Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 41
"Registration and Safety Requirements for Mammography and Stereotactic Breast Biopsy"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 136C and 21 CFR Part 900
State or federal law(s) implemented by the rulemaking: Iowa Code chapter 136C

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 4, 2025 10 a.m.	Microsoft Teams Meeting ID: 256 572 060 444 0 Passcode: SG2Vc96j

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed chapter is one of eight chapters pertaining to radiologic health matters regulated by the Department. This proposed chapter and the seven others underwent a fulsome review as a part of the Red Tape Review process laid out in Executive Order 10. As a result of this review, restrictive terms were removed, areas that were duplicative were combined or eliminated, and editorial updates were made to processes and procedures to ensure they reflect current policies and procedures. This proposed chapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department. Unless otherwise exempted, the provisions of this proposed chapter apply to and provide regulatory guidance to all persons who receive, possess, use, transfer, own, or acquire any source of radiation.

Analysis of Impact

1. **Persons affected by the proposed rulemaking:**

- **Classes of persons that will bear the costs of the proposed rulemaking:**

Individuals and health care facilities seeking registration and credentialing for mammography and stereotactic breast biopsy must pay the fees laid out in this proposed chapter.

- **Classes of persons that will benefit from the proposed rulemaking:**

This proposed rulemaking will benefit those seeking professional services from certified mammography and stereotactic breast biopsy professionals.

2. **Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:**

- **Quantitative description of impact:**

No quantitative impact is expected and no changes to applicable fees have been made.

- **Qualitative description of impact:**

This proposed chapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department.

3. **Costs to the State:**

- **Implementation and enforcement costs borne by the agency or any other agency:**

Enforcement costs are offset by the fees collected from those seeking credentialing as a certified mammography and stereotactic breast biopsy professional.

- **Anticipated effect on State revenues:**

This rulemaking is not expected to have any impact on State revenues.

4. **Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:**

Registration and safety requirements for mammography and stereotactic breast biopsy is required by Iowa Code chapter 136C.

5. **Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:**

Not applicable.

6. **Alternative methods considered by the agency:**

- **Description of any alternative methods that were seriously considered by the agency:**

Not applicable.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

Not applicable.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

This proposed rulemaking is not expected to have an impact on small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 641—Chapter 41 and adopt the following **new** chapter in lieu thereof:

CHAPTER 41
REGISTRATION AND SAFETY REQUIREMENTS FOR MAMMOGRAPHY AND STEREOTACTIC BREAST BIOPSY

641—41.1(136C) Registration and safety requirements for mammography and stereotactic breast biopsy. The following provisions of 21 CFR 900 as amended to August 1, 2025, for mammography are hereby adopted by reference:

41.1(1) 21 CFR 900.2 Definitions.

41.1(2) 21 CFR 900 Subpart B—Quality Standards and Certification.

641—41.2(136C) Definitions. The definitions contained in 21 CFR 900.2, as adopted by reference, apply to the mammography provisions of this chapter. The definitions provided in 641—Chapters 37 and 40 may also apply. Additionally, the definitions set forth below are specific to this chapter.

"Annually" means within 10 to 14 months of previous occurrence.

"Authorization" means the same as defined in 641—Chapter 37.

"Collaborative setting" means a setting in which a qualified radiologist and surgeon are working together in consultation and in performing stereotactically guided breast biopsies with a common goal of the patient's benefit.

"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.

"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.

"Iowa-approved" means recognized or accepted by the department as meeting the training and experience requirements established by MQSA and any additional criteria set forth in this chapter. This may include but is not limited to formal approval by the department based on documentation of education, training, certification, and clinical experience.

"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.

"Procedure" means a stereotactically guided breast biopsy performed on a patient for diagnostic purposes.

"Qualified training physician" means a physician who is qualified under the rules of this chapter to perform stereotactically guided breast biopsies and who has performed at least 24 procedures.

"Radiologic technologist" means the same as defined in 21 CFR 900.2 and also includes the definition of "general radiologic technologist" as set forth in 641—Chapter 38.

"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.

"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.

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

"Stereotactically guided breast biopsy" means a breast biopsy procedure performed with the utilization of a dedicated system that emits ionizing radiation and is designed specifically for that procedure.

"Supervising physician" means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and
2. Establish and conduct the quality assurance program.

641—41.3(136C) General provisions for mammography. All Iowa mammography facilities and personnel shall comply with the applicable regulations of 21 CFR 900 as adopted in rule 641—41.1(136C). In addition, compliance with the requirements of 641—Chapters 37 and 40 and the rules contained herein are required. Where differences exist, compliance with the most stringent applicable standard, whether CFR regulations or the Iowa Administrative Code, applies.

641—41.4(136C) Mammography registration, certification, and general requirements. In addition to the rules of this chapter, mammography facilities shall comply with the requirements of 21 CFR 900.11.

41.4(1) *Registration and certificates.* Each radiation machine used to perform mammography shall be registered according to 641—subrule 37.8(2).

a. A certificate issued by the FDA or this department 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 department, facilities are required to meet the quality standards of this chapter 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 department-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 (within 10 to 14 months of previous occurrence) by a medical physicist.

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

41.4(2) *Inspections.* After initial mammography certification, the department will conduct an inspection of each radiation machine no later than every 14 months thereafter.

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

b. A phantom image taken with the authorized unit(s) will be reviewed at the time of annual inspection by the department.

41.4(3) *Review workstation (RWS) requirements.* RWS used for final interpretation of mammogram images shall meet the following criteria:

a. Have 5 megapixel resolution; or

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

c. The workstation shall 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.

641—41.5(136C) Mammography personnel. In addition to the rules of this chapter, mammography personnel shall comply with the requirements of 21 CFR 900.12. 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.

41.5(1) *Interpreting physicians.* All radiologists interpreting mammograms shall comply with the requirements of 21 CFR 900.12(a)(1) and meet the following qualifications before beginning to interpret mammography independently, unless the exemptions in 21 CFR 900.12(a)(1)(iii)(A) apply.

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

b. Mammography personnel who fail to meet continuing education or experience requirements may requalify once without providing proof of extenuating circumstances. The department will assess any submitted proof and make a determination after reviewing all relevant information. If requalification is denied, individuals may reapply after a 90-day waiting period following the date of expiration.

41.5(2) *Radiologic technologists.* All general radiographers performing mammographic examinations shall comply with the requirements of 21 CFR 900.12(a)(2) and meet the following requirements:

a. A current state of Iowa permit to practice as a general radiologic technologist shall be in effect whenever all mammographic examinations are performed by the radiologic technologist.

b. Mammography personnel who fail to meet continuing education or experience requirements may requalify once without providing proof of extenuating circumstances. The department will assess any submitted proof and make a determination after reviewing all relevant information. If requalification is denied, individuals may reapply after a 90-day waiting period following the date of expiration.

41.5(3) *Medical physicists.* All medical physicists providing any of the following mammography services shall comply with the requirements of 21 CFR 900.12(a)(3).

a. Health physics consultations or surveys of mammography equipment.

b. Health physics consultations or surveys of mammography reading workstations.

c. Oversight of the mammography facility's quality assurance program.

d. Additional mammography services as deemed appropriate by the department.

e. All medical physicists providing mammography surveys as outlined in this chapter must, at the time of the survey(s), be Iowa-approved as defined in this chapter.

f. Medical physicists that are Iowa-approved for mammography may perform only the mammography services outlined in this chapter.

g. Medical physicists wishing to perform services other than those outlined in this chapter must be registered with the department, under the provisions of 641—Chapter 37, as a radiation machine service provider, whether as an individual, as part of a corporation, or any other entity included in the definition of "person" in 641—Chapter 37.

h. A medical physicist cannot perform any services, including those related to mammography modalities, unless such services are specifically listed on the Iowa approval notice or radiation machine service provider notice issued by the department.

641—41.6(136C) Retention of personnel records for mammography. Mammography facilities shall comply with the retention of personnel records requirements of 21 CFR 900.12(a)(4).

641—41.7(136C) Equipment and safety requirements for mammography. Mammography facilities shall comply with the equipment requirements of 21 CFR 900.12(b).

641—41.8(136C) Medical records and reports for mammography. Mammography facilities shall comply with the requirements for medical records and mammography reports of 21 CFR 900.12(c) and of this chapter.

641—41.9(136C) Contents and terminology for mammography. Mammography facilities shall comply with the contents and terminology requirements of 21 CFR 900.12(c)(1) and this chapter.

41.9(1) A separate and distinct section entitled "Assessment" with the appropriate assessment term or an approved equivalent shall be included.

41.9(2) The breast density information as designated in the report pursuant to this chapter 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.

41.9(3) Mammography facilities shall comply with the requirements for the communication of mammography results to patients found in 21 CFR 900.12(c)(2).

41.9(4) Mammography facilities shall comply with the requirements for the communication of mammography results to health care providers found in 21 CFR 900.12(c)(3).

41.9(5) Mammography facilities shall comply with the recordkeeping requirements of 21 CFR 900.12(c)(4) and 641—subrule 37.12(2). Facilities performing mammography shall maintain mammography records for a minimum of seven years.

41.9(6) Mammography facilities shall comply with the mammographic image identification requirements of 21 CFR 900.12(c)(5).

641—41.10(136C) Quality assurance for mammography. Mammography facilities shall comply with the quality assurance requirements of 21 CFR 900.12(d), 21 CFR 900.12(e), 21 CFR 900.12(f) and the requirements of this chapter.

41.10(1) Mammography facilities shall comply with the general quality assurance requirements of 21 CFR 900.12(d).

a. Mammography facilities shall comply with the requirements of responsible individuals found in 21 CFR 900.12(d)(1).

b. Mammography facilities shall comply with the quality assurance records requirements of 21 CFR 900.12(d)(2).

c. Mammography facilities shall comply with the equipment quality assurance requirements of 21 CFR 900.12(e).

d. Mammography facilities shall comply with the quality control test requirements of 21 CFR 900.12(e)(1) through 21 CFR 900.12(e)(6).

e. Mammography facilities shall comply with the mobile unit requirements of 21 CFR 900.12(e)(7).

f. Mammography facilities shall comply with the use of test results requirements of 21 CFR 900.12(e)(8).

g. Mammography facilities shall comply with the survey requirements of 21 CFR 900.12(e)(9).

h. Mammography facilities shall comply with the mammography equipment evaluation requirements of 21 CFR 900.12(e)(10).

i. Mammography facilities shall comply with the facility cleanliness requirements of 21 CFR 900.12(e)(11).

j. Mammography facilities shall comply with the calibration of air kerma measuring instrument requirements of 21 CFR 900.12(e)(12).

k. Mammography facilities shall comply with the infection control requirements of 21 CFR 900.12(e)(13).

l. Mammography facilities shall comply with the mammography medical outcomes audit quality assurance requirements of 21 CFR 900.12(f).

m. Mammography facilities shall comply with the mammographic procedure and techniques for mammography of patients with breast implant requirements of 21 CFR 900.12(g).

n. Mammography facilities shall comply with the consumer compliant mechanism requirements of 21 CFR 900.12(h).

o. Mammography facilities shall comply with the clinical image quality requirements of 21 CFR 900.12(i).

p. Mammography facilities shall comply with the mammography review and patient and referring provider notification requirements of 21 CFR 900.12(j).

41.10(2) Reserved.

641—41.11(136C) Revocation, suspension, reinstatement and appeals for mammography.

41.11(1) *Revocation of accreditation and revocation of accreditation body approval.* Mammography facilities shall comply with the revocation of accreditation and revocation of accreditation body approval requirements of 21 CFR 900.13.

41.11(2) *Suspension or revocation of certificates.* Mammography facilities shall comply with the suspension or revocation of certificate requirements of 21 CFR 900.14.

a. If certification is revoked, the radiation machine cannot be used for mammography until reinstated.

b. If suspension or revocation of a certificate is initiated, the administrative enforcement actions specified in rule 641—37.10(136C) shall apply.

41.11(3) *Reinstatement of mammography certification or authorization after revocation.*

a. An application for reinstatement shall be submitted and processed as an initial application. Appropriate corrective actions shall be submitted with the application.

b. A full certificate shall be issued only after the department has determined the radiation machine meets the requirements of these rules.

41.11(4) *Appeals.*

a. Mammography facilities shall comply with the appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification requirements of 21 CFR 900.15.

b. Mammography facilities shall comply with the appeals of denials of certification requirements of 21 CFR 900.16 and rule 641—37.10(136C).

641—41.12(136C) Alternative requirements for quality standards for mammography. Mammography facilities may also comply with the alternative quality standard requirements of 21 CFR 900.12 and 21 CFR 900.18.

641—41.13(136C) General provisions for stereotactic breast biopsy. All Iowa facilities and persons certified to perform stereotactic breast biopsies shall comply with the applicable requirements of this chapter and the applicable provisions in 641—Chapters 37 and 40.

641—41.14(136C) Registration and application standards and requirements for stereotactic breast biopsy. Each radiation machine used to perform stereotactically guided breast biopsies shall be registered according to the requirements set forth in 641—subrule 37.8(2).

41.14(1) Each facility wishing to perform stereotactically guided breast biopsies shall apply to the department for authorization by providing or verifying the following information for each machine:

a. The stereotactically guided breast biopsy equipment and facility meet the general requirements of the rules for radiation machines.

b. The radiation machine is specifically designed to perform stereotactically guided breast biopsies.

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

d. The radiation machine is operated by individuals meeting the requirements of this rule.

e. The entire stereotactically guided breast biopsy system is evaluated annually by a medical physicist who meets the requirements of this rule.

f. The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

41.14(2) The department will conduct an inspection of each radiation machine no later than 14 months after initial authorization and at least annually thereafter.

641—41.15(136C) Requirements for physicians performing stereotactic breast biopsy. Physicians shall be qualified according to the setting and their role in performing stereotactically guided breast biopsies.

41.15(1) *Requirements for stereotactic breast biopsies for radiologists in collaborative settings.*

a. Initial training and qualifications for radiologists in collaborative settings.

(1) Radiologists shall be qualified according to the rules of this chapter.

(2) Radiologists shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsies under a physician who is qualified under the conditions laid out in this chapter and has performed at least 24 stereotactically guided breast biopsies.

(3) Radiologists shall have at least three hours of Category 1 continuing medical education (CME) or three hours of training approved by the department in stereotactically guided breast biopsy.

(4) Radiologists shall be responsible for mammographic interpretation and be experienced in the specific recommendations for each biopsy and lesion identification at time of each biopsy performed by that physician.

(5) Radiologists shall be responsible for the supervision of the radiologic technologist during the procedure.

b. Maintenance of continuing experience and CME requirements for radiologists performing stereotactic breast biopsy in collaborative settings.

(1) Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures shall be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining six procedures must be clearly documented and can be any combination of the following:

1. Stereotactic breast biopsy procedures.
2. Stereotactic breast biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
3. Stereotactic breast biopsy case review, which shall 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.
4. Image guided breast biopsy or localization procedures utilizing mammography, stereotactic, ultrasound, MRI guidance, or any other department-approved image guided technique.
5. If experience is not maintained, the physician shall requalify by performing three procedures under direct supervision of a qualified training physician or a department-approved manufacturer applications specialist before resuming unsupervised procedures.

(2) 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 department in stereotactic-guided breast biopsy during the 36 months immediately preceding the date of the facility's annual stereotactic breast 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 shall 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) A current state of Iowa medical license shall be in effect whenever procedures are performed independently by the physician.

41.15(2) *Physician requirements for stereotactic breast biopsy in a collaborative setting (nonradiologists).*

a. Initial training and qualifications for physicians in a collaborative setting (nonradiologists):

(1) Physicians shall be licensed to practice medicine in Iowa.

(2) Physicians shall have at least three hours of Category 1 CME or three hours of training approved by the department in stereotactically guided breast biopsy.

(3) Physicians shall have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified to perform stereotactic breast biopsy procedures according to the rules of this chapter and has performed at least 24 stereotactically guided breast biopsies.

(4) Physicians shall be responsible for post-biopsy management of the patient.

(5) Physicians shall be responsible for supervision of the radiologic technologist during the procedure.

b. Maintenance of continuing experience and CME requirements for physicians performing stereotactic breast biopsy in collaborative settings (nonradiologists):

(1) Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures shall be met for each calendar year, with at least 6 being stereotactic breast biopsies. The remaining six procedures must be clearly documented and can be any combination of the following:

1. Stereotactic breast biopsy procedures.
2. Stereotactic breast biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
3. Stereotactic breast biopsy case review, that shall 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.
4. Image guided breast biopsy or localization procedures utilizing mammography, stereotactic, ultrasound, MRI guidance, or any other department-approved image guided technique.
5. If experience is not maintained, the physician shall requalify by performing three procedures under direct supervision of a qualified training physician or a department–approved manufacturer applications specialist before resuming unsupervised procedures.

(2) Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME immediately preceding the date of the facility's annual stereotactic breast 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 shall 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) A current state of Iowa medical license shall be in effect whenever unsupervised procedures are performed by the physician.

41.15(3) *Requirements for stereotactic breast biopsy for radiologists in an independent setting.*

a. Initial training and requirements for radiologists in an independent setting.

(1) Radiologists shall be qualified according to the rules of this chapter.

(2) Radiologists shall have at least three hours of Category 1 CME or three hours of training approved by the department in stereotactically guided breast biopsy.

(3) Radiologists shall obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

(4) Radiologists shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to the rules of this chapter, and has performed at least 24 stereotactically guided breast biopsies.

(5) Radiologists shall be responsible for mammographic interpretation.

(6) Radiologists shall be responsible for patient selection.

(7) Radiologists shall be responsible for the supervision of the radiologic technologist during the procedure.

(8) Radiologists shall be responsible for post-biopsy management of the patient, which may include referral to a surgeon for a follow-up on certain lesions.

b. Maintenance of continuing experience and CME requirements for radiologists performing stereotactic breast biopsy in an independent setting.

(1) Following the first anniversary in which the requirements of this subrule were met, completion of a total of 12 breast biopsy procedures in each calendar year, with at least 6 being stereotactic breast biopsies. The remaining six procedures must be clearly documented and can be any combination of the following:

1. Stereotactic breast biopsy procedures.
2. Stereotactic breast biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
3. Stereotactic breast biopsy case review, that shall 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.
4. Image-guided breast biopsy or localization procedures utilizing mammography, stereotactic, ultrasound, MRI guidance, or any other department-approved image guided technique.
5. If experience is not maintained, the physician shall requalify by performing three procedures under direct supervision of a qualified training physician or a department-approved manufacturer applications specialist before resuming unsupervised procedures.

(2) Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME immediately preceding the date of the facility's annual stereotactic breast 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 shall 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) A current state of Iowa medical license shall be in effect whenever unsupervised procedures are performed by the physician.

41.15(4) *Physician requirements for performing stereotactic breast biopsy in an independent setting (nonradiologist).*

a. Initial training and requirements for physicians performing stereotactic breast biopsy in an independent setting (nonradiologist).

(1) Physicians shall have evaluated at least 480 mammograms in the prior 24 months in consultation with a qualified physician.

(2) Physicians shall have at least 15 hours of Category 1 CME or 15 hours of training approved by the department in stereotactically guided breast imaging and biopsy or three years' experience having performed at least 36 stereotactically guided breast biopsies.

(3) Physicians shall have four hours of Category 1 CME in medical radiation physics.

(4) Physicians shall have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to this chapter, and has performed at least 24 stereotactically guided breast biopsies.

(5) Physicians shall be responsible for patient selection.

(6) Physicians shall be responsible for the supervision of the radiologic technologist during the procedure.

(7) Shall be responsible for post-biopsy management of the patient.

b. Maintenance of continuing experience and CME requirements for physicians performing stereotactic breast biopsy in an independent setting.

(1) Physicians shall continue to evaluate at least 480 mammograms every 24 months in consultation with a qualified physician.

(2) Physicians shall complete a total of 12 breast biopsy procedures in each calendar year with at least 6 being stereotactic breast biopsies. The remaining six procedures must be clearly documented and can be any combination of the following:

1. Stereotactic breast biopsy procedures.
2. Stereotactic breast biopsy of a stereotactic training phantom with documentation of steps taken or a written report.
3. Stereotactic breast biopsy case review, that shall 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.
4. Image-guided breast biopsy or localization procedures utilizing mammography, stereotactic, ultrasound, MRI guidance, or any other department-approved image guided technique.
5. If experience is not maintained, the physician shall requalify by performing three procedures under direct supervision of a qualified training physician or a department-approved manufacturer applications specialist before resuming unsupervised procedures.

(3) Following the first anniversary in which the requirements of this subrule were met, obtain at least three hours of Category 1 CME immediately preceding the date of the facility's annual stereotactic breast 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 shall 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) A current state of Iowa medical license shall be in effect whenever unsupervised procedures are performed by the physician.

641—41.16(136C) Requirements for radiologic technologists performing stereotactic breast biopsy.

41.16(1) Radiologic technologists shall be qualified according to the rules of this chapter.

41.16(2) An Iowa permit to practice radiography as a general radiologic technologist shall be in effect whenever stereotactic procedures are performed by the radiologic technologist and shall meet the following initial requirements:

a. Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a qualified physician or technologist.

b. Three contact hours in stereotactically guided breast biopsy.

41.16(3) Maintenance of continuing experience and continuing education and experience requirements for stereotactic breast biopsy.

a. Following the first anniversary in which the requirements of this subrule were met, a total of 12 breast biopsy procedures shall be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining six must be clearly documented and can be any combination of the following:

(1) Stereotactic breast biopsy procedures.

(2) Stereotactic breast biopsy of a stereotactic training phantom with documentation of steps taken or a written report.

(3) Stereotactic breast biopsy case review, that shall 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.

(4) Image-guided breast biopsy or localization procedures utilizing mammography, stereotactic, ultrasound, MRI guidance, or any other department-approved image guided technique.

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

b. Following the third anniversary in which the requirements of this subrule were met, obtain at least three hours of continuing education in stereotactically guided breast biopsy during the 36 months immediately preceding the date of the facility's annual stereotactic breast 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 three CME credits in the prior 36 months. The CMEs cannot be obtained by the performance of supervised procedures.

641—41.17(136C) Requirements for medical physicists performing surveys of stereotactic breast biopsy systems.

41.17(1) Qualified medical physicists, as outlined in this chapter, shall have performed three hands-on stereotactically guided breast biopsy system physics surveys prior to July 1, 1998; or one hands-on stereotactically guided breast biopsy system physics survey under the guidance of a qualified medical physicist.

41.17(2) Each person engaged in providing health physics services for stereotactic breast biopsy in Iowa who meets the requirements of this chapter shall apply for Iowa approval with the department prior to providing such services in accordance with 641—subrule 37.9(2).

41.17(3) Maintenance of proficiency and continuing education requirements for medical physicists performing surveys of stereotactic breast biopsy systems. Qualified medical physicists shall meet the following requirements:

a. Have performed at least one stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met or requalify by performing one survey supervised by a qualified medical physicist.

b. Following the third anniversary in which the requirements of this subrule were met, have obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach three CME credits in the prior 36 months.

641—41.18(136C) Obtaining and preserving records for stereotactic breast biopsy. Records must be retained for a minimum of ten years. The facility shall make, for each procedure, a record of the services provided, including all of the following:

41.18(1) The date of the procedure;

41.18(2) The name of the patient and one additional patient identifier;

41.18(3) The names of the physicians performing the procedure;

41.18(4) The names of the radiologic technologists performing the procedure or any other department-approved documentation;

41.18(5) A description of the service provided;

41.18(6) The name of the referring physician, if any.

641—41.19(136C) Quality assurance program for stereotactic breast biopsy. The facility shall have an equipment quality assurance program specific to stereotactically guided breast biopsy systems to ensure high-quality images with minimum patient exposure.

41.19(1) The facility shall name a supervising stereotactic breast biopsy physician who shall be responsible for all of the following:

a. Quality assurance activities including the medical audit;

b. Oversight and review of the quality control program at least annually;

c. Supervision of the radiologic technologist(s) and the medical physicist.

41.19(2) Under the direction of the supervising physician, the medical physicist shall have the responsibility for establishing and conducting the equipment quality assurance program.

a. The program shall include equipment performance monitoring conducted at installation and at least annually thereafter. Performance monitoring shall include the following:

(1) Evaluation of biopsy unit assembly. Any failed items shall 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.

1. X-ray field cannot extend beyond the image receptor by more than 5 mm on any side.
2. Any failures shall be corrected within 30 days of the survey.

(3) Evaluation of focal spot. Focal spot cannot degrade from initial measurement. If reduction in lp/mm is found, focal spot shall be corrected within 30 days of survey.

(4) kVp accuracy/reproducibility. kVp accuracy/reproducibility shall be accurate to within +/- 5 percent of nominal kVp setting. Failures shall 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 shall be corrected before further procedures are performed.

(6) Automatic Exposure Control System Assessment.

(7) Digital receptor uniformity. The SNR in each corner shall be within +/- 15 percent of the SNR in the center. Failures shall be corrected within 30 days of the survey.

(8) Breast entrance exposure, average glandular dose and exposure reproducibility. Exposure shall be reproducible to within +/- 15 percent of mean exposure. Average glandular dose shall be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose 4.2 centimeter breast. Failures shall be corrected before further procedures are performed.

(9) Image quality evaluation. Phantom image shall 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. Failures shall be corrected before further procedures are performed.

(10) Artifact evaluation. Any significant black or white artifacts seen in the image detector field shall be corrected within 30 days of the survey.

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

b. Analyzing the performance monitoring results to determine if there are any problems requiring correction.

c. 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 preventative maintenance.

41.19(3) Additional medical physicist evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired.

41.19(4) The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

a. Localization accuracy (daily before use and before using the localization unit after it is adjusted). Each coordinate shall be within manufacturer specifications for the intended target value. Failures shall be corrected before further procedures are performed.

b. Visual checklist (monthly). Any failed items shall be corrected within 30 days.

c. Phantom image (weekly). Phantom image shall 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. Failures shall be corrected before further procedures are performed.

d. Compression (semiannually). The maximum auto drive compression force cannot exceed 45 pounds. Failures shall be corrected within 30 days.

e. Any additional quality control testing indicated by the stereotactic breast biopsy unit manufacturer shall be completed as outlined in the quality control manual applicable to the unit.

41.19(5) Medical audit program. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include all of the following:

a. An imaging-pathology correlation for each biopsy performed;

b. An ongoing analysis of biopsy results and periodic review of the utilization of the procedure;

c. The number of biopsies performed;

d. The number of cancers found;

e. The number of benign lesions found;

f. The number of biopsies repeated.

641—41.20(136C) Equipment and safety standards for stereotactic breast biopsy. Equipment must be specifically designed for stereotactically guided breast biopsy.

41.20(1) Stereotactic facilities shall comply with the requirements of 641—Chapters 37 and 40.

41.20(2) Annual inspections shall be conducted by an inspector from the department to ensure compliance with these rules. Identified hazards shall be promptly corrected.

641—41.21(136C) Suspension, revocation, denial, and reinstatement of authorization for stereotactic breast biopsy.

41.21(1) *Suspension, revocation, or denial of authorization.* Authorization may be suspended or revoked with cause if any machine does not meet one or more of the standards of these rules.

a. Stereotactic facilities shall comply with the administrative enforcement action requirements of rule 641—37.10(136C).

b. If authorization is revoked, the radiation machine cannot be used until reinstated.

c. If suspension, revocation, or denial of authorization is initiated, the administrative enforcement actions in rule 641—37.10(136C) will apply.

41.21(2) *Reinstatement of authorization.*

a. An application for reinstatement shall be submitted and processed as an initial application. Appropriate corrective actions shall be submitted as required by the department.

b. A full reinstatement will be issued only after the department has determined the radiation machine and facility meet the requirements of these rules.

These rules are intended to implement Iowa Code chapter 136C.