel to the anode-cathode axis and 11 lp/mm perpendicular to the anode-cathode axis. Failure to meet the performance criteria must be corrected within 30 days of survey.~~

4. kVp accuracy/reproducibility. kVp accuracy/reproducibility must be accurate to within +/- 5% of nominal kVp setting. Failures must be corrected before further procedures are performed.

5. Half-value layer measurement. HVL shall be greater than kVp/100 (in units of mm Al). Failures must be corrected before further procedures are performed.

6. Exposure reproducibility. Exposure must be reproducible to within +/- 15% of mean exposure. Failures must be corrected before further procedures are performed.

7. Breast entrance exposure, average glandular dose. Average glandular dose must be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose ~~4.5~~ 4.2 centimeter breast. Failures must be corrected before further procedures are performed.

8. Image quality evaluation.

- ~~Digital —~~Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.
- ~~Film-screen—Phantom image must meet the criteria of 4 fibers, 3 speck groups and 3 masses for the ACR phantom or 2 fibers, 2 speck groups and 2 masses for the mini phantom unless otherwise stated by the phantom manufacturer. The background density must be within +/- .20 of the established aim, and the density differences must be within +/- .05 of the established aim.~~
- Failures must be corrected before further procedures are performed.

9. Artifact evaluation. Any significant black or white artifacts seen in the image detector field must be corrected within 30 days of the survey.

10. Digital field uniformity. For units with region of interest (ROI) capability, the SNR in each corner must be within +/- 15% of the SNR in the center. Failures must be corrected within 30 days of the survey.

11. Localization simulation (gelatin phantom) test. Localization accuracy must be within 1 mm of target, and the test must include a portion of the test "lesion" in the sample chamber. Failures must be corrected before further procedures are performed.

ITEM 16. Amend subrule 41.7(9) as follows:

41.7(9) *Safety standards.*

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 wear personnel monitors to monitor their radiation exposure.~~

~~*c.*~~ *b.* Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

~~*d.*~~ *c.* Equipment shall be shockproof and grounded to protect against electrical hazards.

~~*e.*~~ *d.* Records of all ~~inspections,~~ inspection reports and ~~consultations~~ medical physicist surveys shall be maintained for at least seven years.